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Contents

Federal Register
Vol. 61, No. 175
Monday, September 9, 1996

Agriculture Department
See Farm Service Agency
See Food Safety and Inspection Service
See Natural Resources Conservation Service
See Rural Housing Service
NOTICES
Import quotas and fees:
Upland cotton, 47475–47479

Assassination Records Review Board
NOTICES
Meetings; Sunshine Act, 47480

Children and Families Administration
NOTICES
Agency information collection activities:
Submission for OMB review; comment request, 47523

Coast Guard
NOTICES
Meetings:
Houston/Galveston Navigation Safety Advisory Committee, 47544

Commerce Department
See Economics and Statistics Administration
See National Oceanic and Atmospheric Administration
NOTICES
Agency information collection activities:
Submission for OMB review; comment request, 47480–47481

Consumer Product Safety Commission
RULES
Flammable Fabrics Act:
Children's sleepwear (sizes 0–6X and 7–14) flammability standards, 47634–47649
Stay enforcement extended, 47412

Corporation for National and Community Service
NOTICES
Agency information collection activities:
Proposed collection; comment request, 47481
Submission for OMB review; comment request, 47481–47482

Defense Department
See Navy Department
PROPOSED RULES
Privacy Act; implementation:
Defense Special Weapons Agency, 47467–47469
NOTICES
Agency information collection activities:
Submission for OMB review; comment request, 47482–47483

Economics and Statistics Administration
NOTICES
Senior Executive Service:
Performance Review Board; membership, 47481

Education Department
PROPOSED RULES
Federal regulatory review; miscellaneous amendments
Correction, 47550
NOTICES
Agency information collection activities:
Proposed collection; comment request, 47504–47505
Grants and cooperative agreements; availability, etc.:
Federal Pell program, 47652–47655

Energy Department
See Federal Energy Regulatory Commission
NOTICES
Grants and cooperative agreements; availability, etc.:
Advanced drilling systems development, 47505

Environmental Protection Agency
NOTICES
Ecological risk assessment; guidelines; availability and comment request, 47552–47631

Executive Office of the President
See Presidential Documents

Farm Service Agency
NOTICES
Agency information collection activities:
Proposed collection; comment request, 47479–47480

Federal Aviation Administration
RULES
Airworthiness directives:
de Havilland, 47410–47411
Piaggio, 47409–47410
Class E airspace, 47411–47412
PROPOSED RULES
Airworthiness directives:
de Havilland, 47459–47462
Fokker, 47462–47465
Class D and Class E airspace, 47465–47466
Class E airspace, 47466–47467

Federal Communications Commission
RULES
Common carrier services:
Telephone network, connection of terminal equipment; technical amendments, 47434
Radio stations; table of assignments:
Arkansas, 47435
Colorado, 47435–47436
Mississippi, 47436–47437
Missouri et al., 47436
New Mexico, 47436
Washington, 47434–47435
PROPOSED RULES
Radio stations; table of assignments:
Alabama, 47470, 47471
Colorado, 47471–47472
Kansas, 47471
Wisconsin, 47472

Federal Energy Regulatory Commission
NOTICES
Agency information collection activities:
Proposed collection; comment request, 47505–47507
Electric rate and corporate regulation filings:
New England Power Pool et al., 47512–47513
Western Resources, Inc., et al., 47514–47516
Hydroelectric applications, 47516–47518
Natural gas certificate filings:
Transcontinental Gas Pipeline Corp. et al., 47518–47520
Applications, hearings, determinations, etc.:
ANR Storage Co., 47507–47508
Black Marlin Pipeline Co., 47508
Blue Lake Gas Storage Co., 47508
Chandeleur Pipe Line Co., 47508
Florida Gas Transmission Co., 47509
Jupiter Energy Corp., 47509
KN Interstate Gas Transmission Co., 47509
MIGC, Inc., 47509
Northwest Pipeline Corp., 47510
Pacific Gas & Electric Co. et al., 47510–47511
Steuben Gas Storage Co., 47511
Symmetry Device Research, Inc., 47511
Tarpon Transmission Co., 47511–47512
Viking Gas Transmission Co., 47512

Federal Prison Industries
NOTICES
Agency information collection activities:
Submission for OMB review; comment request, 47526–47527

Fish and Wildlife Service
NOTICES
Environmental statements; availability, etc.:
Incidental take permits—
Riverside County, CA, et al.; Stephens' kangaroo rat, etc., 47525

Food and Drug Administration
RULES
Biological products:
Current good manufacturing practices—
Blood and blood components; consignee notification of increased HIV infection transmission risk, 47413–47423
Medical devices:
Cigarettes and smokeless tobacco products; restriction of sale and distribution to protect children and adolescents
Correction, 47550

Food Safety and Inspection Service
PROPOSED RULES
Meat and poultry inspection:
Identity and composition standards, 47453–47459

Health and Human Services Department
See Children and Families Administration
See Food and Drug Administration
See Health Care Financing Administration
NOTICES
Organization, functions, and authority delegations:
Assistant Secretary for Management and Budget et al., 47520–47523

Health Care Financing Administration
RULES
Medicare and Medicaid:
Potentially HIV infectious blood and blood products; hospital standard, 47423–47434

Hearings and Appeals Office, Interior Department
RULES
Hearings and appeals procedures:
Administrative Law Judges; authority to hold hearings, 47434

Housing and Urban Development Department
NOTICES
Grants and cooperative agreements; availability, etc.:
Emergency development initiative program; program guidelines, 47523–47525

Immigration and Naturalization Service
RULES
Immigration:
Fees for motions to reopen or reconsider when filed concurrently with any application for relief under immigration laws for which fee is chargeable
Correction, 47550
NOTICES
Agency information collection activities:
Proposed collection; comment request, 47527

Indian Affairs Bureau
NOTICES
Tribal-State Compacts approval; Class III (casino) gambling:
Confederated Tribes of Umatilla Indian Reservation, OR, 47525–47526

Interior Department
See Fish and Wildlife Service
See Hearings and Appeals Office, Interior Department
See Indian Affairs Bureau
See National Park Service

Internal Revenue Service
NOTICES
Privacy Act:
Systems of records, 47547–47548

Justice Department
See Federal Prison Industries
See Immigration and Naturalization Service
See Juvenile Justice and Delinquency Prevention Office

Juvenile Justice and Delinquency Prevention Office
NOTICES
Agency information collection activities:
Submission for OMB review; comment request, 47527–47528

National Highway Traffic Safety Administration
RULES
Consumer information:
Uniform tire quality grading standards, 47437–47446
NOTICES
Meetings:
Research and development programs, 47544–47545
Motor vehicle safety standards:
Nonconforming vehicles—
Importation eligibility; determinations, 47545–47546

National Oceanic and Atmospheric Administration
RULES
Fishery conservation and management:
South Atlantic Region shrimp, 47446–47449
PROPOSED RULES
Fishery conservation and management:
Northeast multispecies, 47472–47474

National Park Service
NOTICES
Native American human remains and associated funerary objects:
Michigan State University Museum, MI; inventory from Bay County, MI, 47526

Natural Resources Conservation Service
NOTICES
Watershed projects; deauthorization of funds:
McKinney-Buzzard Creek Watershed, OK, 47480
Starkweather Watershed, ND, 47480

Navy Department
NOTICES
Privacy Act:
Systems of records, 47483–47504

Nuclear Regulatory Commission
NOTICES
Applications, hearings, determinations, etc.:
Pennsylvania Power & Light Co., 47529–47530

Personnel Management Office
PROPOSED RULES
Employment:
Temporary and term employment, 47450–47453
NOTICES
Health benefits, Federal employees:
Medically underserved areas, 47530–47533

Presidential Documents
EXECUTIVE ORDERS
Committees; establishment, renewal, termination, etc.:
Consumer Protection and Quality in the Health Care Industry, Advisory Commission on (EO 13017), 47659–47660

Public Health Service
See Food and Drug Administration

Rural Housing Service
NOTICES
Agency information collection activities:
Proposed collection; comment request, 47479–47480

Securities and Exchange Commission
RULES
Securities:
Form BD amendments
Compliance date suspension, 47412–47413
NOTICES
Agency information collection activities:
Submission for OMB review; comment request, 47533–47534, 47534
Self-regulatory organizations; proposed rule changes:
National Securities Clearing Corp., 47534–47535
Options Clearing Corp., 47535–47536
Pacific Stock Exchange, Inc., 47536–47537
Philadelphia Stock Exchange, Inc., 47537–47541

Small Business Administration
NOTICES
Disaster loan areas:
New York, 47541
Tennessee et al., 47541–47542

Social Security Administration
NOTICES
Social security claims:
Disability evaluation; redesigned method development; research plan, 47542–47544

Surface Transportation Board
RULES
Contracts and exemptions:
Rail general exemption authority—
Ferrous recyclables, 47446
NOTICES
Railroad operation, acquisition, construction, etc.:
Atlantic & Western Railway, L.P., 47546–47547
Railroad services abandonment:
Union Pacific Railroad Co., 47547

Transportation Department
See Coast Guard
See Federal Aviation Administration
See National Highway Traffic Safety Administration
See Surface Transportation Board

Treasury Department
See Internal Revenue Service

Veterans Affairs Department
PROPOSED RULES
Human subjects protection:
Research-related injuries treatment; compensation, 47469–47470
NOTICES
Meetings:
Medical Research Service Merit Review Committee, 47548–47549

Separate Parts In This Issue

Part II
Environmental Protection Agency, 47552–47631

Part III
Consumer Product Safety Commission, 47634–47649

Part IV
Department of Education, 47652–47655

Part V
The President, 47659–47660

Reader Aids

Additional information, including a list of public laws, telephone numbers, reminders, and finding aids, appears in the Reader Aids section at the end of this issue.

Electronic Bulletin Board

Free Electronic Bulletin Board service for Public Law numbers, Federal Register finding aids, and a list of documents on public inspection is available on 202–275–1538 or 275–0920.

CFR PARTS AFFECTED IN THIS ISSUE

A cumulative list of the parts affected this month can be found in the Reader Aids section at the end of this issue.

3 CFR
Executive Orders:
13017 of September 5, 1996 47659

5 CFR
Proposed Rules:
316.....47450

8 CFR
3.....47550
103.....47550
242.....47550

9 CFR
Proposed Rules:
319.....47453
381.....47453

14 CFR
39 (2 documents) 47409, 47410
71.....47411
Proposed Rules:
39 (2 documents) 47459, 47462
71 (2 documents) 47465, 47466

16 CFR
1615 (2 documents) 47412, 47634
1616 (2 documents) 47412, 47634

17 CFR
249.....47412

21 CFR
606.....47413
610.....47413
801.....47550
803.....47550
804.....47550
807.....47550
820.....47550
897.....47550

32 CFR
Proposed Rules:
318.....47467

34 CFR
Proposed Rules:
75.....47550
76.....47550
77.....47550
270.....47550
271.....47550
272.....47550
607.....47550
642.....47550
648.....47550
662.....47550
663.....47550
664.....47550

38 CFR
Proposed Rules:
16.....47469

42 CFR
482.....47423

43 CFR
4.....47434

47 CFR
68.....47434
73 (6 documents) 47434, 47435, 47436
Proposed Rules:
73 (5 documents) 47470, 47471, 47472

48 CFR
Proposed Rules:
Ch. 34.....47550

49 CFR
575.....47437
1039.....47446

50 CFR
622.....47446
Proposed Rules:
648 (2 documents) 47472, 47473

Rules and Regulations

Federal Register
Vol. 61, No. 175
Monday, September 9, 1996

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.

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 39

[Docket No. 95–NM–256–AD; Amendment 39–9747; AD 96–18–20]

RIN 2120–AA64

Airworthiness Directives; Piaggio Model P–180 Airplanes

AGENCY: Federal Aviation Administration, DOT.

ACTION: Final rule.

SUMMARY: This amendment adopts a new airworthiness directive (AD), applicable to certain Piaggio Model P–180 airplanes, that requires replacement of outflow/safety valves with serviceable valves. This amendment is prompted by a report of cracking and subsequent failure of outflow safety valves in the pressurization system. The actions specified by this AD are intended to prevent such cracking and subsequent failure of the outflow/safety valves, which could result in rapid decompression of the airplane.

DATES: Effective October 15, 1996.

The incorporation by reference of certain publications listed in the regulations is approved by the Director of the Federal Register as of October 15, 1996.

ADDRESSES: The service information referenced in this AD may be obtained from Allied Signal Aerospace, Technical Publications, Dept. 65–70, P.O. Box 52170, Phoenix, Arizona 85072–2170. This information may be examined at the Federal Aviation Administration (FAA), Transport Airplane Directorate, Rules Docket, 1601 Lind Avenue, SW., Renton, Washington; or at the FAA, Los Angeles Aircraft Certification Office, Transport Airplane Directorate, 3960 Paramount Boulevard, Lakewood, California; or at the Office of the Federal Register, 800 North Capitol Street, NW., suite 700, Washington, DC.

FOR FURTHER INFORMATION CONTACT: Walter Eierman, Aerospace Engineer, Systems and Equipment Branch, ANM–130L, FAA, Los Angeles Aircraft Certification Office, 3960 Paramount Boulevard, Lakewood, California 90712; telephone (310) 627–5336; fax (310) 627–5210.

SUPPLEMENTARY INFORMATION: A proposal to amend part 39 of the Federal Aviation Regulations (14 CFR part 39) to include an airworthiness directive (AD) that is applicable to certain Piaggio Model P–180 airplanes was published in the Federal Register on March 13, 1996 (61 FR 10292). That action proposed to require replacement of certain discrepant outflow/safety valves with serviceable valves.

Interested persons have been afforded an opportunity to participate in the making of this amendment. No comments were submitted in response to the proposal or the FAA's determination of the cost to the public.

Conclusion

The FAA has determined that air safety and the public interest require the adoption of the rule as proposed.

Cost Impact

The FAA estimates that 10 Model P–180 airplanes of U.S. registry will be affected by this AD, that it will take approximately 12 work hours per airplane to accomplish the required actions, and that the average labor rate is $60 per work hour. The parts manufacturer has advised that it will provide replacement parts at no cost to operators. Based on these figures, the cost impact of the AD on U.S. operators is estimated to be $7,200, or $720 per airplane.

The cost impact figure discussed above is based on assumptions that no operator has yet accomplished any of the requirements of this AD action, and that no operator would accomplish those actions in the future if this AD were not adopted.

Regulatory Impact

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

For the reasons discussed above, I certify that this action (1) is not a ''significant regulatory action'' under Executive Order 12866; (2) is not a ''significant rule'' under DOT Regulatory Policies and Procedures (44 FR 11034, February 26, 1979); and (3) will not have a significant economic impact, positive or negative, on a substantial number of small entities under the criteria of the Regulatory Flexibility Act. A final evaluation has been prepared for this action and it is contained in the Rules Docket. A copy of it may be obtained from the Rules Docket at the location provided under the caption **ADDRESSES.**

List of Subjects in 14 CFR Part 39

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

Adoption of the Amendment

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

PART 39—AIRWORTHINESS DIRECTIVES

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

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

§ 39.13 [Amended]

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

96–18–20 I.A.M. Rinaldo Piaggio S.P.A.: Amendment 39–9747. Docket 95–NM–256–AD.

Applicability: Model P–180 airplanes; equipped with Allied Signal outflow/safety valves, as specified in Allied Signal Aerospace Service Bulletins 103742–21–4059 and 103744–21–4060, both dated March 31, 1995; certificated in any category.

Note 1: This AD applies to each airplane identified in the preceding applicability provision, regardless of whether it has been modified, altered, or repaired in the area subject to the requirements of this AD. For airplanes that have been modified, altered, or repaired so that the performance of the

requirements of this AD is affected, the owner/operator must request approval for an alternative method of compliance in accordance with paragraph (c) of this AD. The request should include an assessment of the effect of the modification, alteration, or repair on the unsafe condition addressed by this AD; and, if the unsafe condition has not been eliminated, the request should include specific proposed actions to address it.

Compliance: Required as indicated, unless accomplished previously.

To prevent cracking and subsequent failure of the outflow/safety valves, which would result in rapid decompression of the airplanes, accomplish the following:

(a) Within 18 months after the effective date of this AD, replace the outflow/safety valve in accordance with Allied Signal Aerospace Service Bulletin 103742–21–4059 (for airplanes equipped with valves having part number 103742), or 103744–21–4060 (for airplanes equipped with valves having part number 103744), both dated March 31, 1995, as applicable.

(b) As of the effective date of this AD, no person shall install an outflow/safety valve having a part number and serial number identified in Allied Signal Aerospace Service Bulletin 103742–21–4059 (for airplanes equipped with valves having part number 103742) or 103744–21–4060 (for airplanes equipped with valves having part number 103744), both dated March 31, 1995, on any airplane unless that valve is considered to be serviceable in accordance with the applicable service bulletin.

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

Note 2: Information concerning the existence of approved alternative methods of compliance with this AD, if any, may be obtained from the Los Angeles ACO.

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

(e) The replacement shall be done in accordance with Allied Signal Aerospace Service Bulletin 103742–21–4059, dated March 31, 1995; or Allied Signal Aerospace Service Bulletin 103744–21–4060, dated March 31, 1995; as applicable. This incorporation by reference was approved by the Director of the Federal Register in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. Copies may be obtained from Allied Signal Aerospace, Technical Publications, Dept. 65–70, P.O. Box 52170, Phoenix, Arizona 85072–2170. Copies may be inspected at the FAA, Transport Airplane Directorate, 1601 Lind Avenue, SW., Renton, Washington; or at the FAA, Los Angeles Aircraft Certification Office, Transport Airplane Directorate, 3960 Paramount Boulevard, Lakewood, California; or at the Office of the Federal Register, 800 North Capitol Street, NW., suite 700, Washington, DC.

(f) This amendment becomes effective on October 15, 1996.

Issued in Renton, Washington, on August 29, 1996.

Bill R. Boxwell,

Acting Manager, Transport Airplane Directorate, Aircraft Certification Service.

[FR Doc. 96–22597 Filed 9–4–96; 8:45 am]

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14 CFR Part 39

[Docket No. 95–NM–264–AD; Amendment 39–9746; AD 96–18–19]

RIN 2120–AA64

Airworthiness Directives; de Havilland Model DHC–7 Series Airplanes

AGENCY: Federal Aviation Administration, DOT.

ACTION: Final rule.

SUMMARY: This amendment adopts a new airworthiness directive (AD), applicable to certain de Havilland Model DHC–7 series airplanes, that requires repetitive non-destructive inspections to detect disbonding of fuselage skin panels, and repair, if necessary. This amendment is prompted by a report of disbonding on fuselage skin panels, which was attributed to a manufacturing process error. The actions specified by this AD are intended to prevent disbonding of the skin panels of the fuselage, which could result in degradation of the structural capability of the airplane fuselage.

DATES: Effective October 15, 1996.

The incorporation by reference of certain publications listed in the regulations is approved by the Director of the Federal Register as of October 15, 1996.

ADDRESSES: The service information referenced in this AD may be obtained from Bombardier, Inc., Bombardier Regional Aircraft Division, Garratt Boulevard, Downsview, Ontario, Canada M3K 1Y5. This information may be examined at the Federal Aviation Administration (FAA), Transport Airplane Directorate, Rules Docket, 1601 Lind Avenue, SW., Renton, Washington; or at the FAA, New York Aircraft Certification Office, Engine and Propeller Directorate, 10 Fifth Street, Third Floor, Valley Stream, New York; or at the Office of the Federal Register, 800 North Capitol Street, NW., suite 700, Washington, DC.

FOR FURTHER INFORMATION CONTACT: Sol Maroof, Aerospace Engineer, Airframe and Propulsion Branch, ANE–171, FAA, New York Aircraft Certification Office, Engine and Propeller Directorate, 10 Fifth Street, Third Floor, Valley Stream, New York 11581; telephone (516) 256–7522; fax (516) 568–2716.

SUPPLEMENTARY INFORMATION: A proposal to amend part 39 of the Federal Aviation Regulations (14 CFR part 39) to include an airworthiness directive (AD) that is applicable to certain de Havilland Model DHC–7 series airplanes was published in the Federal Register on May 21, 1996 (61 FR 25417). That action proposed to require repetitive non-destructive inspections to detect disbonding of the fuselage skin panels, and repair, if necessary.

Interested persons have been afforded an opportunity to participate in the making of this amendment. Due consideration has been given to the single comment received.

The commenter supports the proposed rule.

Conclusion

After careful review of the available data, including the comment noted above, the FAA has determined that air safety and the public interest require the adoption of the rule as proposed.

Cost Impact

The FAA estimates that 50 de Havilland Model DHC–7 series airplanes of U.S. registry will be affected by this AD, that it will take approximately 18 work hours per airplane to accomplish the required actions, and that the average labor rate is $60 per work hour. Based on these figures, the cost impact of the AD on U.S. operators is estimated to be $54,000, or $1,080 per airplane, per inspection cycle.

The cost impact figure discussed above is based on assumptions that no operator has yet accomplished any of the requirements of this AD action, and that no operator would accomplish those actions in the future if this AD were not adopted.

Regulatory Impact

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

For the reasons discussed above, I certify that this action (1) is not a ''significant regulatory action'' under

Executive Order 12866; (2) is not a ''significant rule'' under DOT Regulatory Policies and Procedures (44 FR 11034, February 26, 1979); and (3) will not have a significant economic impact, positive or negative, on a substantial number of small entities under the criteria of the Regulatory Flexibility Act. A final evaluation has been prepared for this action and it is contained in the Rules Docket. A copy of it may be obtained from the Rules Docket at the location provided under the caption **ADDRESSES.**

List of Subjects in 14 CFR Part 39

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

Adoption of the Amendment

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

PART 39—AIRWORTHINESS DIRECTIVES

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

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

§ 39.13 [Amended]

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

96–18–19 De Havilland, Inc.: Amendment 39–9746. Docket 95–NM–264–AD.

Applicability: Model DHC–7 series airplanes, serial numbers 003 through 113 inclusive; certificated in any category.

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

Compliance: Required as indicated, unless accomplished previously.

To prevent disbonding of the skin panels of the fuselage, which could result in degradation of the structural capability of the airplane fuselage, accomplish the following:

(a) Within 6 months after the effective date of this AD, perform a non-destructive inspection to detect disbonding of the fuselage skin panels, in accordance with the Accomplishment Instructions of Bombardier Service Bulletin S.B. 7–51–1, Revision 'A', dated March 31, 1995.

(1) If no disbonding is detected, repeat the inspection thereafter at intervals not to exceed 3 years.

(2) If any disbonding is detected, prior to further flight, repair it in accordance with a method approved by the Manager, New York Aircraft Certification Office (ACO), FAA, Engine and Propeller Directorate.

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

Note 2: Information concerning the existence of approved alternative methods of compliance with this AD, if any, may be obtained from the New York ACO.

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

(d) The inspections shall be done in accordance with Bombardier Service Bulletin S.B. 7–51–1, Revision 'A', dated March 31, 1995. This incorporation by reference was approved by the Director of the Federal Register in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. Copies may be obtained from Bombardier, Inc., Bombardier Regional Aircraft Division, Garratt Boulevard, Downsview, Ontario, Canada M3K 1Y5. Copies may be inspected at the FAA, Transport Airplane Directorate, 1601 Lind Avenue, SW., Renton, Washington; or at the FAA, New York Aircraft Certification Office, Engine and Propeller Directorate, 10 Fifth Street, Third Floor, Valley Stream, New York; or at the Office of the Federal Register, 800 North Capitol Street, NW., suite 700, Washington, DC.

(e) This amendment becomes effective on October 15, 1996.

Issued in Renton, Washington, on August 29, 1996.

Bill R. Boxwell,

Acting Manager, Transport Airplane Directorate, Aircraft Certification Service.

[FR Doc. 96–22600 Filed 9–4–96; 8:45 am]

BILLING CODE 4910–13–U

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14 CFR Part 71

[Airspace Docket No. 96–AGL–3]

Revision of Class E Airspace; Delta County Airport Escanaba, MI

AGENCY: Federal Aviation Administration (FAA) DOT.

ACTION: Final rule.

SUMMARY: This action revises Class E airspace to accommodate the addition of an Automatic Weather Observation System (AWOS–3) at Delta County Airport, Escanaba, MI, to operate turbo-jet charter service on a 24 hour basis. The intended effect of this action is to provide segregation of aircraft using instrument approach procedures in instrument conditions from other aircraft operating in visual weather conditions.

EFFECTIVE DATE: 0901 UTC, December 5, 1996.

FOR FURTHER INFORMATION CONTACT: John A. Clayborn, Air Traffic Division, Operations Branch, AGL–530, Federal Aviation Administration, 2300 East Devon Avenue, Des Plaines, Illinois 60018, telephone (847) 294–7568.

SUPPLEMENTARY INFORMATION:

History

On May 29, 1996, the FAA proposed to amend part 71 of the Federal Aviation Regulations (14 CFR part 71) to revise Class E airspace at Delta County Airport, Escanaba, MI (61 FR 26856). The proposal was to add controlled airspace extending upward from 700 to 1200 feet AGL to contain Instrument Flight Rules (IFR) operations in controlled airspace during portions of the terminal operation and while transiting between the enroute and terminal environments.

Interested parties were invited to participate in this rulemaking proceeding by submitting written comments on the proposal to the FAA. No comments objecting to the proposal were received. Class E airspace designations for surface area are published in paragraph 6002 of FAA Order 7400.9C dated August 17, 1995, and effective September 16, 1995, which is incorporated by reference in 14 CFR 71.1. The Class E airspace designation listed in this document will be published subsequently in the Order.

The Rule

This amendment to part 71 of the Federal Aviation Regulations (14 CFR part 71) revises Class E airspace to accommodate the addition of an Automatic Weather Observation System (AWOS–3) at Delta County Airport, Escanaba, MI. Controlled airspace extending upward from 700 to 1200 feet AGL is needed to contain aircraft executing the approach. The area will be depicted on appropriate aeronautical charts thereby enabling pilots to circumnavigate the area or otherwise comply with IFR procedures.

The FAA has determined that this regulation only involves an established body of technical regulation for which frequent and routine amendments are necessary to keep them operationally current. Therefore, this regulation—(1)

is not a ''significant regulatory action'' under Executive Order 12866; (2) is not a ''significant rule'' under DOT Regulatory Policies and Procedures (44 FR 11034; February 26, 1979); and (3) does not warrant preparation of a Regulatory Evaluation as the anticipated impact is so minimal. Since this is a routine matter that will only affect air traffic procedures and air navigation, it is certified that this rule will not have a significant economic impact on a substantial number of small entities under the criteria of the Regulatory Flexibility Act.

List of Subjects in 14 CFR Part 71

Airspace, Incorporation by reference, Navigation (air).

Adoption of the Amendment

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

PART 71—[AMENDED]

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

Authority: 49 U.S.C. 106(g), 40103, 40113, 40120; E.O. 10854, 24 FR 9565, 3 CFR, 1959–1963 Comp., p. 389; 14 CFR 11.69.

§ 71.1 [Amended]

2. The incorporated by reference in 14 CFR 71.1 of the Federal Aviation Administration Order 7400.9C, Airspace Designations and Reporting Points, dated August 17, 1995, and effective September 16, 1995, is amended as follows:

Paragraph 6002 The Class E airspace areas designated as a surface area for an airport.

* * * * *

AGL MI E2 Escanaba, MI [Revised]

Escanaba, Delta County Airport, MI
(Lat. 45°43′18″N., long. 87°05′40″W.)
Escanaba VORTAC
(Lat. 45°43′21″N., long. 87°05′23″W.)

Within a 4.2-mile radius of the Escanaba VORTAC, and within 2.6 miles each side of the Escanaba VORTAC 007 radial, extending from the 4.2-mile radius to 7.4 miles northeast, and within 2.6 miles each side of the Escanaba VORTAC 101 radial, extending from the 4.2-mile radius to 7.4 miles east, and within 2.6 miles each side of the Escanaba VORTAC 266 radial extending from the 4.2-mile radius to 7 miles west of the VORTAC.

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Issued in Des Plaines, Illinois on August 26, 1996.

Peter H. Salmon,

Acting Manager, Air Traffic Division.

[FR Doc. 96–22945 Filed 9–6–96; 8:45 am]

BILLING CODE 4910–13–M

CONSUMER PRODUCT SAFETY COMMISSION

16 CFR Parts 1615 and 1616

Standards for the Flammability of Children's Sleepwear: Sizes 0 Through 6X and 7 Through 14; Stay of Enforcement

AGENCY: Consumer Product Safety Commission.

ACTION: Extension of stay of enforcement.

SUMMARY: The Commission announces that it is extending the stay of enforcement of the Standard for the Flammability of Children's Sleepwear: Sizes 0 Through 6X and the Standard for the Flammability of Children's Sleepwear: Sizes 7 Through 14 in all cases involving garments currently used or likely to be used as sleepwear if those garments are skin-tight or nearly skin-tight, similar in design, material, and fit to underwear, and labeled as ''underwear.''

EFFECTIVE DATE: This stay of enforcement first published at 58 FR 4078, January 13, 1993, which became effective January 13, 1993, and was extended at 59 FR 53584, October 25, 1994, and will continue until March 9, 1998.

FOR FURTHER INFORMATION CONTACT: Patricia A. Fairall, Office of Compliance, Consumer Product Safety Commission, Washington D.C. 20207; telephone: (301) 504–0400, extension 1369.

SUPPLEMENTARY INFORMATION: In the Federal Register of January 13, 1993 (4078), the Commission published a notice to announce a stay of enforcement of the flammability standards for children's sleepwear. In that notice, the Commission announced that it would not enforce the Standard for the Flammability of Children's Sleepwear: Sizes 0 Through 6X (16 CFR Part 1615) or the Standard for the Flammability of Children's Sleepwear: Sizes 7 Through 14 (16 CFR Parts 1616) in cases involving garments used by children for sleeping which are: (1) skin-tight or nearly skin-tight; (2) manufactured from fabrics such as rib knit, interlock knit, or waffle knit; (3) relatively free of ornamentation; and (4) labeled and marketed as ''underwear.'' On the same date, the Commission published an advance notice of proposed rulemaking to begin a proceeding to consider whether the children's sleepwear standards should be amended to exempt tight-fitting sleepwear garments, and garments in infant sizes. See 58 FR 4111.

In the Federal Register of October 25, 1994 (59 FR 53584), the Commission announced that it was extending the stay of enforcement of the children's sleepwear flammability standards until further notice. On the same date, the Commission published proposed amendments of the sleepwear flammability standards to exempt tight-fitting sleepwear garments and some infant garments from the requirements of those standards. See 59 FR 53616.

Elsewhere in this issue of the Federal Register, the Commission has issued final amendments to exempt certain tight-fitting garments and garments sized for children nine months of age or younger from the requirements of the children's sleepwear flammability standards. These amendments become effective January 1, 1997.

By publication of this notice, the Commission is also extending until March 9, 1998 the stay of enforcement issued on January 13, 1993, and continued on October 25, 1994. Garments covered by this stay must meet applicable requirements of the Standard for the Flammability of Clothing Textiles (16 CFR part 1610) and the Standard for the Flammability of Vinyl Plastic Film (16 CFR part 1611).

Dated: August 29, 1996.

Todd A. Stevenson,

Deputy Secretary, Consumer Product Safety Commission.

[FR Doc. 96–22713 Filed 9–6–96; 8:45 am]

BILLING CODE 6355–01–P

SECURITIES AND EXCHANGE COMMISSION

17 CFR Part 249

[Release No. 34–37632; File No. S7–2–95]

RIN 3235–AG25

Form BD Amendments

AGENCY: Securities and Exchange Commission.

ACTION: Final rule: Suspension of compliance date for Form BD amendments.

SUMMARY: The Securities and Exchange Commission is suspending the compliance date for recent amendments to Form BD, the uniform broker-dealer registration form under the Securities Exchange Act of 1934, as it applies to filings made by all registered broker-dealers and broker-dealer applicants.

EFFECTIVE DATE: The effective date for amendments to Form BD adopted by the Securities and Exchange Commission on July 12, 1996 and published on July 18,

1996 (61 FR 37357) remains August 19, 1996. Effective September 9, 1996, the compliance date with respect to these amendments to Form BD is suspended. The Commission will publish in the Federal Register a document notifying the public of a new compliance date.

FOR FURTHER INFORMATION CONTACT: Glenn J. Jessee, Special Counsel, (202) 942–0073, Office of Chief Counsel, Division of Market Regulation, Securities and Exchange Commission, 450 Fifth Street, N.W., Mail Stop 5–10, Washington, D.C. 20549.

SUPPLEMENTARY INFORMATION: On July 12, 1996, the Securities and Exchange Commission (''Commission'') adopted amendments to Form BD,[1] the uniform application form for broker-dealer registration under the Securities Exchange Act of 1934.[2] As discussed in the Adopting Release, the use of Form BD, as amended on July 12, 1996, is intended to coincide with the implementation of the redesigned Central Registration Depository (''CRD''), a computer system operated by the National Association of Securities Dealers, Inc. (''NASD'') that maintains registration information regarding broker-dealers and their registered personnel. Among other things, the redesigned CRD system will allow broker-dealers to file Form BD electronically.

The implementation of the redesigned CRD is being accomplished in phases. On May 20, 1996, the NASD began a two-month test of the system with the voluntary participation of several NASD member firms and one service bureau. Following completion of the test, it was expected that on July 29, 1996, broker-dealers participating in the test would begin filing all of their registration and licensing information electronically with the redesigned CRD on a pilot basis. Then, on September 9, 1996, it was expected that the NASD would begin Phase I of the implementation of the redesigned CRD system, at which time registered broker-dealers and broker-dealer applicants would be required to begin using Form BD, as amended on July 12, 1996. The test of the redesigned CRD system that began on May 20, however, revealed that additional changes are needed in the software that will be used by broker-dealers to make electronic filings and that broker-dealers need more time to prepare their internal operations and infrastructure to support electronic filing. As a result, the NASD has determined to delay further implementation of the redesigned CRD system until early in 1997.

Because of this delay, the Commission is suspending the compliance date for Form BD, as amended on July 12, 1996, for all registered broker-dealers and broker-dealer applicants. Accordingly, broker-dealers and broker-dealer applicants should continue to use Form BD, as revised November 16, 1992. At such time as another date for the start of Phase I is determined, the Commission expects that it will set appropriate compliance dates for the amendments to Form BD and publish a document in the Federal Register notifying the public of such compliance dates.

Dated: September 4, 1996.

By the Commission.

Jonathan G. Katz,

Secretary.

[FR Doc. 96–22939 Filed 9–6–96; 8:45 am]

BILLING CODE 8010–01–P

[1] 17 CFR 240.15b1–1; 17 CFR 249.501.

[2] Securities Exchange Act Release No. 37431 (Jul. 12, 1996), 61 FR 37357 (Jul. 18, 1996) (''Adopting Release'').

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Parts 606 and 610

[Docket No. 91N–0152]

RIN 0910–AA05

Current Good Manufacturing Practices for Blood and Blood Components: Notification of Consignees Receiving Blood and Blood Components at Increased Risk for Transmitting HIV Infection

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is amending the biologics regulations to require that blood establishments (including plasma establishments) prepare and follow written procedures for appropriate action when it is determined that Whole Blood, blood components (including recovered plasma), Source Plasma and Source Leukocytes at increased risk for transmitting human immunodeficiency virus (HIV) infection have been collected. This final rule requires that when a donor who previously donated blood is tested on a later donation in accordance with the regulations, and tests repeatedly reactive for antibody to HIV, the blood establishment shall perform more specific testing using a licensed test, if available, and notify consignees who received Whole Blood, blood components, Source Plasma or Source Leukocytes from prior collections so that appropriate action is taken. Blood establishments and consignees are required to quarantine previously collected Whole Blood, blood components, Source Plasma and Source Leukocytes from such donors, and if appropriate, notify transfusion recipients.

The Health Care Financing Administration (HCFA) is also issuing a final rule, published elsewhere in this Federal Register, which requires all transfusion services subject to HCFA's conditions of Medicare participation for hospitals to notify transfusion recipients who have received Whole Blood or blood components from a donor whose subsequent donation test results are positive for antibody to HIV (hereinafter referred to as HCFA's final rule). FDA is requiring transfusion services that do not participate in Medicare and are, therefore, not subject to HCFA's final rule, to take steps to notify transfusion recipients.

FDA is taking this action to help ensure the continued safety of the blood supply, and to help ensure that information is provided to consignees of Whole Blood, blood components, Source Plasma and Source Leukocytes and to recipients of Whole Blood and blood components from a donor whose subsequent donation tests positive for antibody to HIV.

DATES: This regulation is effective November 8, 1996. Written comments on the information colelction requirements should be submitted by February 7, 1997.

ADDRESSES: Submit written comments on the information collection requirements to the Dockets Management Branch (HFA–305), Food and Drug Administration, 12420 Parklawn Dr., rm. 1–23, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: Sharon Carayiannis, Center for Biologics Evaluation and Research (HFM–630), Food and Drug Administration, 1401 Rockville Pike, suite 200N, Rockville, MD 20852–1448, 301–594–3074.

SUPPLEMENTARY INFORMATION:

I. Introduction

FDA has implemented an extensive system of donor screening and testing procedures performed by blood establishments before, during, and after donation, to help prevent the transfusion of blood products that are at increased risk for transmitting HIV. HIV is the virus that causes acquired immune deficiency syndrome (AIDS), a

communicable disease that can be transmitted through transfusion.

As a result of the screening and testing procedures, the risk of transmitting HIV infection through blood transfusion is very low. Despite the best practices of blood establishments, however, a person may donate blood early in infection, during the period when the antibody to HIV is not detectable by a screening test, but HIV is present in the donor's blood (a so-called ''window'' period). If the donor attempts to donate blood at a later date, the test for antibody to HIV may, at that time, be repeatedly reactive. Therefore, FDA believes such circumstances require clarification of the donor's status through testing with a more specific antibody test and procedures to ''lookback'' at prior collections. Previously collected Whole Blood and blood components would be at increased risk for transmitting HIV and a recipient of a transfusion of Whole Blood and blood components collected during the ''window'' period would not know that he or she may have become infected with HIV through the transfusion unless notified.

In the Federal Register of June 30, 1993 (58 FR 34962), FDA issued a proposed rule to require appropriate action when it is later determined that blood and blood components might have been collected during the ''window'' period. FDA has reviewed comments submitted on the proposed rule and is now issuing this final rule to require facilities involved in the collection, processing, and administration of blood to quarantine Whole Blood, blood components, Source Plasma and Source Leukocytes which were collected from a donor who tested negative at the time of previous donations but subsequently tests repeatedly reactive for antibody to HIV. The final rule requires blood establishments to inform consignees (e.g., hospital transfusion services and manufacturers of plasma derivatives) of the collection and distribution of such previously donated Whole Blood, blood components, Source Plasma and Source Leukocytes.

In the Federal Register of June 30, 1993 (58 FR 34977), HCFA also issued a proposed rule which would require certain transfusion services to notify recipients of transfusions determined to be from a donor whose subsequent donation tests positive for antibody to HIV (hereinafter referred to as HCFA's proposed rule). The final rules issued by both FDA and HCFA require transfusion services to perform such notifications.

In a memorandum of understanding (MOU), FDA and HCFA agreed to coordinate the inspections of transfusion services in medicare participating hospitals to minimize duplication of effort and to reduce the burden on affected facilities. Blood establishments, including those hospital transfusion services not subject to HCFA's regulations on the conditions of Medicare participation for hospitals, such as Indian Health Service and Veteran's Administration Hospitals, are subject to FDA's final rule. Thus, all transfusion services are subject to the requirements for quarantine and transfusion recipient notification under either the FDA or HCFA rule.

II. Highlights of the Final Rule

Under the biologics licensing and quarantine provisions of the Public Health Service Act (42 U.S.C. 262–264) and the drug, device, and the general administrative provisions of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 351–353, 355–360, and 371–374), FDA has the authority to promulgate regulations designed to protect the public from unsafe or ineffective biological products and to issue regulations necessary to prevent the transmission of communicable diseases into the United States or from one State to another.

Under these statutory authorities, FDA currently requires that each donation be tested and found negative for antibody to HIV under § 610.45 (21 CFR 610.45). Existing regulations already restrict the use, for transfusion or further manufacture, of a donation testing repeatedly reactive for antibody to HIV. Even though current licensed screening tests for antibody to HIV are very sensitive, testing may not identify all units capable of transmitting HIV infection. For this reason, many blood establishments have instituted special procedures when blood or plasma has been collected from a donor testing positive for antibody to HIV at a later date. These procedures, commonly referred to as ''lookback'' procedures, involve determining the suitability of prior collections of Whole Blood, blood components, Source Plasma and Source Leukocytes from such a donor. These existing procedures may also involve notifying consignees that have received prior collections from the donor so consignees can quarantine such products and, as appropriate, take steps to notify the transfusion recipients of such Whole Blood and blood components.

While many blood establishments have voluntarily developed written ''lookback'' procedures, these existing procedures vary significantly among blood establishments. As proposed in the Federal Register of June 30, 1993, FDA is amending the biologics regulations to require blood establishments to prepare and follow written standard operating procedures (SOP's), defining steps to be taken when ''lookback'' circumstances arise.

The final rule requires blood establishments to perform more specific testing of the donor's blood using a licensed test, and to notify consignees who received Whole Blood, blood components, Source Plasma and Source Leukocytes from prior collections so that appropriate action is taken. Blood establishments and consignees shall quarantine, as described later in this document, previously collected Whole Blood, blood components, Source Plasma and Source Leukocytes from such donors until the donor's status is clarified through further testing. FDA is requiring that other informative test results, if available, be considered when determining the status of the donor and the suitability of prior collections.

Upon completion of more specific testing, the final rule also requires hospital transfusion services that do not participate in Medicare and are, therefore, not subject to HCFA's final rule, to take steps to notify transfusion recipients, as appropriate. Such transfusion recipients shall receive notification for the purpose of testing for evidence of HIV infection, early treatment, if indicated, and counseling to take appropriate precautions to prevent the further spread of the virus such as to sexual partners.

III. HCFA's Companion Rule

Under HCFA's proposed rule, transfusion services operated by hospitals participating in Medicare and inspected by HCFA that receive notification of previously collected Whole Blood and blood components at increased risk for transmitting HIV, would be required to quarantine such prior collections and notify the transfusion recipient's attending physician, the transfusion recipient, or other authorized person, as appropriate. HCFA's final rule requires the hospital transfusion service to have a written agreement with each blood supplier documenting these procedures.

As referenced in section I. of this document, FDA and HCFA coordinate the inspections of transfusion services in medicare participating hospitals to minimize duplication of effort and to reduce the burden on affected facilities. In the MOU, it was estimated that HCFA would be responsible for inspecting and surveying approximately 3,000 transfusion services. FDA continues to conduct the inspections of

establishments were activities include more than the performance of compatibility testing. (See 49 FR 34448, August 31, 1984, and 21 CFR 607.65.)

IV. Other Sources of Information

As FDA recognized in the preamble to the proposed rule, blood establishments may receive information from other sources which indicate that a donor may be infected with HIV. FDA encourages blood establishments to initiate ''lookback'' procedures whenever they have information that a donor has become infected with HIV. FDA recognizes the existence of diagnostic modalities for HIV infection, other than antibody testing, such as virus culture or direct viral assays. FDA encourages blood establishments to consider such test results, when available and reliable, and to voluntarily initiate the ''lookback'' process as described in this final rule. Additionally, the final rule requires that such results be considered prior to release of units quarantined in a ''lookback'' procedure.

In particular, FDA recommends that blood establishments voluntarily initiate ''lookback'' procedures based on HIV antigen testing, as indicated in the August 8, 1995, Memorandum to All Registered Blood Establishments, Regarding Recommendations for Donor Screening with a Licensed Test for HIV-1 Antigen. In the August 8, 1995, memorandum FDA provided recommendations for the implementation of donor screening tests for HIV type 1 (HIV–1) antigen(s) within 3 months of the commercial availability of the first test for HIV–1 antigen(s). The August 8, 1995, memorandum stated that the average infectious ''window'' period, when HIV antibody is not detectable by the screening test, is estimated to be approximately 22 to 25 days for screening with combination assays for antibodies to HIV–1 and HIV–2. The memorandum further stated that HIV antigen screening could reduce the ''window'' period by an estimated 6 days and could be expected to prevent up to 25 percent of the current ''window'' period donations or about 5 to 10 cases of transfusion associated HIV per year. Because HIV–1 antigen screening will reduce but not eliminate the residual risk for HIV–1 from transfusion, FDA regards such screening as an interim measure pending the availability of improved technology for this purpose. FDA encourages continued development of new methods no further reduce the risk of HIV transmission due to ''window'' period donations.

V. Responses to Letters of Comment

FDA provided interested individuals 60 days to submit written comments on the proposed rule. FDA received a total of 25 letters of comment, which included 10 from blood collection facilities or blood banks, 8 from pathologists or pathology associations, 6 from blood banking associations, and 1 from a parent of children with hemophilia.

Twenty-one comments agreed with the concept of ''lookback''. There were differences of opinion as to how the ''lookback'' process should be conducted and concerns regarding liability of various individuals involved in the process. Three comments indicated support for the strengthening of the ''lookback'' requirements, while eight comments suggested that the proposed rule's cost to industry would pose a significant burden with little benefit to public health.

After review and consideration of all comments, FDA continues to believe that the new requirements for the handling of prior collections of Whole Blood, blood components, Source Plasma and Source Leukocytes later found to be at increased risk for transmitting HIV infection are important public health measures. Below, FDA provides responses to the comments received.

A. General Comments

1. Terminology Used by FDA and HCFA

Two comments expressed some confusion over specific terminology and the differences in terminology used by FDA and HCFA. One comment suggested the use of ''transfusion service'' instead of ''consignee.'' One comment suggested the use of a more specific term for ''recipient.''

FDA's use of the term consignee includes any facility to which the Whole Blood, blood components, Source Plasma and Source Leukocytes have been shipped (e.g., a transfusion service, a manufacturer of blood products, or another blood banking establishment). As written, when the rule uses the term consignee, it refers to more than a transfusion service. The FDA and HCFA rules refer to ''transfusion services'' when the rules are specific to transfusion services. To interchange these terms would cause more confusion and would not achieve the goals sought.

As suggested by one comment, FDA has amended the rule to use the terms transfusion recipient or transfused patient in a number of places to make it clear that FDA is referring to the recipient of the transfusion. Where the term ''recipient'' is used alone, FDA believes that the context makes it clear that the term refers to patients and not to consignees.

FDA believes that the terminology used in the rules is appropriate and understood by the entities subject to FDA regulation. FDA also believes that the terminology used by HCFA is understood by the entities regulated by HCFA.

2. Blood Donor Locator Service

Three comments stated an interest in using the Blood Donor Locator Service (BDLS) as a part of the ''lookback'' process. One request was to expand this service to locate recipients also.

The BDLS final rule which was published in the Federal Register of December 24, 1991 (56 FR 66561), addressed similar comments calling for the expanded use of the service. The statutory authority to conduct the BDLS, as defined by section 8008 of the Technical and Miscellaneous Revenue Act of 1988 (Pub. L. 100–647), only authorizes the Social Security Administration to provide address information for blood donors whose test results for antibody to HIV show that they are, or may be, infected with HIV. The legislation authorizing the BDLS does not extend to transfusion recipients or to any other individual. Participation in the BDLS by State agencies and blood donation facilities is voluntary, but participants must agree to comply with the provisions of the statute and the regulations as defined in the BDLS final rule.

3. Organization of Information in the Final Rule

One comment suggested that the organization of information in the regulations was confusing, and asked for clarification of the intent of the regulations.

The rule is divided into subsections that provide specific direction on each aspect of the ''lookback'' process. Each subsection of the rule must be reviewed for a complete understanding of all aspects of this important information. The following description serves as a brief overview of the regulations. Section 606.100 (21 CFR 606.100) states the requirements for SOP's, and § 606.160 (21 CFR 606.160) states the requirements for recordkeeping. Section 610.45(d) identifies the circumstances under which the ''lookback'' process shall be initiated. Section 610.46(a) (21 CFR 610.46(a)) states the requirements for the initial steps of the ''lookback'' process. Section 610.46(a)(1) establishes the circumstances for quarantine and requires notification of consignees to

quarantine such products. Section 610.46(a)(2) discusses quarantine of products held by consignees.

Section 610.46(b) specifies the time limit for completion of the licensed, more specific test and the notification of the consignee of those test results. Section 610.46(c) addresses products that are exempt from quarantine and § 610.46(d) discusses requirements for release from quarantine. Section 610.46(e) makes clear that these actions are not considered to be product recalls. Section 610.47(a) (21 CFR 610.47(a)) covers those transfusion services not subject to HCFA's regulations. Section 610.47(b) contains requirements for notification of recipients and § 610.47(c) addresses the notification of a legal representative or relative acting on behalf of the recipient.

B. Comments on § 606.100

Four comments requested more specific direction regarding the content of SOP's.

It is intention of FDA to allow appropriate flexibility to blood establishments in the development of their procedures. For example, as mentioned in one comment, a blood establishment could identify by title or name the individuals authorized to provide and receive consignee notification in the ''lookback'' process. FDA further discusses the content of SOP's in the responses to comments on specific subsections of the rule.

C. Comments on § 610.45(d)

1. Use of Information from Other Sources to Initiate ''Lookback'' Process

One comment stated that there will be additional circumstances when a blood establishment can reliably and consistently receive information that should result in the initiation of a ''lookback'' process. The sources of this information may include the U.S. military, health departments or physicians of former donors now found to be HIV-infected or diagnosed as having AIDS.

FDA agrees that there will be circumstances when the initiation of ''lookback'' may be based on reliable information provided by the U.S. military, health departments, and other sources and recommends appropriate action in those instances. However, a blood establishment generally has no control over whether they will be appropriately contacted by these outside sources. In addition, the laws and procedures governing such notifications will vary from State to State. Therefore, FDA's final rule does not contain specific additional circumstances under which ''lookback'' is required because the ability for each establishment to meet the requirements will vary so widely, based upon varying State laws, local practices, and confidentiality issues.

2. Initiation of ''Lookback'' Process Based on Repeatedly Reactive Screening Results

Three comments objected to the initiation of the ''lookback'' process based on the repeatedly reactive antibody screening test results before the completion of the licensed, more specific test. One comment stated that any ''lookback'' action, beyond the quarantine of product, based on the antibody screening test results would be inappropriate because those tests have a high rate of false positive results and were not intended to be diagnostic without further confirmatory testing.

One comment stated that there is a very high cost associated with preventing the transfusion of very few infectious units based on: (1) The estimate that of all donations made each year, most blood and blood components will be transfused before a donor is permitted to donate again 56 days later; (2) the estimate that only one half of donors will return to donate again; and (3) the very low number of units expected to be infectious despite proper testing.

One comment in support of the rule stated that the rule did not place undue hardship on the blood banking industry. One comment objected to the more stringent requirements for notification due to the current burden of escalating demands and diminishing resources, including increased workload due to more complicated patient illnesses, vacant technical positions that cannot be filled due to the declining numbers of skilled, qualified medical technologists, and hospital costs rising faster than revenues. One comment stated concern that patient needs would not be met because the increased regulation would force hospital based donor centers to close as a result of economic pressures.

One comment cited a threefold increase in the rate of repeatedly reactive screening tests for antibody to HIV with none of those confirmed by Western Blot in the past year, which would result in much higher expected total annualized costs than projected by FDA. Two comments stated that the actual costs would be twice that estimated by FDA. Three comments stated that the goals of the proposed rule are laudable but also estimated that most HIV infections are spread through other modes of transmission and, therefore, our limited health care dollars are better spent in other ways.

FDA is charged with the responsibility of protecting the public from unsafe biological products and has the authority to promulgate regulations to accomplish its public health mission. Comments on the proposed rule indicate that SOP's for the ''lookback'' process are already in place in a large percentage of blood establishments. Based on comments received, FDA believes that the modification of existing SOP's to meet the requirements of this rule would not impose an unreasonable burden or expense to the large number of establishments with an existing system for handling ''lookback'' circumstances.

FDA believes the prevention of a small number of transmissions of HIV per year that will result from the initiation of the ''lookback'' process based on the repeatedly reactive antibody screening test results or other informative test results is a clear benefit. FDA believes that steps must be taken to avoid transfusion of potentially unsuitable Whole Blood and blood components while waiting for the completion of further testing, especially since the time limit for such testing has been extended to 30 days, as described later in this document. FDA recognizes that the requirement for the initiation of this process at the time of the repeatedly reactive HIV antibody test will result in some additional costs to blood establishments that currently do not begin the process at this point. However, FDA believes these steps are warranted to increase the safety of the nation's blood supply.

D. Comments on § 610.46(a)

1. Notification of Consignees

One comment stated concern regarding the notification of consignees of the results of the licensed, more specific test and the potential for confusion if the product in question had already been returned to the blood donor center.

The final rule requires that blood establishments notify consignees to quarantine Whole Blood, blood components, Source Plasma and Source Leukocytes that are at increased risk for transmitting HIV infection. Upon notification by the blood establishment, the consignee is to promptly, within 72 hours, quarantine the affected products until notified of the negative results of a licensed, more specific test. Return of such products to the blood establishment is not a requirement of this rule, and, therefore, should not create confusion. However, if the

consignee does return the blood or blood components to the blood establishment, no further consignee notification would be required. FDA has amended the final rule to clarify the requirement to promptly notify consignees, within 72 hours, for the purpose of identifying those products that remain in inventory and require quarantine.

2. Products for Further Manufacture

One comment concerned § 610.46(a)(2), which requires that unpooled products held by the consignee shall be quarantined. The comment stated that while it appears that the proposed rule is structured to exclude large pools of plasma from some requirements, the rule might be interpreted to have a different result when the collecting facility and the manufacturing facility hold the same license. The comment stated further that in this situation, both large and small pools would be quarantined since the products were not shipped to a consignee to be pooled.

The comment also asked that small pools of plasma intended for further manufacture into noninjectable products also be exempt from quarantine because they are sometimes pooled at the collection facility and may include plasma considered to be in short supply. The comment stated that small pools of plasma intended for the manufacture of noninjectable products should be exempt from quarantine because they are sufficiently safe as noninjectable products.

A collection facility would be required to quarantine all in-house or ''on-site'' Whole Blood, blood components, Source Plasma and Source Leukocytes. A manufacturing facility that shares an establishment license with the collecting facility is not required to quarantine pooled products. To avoid a shortage of injectable and noninjectable products the final rule exempts from quarantine pooled Source Plasma and Source Leukocytes intended for further manufacture into injectable and noninjectable products, as described in § 610.46(c). FDA believes this requirement will better identify those affected products to be quarantine while ensuring the availability of blood products for further manufacture.

Additionally, FDA agrees that pools intended for further manufacture into noninjectable products are sufficiently safe due to their intended use as noninjectable products and are, therefore, exempt from quarantine. The rule has been amended to clarify that Pooled Source Plasma and Pooled Source Leukocytes are exempt from quarantine. Appropriate safeguards must be used to prevent such products intended for further manufacture into non-injectable products from being used for further manufacture into injectable products.

E. Comments on § 610.46(b)

1. Two Week Limit for Completion of Licensed, More Specific Test

One comment supported proposed § 610.46(b) which requires the 2-week time limit for completion of the licensed, more specific test and consignee notification, while twenty-three comments expressed disagreement with the time limit. The 2-week time limit was cited as too short due to shipping of samples, batching of laboratory work, the additional number of tests run when the sample is not negative, dependence upon reference laboratories for this work, and unforeseen circumstances that are beyond the control of the blood establishment. The suggestions for a more appropriate timeframe ranged from 3 weeks to 8 weeks to ''as soon as possible''.

After consideration of the additional information provided in the comment letters, FDA believes that it is appropriate and reasonable to change the time limit for completion of the licensed, more specific test and consignee notification of the test results. FDA is amending § 610.46(b) by allowing a maximum of 30 calendar days for completion of the licensed, more specific test for antibody to HIV and consignee notification of the test results.

FDA's concern for the prompt notification of the transfusion recipient, without undue burden to industry, dictates that the time limit for completion of testing not exceed 30 days. FDA's extension of the time limit for the completion of these steps is intended to give blood establishments a reasonable time period to comply with the regulation. FDA expects that blood establishments will initiate and complete such testing expeditiously, but take no longer than 30 calendar days.

The written SOP's of the establishment required under § 606.100(b)(19) should be adequate to ensure that the required testing and consignee notification is routinely completed within 30 days. In rare circumstances, such as when there are testing problems, testing and notification may take longer than 30 days. In such cases the establishment should document in its records the reason for the failure to meet the requirement. If the establishment frequently fails to meet the required time limits, the establishment should review its procedures to determine how testing and consignee notification can be expedited.

2. Positive Test for Antibody to HIV-2

Two comments on § 610.46(b) requested clarification on further testing and notification of consignee and recipients when donors subsequently test positive for antibody to HIV-2.

In the Memorandum to All Registered Blood Establishments, Revised Recommendations for the Prevention of HIV Transmission by Blood and Blood Products, dated April 23, 1992, FDA provided guidance recommending that all blood establishments collecting Whole Blood, blood components, Source Plasma, or Source Leukocytes implement a licensed test for detection of antibody to HIV-2 by June 1, 1992. FDA modified existing recommendations for prevention of HIV transmission by blood and blood products to include HIV-2 testing at that time. The revised recommendations for donor testing, deferral, and reentry are found in section II. and the recommendations on ''lookback'' are found in section IV. of the April 23, 1992, memorandum.

This final rule is similar to the FDA guidance on supplemental tests recommended in the April 23, 1992, Memorandum. FDA has amended § 610.46(b) of the final rule to clarify requirements for HIV-2 testing. Currently, there is no ''licensed, more specific'' test for antibody to HIV-2. Thus, the final rule requires the following:

(1) When a donor's screening test for antibody to HIV is repeatedly reactive, a licensed, more specific test for antibody to HIV shall be performed.

(2) When the repeatedly reactive screening test is performed using a single virus test for antibody to HIV–2 or combination test for antibody to HIV–1/HIV–2, a second screening test for HIV–2, which is different from the original HIV–2 test, must also be performed. This second, different enzyme immuno-assay (EIA) test must be a licensed test and can be either a single virus test or a combination test.

Whole Blood, blood components, Source Plasma and Source Leukocytes from prior collections may be released from quarantine only if the donor is tested for antibody to HIV–1 by a licensed, more specific test and the result is negative; and if the screening test is repeated using a different EIA test for antibody to HIV–2, either single virus or combination test, and the result is negative, absent other informative test

results. Release from quarantine is not permitted under any other test results. Transfusion recipient notification is required when the licensed, more specific test for HIV–1 is positive or when the second, different EIA test for antibody to HIV–2 is repeatedly reactive.

Whole Blood, blood components, Source Plasma and Source Leukocytes are exempt from quarantine if the collection occurred more than 12 months prior to the donor's most recent negative screening test(s). If the most recent negative screening test for antibody to HIV was performed prior to the implementation of HIV–2 testing in June of 1992, then the negative screening test for HIV–1 is sufficient to establish the 12-month time period.

This final rule supersedes the existing recommendations for ''lookback'' procedures in section IV. of the April 23, 1992, Memorandum, Exclusion/Retrieval of Potentially Contaminated Units From Prior Collections and Notification of Consignees.

F. Comments on § 610.46 (c) and (d)

1. Release From Quarantine and Western Blot Indeterminate Results

Two comments indicated confusion regarding the disposition of components collected both greater than and less than the 12-month period prior to the most recent nonreactive test result. Additionally, two comments on the subject of Western blot indeterminate results asked for clarification and for exemption from the ''lookback'' process due to what the commentor believes is the unlikely occurrence that a unit with an indeterminate Western blot test result would be infectious.

FDA is requiring prompt quarantine for Whole blood, blood components, Source Plasma and Source Leukocytes collected from a donor at increased risk for transmitting HIV infection. Quarantine is required for units from such a donor collected within the 5years prior to the repeatedly reactive test for antibody to HIV, if intended for transfusion, or collected within 6 months prior to the repeatedly reactive test result, if intended for further manufacture. Section 610.46(c) describes the situation in which Whole Blood, blood components, Source Plasma and Source Leukocytes are exempt from quarantine because there is serological evidence that the donation(s) was not made during the ''window'' period.

In the preamble to the proposed rule, FDA stated that, based on experience, current estimates predict with approximately 95 percent confidence that in all cases of HIV infection, the person will test positive for antibody to HIV by a licensed test within 6 months from the date of infection. As stated in the preamble to the proposed rule, to provide an additional margin of safety, FDA has extended the period for quarantine to 12 months, to more closely approximate a 99 percent confidence interval. Accordingly, FDA's requirement to quarantine all Whole Blood, blood components, Source Plasma and Source Leukocytes collected within 12 months prior to the most recent negative screening test provides an added margin of safety during the months when an infected donor may not yet test positive for antibody to HIV. All donations made before this 12-month period would be outside the ''window'' period and would be exempt from quarantine.

The final rule is amended to clarify the requirements when other informative test results are available. Section 610.46(d) of the final rule states that a product may be released from quarantine if the donor's blood is tested for antibody to HIV by a licensed, more specific test and the test result is negative, absent other informative test results. FDA believes that release from quarantine is possible only if the more specific test is negative and there are no other informative test results that show evidence of HIV infection. This regulation does not allow the release from quarantine following and indeterminate Western blot test result.

Blood establishments may voluntarily perform other FDA approved informative tests for HIV and must consider those test results when determining the status of the donor and the suitability of prior collections. For example, FDA has recently recommended donor screening for HIV–1 antigen(s) using approved tests. Testing for HIV–1 antigen(s) using seroconversion samples has shown that donors with recent HIV infection test repeatedly reactive for antibody to HIV, yet test as negative or indeterminate by a more specific antibody test but positive for HIV–1 antigen(s). Prior collections from such a donor would not be exempt from quarantine unless collected more than 12 months prior to the donor's most recent negative screening test for HIV antibody.

Disposition of prior collections at increased risk for transmitting HIV infection should follow the establishment's SOP for appropriate disposal of blood products that are unsuitable for transfusion, in accordance with § 606.40. The Memorandum to All Registered Blood Establishments from the Director, Center for Biologics Evaluation and Research, Control of Unsuitable Blood and Blood Components, dated April 6, 1988, provides additional guidance for quarantine and disposition of products unsuitable for transfusion.

In situations where an establishment fails to comply within the 30-day limit for completion of further testing, and subsequently the test result is negative, the Whole Blood, blood components, Source Plasma and Source Leukocytes may be released from quarantine and consignees must be notified promptly upon availability of the test results. Destruction of quarantined units is not required merely because further testing was completed after the 30-day deadline. No release of quarantined Whole Blood, blood components, Source Plasma and Source Leukocytes is permitted before the results of the further testing are available.

2. Use of Test Results From Other Laboratories

Two comments asked that blood establishments be allowed to use the laboratory test results from other laboratories as evidence of the most recent negative screening test for antibody to HIV, thus allowing the quarantine and notification to be limited to units collected within 12 months prior to that negative result. One comment stated that evidence of such negative screening results could be provided by independent clinical laboratories, State health departments, military laboratories, other blood banks, etc.

FDA agrees that test results from the Clinical Laboratories Improvement Amendments of 1988 (42 U.S.C. 263a) certified laboratories or licensed blood establishments may be accepted as evidence of the most recent negative screening test for antibody to HIV, provided that the blood establishment has assurance that the laboratory is certified and is using a licensed test kit. The blood establishment should receive and retain testing records documenting the test results.

G. Comments on § 610.47(a)

1. Notification of Transfusion Recipient Prior to Completion of Licensed, More Specific Test

Two comments disagreed with the proposed requirement to notify recipients of potentially infectious units based upon screening results if the licensed, more specific test results are not available within 2 weeks. One comment stated that upon notification, the transfusion recipient would experience unnecessary worry since

more than 90 percent of repeatedly reactive screening results are not confirmed by Western Blot testing.

As previously discussed in this final rule, the time limit for the completion of the licensed, more specific test for HIV and the consignee notification of those test results has been extended from 2 weeks to a maximum of 30-calendar days. This change makes it highly unlikely that complete results will not be available prior to the deadline for notification. If a situation of noncompliance occurs, however, FDA has amended § 610.47(a) so that recipient notification prior to completion of the licensed, more specific test for HIV is not required. This change is consistent with FDA's proposal to notify recipients only if there are positive test results but not when the test results are indeterminate.

FDA agrees that notification of transfusion recipients that the transfused blood or blood component was at increased risk for transmitting HIV is very likely to cause the recipient, and possibly others, extreme anxiety and concern. Based on the rate of repeatedly reactive screening tests that are not confirmed by further testing, a significant percentage of recipients would be subjected to a tentative notification which would prove to be alarming, confusing, and unnecessary. Such recipients would be notified when the increased risk for transmitting HIV has been confirmed by further testing.

2. Establishments Subject to ''Lookback'' Regulations

One comment asked for clarification on § 610.47(a) which addresses those establishments subject to FDA's rule and those hospitals subject to HCFA's rule. Two comments asked if these regulations apply to all regulated blood establishments, including small, hospital-based transfusion services that also draw blood donors. Section 610.47(a) specifically states that transfusion services that are not subject to HCFA's regulations on the conditions of Medicare participation for hospitals (42 CFR part 482) are subject to this rule. FDA inspects establishments where activities include more than the performance of compatibility testing, e.g., blood collection, washing or freezing of red blood cells, and irradiating of blood components. Therefore, small, hospital-based transfusion services that also draw blood donors would be subject to this rule and inspection by FDA. Certain establishments that do not participate in Medicare, such as Indian Health Services and Veteran's Administration hospitals, are also subject to FDA regulations.

HCFA's regulations apply to hospital transfusion services where activities do not include more than the performance of compatibility testing and that participate in Medicare. Section III. of this document describes the division of responsibilities between FDA and HCFA for inspections of blood establishments. HCFA's final rule is published elsewhere in this issue of the Federal Register. This division of responsibilities between FDA and HCFA, consistent with the MOU, eliminates duplication of effort and reduces the burden on blood establishments and hospitals.

H. Comments on § 610.47(b)

1. Clarification of Responsibility for Transfusion Recipient Notification

Two comments asked for clarification as to which entity is responsible for notification of the transfusion recipient or his or her physician in situations where the transfusion services are provided to hospitals by community blood centers. One comment suggested more consistent requirements between FDA and HCFA because it appeared that the HCFA proposal makes the hospital responsible for the notification of the recipient's physician rather than the transfusion service, as is the case in the FDA proposed rule.

It is not the intention of FDA to designate the individual or the department that will contact the recipient but rather to designate that the transfusion service that issues the Whole blood or blood component for transfusion will be ultimately responsible for ensuring that the notification takes place. In a similar manner, HCFA holds the hospital responsible for ensuring the notification is completed.

2. Process and Documentation for Transfusion Recipient Notification

Twenty-five comments expressed concern over the process and timeframe for notification of the transfusion recipient. There were some questions as to where the ultimate responsibility falls for transfusion recipient notification and as to the documentation that is required. Three comments asked that attending physicians be required to comply with these regulations and asked for guidance in situations where the recipient's physician declines to notify the recipient due to conditions such as terminal illness, celibacy, or when the harmful effects may exceed the benefits of notification. Additionally, two comments expressed concern over respect for the doctor-patient relationship and the authority to interfere with that relationship.

As stated previously, FDA intends that each establishment have the flexibility to develop SOP's that describe the steps in this process and all appropriate documentation. The SOP should address documentation of person(s) contacted, by whom, when and whether the physician agreed to notify the recipient, and any additional, pertinent information. Some institutions may choose to designate a specific department or person within the hospital to conduct the notification and counseling for the recipient.

The SOP should be consistent with applicable local and State laws and shall specify both a well designed system for accomplishing notification and the required documentation of the outcome of these efforts.

FDA believes that because the attending physician has developed as relationship with the patient and is most familiar with that patient's history, the patient's interests are best served when the attending physician takes the responsibility for contact and counseling. In those instances when this does not prove to be appropriate or possible, the transfusion service is ultimately responsible for ensuring that the notification takes place. If the patient is competent, but the physician believes the information should not be given to the patient and State law permits a legal representative or relative to receive information on the patient's behalf, then the transfusion service or physician should notify the patient's legal representative or relative. Further, FDA believes that transfusion services should, upon learning of the death of the transfusion recipient, continue the notification process to inform the patient's family. Public health concerns would warrant the notification process continue and include the deceased patient's legal representative or relative. It would not be appropriate for a physician or transfusion service to determine that the patient or someone acting on his or her behalf need not be informed. The final rule has been amended to clarify the notification requirements in §§ 610.46(c) and 610.47(b).

FDA has no regulatory authority over physicians in their role as attending physicians, and for that reason, the agency is not able to require their participation. Upon accepting responsibility for recipient notification and counseling, it is reasonable to expect that the physician would, in good faith, determine the appropriate

content and completeness of information provided to the recipient.

FDA is relying on HCFA's expertise in the area of hospital practice in setting time limits for transfusion recipient notification. Consistent with HCFA's final rule, published elsewhere in this issue of the Federal Register, FDA believes that the hospital's notification effort should consist of, at the minimum, three attempts by telephone or in writing to reach the recipient, the recipient's legal representative or relative. The final rule has been amended to clarify that the transfusion service's notification effort should begin immediately after receiving results of further testing for HIV and should be completed 8 weeks later. The rule has also been amended to clarify that the transfusion service should notify the patient, the patient's legal representative or relative, as appropriate.

VI. Analysis of Impacts

FDA has examined the impacts of the final rule under Executive Order 12866 and the Regulatory Flexibility Act (Pub. L. 96–354). Executive Order 12866 directs agencies to assess all costs and benefits of available regulatory alternatives and, when regulation in 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, and has determined that this is not a significant regulatory action.

The purpose of the ''lockback'' requirement is to reduce the risk of transfusion transmitted HIV infection through the quarantine of blood and blood components that might have been collected during the ''window'' period, when the antibody to HIV is not yet detectable by a screening test. Notification of consignees to quarantine the affected products, until a more specific test for antibody to HIV is completed, will prevent any further transmission of the virus. Upon completion of more specific testing, all recipients of prior collections from a donor that subsequently tests positive for antibody to HIV will be notified by their attending physician, when possible, or by the transfusion service. Such transfusion recipients shall receive notification for the purpose of testing for evidence of HIV infection, early treatment, if indicated, and counseling to take appropriate precautions to prevent the further spread of the virus such as to sexual partners.

Most blood establishments already participate in a ''lookback'' program. Ninety-five percent of blood establishments, collecting 98 percent of the nation's blood supply, already participate in a ''lookback'' notification of their customers to quarantine previously shipped blood later determined to be at increased risk for transmitting HIV. Thus, requirements for written procedures, records of consignee notification, and records that relate the prior collections to the donor, later found to be repeatedly reactive for antibody to HIV, would affect at most about 5 percent of blood establishments; the remaining establishments may need to make minor changes to their existing procedures. Therefore, FDA believes this final rule should have a minimal impact. FDA expects the total annualized cost of the final rule to blood establishments to be $3,248,354. FDA anticipates only a small number of cases per year that will involve transfusion recipient notification. In conclusion, FDA has determined that the final rule is not a significant regulatory action as defined in Executive Order 12866.

At the time of the proposed rule, the agency certified that the proposed requirements would not have a significant impact on a substantial number of small entities. However, in response to industry comments and in light of amended requirements for analyzing impact on small entities (as enacted by Pub. L. 104–121), it was determined that a final regulatory flexibility analysis would be useful. Accordingly, the agency has assessed this final rule in accordance with the Regulatory Flexibility Act, with the following results:

Need for, and objective of, the rule. As described elsewhere in this preamble, FDA is taking this action to help ensure the continued safety of the blood supply, and to help ensure that information is provided to consignees of Whole Blood, blood components, Source Plasma and Source Leukocytes and to recipients of Whole Blood and blood components from a donor whose subsequent donation test positive for antibody to HIV.

Types and number of small entities affected. This rule will affect all of the 3,015 registered U.S. blood establishments. Of these registered establishments, approximately 400 are part of the American Red Cross, which supplies approximately 45 percent of blood products nationally. An additional 286 are Federal or State facilities. Many, or most, of the remaining 2,204 establishments may be small entities as defined by the Regulatory Flexibility Act.

The affect of this rule is greatest for those blood establishments that have not already voluntarily implemented ''lookback'' procedures similar to those required here. As stated in the proposed rule (58 FR 34962), FDA estimated that at least 95 percent of establishments, supplying 98 percent of the nation's blood, have such voluntary procedures and would need to make only minor changes to ensure that they are in compliance with this rule. The remaining up to 150 establishments would require more substantial changes in their procedures. FDA considers 150 to be an upper bound, since it is likely that liability concerns and advances in automated data technology have prompted most establishments that did not previously have ''lookback'' procedures to have them in place by now.

Projected reporting, recordkeeping, and other compliance requirements. To comply with this rule, all blood establishments subject to this rule, including small entities, must: (1) Review and, if necessary, modify their SOP's; (2) maintain the necessary records to carry out these procedures; and (3) notify consignees within 72 hours of repeatedly reactive test results. Blood establishments that provide transfusion services and that are not subject to HCFA regulations must also notify physicians of prior donation recipients, or the recipients themselves, of the need for HIV testing and counseling. The estimated time needed for establishments to comply with the reporting, disclosure, and recordkeeping requirements of this rule are described in detail in the reporting and recordkeeping tables in section VII. of this document.

FDA estimates that two types of skills will be necessary to meet these reporting and recordkeeping requirements. The skills of a medical technologist, or a person with equivalent training and experience, will be necessary to record donor, quarantine, testing, and disposition information, and to notify consignees of test results. Updating SOP's and notifying physicians and recipients of test results will require a person knowledgeable and experienced in medical laboratory practice.

Based on the reporting, disclosure, and recordkeeping burden described in section VII. of this document, FDA estimates that establishments that currently have ''lookback'' procedures will require approximately 27 hours per year to bring their procedures into compliance with this rule, while establishments without such procedures will require approximately 40 hours

annually to complete the required tasks. Establishments whose transfusion services are also covered by this rule will require an additional 8 hours per year to comply. Based on an estimated average hourly cost of $37.98 to perform the required tasks, FDA predicts that the average annual cost of these requirements for establishments that currently lack ''lookback'' procedures is $1,520 per facility for most establishments and $1,820 for facilities that transfuse as well as collect blood. Average annual costs for the great majority of establishments that already have ''lookback'' procedures are expected to be approximately $1,030 for most establishments and $1,340 for covered establishments that also provide transfusions.

In addition to these reporting and recordkeeping costs, all facilities will bear the additional cost of disposing of any affected units; conducting licensed, more specific tests for HIV; and replacing discarded units.

With the exception of the initial development of SOP's, all costs related to implementing the requirements of this rule are related to the number of units of blood collected from repeat donors who test positive for HIV, which in turn is related to total blood collections. The average number of units of blood drawn per establishment covered by this rule is approximately 8,000 units per year. Smaller establishments will have lower costs of compliance than the averages described above, while larger blood facilities will have higher costs, in proportion to the number of units of blood drawn per year.

Steps to minimize the economic impact on small entities. The significant issues raised by public comments on the costs of putting in place the required procedures, and the burdens imposed by the timeframes in the proposed rule, are described elsewhere in this preamble, FDA agrees with the numerous comments suggesting that 2 weeks is too short a time period to allow for completion of the licensed, more specific test and subsequent notification of consignees, and that 4 weeks is a more reasonable period. Accordingly, FDA has amended the rule to allow 30 calendar days for the completion of these tasks. This change should reduce the impact of the rule on small entities and reduce the chance that blood transfusion recipients will fail to receive notification that they had received blood or blood components that are at increased risk of transmitting HIV infection and or fail to receive appropriate counseling. In response to another comment, FDA amended the proposed rule to specify that certain pooled blood products intended for further manufacture into noninjectable products are exempt from quarantine. This change should also reduce the burden of the rule on some small entities. FDA rejected the option of excluding all small entities from the rule, because to do so would exempt a substantial proportion of establishments and defeat the objective of ensuring that all establishments have appropriate procedures in place to ensure the continued safety of the blood supply.

FDA's selection of the regulatory option described in this rule is based on its legal authority under sections 351 and 361 of the Public Health Service Act and section 501 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 351). The need for regulatory action results from the fact that a small but significant number of new HIV infections each year continue to be transmitted through blood transfusions; the fact that a small minority of blood establishments still lack appropriate procedures for identification of blood products at increased risk for transmitting HIV infection and notification of recipients of such products; and the need to ensure that those establishments with voluntary ''lookback'' procedures in place have procedures that are adequate and vigorously followed. The primary policy consideration in the formulation of this rule is to protect the public health.

VII. Paperwork Reduction Act of 1995

This final rule contains information collections which are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995. The title, description, and respondent description of the information collection are shown below with an estimate of the annual reporting and recordkeeping burden. Included in the estimate is the time for reviewing procedures, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information.

Title: Current Good Manufacturing Practices for Blood and Blood Components; Notification of Consignees Receiving Blood and Blood Components at Increased Risk for Transmitting HIV Infection.

Description: The final rule requires that blood establishments prepare and follow written procedures when the blood establishments have collected Whole Blood, blood components, Source Plasma and Source Leukocytes later determined to be at risk for transmitting HIV infections. This final rule requires that when a donor who previously donated blood is tested in accordance with § 610.45 on a later donation, and tests repeatedly reactive for antibody to HIV, the blood establishment shall perform more specific testing using a licensed test, and notify consignees who received Whole Blood, blood components, Source Plasma or Source Leukocytes from prior collections so that appropriate action is taken. Blood establishments and consignees are required to quarantine previously collected Whole Blood, blood components, Source Plasma and Source Leukocytes from such donors, and if appropriate, notify transfusion recipients. The agency is issuing this final rule to help ensure the continued safety of the blood supply, to help ensure that information is provided to users of blood and blood components, and to help ensure that transfusion recipients of blood and blood components at risk for transmitting HIV will be notified as appropriate.

Description of Respondents: Blood establishments (Business and Not-for-Profit).

Individuals and organizations had an opportunity to comment on the information collection requirements in the proposed rule. FDA has revised these estimates based on current data. These estimates are an approximation of the average time expected to be necessary for the collection of information. They are based on such information as is available to FDA. There are no capital costs, or operating and maintenance costs associated with this information collection.

As required by the Paperwork Reduction Act of 1995, FDA will submit a copy of this rule to OMB for review and approval of these information requirements. Individuals and organizations may submit comments on the information collection requirements by November 8, 1996. FDA particularly invites comments on: (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 collection of information, including the validity of the methodology and assumption 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. Comments

should be directed to the Dockets Management Branch (address above).

At the close of the 60-day comment period, FDA will review the comments received, make revisions as necessary to the information collection requirements, and submit the requirements to OMB for review and approval. Additional time will be allotted for public comment to OMB on the requirements and OMB review. Prior to the effective date of this final rule, FDA will publish a notice in the Federal Register of OMB's decision to approve, modify, or disapprove the information collection requirements. 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.

ESTIMATED ANNUAL REPORTING/DISCLOSURE BURDEN

21 CFR section	Number of respondents	Annual frequency per response	Total annual responses	Hours per response	Total hours
610.46(a)	3,015	60	180,900	.17	30,753
610.46(b)	3,015	60	180,900	.17	30,753
610.47(b)	200	16	3,200	.5	1,600
Total					63,106

ESTIMATED ANNUAL RECORDKEEPING BURDEN

21 CFR section	Number of record-keepers	Annual frequency of record-keeping	Total annual records	Hours per record-keeper	Total hours
606.100(b)(19)	3,015	1	3,015	2	6,300
606.160(b)(1)(vii)	150	160	24,000	12.8	1,920
606.160(b)(1)(viii)	3,015	60	180,900	4.8	14,472
Total					22,422

VIII. Environmental Impact

The agency has determined under 21 CFR 25.24(c)(10) 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.

List of Subjects

21 CFR Part 606

Blood, Labeling, Laboratories, Reporting and recordkeeping requirements.

21 CFR Part 610

Biologics, Labeling, Reporting and recordkeeping requirements.

Therefore, under the Federal Food, Drug, and Cosmetic Act, the Public Health Service Act, and under authority delegated to the Commissioner of Food and Drugs, 21 CFR parts 606 and 610 are amended as follows:

PART 606—CURRENT GOOD MANUFACTURING PRACTICE FOR BLOOD AND BLOOD COMPONENTS

1. The authority citation for 21 CFR part 606 continues to read as follows:

Authority: Secs. 201, 301, 501, 502, 505, 510, 520, 701, 704 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321, 331, 351, 352, 355, 360 360j, 371, 374); secs. 215, 351, 353, 361 of the Public Health Service Act (42 U.S.C. 216, 262, 263a, 264).

2. Section 606.100 is amended by adding new paragraph (b)(19) to read as follows:

§ 606.100 Standard operating procedures.

* * * * *

(b) * * *

(19) Procedures in accordance with § 610.46 of this chapter to look at prior donations of Whole Blood, blood components, Source Plasma and Source Leukocytes from a donor who has donated blood and subsequently tests repeatedly reactive for antibody to human immunodeficiency virus (HIV) or otherwise is determined to be unsuitable when tested in accordance with § 610.45 of this chapter. Procedures to quarantine in-house Whole Blood, blood components, Source Plasma and Source Leukocytes intended for further manufacture into injectable products that were obtained from such donors; procedures to notify consignees regarding the need to quarantine such products; procedures to determine the suitability for release of such products from quarantine; procedures to notify consignees of Whole Blood, blood components, Source Plasma and Source Leukocytes from such donors of the results of the antibody testing of such donors; and procedures in accordance with § 610.47 of this chapter to notify attending physicians so that transfusion recipients are informed that they may have received Whole Blood and, blood components at increased risk for transmitting human immunodeficiency virus.

* * * * *

3. Section 606.160 is amended by adding paragraphs (b)(1)(vii) and (b)(1)(viii) to read as follows:

§ 606.160 Records.

* * * * *

(b) * * *

(1) * * *

(vii) Records to relate the donor with the unit number of each previous donation from that donor.

(viii) Records of quarantine, notification, testing, and disposition performed pursuant to §§ 610.46 and 610.47 of this chapter.

* * * * *

PART 610—GENERAL BIOLOGICAL PRODUCTS STANDARDS

4. The authority citation for 21 CFR part 610 continues to read as follows:

Authority: Secs. 201, 501, 502, 503, 505, 510, 701 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321, 351, 352, 353, 355, 360, 371); secs. 215, 351, 352, 353, 361 of the Public Health Service Act (42 U.S.C. 216, 262, 263, 263a, 264).

5. Section 610.45 is amended by adding a new paragraph (d) to read as follows:

§ 610.45 Human immunodeficiency virus (HIV) requirements.

* * * * *

(d) For a donor whose test results for antibody to HIV are repeatedly reactive or otherwise determined to be unsuitable when tested in accordance with paragraph (a) of this section, the blood establishment shall comply, as applicable, with §§ 610.46 and 610.47.

6. New §§ 610.46 and 610.47 are added to subpart E to read as follows:

§ 610.46 "Lookback" requirements.

(a) *Quarantine and notification.* (1) All blood and plasma establishments are required to take appropriate action when a donor of Whole Blood, blood components, Source Plasma and Source Leukocytes tests repeatedly reactive for antibody to human immunodeficiency virus (HIV), or otherwise is determined to be unsuitable when tested in accordance with § 610.45. For Whole Blood, blood components, Source Plasma and Source Leukocytes collected from that donor within the 5 years prior to the repeatedly reactive test, if intended for transfusion, or collected within the 6 months prior to the repeatedly reactive test, if intended for further manufacture into injectable products, except those products exempt from quarantine in accordance with § 610.46(c), the blood establishment shall promptly, within 72 hours:

(i) Quarantine all such Whole Blood, blood components, Source Plasma and Source Leukocytes from previous collections held at that establishment; and

(ii) Notify consignees of the repeatedly reactive HIV screening test results so that all Whole Blood, blood components, Source Plasma and Source Leukocytes from previous collections they hold are quarantined.

(2) Consignees notified in accordance with paragraph (a)(1)(ii) of this section shall quarantine Whole Blood, blood components, Source Plasma and Source Leukocytes held at that establishment except as provided in paragraph (c) of this section.

(b) *Further testing and notification of consignees of results.* Blood establishments that have collected Whole Blood, blood components, Source Plasma or Source Leukocytes from a donor as described in paragraph (a) of this section shall perform a licensed, more specific test for HIV on the donor's blood, and in the case of distributed products, further shall notify the consignee(s) of the results of this test, within 30 calendar days after the donor's repeatedly reactive test. Pending the availability of a licensed, more specific test for HIV–2, a second, different screening test for antibody to HIV–2 shall be used along with a licensed, more specific test for HIV–1.

(c) *Exemption from quarantine.* Products intended for transfusion need not be held in quarantine if a determination has been made that the Whole Blood, blood components, Source Plasma or Source Leukocytes was collected more than 12 months prior to the donor's most recent negative antibody screening test when tested in accordance with § 610.45. Pooled Source Plasma and Source Leukocytes are exempt from quarantine.

(d) *Release from quarantine.* Whole Blood, blood components, Source Plasma and Source Leukocytes intended for transfusion or further manufacture which have been quarantined under paragraph (a) of this section may be released if the donor is subsequently tested for antibody to HIV as provided in paragraph (b) of this section and the test result is negative, absent other informative test results.

(e) Actions under this section do not constitute a product recall as defined in § 7.3(g) of this chapter.

§ 610.47 "Lookback" notification requirements for transfusion services.

(a) Transfusion services that are not subject to the Health Care Financing Administration's regulations on conditions of Medicare participation for hospitals (42 CFR part 482) are required to take appropriate action in accordance with paragraphs (b) and (c) of this section when a recipient has received Whole Blood or blood components from a donor determined to be unsuitable when tested for human immunodeficiency virus (HIV) infection in accordance with § 610.45 and the results of the additional tests as provided for in § 610.46(b) are positive.

(b) *Notification of recipients of prior transfusion.* If the transfusion service has administered Whole Blood or blood components as described in paragraph (a) of this section, the transfusion service shall notify the recipient's attending physician (physician of record) and ask him or her to inform the recipient of the need for HIV testing and counseling. If the physician is unavailable or declines to notify the recipient, the transfusion service shall notify the recipient and inform the recipient of the need for HIV testing and counseling. The notification process shall include a minimum of three attempts to notify the recipient and be completed within a maximum 8 weeks of receipt of the result of the licensed, more specific test for HIV. The transfusion service is responsible for notification, including basic explanations to the recipient and referral for counseling, and shall document the notification or attempts to notify the attending physician or the recipient, pursuant to § 606.160 of this chapter.

(c) *Notification to legal representative or relative.* If the transfusion recipient has been adjudged incompetent by a State court, the transfusion service or physician must notify a legal representative designated in accordance with State law. If the transfusion recipient is competent, but State law permits a legal representative or relative to receive the information on the recipient's behalf, the transfusion service or physician must notify the recipient or his or her legal representative or relative. If the transfusion recipient is deceased, the transfusion service or physician must continue the notification process and inform the deceased recipient's legal representative or relative. Reasons for notifying the recipient's relative or legal representative on his or her behalf shall be documented pursuant to § 606.160 of this chapter.

Dated: July 11, 1996.

David A. Kessler,

Commissioner of Food and Drugs.

Donna E. Shalala,

Secretary of Health and Human Services.

[FR Doc. 96–22709 Filed 9–6–96; 8:45 am]

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Health Care Financing Administration

42 CFR Part 482

[BPD–633–F]

RIN 0938–AE40

Medicare and Medicaid Programs; Hospital Standard for Potentially HIV Infectious Blood and Blood Products

AGENCY: Health Care Financing Administration (HCFA), HHS.

ACTION: Final rule.

SUMMARY: This final rule requires hospitals participating in the Medicare and Medicaid programs to take appropriate action when the hospitals learn that they have received whole blood, blood components (including recovered plasma), source plasma, and source leukocytes (hereafter referred to as blood or blood products) that are at increased risk of transmitting Human Immunodeficiency Virus (HIV)

infection. If the hospital learns that it has received blood or blood products collected from a donor recently exposed to HIV, before the donor has a sufficient level of antibody to be detected by the screening test for antibody to HIV, the hospital must quarantine any blood or blood products remaining in inventory pending confirmatory testing. If the presence of HIV is confirmed by more specific testing, the hospital must notify patients who received the blood or blood product.

This final rule is intended to ensure that proper health and safety steps are taken to minimize further spread of HIV infection. A final rule published elsewhere in this Federal Register by the Food and Drug Administration applies the same requirements to entities furnishing transfusion services that do not participate in the Medicare and Medicaid programs and clarifies the responsibilities of blood establishments to identify and notify the transfusion service that received affected blood and blood products.

EFFECTIVE DATES: This rule is effective on November 8, 1996.

FOR FURTHER INFORMATION CONTACT: Janet Samen, (410) 786–9161.

SUPPLEMENTARY INFORMATION:

I. Background

Hospitals must meet certain conditions in order to participate in the Medicare program. These conditions are intended to protect patient health and safety and ensure that high-quality care is provided. Hospitals receiving payment under Medicaid must meet the conditions for participation in Medicare.

Regulations containing the Medicare conditions of participation for hospitals are located in the Code of Federal Regulations at 42 CFR part 482, with the condition for hospital laboratory services at § 482.27. Section 482.27 contains general requirements for hospital laboratories. The more detailed requirements for laboratories appear in part 493, which sets forth requirements for all laboratories participating in the Medicare, Medicaid, and Clinical Laboratories Improvement Act (CLIA) programs.

In the Department of Health and Human Services, the Food and Drug Administration (FDA) and HCFA are responsible for different aspects of ensuring the safety of blood and blood products. Blood banks (referred to as blood establishments in FDA regulations) are subject to the FDA regulations for current good manufacturing practices and additional standards for the manufacture of blood and blood components under 21 CFR parts 211 and 600, 601, 606, 610, and 640. Laboratories that provide transfusion services are subject to CLIA requirements for quality control and health and safety standards (42 CFR part 493, subpart K) and laboratories in hospitals are also subject to the hospital conditions of participation for adequacy of laboratory services (§ 482.27). FDA and HCFA coordinate inspections of hospital-based blood banks to minimize duplication of effort and reduce the burden on affected facilities.

Human Immunodeficiency Virus (HIV) is a virus whose presence is associated with Acquired Immune Deficiency Syndrome (AIDS). In response to scientific data that show HIV is transmissible through infectious blood and blood products, FDA has implemented an extensive system of donor screening and testing procedures performed before, during, and after a donation takes place to help prevent the transfusion of blood and blood products that are infected with HIV.

Existing FDA regulations require each donation of blood to be tested and found negative for the antibody to HIV and restrict the use, for transfusion or further manufacture, of a donation testing repeatedly reactive for the antibody to HIV. Repeatedly reactive means that the initial HIV antibody screening test is reactive, retested in duplicate, and one or both of the duplicate tests are reactive. As a result of the FDA blood donor screening and testing procedures, the risk of transmitting HIV infection through blood transfusion is very low. However, despite the best practices of blood establishments, a person may donate blood early in infection when the antibody to HIV is not detectable by the screening test, but HIV is present in the donor's blood (a so-called ''window'' period). If the donor attempts to donate blood at a later date, the test for the antibody to HIV may at that time be repeatedly reactive. Under such circumstances, previously collected blood and blood products would be at increased risk for transmitting HIV and a recipient of a blood product collected during the ''window'' period would not know whether the donor was infected with HIV at the time of the previous donation. Steps taken to identify and quarantine remaining blood and blood products in storage and notify recipients of the blood are known as ''lookback.''

As a result of advances in identifying the presence of HIV, the ''window'' period continues to shrink. The FDA final rule published elsewhere in this Federal Register provides more information on the length of the window period and discusses various diagnostic modalities for HIV infection.

II. Proposed Regulations

FDA and HCFA published proposed regulations in the Federal Register on June 30, 1993 (58 FR 34962 and 58 FR 34977, respectively) to require lookback by blood establishments and transfusion services when it is later determined that potentially HIV infectious blood or blood products might have been collected and administered.

FDA proposed to require blood establishments (that is, facilities involved in the manufacture of blood and blood components) to quarantine previously collected blood and blood products collected from a donor who tested negative at the time of a previous donation but tests repeatedly reactive for the antibody to HIV on a later donation. A donor would be considered to be infected by HIV if the results of the FDA's licensed tests described at 21 CFR 610.45 show the presence of the antibody to HIV and if the screening results are confirmed positive by a licensed, more specific test. Blood establishments would be required to promptly notify the hospital transfusion service of the need to quarantine the potentially HIV infectious blood or blood products that were distributed.

In the HCFA regulation, we proposed to add a new paragraph (c) to § 482.27 (''Conditions of participation: Laboratory services.'') to set forth the standard for potentially HIV infectious blood and blood products. Under the proposed rule, when the hospital learns that it has administered blood that may have been collected during the ''window'' period, the hospital would be required to make several attempts to notify the patient's attending physician (physician of record) and ask the physician to inform the patient of the need for HIV testing and counseling. If the physician is unavailable or declines to notify the patient, the hospital must make several attempts to inform the patient of the need for HIV testing and counseling. We proposed that the notification include basic explanations to the patient and referral for counseling and that the hospital document the notification or attempts to notify the attending physician and the patient.

In addition, we proposed to require that, when services are furnished to a hospital by an outside blood bank, there must be an agreement governing the procurement, transfer, and availability of blood and blood products specifying that the blood bank promptly notify the hospital if potentially HIV infectious blood or blood products have been made available to the hospital.

Notification would enable the hospital to take proper health and safety steps to minimize further spread of HIV infection.

III. Analysis of and Responses to Public Comments

In response to the June 1993 HCFA proposed rule, we received 28 timely items of correspondence from national organizations, nurses, hospital administrators, State offices, law firms, and various organizations representing infection control officers and blood banks. A summary of individual comments we received on the June 1993 proposed rule, our responses, and the changes we have made are discussed below.

Coordination of FDA and HCFA Efforts

When HCFA and FDA published the June 1993 proposed rules, we intended that all blood banks (that is, blood establishments involved in the manufacture of blood and blood components) and transfusion services (that is, consignees that receive blood and blood products from blood banks/blood establishments and perform compatibility testing) comply with the quarantine and patient notification requirements. However, based on public comments received by both agencies, it appears that there was public misunderstanding of the mission of each agency and the scope of the rulemaking, as discussed below.

Comment: One commenter indicated that terminology used by HCFA and FDA is not consistent. In the FDA regulation, the terms ''consignees'' and ''transfusion services'' are used while the HCFA regulations refer to ''hospitals'' and ''blood banks.'' The commenter requested more consistent use of the terms. In addition, the commenter noted that the term ''blood banks'' may refer to a transfusion service or a freestanding community blood center. Finally, the commenter noted that the term ''consignee'' may mean the facility providing the transfusion service and that the term ''recipient'' may refer to the transfused patient. The commenter asked that ''transfusion service'' and ''transfused patient'' be the preferred terms.

Response: While we agree that the use of different terms can be confusing, we do not believe it would be appropriate to revise the terminology used in the HCFA regulation because it is consistent with that used elsewhere in title 42 of the Code of Federal Regulations, including the hospital conditions of participation and the CLIA regulations. Likewise, although the FDA terminology is different, it is understood by the entities regulated by FDA and described by FDA as follows.

- A transfusion service is a facility that is part of either a hospital or an independent clinical laboratory, that performs compatibility tests, stores and distributes blood components, but is not engaged in the routine collection or preparation of blood or plasma except for therapeutic collections or separation of recovered plasma or red blood cells.
- A blood establishment is an FDA registered facility or portion of a facility registered as such with FDA pursuant to 21 U.S.C. section 510 and 21 CFR part 607 that manufactures blood or blood products. These include hospital and non-hospital blood banks, plasmapheresis centers, donor centers, and the laboratories performing testing for these establishments.

To avoid confusion concerning whether FDA requirements regarding lookback and quarantine apply to hospital transfusion services, we are adding those requirements to the hospital conditions of participation. We have added a paragraph (c)(3) to § 482.27 to include the following requirements:

- Upon notification by the blood bank (blood establishment) that certain blood and blood products are at increased risk for transmitting HIV infection, the hospital (transfusion service) must determine the disposition of the blood or blood product and if it is holding any of the blood or blood product in inventory. If so, the hospital must quarantine the blood or blood products until notified by the blood bank of the results of an FDA-licensed, more specific test or other followup testing recommended or required by FDA.
- The hospital may release the blood or blood product from quarantine only after notification by the blood bank that the additional testing was negative for the HIV antibody, absent other informative test results. If the testing confirms the presence of the antibody for HIV, the hospital must dispose of the blood and blood products in accordance with FDA regulations at 21 CFR 606.40 and notify any patients who received the affected blood or blood products of the need for HIV testing and counseling. (The FDA final regulation requires the blood bank to complete the licensed, more specific test for the antibody to HIV within 30 days and promptly notify the hospital transfusion service of the test results.)

Comment: Several commenters suggested that any facility receiving and administering blood or blood products be required to comply with the same notification requirements as set forth in the proposed rule. Two commenters also suggested this standard for ambulatory surgical centers.

Response: When we published the proposed regulation, we specifically requested public comment regarding the need to develop similar requirements for other facilities that provide transfusion services. Although we did not receive specific suggestions, we have revised § 482.27(c)(4) to clarify that when a hospital (transfusion service) furnishes blood or blood products to another entity or appropriate individual, the hospital retains responsibility for patient notification.

We believe this approach is reasonable and consistent with the usual path followed by blood from donation to transfusion. As clarified in FDA regulations, blood establishments (defined in 21 CFR 607.3(c)) collect, screen, and test the blood, prepare blood components or process blood for further manufacture, and label blood components for distribution to a transfusion service. The transfusion service is the entity responsible for determining compatibility with the patient's sample and sending the blood to the patient's location (for example, the hospital, clinic, nursing facility, or home setting). In order to release the blood and blood products for transfusion, the hospital must crossmatch the blood for compatibility with the patient's sample. In doing so, the hospital would obtain enough information to enable them to notify the patient. Thus, the hospital has patient information and a notification system in place and is in the best position to perform patient notification.

We note that FDA is adopting the patient notification requirements for hospitals that do not participate in Medicare and Medicaid. Thus, all hospitals that administer blood and blood products or release the blood and blood products must comply with the same patient notification requirements.

Timeframe for Completing Notification

In the proposed rule, we did not require a specific timeframe for completion of the notification effort. Rather, we required the hospital to make several attempts to notify the patient's attending physician and, if the physician is unavailable or declines to notify, make several attempts to notify the patient. We indicated in the preamble that the hospital's notification effort should begin immediately after receiving the information from the blood bank and be completed within 8 weeks. Although we specifically invited public comment on the sufficiency of this level of effort, we did not receive enough information to draw any

conclusions about existing patient notification activities. In addition, the information we received indicated fundamental differences in the viewpoints of the commenters as described below.

Comment: Two commenters agreed with the approach contained in the proposed rule and did not want the hospital's search for the patient's physician or the patient to be bound by a specific timeframe. One commenter suggested that we only include the following requirements in the final rule: (1) Require that hospitals have written procedures for notifying patients; (2) provide for an appropriate, knowledgeable person to talk with the patient if the physician cannot be reached or chooses not to be involved; and (3) require that the notice be expeditious and confidential and include recommendations to seek HIV testing and counseling. Another commenter suggested that we require only that the hospital exercise due diligence and document its notification efforts.

Response: In order to respond to these commenters, we consulted with FDA on the best approach to the notification timeframe. We have decided to include a specific timeframe for completion of the notification effort in order to prevent hospitals from making sporadic efforts over a protracted period of time and to provide a reasonable minimum standard (§ 482.27(c)(5)). We believe requiring at least three attempts to notify the physician and, as necessary, three attempts to notify the patient within 8 weeks is reasonable. Since patient notification by the hospital rarely will be necessary, we do not believe that requiring as many as six notification attempts will be burdensome to hospitals.

Comment: One commenter asserted that the search could be performed in less than 8 weeks depending on a hospital's ability to locate records and contact the patient by mail. Still another commenter questioned whether we had considered the possible delay in starting treatment that may occur because of the 8-week period allowed for notification and expressed concern that an 8-week delay could contribute to individuals unknowingly transmitting HIV. One commenter indicated that four or five attempts over a 3- to 5-day period would be sufficient while another commenter suggested that we require a 12-week timeframe based on their concern that the physician might decline at the end of the 8 weeks and leave little time for the hospital to perform the notification.

Response: We believe that most, if not all, notifications would be accomplished with relatively little effort and that three attempts should be sufficient in most cases. On the other hand, if a hospital has made a good faith effort of at least three attempts but is not able to locate the patient within 8 weeks, we do not expect the hospital to continue its search. Of course, there is no limit on how much time a hospital may choose to expend on this effort.

We do not intend for the hospital to use the entire 8 weeks to attempt to locate a physician who, at the end of the 8-week period, may be determined to be unavailable. Rather, we intend that the majority of the 8 weeks be used to locate and notify the patient. We recommend that the hospital promptly make three attempts within one week to notify the physician. If the hospital is unable to locate the physician or the physician does not agree to notify the patient, the hospital should promptly start attempts to locate the patient.

In addition, it would be inappropriate for the physician to wait until the end of the 8-week period to inform the hospital that he or she is unwilling to notify the patient. In most cases, we believe that the hospital will contact the physician by telephone and the physician will make an immediate decision to agree or decline to notify the patient. However, if the physician is not able to make an immediate decision, the physician should indicate his or her decision within 1 week of the hospital's request. In this way, it is reasonable to expect the hospital to locate and notify the patient in the remaining 7 weeks.

We are aware that there may be instances where the hospital's notification efforts will extend beyond the 8-week period due to circumstances beyond the hospital's control. For example, a physician who agrees to notify the patient may later inform the hospital that he or she was unable to notify the patient or the patient may not respond timely to notification efforts because he or she is away from home. In these cases, the hospital must document in the patient's medical record the extenuating circumstances that prevented patient notification within the 8-week timeframe (§ 482.27(c)(5)).

Comment: One commenter questioned whether patient notification is necessary if several years have passed after receipt of a transfusion, or whether the hospital can establish timeframes after which patient notification need not be made.

Response: Section 610.46(a) of the FDA regulation published elsewhere in this Federal Register defines the quarantine and notification process to be followed by blood establishments supplying blood to hospitals. Under this rule, when a blood establishment learns of a change in the HIV status of a donor, the blood establishment must determine if any prior donations meet the quarantine and notification requirements set forth in 21 CFR 610.46(a) and, as appropriate, inform the hospital(s) that received any prior donations from the donor. Once the blood establishment notifies the hospital(s), we do not believe that there is ever a time that patient notification need not be attempted. It is only when the physician or the hospital cannot locate the patient that the process may come to an end.

Role of the Physician in the Notification Process

Comment: One commenter suggested that we require any physician who wishes to participate in the Medicare or Medicaid program to assume the responsibility for notifying the patient and providing or making available appropriate HIV counseling to the patient. Another commenter requested that we indicate the consequences for physicians who fail to notify the patient.

Response: Although we believe that it is appropriate for attending physicians to notify their patients, we do not have authority under current law to require that physicians do so. Thus, while it is true that there are no Federal penalties imposed on physicians who decline or do not take appropriate steps to notify the patient, we believe most physicians will choose to notify the patient and voluntarily inform the hospital whether notification occurred. Since we have an agreement with each Medicare and Medicaid participating hospital and the law authorizes us to include provisions such as these under the hospital conditions of participation, we have determined that if the physician does not agree to notify the patient, the hospital must assume responsibility for patient notification.

Comment: Several commenters wanted clarification regarding when a physician could decline to notify the patient. Many commenters disagreed with permitting the physician the option to decline notification. Four commenters stated that this policy contradicts principles of continuity of care and sound medical practice. One commenter asserted that no physician will notify patients if given the option and that the requirement for hospitals to notify patients when physicians decline removes any incentive for the physicians to participate in the notification process.

Response: In the interest of continuity of care and sound medical practice, we believe that most physicians will notify

their patients. However, we continue to believe there could be legitimate reasons why a physician might refuse to notify the patient; for example, the physician determines that the patient has moved to another State and it would be difficult for the physician to identify HIV counseling and testing programs in the patient's new location, or the physician has had very limited or no contact with the patient in several years.

Comment: Several commenters asked us to publish a definition of ''attending physician'' to clarify who should be responsible for patient notification.

Response: In § 482.27(c)(4), we have included the phrase ''physician of record'' in parentheses next to the term ''attending physician.'' Although many physicians may have contact with a patient in the course of a hospital stay, the admitting physician is identified on the admission form. We believe that this physician is the ''physician of record'' and should be responsible for the notification. However, if the physician who orders the transfusion is not the same physician as the physician identified on the admitting form, the hospital may ask either physician to perform the notification.

Comment: One commenter questioned the role the hospital plays in determining whether a physician provided information and referred the patient for counseling. One commenter asked that we specify whether the hospital is obligated to complete any part of the notification that the physician fails to carry out. Additionally, the commenter questioned how the hospital would know what the physician had done.

Response: Under this regulation, when the physician accepts responsibility for the notification, the hospital is not required to follow up with the physician to determine whether patient notification occurred. Since the hospital may not be aware of the information the physician provides, we cannot require that the hospital complete the notification. In light of physicians' professional relationship with hospitals, we believe physicians will inform the hospital whether notification occurred. If the physician informs the hospital that he or she was unable to notify the patient, the hospital must proceed with patient notification.

Comment: One commenter wanted to know at what point the hospital resumes responsibility for notification if the physician is unable to contact the patient. Two commenters questioned whether the physician is required to inform the hospital of the results of notification, for example, whether the physician was unable to locate the patient, whether the patient was tested, and the results of the testing.

Response: Although we believe that the physician, as part of his or her professional responsibility, will inform the hospital of the results of notification, he or she is not required to do so. If the physician accepts responsibility for notification, and later informs the hospital that the patient was not notified, the hospital must attempt notification, regardless of the time that elapsed after the hospital first notified the physician.

Some State or local health groups may require further followup and other epidemiological information but release of information is dependent upon State and local laws, the medical practice, and the patient-physician relationship. Finally, having the physician notify the hospital of the results of testing of the referred patient is outside the scope of the notification requirements of this regulation.

Comment: One commenter noted that the laws in his State require the physician to provide information to the patient regarding blood products in advance of any non-emergency transfusion and, when the physician orders an HIV test, to obtain the patient's informed consent.

Response: While these precautions are indeed important to the risk management of blood and blood products, they do not remove the need for notification by the hospital or physician of possible contamination.

Comment: One commenter indicated that assigning patient notification responsibility to the hospital means that a clinician must be identified to handle the cases declined by the physician. Several commenters questioned whether the appropriate individual to notify the patient should be limited to someone with medical experience or whether the hospital may designate any nonmedical personnel to perform these notifications. One commenter indicated that the physician is the only individual who should notify the patient, while another commenter noted that the infection control representative in his facility is responsible for notification. Another commenter requested that we permit the hospital to bypass the doctor/patient relationship if the physician resists the hospital's request to notify the patient. One commenter suggested that when the physician declines to notify the patient, the hospital should use the mail system, rather than have a hospital employee unknown to the patient, to provide the notification.

Response: We continue to believe it is preferable that notification be made by a physician with whom the patient has a professional relationship, such as the attending physician who coordinated the care during the patient's hospitalization or the physician who ordered the blood or blood product. Nevertheless, the hospital may designate another physician or an appropriate hospital representative to inform the patient. We believe that the hospital in its policies and practices will designate an appropriate, competent individual to perform this type of notification such as an infection control officer, a nurse, a clinical laboratory scientist, an individual with medical expertise who is not a physician, or a social worker. We note that the hospital must review any voluntary notification procedures to ensure that they conform to the requirements of this regulation.

Comment: Several commenters indicated that hospitals should develop policies to identify the appropriate physician to assist in notification and counseling, in the event efforts to locate the attending physician are unsuccessful.

Response: We have revised the regulation to require hospitals to establish policies and procedures for notification (§ 482.27(c)(6)). The final regulation does not require a hospital to provide HIV testing or counseling, but merely to refer the patient for testing and counseling. We expect that the referral for testing and counseling will be made to a physician or organization that provides high quality HIV testing and has extensive experience in providing HIV counseling.

Notification Requirements

Comment: We invited comment on whether our proposed rule should be implemented as part of a Medicare hospital standard or as part of the FDA requirements applicable to blood establishments. While most commenters indicated that hospitals, not blood banks, should be responsible for assuring that patients are properly notified of the possibility that they have received infectious blood, some commenters recommended that blood banks should be required to make notification.

Response: Based on the comments we received, we have determined that the hospital could best perform the notifications since it has access to medical records. Blood banks that are not departments of hospitals do not routinely receive hospital patient information. If the blood bank were a department within the hospital or performed compatibility testing for the hospital, it would have access to patient information and could perform the

notification as designated by hospital policy. Under this final regulation, blood banks must notify the hospital of receipt of potentially HIV infectious blood and blood products and hospitals are responsible for patient notification.

Comment: Two commenters recommended that specific operational issues should be developed at the hospital level within general guidelines established by regulation. Another commenter suggested that the regulation describe what hospitals are expected to accomplish and let hospitals determine, based on their own experience and circumstances, how best to notify patients. However, two others requested that the mechanics of notification be spelled out for standardization.

Response: As noted previously, we added § 482.27 (c)(4) and (c)(5) to require three attempts to notify the physician, and, as necessary, three attempts to notify the patient with 8 weeks. We believe that, within these parameters, the hospital retains flexibility to develop its own policies and procedures in order to meet the notification requirements.

Comment: One commenter indicated that the language of proposed § 482.27(c)(2) is inconsistent with the preamble because it implies that the hospital is obligated to notify both the physician and the patient.

Response: We are clarifying in this final rule that the hospital must notify the patient only if the physician is unavailable, declines, or later informs the hospital that he or she was unable to notify the patient (§ 482.27(c)(4)).

Comment: One commenter indicated that a search should be terminated only after a review is conducted by a hospital-sponsored ''lookback advisory committee'' composed of relevant specialists and expert staff members.

Response: While we support the use of an advisory committee to determine when it is appropriate for patient notification efforts to cease, we have decided not to adopt this suggestion in the regulation. We would prefer to allow a hospital flexibility to develop responsible policies and procedures. Of course, a hospital may choose to incorporate the commenter's suggested approach into its policies and procedures.

Comment: Four commenters indicated that there are no requirements that identify the information to be released during patient notification. The commenters suggested that we establish uniform and standard minimum requirements for disclosing information to patients during the notification process.

Response: We agree and have added § 482.27(c)(6)(iii) to clarify that when a physician or hospital notifies a patient about the need for HIV testing and counseling, the patient will also be given the names of several programs or places in the area where the patient resides that provide these services. In addition, the patient will be told about any requirements or restrictions the programs may impose such as whether the program requires a fee, a physician request form, identification or public assistance cards, or a residency requirement. In some situations, the hospital, in conjunction with its advisory groups, will provide the materials for the physician to use or identify programs that provide the HIV testing and counseling. Some groups have developed packages of materials, brochures, and information about the risks of blood and blood products and how HIV infection is transmitted. The Centers for Disease Control and Prevention (CDC) National AIDS Hotline operates a toll-free number (1–800–342–2437) 24 hours a day that the hospital or physician can give to the patient for more assistance. (The Hotline offers anonymous, confidential AIDS information to the American public. Trained information specialists answer questions about HIV infection and AIDS. The physician or hospital can give the patient the Hotline number (1–800–342–AIDS/2437 (English); 1–800–344–7432 (Spanish) and 1–800–243–7889 (TDD/Deaf Access)). We encourage physicians and hospitals to make available to the patient any additional information that would be useful to the patient and consult with and obtain resource materials from programs that are funded by the Ryan White Comprehensive AIDS Resources Emergency Act, the CDC, county and State health departments, and AIDS awareness groups.

Privacy and Recordkeeping

Comment: One commenter expressed concern that the proposed regulation did not address the issue of privacy in recordkeeping, including access to the information from the Blood Donor Locator Service (BDLS) operated by the Social Security Administration (SSA), and blood bank and hospital records. The commenter suggested that, even though these issues may be addressed elsewhere, they needed to be restated in this regulation.

Response: Hospital requirements for confidentiality in recordkeeping are already in existing regulations at § 482.24. Documents related to notification become part of the patient's medical record and are subject to the normal safeguards for access, information release, patient consent, and other precautions for confidential information, whether in hard copies, films, or computer records. If there is any doubt about confidentiality or disclosure, a medical record administrator can be consulted to provide adequate instructions. In addition, the hospital must establish procedures that conform to all Federal, State and local laws regarding confidentiality.

Comment: One commenter suggested that the hospital send the physician a return postcard and ask that the postcard be sent back to the hospital indicating whether the patient was notified, and, if so, the date the physician notified the patient.

Response: As noted earlier, we have revised the regulation to require hospitals to establish policies and procedures for notification, including requirements for confidentiality (§ 482.27(c)(7)). We have concerns about maintaining patient confidentiality through use of postcards to convey information about potentially HIV infectious blood and blood products. Although this final rule affords the hospital the flexibility to establish policies and procedures for the notification process, the policies and procedures must protect patient confidentiality.

Comment: In addition to any State requirements or laws concerning HIV confidentiality, many commenters recommended that all written patient notifications be marked ''confidential'' and be sent only by certified mail. Two commenters asked for a ''return receipt.''

Response: While we would support efforts by hospitals to use certified mail when written patient notification is necessary, we have decided not to incorporate this requirement in the regulation. Similarly, although use of a return receipt would provide the hospital with confirmation that the individual received the information, incorporating this specific requirement may conflict with State laws that require ''marking for confidentiality'' and would limit the hospital's flexibility to develop a process based on its experience and circumstances.

Comment: One commenter did not want all patients notified based on a concern that once a patient's HIV status is known, the patient may be subjected to ostracism and discrimination in receiving care. Since many hospitals use universal precautions for infection control, the commenter believed that there is no need to know the HIV status of patients. However, information about

the HIV status could be retained by the patient's physician.

Response: We believe it is important for the patient to know of his or her potential exposure to HIV so that he or she will be informed of the need for testing and counseling in order to promote behavior changes that will reduce the risk for transmission of HIV and to detect HIV infection in persons so that their need for medical treatment and other services can be assessed.

Comment: One commenter recommended that we clarify the documentation needed to be filed by the attending physician and materials to be developed and retained by the hospital. Another commenter wanted to know which steps in the process should be documented, that is, the attempts to notify patients, counseling, patient referral, etc. One commenter questioned whether compliance can be evaluated by Medicare, the FDA, or the Joint Commission on Accreditation of Healthcare Organizations (JCAHO) without specific documentation requirements for notifying patients of potentially infectious blood or blood products.

Response: We are not looking for lengthy documentation, but sufficient recordkeeping that indicates when attempts were made to notify the patient and the results of those attempts. We are not prescribing forms that a hospital must use; however, a hospital may develop its own record forms. We do not believe that additional files or new systems of data should be kept on this matter. The surveyor, in determining compliance, must be able to determine satisfactorily that the manner in which the hospital performs notifications comports with the regulation.

Comment: One commenter requested that we clarify the type of information regarding the patient, for example, patient testing results, that can be shared between physician and hospital.

Response: The hospital and the physician may determine if any information should be shared. This rule does not require the sharing of information between the physician and the hospital. Patient testing results are outside the scope of this regulation.

Comment: One commenter asked for standardized recommendations for record retention by blood banks and by institutions accepting and administering blood and blood products. The commenter asserted that his facility requires that employee health records be kept for 30 years after terminating employment.

Response: Although a facility may require that employee health records be kept for 30 years after the employee leaves employment, this is not the current Federal standard for records involving blood and blood products. The hospital conditions of participation require that hospital medical records must be kept at least 5 years (§ 482.24(b)(1)). The notification records and blood bank records are subject to the same 5-year requirement. Additionally, the FDA regulations at 21 CFR 606.160(d) require that blood and blood product records be kept for at least 5 years after processing, or 6 months after the latest expiration date, whichever is later. Under CLIA, the laboratory regulations on quality control records for blood and blood products (§ 493.1221) reflect the FDA regulation. Any longer timeframe for retention of medical records is dependent upon hospital policies, State laws, computerization, storage space, and investigational studies.

Comment: Two commenters interpreted the proposed rule as requiring notification by the hospital when the patient is terminally ill, debilitated, or celibate, and is not (and has not been) an infection risk to others. The commenters expressed concern that these patients would be adversely affected by the notification. The commenter interpreted the proposed rule to require the hospital to inform the patient even if the physician caring for the patient, either alone or in consultation with relatives, believes the harmful effects of notification exceed the benefits of notification.

Response: We have revised the regulation at § 482.27(c)(8) to clarify that the physician or hospital may notify a legal representative designated in accordance with State law. Further, if the patient is competent, but the physician believes the information should not be given to the patient and State law permits a legal representative or relative to receive information on the patient's behalf (for example, when the patient is under age 18), then the physician must notify the patient's representative or relative. Upon learning of the death of a transfusion patient, the hospital must pursue the notification process to inform the patient's family. Public health concerns would warrant that the notification process continue and include the deceased patient's legal representative or relative. It would not be appropriate for a physician or hospital to determine that the patient or someone acting on his or her behalf need not be informed.

Comment: Three commenters wanted epidemiologic information, demographics, or other information to be provided to the State health department or other appropriate entity for patient followup. Another commenter requested that the blood bank notify the physician and the regional health departments about potentially HIV infectious blood and blood products being administered. The commenter referred to the health department's ability to track various diseases and to provide pre- and post-counseling of possible HIV-infected individuals.

Response: Disclosure of information to entities other than the hospital, the patient, and, as appropriate, the patient's legal representative or relative, is governed by State law and hospital policies and is outside the scope of this rulemaking.

Comment: One commenter suggested that the notification about a patient's HIV status be given to good samaritan bystanders. The commenter stated that there are circumstances when an individual injured in an accident or fire requires subsequent medical care. When that care is given and the patient is found to be HIV positive, the commenter stated that all those who have given the patient medical care should be informed of the patient's status. The commenter wants State and Federal regulations to protect health care workers, emergency medical technicians, and public safety officials.

Response: The comment, while addressing an important public health and safety issue, is beyond the scope of this regulation. However, the CDC published a final rule on March 21, 1994 to address this issue (59 FR 13418).

Comment: One commenter wanted the hospital to be informed promptly by outside blood sources if there is any doubt about its blood supplies possibly being infected by the HIV virus.

Response: The issue raised by the commenter is addressed in the FDA final regulation published elsewhere in this Federal Register.

Hospital Agreements With Blood Banks

Comment: One commenter indicated that government intrusion in mandating agreements between hospitals and blood banks would not permit the organizations to work out their own agreements. Another commenter stated that if hospitals are required by regulation to have an agreement for procurement, transfer, and availability of blood and blood products, the blood banks would be in a position to impose additional terms through the agreements that the hospital would not otherwise wish to accept, for example, an agreement under which a hospital would never seek indemnification from the blood bank for infectious blood or

blood products. Another commenter suggested that his facility occasionally obtains blood or blood products from a source other than the blood bank that regularly supplies it. The commenter questioned whether the hospital is required to have an agreement with all sources supplying blood to the hospital.

Response: The laboratory requirements at § 493.1277 already require that in the case of services regularly furnished by an outside blood bank, the hospital laboratory must have an agreement reviewed and approved by the director that governs the procurement, transfer, and availability of blood and blood products. We note that a blood bank that is part of a hospital is not required to have an agreement with the hospital administration, but the laboratory still would have policies of proper practice that meet the FDA regulations and requirements of other regulatory and accrediting bodies. We intend that the details of the agreements or practice policies that are worked out between the blood bank and the hospital be consistent with Federal, State and local laws. Finally, we recognize that, under certain circumstances, hospitals may receive blood from a source other than the blood bank that has an agreement with the hospital. For example, during a blood emergency, a hospital may receive blood from another blood bank that may have a surplus of a special blood type that is needed by the hospital's patient. In this situation, if the blood bank becomes aware that the blood it furnished the hospital is potentially infected with HIV, the FDA regulations require the blood bank to notify the hospital.

Comment: One commenter indicated that the blood bank obligations are better achieved through regulations by the FDA. Further, the commenter suggested that since requirements change from time to time, all agreements would need to be changed every time. The commenter also concluded that establishing requirements by regulation alone is more flexible and efficient than regulations and contractual agreements.

Response: As noted previously, FDA and HCFA are responsible for different aspects of ensuring the safety of blood and blood products. Blood banks are subject to FDA regulations for current good manufacturing practices and additional standards for the manufacture of blood and blood components under 21 CFR parts 211 and 600, 601, 606, 610, and 640. HCFA regulations cover quality control, health and safety issues, and adequacy of laboratory services. Since the hospital has access to medical records and it is preferable that the notification is made by an individual with whom the patient has a professional relationship, such as the attending physician who coordinated the care during the patient's hospitalization, we believe that the requirements of this regulation should be addressed through the hospital conditions of participation. Agreements can be written flexibly so that any changes in FDA or HCFA requirements can be incorporated into operating procedures rather than by constructing a new contractual agreement.

Comment: One commenter recommended that the SSA BDLS be expanded and adapted to provide assistance in mandated lookback programs to locate patients. Another commenter asked that the SSA BDLS program be available for locating the last address of known sexual partners of lookback patients if notifying them is determined to be necessary.

Response: The SSA BDLS was implemented to enable States and authorized blood donation facilities to notify blood donors whose donations indicate that they are or may be infected with HIV. Section 8008 of the Technical and Miscellaneous Revenue Act of 1988 (Pub. L. 100–647) provides for furnishing only to participating States and authorized blood donation facilities at their request the last known personal mailing address of blood donors whose blood donation shows that they are or may be infected with HIV, if the State or authorized blood donation facility has been unable to locate the donors. The SSA BDLS cannot be used for any other purpose. To expand the program to include obtaining information on the patient or known sexual partner would require a legislative amendment.

Comment: One commenter stated that the rule did not address requirements for hospitals that have their own blood banks.

Response: We have clarified in § 482.27(c)(4) that if the hospital has administered potentially HIV infectious blood and blood products directly through its own blood bank or under an agreement with an outside blood bank, the hospital must promptly notify the patient's physician. We note that a hospital transfusion service that also functions as a blood establishment, that is, collects and manufactures blood and blood products, is subject to HCFA's final rule as a transfusion service and FDA's final rule as a blood establishment.

Contracting for Notification

Comment: Four commenters recommended that we permit a hospital to formally contract with a blood center to supervise the notification of the patient, testing, and counseling procedures, if the physician is unavailable or declines to do so. One commenter mentioned that the departments of health in three States perform notification and tracing of HIV/AIDS patients and contacts. Another commenter suggested public health departments as an alternative for notification and counseling because of the expertise and mechanisms that are already in place.

Response: There is no barrier to a hospital contracting with another organization to perform the notification, testing, and counseling. However, under this rule, the hospital is responsible for the notification and referral. We are aware that a number of State departments of health provide notification and tracing of HIV/AIDS patients and contacts. Nonetheless, we continue to believe that the hospital and the physician are in a better position to perform the notification because of their prior involvement with the patient. A hospital that delegates notification must ensure that the notification and referral for counseling are performed in accordance with this regulation. If the blood center or organization fails to comply with the conditions of participation, the hospital would be subject to a noncompliance action.

Counseling

Comment: Two commenters stated that some State laws require specific counseling procedures and clinical information for those undergoing counseling for HIV testing.

Response: We believe individual State laws should be followed to provide information and counseling procedures following the notification process. The notification and referral requirements in the rule do not conflict with any such State laws.

Enforcement

Comment: One commenter urged us to recognize the Joint Commission on Accreditation of Healthcare Organizations (JCAHO) and the American Osteopathic Association (AOA) standards to avoid a second survey by Medicare.

Response: We have been in contact with the JCAHO and AOA and have evaluated their standards to ensure comparability with the requirements in this final regulation. Both organizations plan to incorporate the new requirements into the 1996 update to their accreditation standards. Therefore, a hospital accredited by the JCAHO or the AOA would be deemed to meet the Medicare requirement for the standards

on potentially HIV infectious blood and blood products. A second survey by HCFA would not be routinely required. However, if a complaint was filed regarding a look-back situation and HCFA decided the situation warranted an investigation, HCFA may authorize a complaint investigation.

Burden on Hospitals

Comment: One commenter disputed the estimate in the proposed rule of 1 hour of public reporting burden (58 FR 34980) and suggested that notification takes more than 1 hour to complete.

Response: We estimated the 1-hour timeframe based on several assumptions: (1) The records on the patient had already been retrieved, (2) the physician of record was noted on the admission sheet, and (3) the hospital had the physician's correct phone number or address. We anticipated that the phone conversation between the hospital representative and physician would last approximately 10 minutes. We inflated this figure to 1 hour because we wanted to include any time necessary for recalls and wrong numbers. We also considered time necessary for preparation of written notices and delivery of notices to the mail room. We expect that a hospital will rarely need to notify a patient directly, although we recognize that it would take additional time. We did not receive any comments that cited examples of the time involved to notify a patient. Some hospitals have computer linkup between departments and can easily retrieve information. The time involved for each case also may differ depending upon whether it was a single unit of blood given to one patient versus a unit of blood that was separated into several blood products and given to several patients. If a single unit of blood is separated into several components or blood products, each individual affected by the donor represents a separate notification case.

Comment: Two commenters stated that the cost associated with an additional standard would add an unnecessary regulatory burden.

Response: We disagree that the cost of this standard would be burdensome. Although initial implementation of notification procedures will require some expenditure of time and effort, we believe most hospitals, blood banks, and physicians are currently voluntarily complying with the requirements of this final regulation. We estimate that the ongoing cost of complying with this regulation will be small because the risk of a person being transfused with potentially HIV infectious blood and blood products is small and declining.

IV. Provisions of the Final Regulations

After consideration of the public comments, we are adopting the June 1993 proposed rule with the following changes.

- We have clarified that when the blood bank notifies the hospital that certain blood and blood products are at increased risk for HIV infection, the hospital must determine if it is holding any of the blood or blood product in inventory. If so, the hospital must quarantine the blood or blood products until notified by the blood bank of the results of a licensed, more specific test or other followup testing recommended or required by FDA. The hospital may release the blood or blood product from quarantine only after notification by the blood bank that the licensed, more specific test was negative for HIV antibody, absent other informative test results. (§ 482.27(c)(3))
- We have clarified that when patient notification is necessary, hospitals are required to make three attempts to notify the patient's attending physician or the physician who ordered the blood or blood product and ask the physician to notify the patient. If the physician is unavailable, declines, or later informs the hospital that he or she was unable to notify the patient, the hospital must make three attempts to notify the patient. (§ 482.27(c)(4)
- We have clarified that when a hospital releases blood and blood products to another entity or appropriate individual for transfusion, the hospital is responsible for the patient notification process. (§ 482.27(c)(4))
- We have specified that notification to a legal representative or relative of the patient may be appropriate in those instances permitted by State law or where the patient is deceased. (§ 482.27(c)(8))
- We have clarified that we are not requiring the physician to make the actual counseling appointment for the patient and expanded the description of the content of notification. (§ 482.27(c)(6)(ii) and (iii))
- We have clarified that a hospital's steps to notify must be initiated promptly and completed within 8 weeks. (§§ 482.27(c)(4)(i) and (c)(5))
- We have required that hospitals establish policies and procedures for notification and documentation that conform to Federal, State, and local laws, including requirements for confidentiality and for medical records. (§ 482.27(c)(7))
- We clarified that, if the hospital uses the services of an outside blood bank, the agreement governing the procurement, transfer, and availability of blood and blood products must require the blood bank to promptly notify the hospital about potentially HIV infectious blood and blood products. (§ 482.27(c)(2))

V. Collection of Information Requirements

Under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 et seq.), agencies are required to provide 60-day notice in the Federal Register and solicit public comment before a collection of information requirement is submitted to the Office of Management and Budget (OMB) for review and approval. In order to fairly evaluate whether an information collection should be approved by OMB, the Paperwork Reduction Act of 1995 requires that we solicit comment on the following issues:

- Whether the information collection is necessary and useful to carry out the proper functions of the agency;
- The accuracy of the agency's estimate of the information collection burden;
- The quality, utility, and clarity of the information to be collected; and
- Recommendations to minimize the information collection burden on the affected public, including automated collection techniques.

Since this final rule contains information collections that are subject to OMB review under the Paperwork Reduction Act of 1995, we are soliciting public comment on these information collections as discussed below.

As discussed in detail section III. of this preamble, we are requiring in § 482.27(c) that Medicare participating hospitals undertake certain activities when they learn that they have received blood or blood products that are at increased risk of transmitting HIV infection. These activities include the identification and quarantine of affected blood and blood products that remain in inventory pending confirmatory testing. If the testing confirms that blood or blood products the hospital received are potentially HIV infectious, the hospital must promptly make at least three attempts to notify the patient's attending physician and ask the physician to inform the patient of the need for HIV testing and counseling. If the physician is unavailable, declines, or later informs the hospital that he or she was unable to notify the patient, the hospital must promptly make at least three attempts to notify the patient, the patient's surviving relative, or other person designated in accordance with State law. The hospital must document in the patient's medical record the notification

or attempts to give the required notification. Hospitals must establish policies and procedures for patient notification and documentation that conform to Federal, State, and local laws, including requirements for confidentiality. Finally, if the hospital uses the services of an outside blood bank, the agreement governing procurement, transfer, and availability of blood and blood products must be revised to require the blood bank to promptly notify the hospital about potentially HIV-infectious blood or blood products. We note that the burden associated with these requirements involves the establishment of a system to facilitate information collection (that is, the notification and documentation of notification), but are not themselves information collections.

These changes would not increase significantly the paperwork and information collection burden on the approximately 6,400 Medicare-participating hospitals. We estimate that development of policies and procedures for handling potentially HIV-infectious blood and blood products and revision of agreements between hospitals and their blood banks will increase each hospital's recordkeeping burden by approximately 2 hours. Since this 2 hour burden is a one-time occurrence for each hospital, the total burden associated with this particular requirement is 12,800 hours.

We further estimate that notifying patients and documenting notification efforts in patients' medical records will take approximately 1 hour per occurrence. As indicated in section III. of this preamble, we based this estimate on several assumptions: (1) The records on the patient had already been retrieved; (2) the physician of record was noted on the admission sheet; and (3) the hospital had the physician's correct telephone number or address. The time involved for each lookback case also may differ depending upon whether it was a single unit of blood given to one patient versus a unit of blood that was separated into several blood products and given to several patients. We considered each individual affected by the donor to be a separate notification case. FDA has estimated that approximately 60 lookback cases occur annually, with 16 involving patient notification. These cases are spread over approximately 6,600 hospitals, including approximately 200 hospitals that do not participate in the Medicare program. If we assume that all 16 cases involving patient notification were to occur in Medicare-participating hospitals, this requirement would increase the recordkeeping burden on these hospitals by a total of 16 hours.

The total paperwork and reporting burden on Medicare participating hospitals as a result of the information collection requirements in this rule is, therefore, estimated to be 12,816 (12,800+16) hours.

Organizations and individuals were given an opportunity to comment on these information collection requirements at the time the June 30, 1993 rule was published. However, because of the new estimate of the two-hour recordkeeping burden on hospitals resulting from the need to establish policies and procedures and to amend agreements with blood banks, we are again soliciting public comment on these information collection requirements and providing the 60-day notice. As also stated in the June 30, 1993 rule, a document will be published in the Federal Register after Office of Management and Budget approval is obtained.

Organizations and individuals desiring to submit comments on these information collection and recordkeeping requirements should send them to HCFA, OFHR, MPAS, C2–26–17, 7500 Security Boulevard, Baltimore, Maryland 21244–1850.

VI. Regulatory Impact Statement

Consistent with the Regulatory Flexibility Act (RFA) (5 U.S.C. 601 through 612), we prepare a regulatory flexibility analysis unless we certify that a rule will not have a significant economic impact on a substantial number of small entities. For purposes of the RFA, we consider hospitals, blood banks, and physicians to be small entities.

In addition, section 1102(b) of the Act requires us to prepare a regulatory impact analysis if a rule may have a significant impact on the operations of a substantial number of small rural hospitals. This analysis must conform to the provisions of section 604 of the RFA. For purposes of section 1102(b) of the Act, we define a small rural hospital as a hospital that is located outside of a Metropolitan Statistical Area and has fewer than 50 beds.

This final rule expands the scope of the notification requirements to include hospitals that release blood and blood products to another entity or appropriate individual. Physicians will be asked to inform the recipient of a potentially HIV infectious blood or blood product of the need for HIV testing and counseling. If the physician is unavailable, declines, or informs the hospital that he or she was unable to notify the patient, the hospital is responsible for notification. It also requires hospitals to quarantine blood or blood products collected during the ''window'' period pending completion of more specific testing.

The most recent estimates of the current HIV risk per unit is 1 in 420,000. These estimates are a dramatic improvement over the 1 in 487 odds that prevailed before HIV testing of the blood supply began in 1985. Appropriate efforts to further reduce the risk have occurred by public education, improved tests, donor questionnaires, and revised criteria for donor self-referral. However, it remains possible, despite the best practices of a blood bank, that a person might donate blood and blood products early in infection during the ''window'' period, the time it takes a recently infected person to develop the antibodies that screening tests are designed to detect. That window period is estimated to range from a few weeks to 6 months. Section 482.24 (''Condition of participation: Medical record services.'') currently requires hospitals to maintain records for a period of 5 years. We expect hospitals will identify recipients of blood and blood products and meet the requirements of this rule to the extent the hospitals have records that permit them to do so.

As for ongoing activities, we anticipate that only a small number of cases per year can be traced to potentially HIV infectious blood and blood products, and thus, we do not expect these final regulations will result in a substantial economic or resource burden on small entities. In addition, since most hospitals, blood banks, and physicians are currently voluntarily complying with the requirements of these final regulations, the ramifications of these final regulations are not expected to be substantial. Because of the small number of cases detected, individual hospitals will be required to quarantine blood and blood products and notify blood recipients in only a few, if any, cases. Nevertheless, the policies and procedures must be written and periodically updated to ensure that appropriate and timely quarantine and patient notification take place. Though not significant, there will be an additional burden of time and resources on hospitals not currently involved in the notification process.

We believe the ongoing cost of notification after implementation of this regulation will not be significant or burdensome because the risk of a person being transfused with potentially HIV infectious blood and blood products is declining. Even though this final rule will affect few people per year, it is

important that we ensure that potentially infected people are notified so they may seek appropriate medical care or consider behavior changes so as not to infect others.

Therefore, we are not preparing analyses for either the RFA or small rural hospitals since we have determined, and we certify, that this final rule will not likely have a significant economic impact on a substantial number of small entities or have a significant impact on the operations of a substantial number of small rural hospitals.

In accordance with the provisions of Executive Order 12866, this regulation was not reviewed by the Office of Management and Budget.

Under the provisions of Public Law 104–121, we have determined that this final rule is not a major rule.

List of Subjects in 42 CFR Part 482

Grant programs—health, Hospitals, Medicaid, Medicare, Reporting and recordkeeping requirements.

42 CFR part 482 is amended as follows:

PART 482—CONDITIONS OF PARTICIPATION FOR HOSPITALS

1. The authority citation for part 482 continues to read as follows:

Authority: Secs. 1102 and 1871 of the Social Security Act (42 U.S.C. 1302 and 1395hh).

Subpart C—Basic Hospital Functions

2. Section 482.27 is amended by adding a new paragraph (c) to read as follows:

§ 482.27 Condition of participation: Laboratory services.

* * * * *

(c) *Standard: Potentially infectious blood and blood products*—(1) *Potentially HIV infectious blood and blood products* are prior collections from a donor who tested negative at the time of donation but tests repeatedly reactive for the antibody to the human immunodeficiency virus (HIV) on a later donation, and the FDA-licensed, more specific test or other followup testing recommended or required by FDA is positive and the timing of seroconversion cannot be precisely estimated.

(2) *Services furnished by an outside blood bank.* If a hospital regularly uses the services of an outside blood bank, it must have an agreement with the blood bank that governs the procurement, transfer, and availability of blood and blood products. The agreement must require that the blood bank promptly notify the hospital of the following:

(i) If it supplied blood and blood products collected from a donor who tested negative at the time of donation but tests repeatedly reactive for the antibody to HIV on a later donation; and

(ii) The results of the FDA-licensed, more specific test or other followup testing recommended or required by FDA completed within 30 calendar days after the donor's repeatedly reactive screening test. (FDA regulations concerning HIV testing and lookback procedures are set forth at 21 CFR 610.45-et seq.)

(3) *Quarantine of blood and blood products pending completion of testing.* If the blood bank notifies the hospital of the repeatedly reactive HIV screening test results as required by paragraph (c)(2)(i) of this section, the hospital must determine the disposition of the blood or blood product and quarantine all blood and blood products from previous donations in inventory.

(i) If the blood bank notifies the hospital that the result of the FDA-licensed, more specific test or other followup testing recommended or required by FDA is negative, absent other informative test results, the hospital may release the blood and blood products from quarantine.

(ii) If the blood bank notifies the hospital that the result of the FDA-licensed, more specific test or other followup testing recommended or required by FDA is positive, the hospital must dispose of the blood and blood products in accordance with 21 CFR 606.40 and notify patients in accordance with paragraph (c)(4) of this section.

(4) *Patient notification.* If the hospital has administered potentially HIV infectious blood or blood products (either directly through its own blood bank or under an agreement described in paragraph (c)(2) of this section) or released such blood or blood products to another entity or appropriate individual, the hospital must take the following actions:

(i) Promptly make at least three attempts to notify the patient's attending physician (that is, the physician of record) or the physician who ordered the blood or blood product that potentially HIV infectious blood or blood products were transfused to the patient.

(ii) Ask the physician to immediately notify the patient, or other individual as permitted under paragraph (c)(8) of this section, of the need for HIV testing and counseling.

(iii) If the physician is unavailable, declines to make the notification, or later informs the hospital that he or she was unable to notify the patient, promptly make at least three attempts to notify the patient, or other individual as permitted under paragraph (c)(8) of this section, of the need for HIV testing and counseling.

(iv) Document in the patient's medical record the notification or attempts to give the required notification.

(5) *Timeframe for notification.* The notification effort begins when the blood bank notifies the hospital that it received potentially HIV infectious blood and blood products and continues for 8 weeks unless—

(i) The patient is located and notified; or

(ii) The hospital is unable to locate the patient and documents in the patient's medical record the extenuating circumstances beyond the hospital's control that caused the notification timeframe to exceed 8 weeks.

(6) *Content of notification.* The notification given under paragraphs (c)(4) (ii) and (iii) of this section must include the following information:

(i) A basic explanation of the need for HIV testing and counseling.

(ii) Enough oral or written information so that the transfused patient can make an informed decision about whether to obtain HIV testing and counseling.

(iii) A list of programs or places where the patient can obtain HIV testing and counseling, including any requirements or restrictions the program may impose.

(7) *Policies and procedures.* The hospital must establish policies and procedures for notification and documentation that conform to Federal, State, and local laws, including requirements for confidentiality and medical records.

(8) *Notification to legal representative or relative.* If the patient has been adjudged incompetent by a State court, the physician or hospital must notify a legal representative designated in accordance with State law. If the patient is competent, but State law permits a legal representative or relative to receive the information on the patient's behalf, the physician or hospital must notify the patient or his or her legal representative or relative. If the patient is deceased, the physician or hospital must continue the notification process and inform the deceased patient's legal representative or relative.

(Catalog of Federal Domestic Assistance Program No. 93.773, Medicare—Hospital Insurance; Program No. 93.774, Medicare—Supplementary Medical Insurance; and Program No. 93.778, Medical Assistance Program)

Dated: July 11, 1996.

Bruce C. Vladeck,

Administrator, Health Care Financing Administration.

Dated: July 11, 1996.

Donna E. Shalala,

Secretary.

[FR Doc. 96–22708 Filed 9–6–96; 8:45 am]

BILLING CODE 4120–01–P

DEPARTMENT OF THE INTERIOR

Office of Hearings and Appeals

43 CFR Part 4

Department Hearings and Appeals Procedures

AGENCY: Office of Hearings and Appeals, Interior.

ACTION: Final rule.

SUMMARY: This document eliminates redundant words in 43 CFR 4.1(a) addressing authority of Administrative Law Judges to hold hearings within the Department of the Interior.

EFFECTIVE DATE: September 9, 1996.

FOR FURTHER INFORMATION CONTACT: James P. Terry, Deputy Director, Office of Hearings and Appeals, U.S. Department of the Interior, 4015 Wilson Blvd., Arlington, VA 22203 Telephone: (703) 235–3810.

SUPPLEMENTARY INFORMATION: Because this action reflects agency management in deleting non-substantive, redundant language relating to scope of actions for which Administrative Law Judges within the Department of the Interior have existing hearing responsibility, the Department has determined that the provisions of the Administrative Procedures Act, 5 U.S.C. 553 (b) and (d), allowing for public notice and comment and a 30-day delay in the effective date of a rule, are unnecessary and impracticable.

List of Subjects in 43 CFR Part 4

Administrative practice and procedure, Scope of authority, Applicable regulations.

Therefore, under the authority of the Secretary of the Interior contained in 5 U.S.C. 301, section 4.1(a) in Subpart A in Part 4 of Title 43 of the Code of Federal Regulations, is amended as follows:

PART 4—[AMENDED]

Subpart A—General; Office of Hearings and Appeals

1. The authority citation for Part 4 continues to read:

Authority: R.S. 2478, as amended, 43 U.S.C. 1201, unless otherwise noted.

2. Section 4.1(a) is revised to read as follows:

§ 4.1 [AMENDED]

* * * * *

(a) A Hearings Division comprised of administrative law judges who are authorized to conduct hearings in cases required by law to be conducted pursuant to 5 U.S.C. 554, and hearings in other cases arising under statutes and regulations of the Department, including rule making hearings, and

* * * * *

Dated: August 28, 1996.

Bonnie R. Cohen,

Assistant Secretary—Policy, Management and Budget.

[FR Doc. 96–22815 Filed 9–6–96; 8:45 am]

BILLING CODE 4310–79–M

FEDERAL COMMUNICATIONS COMMISSION

47 CFR Part 68

Connection of Terminal Equipment to the Telephone Network

AGENCY: Federal Communications Commission.

ACTION: Correcting amendments.

SUMMARY: This document contains corrections to the final regulations which related to the connection of terminal equipment to the telephone network.

EFFECTIVE DATE: September 9, 1996.

FOR FURTHER INFORMATION CONTACT: William von Alven, (202) 418–2342.

SUPPLEMENTARY INFORMATION:

Background

The final regulations that are the subject of these corrections relate to the means of connection of data terminal equipment to the telephone network and to the on-hook impedance limitations for all types of terminal equipment.

Need for Correction

As published, the final regulations contain errors which may prove to be misleading and are in need of clarification.

List of Subjects in 47 CFR Part 68

Communications equipment, Telephone.

PART 68—CONNECTION OF TERMINAL EQUIPMENT TO THE TELEPHONE NETWORK

Accordingly, 47 CFR Part 68 is corrected by making the following correcting amendments:

1. The authority citation for Part 68 continues to read as follows:

Authority: Secs 4, 5, 201–5, 208, 15, 218, 226, 227, 303, 313, 314, 403, 410, 602 of the Communications Act of 1934, as amended, 47 U.S.C. 151, 154, 155, 201–5, 208, 215, 218, 226, 227, 303, 313, 314, 403, 404, 410, 602.

§ 68.104 [Corrected]

2. In § 68.104, paragraph (b), in the first sentence, the reference to ''§ 68.308(a)(4) (i) or (ii)'' is revised to read ''§ 68.308(b)(4) (i) or (ii)''.

§ 68.312 [Corrected]

3. In § 68.312, paragraph (b)(2), the reference to ''paragraph (a)(1)(v)'' is revised to read ''paragraph (b)(1)(v)''.

4. In § 68.312, paragraph (c)(2), in the tenth sentence, the reference to ''paragraph (a)(2)'' is revised to read ''paragraph (b)(2)''.

5. In § 68.312, paragraph (d)(1)(iv), the reference to ''paragraph (a)(1)(iv)'' is revised to read ''paragraph (b)(1)(iv)''.

Federal Communications Commission.

William F. Caton,

Acting Secretary.

[FR Doc. 96–22701 Filed 9–6–96; 8:45 am]

BILLING CODE 6712–01–U

47 CFR Part 73

[MM Docket No. 95–14; RM–8552]

Radio Broadcasting Services; Leavenworth, Othello, and East Wenatchee, WA

AGENCY: Federal Communications Commission.

ACTION: Final rule.

SUMMARY: The Commission, at the request of Ronald A. Murray, d/b/a Murray Broadcasting, substitutes Channel 266A for Channel 249A at Leavenworth, Washington, and modifies Station KLVH(FM)'s construction permit accordingly. To accommodate the substitution, we also downgrade Channel 248C1 to Channel 248C3 at Othello, Washington, and modify Station KZLN-FM's construction permit accordingly; and substitute Channel 249A for Channel 266A at East Wenatchee, Washington, and modify Station KYSN(FM)'s license accordingly. *See* 60 FR 6689, February 3, 1995. Channel 266A can be allotted at Leavenworth in compliance with the Commission's minimum distance

separation requirements without the imposition of a site restriction at petitioner's authorized site. The coordinates for Channel 266A at Leavenworth are North Latitude 47–35–32 and West Longitude 120–38–35. Channel 248C3 can be allotted to Othello without the imposition of a site restriction at Station KZLN-FM's authorized site. The coordinates for Channel 248C3 at Othello are North Latitude 46–45–55 and West Longitude 119–16–49. *See* Supplementary Information, *infra*.

EFFECTIVE DATE: October 15, 1996.

FOR FURTHER INFORMATION CONTACT: Sharon P. McDonald, Mass Media Bureau, (202) 418–2180.

SUPPLEMENTARY INFORMATION: This is a synopsis of the Commission's *Report and Order*, MM Docket No. 95–14 adopted August 23, 1996, and released August 30, 1996. The full text of this Commission decision is available for inspection and copying during normal business hours in the FCC Reference Center (Room 239), 1919 M Street, NW., Washington, DC. The complete text of this decision may also be purchased from the Commission's copy contractors, International Transcription Service, Inc., (202) 857–3800, 2100 M Street, NW., Suite 140, Washington, DC 20037.

Channel 249A can be allotted to East Wenatchee without the imposition of a site restriction at Station KYSN(FM)'s authorized site. The coordinates for Channel 249A at East Wenatchee are North Latitude 47–22–52 and West Longitude 120–17–16. Since Leavenworth, Othello, and East Wenatchee are located within 320 kilometers (200 miles) of the U.S.-Canadian border, concurrence of the Canadian government has been obtained. With this action, this proceeding is terminated.

List of Subjects in 47 CFR Part 73

Radio broadcasting.

Part 73 of title 47 of the Code of Federal Regulations is amended as follows:

PART 73—[AMENDED]

1. The authority citation for Part 73 continues to read as follows:

Authority: Sections 303, 48 Stat., as amended, 1082; 47 U.S.C. 154, as amended.

§ 73.202 [Amended]

2. Section 73.202(b), the Table of FM Allotments under Washington, is amended by removing Channel 249A and adding Channel 266A at Leavenworth; removing Channel 248C1 and adding Channel 248C3 at Othello; and by removing Channel 266A and adding Channel 249A at East Wenatchee.

Federal Communications Commission.

John A. Karousos,

Chief, Allocations Branch, Policy and Rules Division, Mass Media Bureau.

[FR Doc. 96–22845 Filed 9–6–96; 8:45 am]

BILLING CODE 6712–01–F

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47 CFR Part 73

[MM Docket No. 95–96; RM–8645]

Radio Broadcasting Services; Lakeview, AR

AGENCY: Federal Communications Commission.

ACTION: Final rule.

SUMMARY: This document allots FM Channel 228C3 to Lakeview, Arkansas, as that community's first local aural transmission service, in response to a petition for rule making filed by Dale Hendrix. *See* 60 FR 35372, July 7, 1995. With this action, the proceeding is terminated.

DATES: Effective October 7, 1996. The window period for filing applications will open on October 7, 1996, and close on November 7, 1996.

FOR FURTHER INFORMATION CONTACT: Nancy Joyner, Mass Media Bureau, (202) 418–2180. Questions related to the window application filing process for Channel 228C3 at Lakeview, Arkansas, should be addressed to the Audio Services Division, (202) 418–2700.

SUPPLEMENTARY INFORMATION: This is a synopsis of the Commission's *Report and Order*, MM Docket No. 95–96, adopted August 16, 1996, and released August 23, 1996. The full text of this Commission decision is available for inspection and copying during normal business hours in the FCC's Reference Center (Room 239), 1919 M Street, NW., Washington, DC. The complete text of this decision may also be purchased from the Commission's copy contractors, International Transcription Service, Inc., (202) 857–3800, located at 1919 M Street, NW., Room 246, or 2100 M Street, NW., Suite 140, Washington, DC 20037.

List of Subjects in 47 CFR Part 73

Radio broadcasting.

Part 73 of title 47 of the Code of Federal Regulations is amended as follows:

PART 73—[AMENDED]

1. The authority citation for part 73 continues to read as follows:

Authority: Secs. 303, 48 Stat., as amended, 1082; 47 U.S.C. 154, as amended.

§ 73.202 [Amended]

2. Section 73.202(b), the Table of FM Allotments under Arkansas, is amended by adding Lakeview, Channel 228C3.

Federal Communications Commission.

John A. Karousos,

Chief, Allocations Branch, Policy and Rules Division, Mass Media Bureau.

[FR Doc. 96–22846 Filed 9–6–96; 8:45 am]

BILLING CODE 6712–01–F

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47 CFR Part 73

[MM Docket No. 95–106; RM–8655, RM–8698]

Radio Broadcasting Services; Hayden and Meeker, CO

AGENCY: Federal Communications Commission.

ACTION: Final rule.

SUMMARY: This document allots Channel 297A to Hayden, Colorado, as that community's second local FM transmission service, in response to a petition for rule making filed on behalf of Thomas Broadcasting. *See* 60 FR 36772, July 18, 1995. Additionally, Channel 251C is allotted to Meeker, Colorado, in response to a counterproposal filed on behalf of 1530, LLC (RM–8698). Coordinates used for Channel 297A at Hayden, Colorado, are 40–29–42 and 107–15–30. Coordinates used for Channel 251C at Meeker, Colorado, are 40–02–24 and 107–55–00. With this action, the proceeding is terminated.

DATES: Effective October 15, 1996. The window period for filing applications will open on October 15, 1996, and close on November 15, 1996.

FOR FURTHER INFORMATION CONTACT: Nancy Joyner, Mass Media Bureau, (202) 418–2180. Questions related to the window application filing process for Channel 297A at Hayden, Colorado, and for Channel 251C at Meeker, Colorado, should be addressed to the Audio Services Division, FM Branch, (202) 418–2700.

SUPPLEMENTARY INFORMATION: This is a synopsis of the Commission's Report and Order, MM Docket No. 95–106, adopted August 23, 1996, and released August 30, 1996. The full text of this Commission decision is available for inspection and copying during normal business hours in the FCC's Reference Center (Room 239), 1919 M Street, NW., Washington, DC. The complete text of this decision may also be purchased from the Commission's copy

contractors, International Transcription Service, Inc., (202) 857–3800, located at 1919 M Street, NW., Room 246, or 2100 M Street, NW., Suite 140, Washington, DC 20037.

List of Subjects in 47 CFR Part 73

Radio broadcasting.

Part 73 of title 47 of the Code of Federal Regulations is amended as follows:

PART 73—[AMENDED]

1. The authority citation for part 73 continues to read as follows:

Authority: Secs. 303, 48 Stat., as amended, 1082; 47 U.S.C. 154, as amended.

§ 73.202 [Amended]

2. Section 73.202(b), the Table of FM Allotments under Colorado, is amended by adding Channel 297A at Hayden.

3. Section 73.202(b), the Table of FM Allotments under Colorado, is amended by adding Meeker, Channel 251C.

Federal Communications Commission.

John A. Karousos,

Chief, Allocations Branch, Policy and Rules Division, Mass Media Bureau.

[FR Doc. 96–22847 Filed 9–6–96; 8:45 am]

BILLING CODE 6712–01–F

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47 CFR Part 73

[MM Docket No. 96–32; RM–8719]

Radio Broadcasting Services; Canton, MO and Canton, IL

AGENCY: Federal Communications Commission.

ACTION: Final rule.

SUMMARY: This document substitutes Channel 265C2 for Channel 265C3 at Canton, Missouri, and modifies the license for Station KRRY to specify operation on Channel 265C2, in response to a proposal filed by Bick Broadcasting Co. *See* 61 FR 10300, March 13, 1996. The coordinates for Channel 265C2 at Canton, Missouri, are 40–07–33 and 91–31–42. To accommodate the upgrade at Canton, Missouri, we shall substitute Channel 266A for Channel 265A at Canton, Illinois, and provide cut-off protection to the applicant for Channel 266A (BPH–951011MA). The coordinates for Channel 266A at Canton, Illinois, are 40–36–49 and 89–56–22. With this action this proceeding is terminated.

EFFECTIVE DATE: October 7, 1996.

FOR FURTHER INFORMATION CONTACT: Kathleen Scheuerle, Mass Media Bureau, (202) 418–2180.

SUPPLEMENTARY INFORMATION: This is a summary of the Commission's *Report and Order,* MM Docket No. 96–32, adopted August 16, 1996, and released August 23, 1996. The full text of this Commission decision is available for inspection and copying during normal business hours in the Commission's Reference Center (Room 239), 1919 M Street, NW., Washington, DC. The complete text of this decision may also be purchased from the Commission's copy contractors, International Transcription Services, Inc., 2100 M Street, NW., Suite 140, Washington, DC 20037, (202) 857–3800.

List of Subjects in 47 CFR Part 73

Radio broadcasting.

Part 73 of title 47 of the Code of Federal Regulations is amended as follows:

PART 73—[AMENDED]

1. The authority citation for part 73 continues to read as follows:

Authority: Secs. 303, 48 Stat., as amended, 1082; 47 U.S.C. 154, as amended.

§ 73.202 [Amended]

2. Section 73.202(b), the Table of FM Allotments under Missouri, is amended by removing Channel 265C3 and adding Channel 265C2 at Canton.

3. Section 73.202(b), the Table of FM Allotments under Illinois is amended by removing Channel 265A and adding Channel 266A at Canton.

Federal Communications Commission.

John A. Karousos,

Chief, Allocations Branch, Policy and Rules Division, Mass Media Bureau.

[FR Doc. 96–22851 Filed 9–6–96; 8:45 am]

BILLING CODE 6712–01–F

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47 CFR Part 73

[MM Docket No. 95–166; RM–8717]

Radio Broadcasting Services; Chama, NM

AGENCY: Federal Communications Commission.

ACTION: Final rule.

SUMMARY: The Commission, at the request of KNXX, Inc., allots Channel 255A to Chama, New Mexico, as the community's first local aural service. *See* 60 FR 56553, November 9, 1995. Channel 255A can be allotted to Chama in compliance with the Commission's minimum distance separation requirements without the imposition of a site restriction, at coordinates 36–54–12 North Latitude and 106–34–42 West Longitude. With this action, this proceeding is terminated.

DATES: Effective October 15, 1996. The window period for filing applications will open on October 15, 1996, and close on November 5, 1996.

FOR FURTHER INFORMATION CONTACT: Leslie K. Shapiro, Mass Media Bureau, (202) 418–2180.

SUPPLEMENTARY INFORMATION: This is a synopsis of the Commission's *Report and Order,* MM Docket No. 95–166, adopted August 23, 1996, and released August 30, 1996. The full text of this Commission decision is available for inspection and copying during normal business hours in the FCC Reference Center (Room 239), 1919 M Street, NW., Washington, DC. The complete text of this decision may also be purchased from the Commission's copy contractor, International Transcription Service, Inc., (202) 857–3800, 2100 M Street, NW., Suite 140, Washington, DC 20037.

List of Subjects in 47 CFR Part 73

Radio broadcasting.

Part 73 of title 47 of the Code of Federal Regulations is amended as follows:

PART 73—[AMENDED]

1. The authority citation for part 73 continues to read as follows:

Authority: Secs. 303, 48 Stat., as amended, 1082; 47 U.S.C. 154, as amended.

§ 73.202 [Amended]

2. Section 73.202(b), the Table of FM Allotments under New Mexico, is amended by adding Chama, Channel 255A.

Federal Communications Commission.

John A. Karousos,

Chief, Allocations Branch, Policy and Rules Division, Mass Media Bureau.

[FR Doc. 96–22850 Filed 9–6–96; 8:45 am]

BILLING CODE 6712–01–F

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47 CFR Part 73

[MM Docket No. 96–93; RM–8788]

Radio Broadcasting Services; Oxford, MS

AGENCY: Federal Communications Commission.

ACTION: Final rule.

SUMMARY: The Commission, at the request of Angel Broadcasting, allots Channel 286A to Oxford, Mississippi, as the community's fourth local FM service. *See* 61 FR 20207, May 6, 1996. Channel 286A can be allotted to Oxford in compliance with the Commission's minimum distance separation requirements with a site restriction of

11.2 kilometers (6.9 miles) north in order to avoid short-spacing conflicts with the licensed site of Station WBKJ(FM), Channel 286C1, Kosciusko, Mississippi, and with a construction permit for Station WLPX(FM)[formerly WYCG(FM)], Channel 288A, Water Valley, Mississippi. The coordinates for Channel 286A are at Oxford 34–28–06 and 89–30–33. With this action, this proceeding is terminated.

DATES: Effective October 7, 1996. The window period for filing applications will open on October 7, 1996, and close on November 7, 1996.

FOR FURTHER INFORMATION CONTACT: Pam Blumenthal, Mass Media Bureau, (202) 418–2180.

SUPPLEMENTARY INFORMATION: This is a synopsis of the Commission's *Report and Order*, MM Docket No. 96–93, adopted August 16, 1996, and released August 23, 1996. The full text of this Commission decision is available for inspection and copying during normal business hours in the FCC Reference Center (Room 239), 1919 M Street, NW., Washington, DC. The complete text of this decision may also be purchased from the Commission's copy contractor, ITS, Inc., (202) 857–3800, 2100 M Street, NW., Suite 140, Washington, DC 20037.

List of Subjects in 47 CFR Part 73

Radio broadcasting.

Part 73 of title 47 of the Code of Federal Regulations is amended as follows:

PART 73—[AMENDED]

1. The authority citation for part 73 continues to read as follows:

Authority: Secs. 303, 48 Stat., as amended, 1082; 47 U.S.C. 154, as amended.

§ 73.202 [Amended]

2. Section 73.202(b), the Table of FM Allotments under Mississippi, is amended by adding Channel 286A at Oxford.

Federal Communications Commission.

John A. Karousos,

Chief, Allocations Branch, Policy and Rules Division, Mass Media Bureau.

[FR Doc. 96–22843 Filed 9–6–96; 8:45 am]

BILLING CODE 6712–01–F

DEPARTMENT OF TRANSPORTATION

National Highway Traffic Safety Administration

49 CFR Part 575

[Docket No. 94–30, Notice 06]

RIN 2127–AF17

Consumer Information Regulations: Uniform Tire Quality Grading Standards

AGENCY: National Highway Traffic Safety Administration (NHTSA), Department of Transportation (DOT).

ACTION: Final rule.

SUMMARY: This final rule amends the Uniform Tire Quality Grading Standards to: Revise treadwear testing procedures to maintain the base course wear rate of course monitoring tires at its current value of 1.34. This revision is expected to eliminate treadwear grade inflation, reduce testing expenses, and reduce the environmental consequences of operating test convoys for the purpose of calculating the base course wear rate for each new batch of course monitoring tires; and add a top end traction grading category of ''AA'' to the current traction grading categories of A, B, and C. The new AA category will make possible the differentiation of tires with the very highest traction characteristics from those with lower traction characteristics.

DATES: This final rule is effective March 9, 1998.

Any petition for reconsideration of this rule must be received by NHTSA not later than October 24, 1996.

ADDRESSES: Petitions for reconsideration should refer to the docket and notice numbers noted above for this rule and be submitted to the Docket Section, National Highway Traffic Safety Administration, 400 Seventh Street SW, Room 5109, Washington, DC 20590; telephone (202) 366–4949. Docket room hours are from 9:30 a.m. to 4 p.m., Monday through Friday.

FOR FURTHER INFORMATION CONTACT: For technical issues: Mr. Orron Kee, Chief, Consumer Programs Division, Office of Planning and Consumer Programs, National Highway Traffic Safety Administration, 400 Seventh Street SW, Room 5307, Washington, DC 20590; telephone (202) 366–0846; FAX (202) 493–2739. For legal issues: Mr. Walter K. Myers, Office of the Chief Counsel, National Highway Traffic Safety Administration, 400 Seventh Street SW, Room 5219, Washington, DC 20590; telephone (202) 366–2992; FAX (202) 366–3820.

SUPPLEMENTARY INFORMATION:

Preamble Table of Contents

I. Introduction
II. Background
(a) Current Provisions
(1) Treadwear
(2) Traction
(b) Request for Comments
(c) Notice of Proposed Rulemaking
(1) Treadwear
(2) Traction
(3) Fuel Economy
(4) Comments
(d) DOT Appropriations Act of 1996
(e) Public Comments on the NPRM
(1) Treadwear
(2) Traction
III. Agency Decision
(a) Treadwear
(b) Traction
IV. Cost/Benefit Analysis
(a) Treadwear
(b) Traction
V. Rulemaking Analyses and Notices
(a) EO 12866 and DOT Regulatory Policies and Procedures
(b) Regulatory Flexibility Act
(c) EO 12612—Federalism
(d) National Environmental Policy Act
(e) Paperwork Reduction Act
(f) Civil Justice Reform

I. Introduction

This final rule amends the Uniform Tire Quality Grading Standards (49 CFR 575.104) to fix the base course wear rate of course monitoring tires at a permanent value of 1.34, and establishes an AA traction grade. A proposal in the agency's Notice of Proposed Rulemaking of May 24, 1995 (60 FR 27472) to rescind the temperature resistance grade and substitute therefor a fuel economy grade based on low rolling resistance characteristics of tires is not addressed in this notice (see the discussion in paragraph II(d) below).

II. Background

(a) *Current Provisions.* Section 30123(e) of Title 49, United States Code requires the Secretary of Transportation to prescribe a uniform system for grading motor vehicle tires to assist consumers in making informed choices when purchasing tires. Pursuant to that congressional mandate, NHTSA promulgated the Uniform Tire Quality Grading Standards (UTQGS) in 49 CFR 575.104. The UTQGS apply to new pneumatic tires for use on passenger cars, except deep tread, winter-type snow tires, space-saver or temporary-use spare tires, tires with nominal rim diameters of 10 to 12 inches, and limited production tires as defined in § 575.104(c)(2).

The UTQGS require tire manufacturers and tire brand name owners to grade their tires with respect to their relative treadwear, traction, and

temperature resistance performance. Treadwear grades are shown by numbers, such as 100, 150, and 200, while traction and temperature resistance grades are indicated by the letters A, B, and C, with A representing the best performance and C indicating the minimum level of performance necessary to comply with Federal Motor Vehicle Safety Standard No. 109, *New pneumatic tires.*

(1) *Treadwear.* Treadwear is graded by first running the tires being graded, called ''candidate tires,'' over a selected 400-mile segment of public highway near San Angelo, Texas. After an 800-mile ''break-in'' run, the candidate tires are driven over the test course for a total of 6,400 miles in test convoys composed of 4 passenger cars and/or light truck vehicles. Each driver remains in the same position within the convoy. The vehicles are rotated among the 4 positions in the convoy regularly as are the positions of the tires on the test vehicles so that the tires get equal time with each driver, each vehicle, and each wheel position.

''Course monitoring tires'' (CMT) are used as the control standard in grading candidate tires. CMTs are specially designed and built to American Society for Testing and Materials (ASTM) standard E1136 to have narrow limits of variability. When NHTSA procures a new batch, or lot, of CMTs, the agency establishes a new base course wear rate (BCWR) for that lot. The BCWR, measured in miles per thousand miles (MPTM), is established by running tires from the new lot of CMTs over the 6,400-mile test course, in the same manner as candidate tires, with tires from the previous batch of CMTs. A course severity adjustment factor (CSAF) for the CMTs is determined by dividing the BCWR for the old CMTs by the average wear rate of the old CMTs in the test. The wear rate of the new CMTs is then multiplied by the CSAF to determine the adjusted wear rate (AWR) of the new CMTs, which then becomes the BCWR for the new CMTs.

Once the BCWR for the new CMTs is established, these CMTs are used to grade candidate tires. Upon completion of the 6,400-mile test, the BCWR is divided by the average wear rate of the CMTs to determine the CSAF for the candidate tires. That factor is then applied to the wear rates of the candidate tires to obtain the AWR of the candidate tires. That AWR is then extrapolated to the point of wearout (considered to be 1/16th inch of remaining tread depth), which is then converted to the treadwear rating of the tire.

The BCWR is intended to provide a common baseline by which to grade candidate tires by relating all new CMTs to the original lot of CMTs. However, NHTSA has noted that the BCWRs of successive new lots of CMTs have been steadily declining over the years. Specifically, the first lot of CMTs procured from Goodyear Tire and Rubber Company (Goodyear) in 1975 yielded a BCWR of 4.44. The latest batch, procured by the agency in 1995, produced a BCWR of 1.34.

The significance of the decrease in the BCWR rate is that as the BCWR decreases, the treadwear grade increases. Consequently, the newer treadwear grades have increased to the point that they have become a somewhat misleading indicator of actual tread life when compared to tires tested with higher BCWRs.

(2) *Traction.* Traction grades are established by locked-wheel braking tests of traction on wet asphalt and wet concrete surfaces at the Uniform Tire Quality Grading Test Facility (UTQGTF), located at Goodfellow Air Force Base near San Angelo, Texas. A test trailer is equipped first with two control tires manufactured in accordance with ASTM standard E501. The trailer is towed over the wet asphalt surface at a speed of 40 miles per hour (mph) and one wheel equipped with a control tire is locked. The traction coefficient of that tire is recorded continuously and averaged for a period of 0.5 to 1.5 seconds after lockup. The UTQGTF is arranged so that the test trailers traverse both the asphalt and the concrete test surfaces in a loop. The test is repeated for a total of 10 times on each surface for each tire and the measurements taken on a surface are averaged to determine the control tire's traction coefficient for that surface. The purpose of testing the control tires is to monitor the friction properties of the asphalt and concrete surfaces to account for daily fluctuation due to environmental factors and the polishing effects of sustained use.

The same procedure is used to measure the locked-wheel braking traction coefficients of candidate tires. The measured traction coefficients of candidate tires are adjusted by the difference between the nominal coefficients of the control tires on the test surfaces (0.50 for the asphalt surface and 0.35 for the concrete surface) and the actual coefficient of the control tire run simultaneously with the candidate tire. Using this procedure, the measured coefficients of all candidate tires are adjusted to a common pavement friction basis for each of the test surfaces.

The grades of the candidate tires are currently designated as ''A'', ''B'', and ''C''. A tire achieving a high level of traction performance on both the wet asphalt (above 0.47μ) and the wet concrete (above 0.35μ) surfaces is graded ''A.'' A tire achieving medium traction performance (above 0.38μ on wet asphalt and above 0.26μ on wet concrete) is graded ''B.'' A tire achieving a traction performance level of 0.38μ or less on the wet asphalt and 0.26μ or less on wet concrete is graded ''C.''

(b) *Request for Comments.* As a result of the White House Conference on Global Climate Change held on June 10 and 11, 1993, the White House issued a report announcing nearly 50 initiatives to reduce greenhouse gas emissions in the United States. The report, entitled ''Climate Change Action Plan,'' was issued on October 19, 1993 and, among other things, calls for reduction of greenhouse gas emissions to 1990 levels by the year 2000. One such initiative called for DOT, through NHTSA, to issue new rules and test procedures requiring tire manufacturers to test and label tires relative to their fuel economy based on their rolling resistance. [1]

Pursuant to the Climate Change Action Plan, NHTSA published a Request for Comments on April 25, 1994 (59 FR 19686) seeking responses to a series of questions regarding available data on rolling resistance and testing procedures. The notice also posed questions concerning whether and how the treadwear testing procedures should be changed; and whether a traction grade of ''AA'' should be created to identify those tires with clearly superior traction characteristics. NHTSA also asked whether the UTQGS should include peak traction, how it should be measured and expressed, and the cost of measuring peak traction. [2] NHTSA noted that if peak traction performance of tires differed substantially from sliding traction, an alternative traction grading procedure might be necessary.

(c) *Notice of Proposed Rulemaking.* After consideration of the 34 timely comments received in response to the Request for Comments, NHTSA published a Notice of Proposed

[1] Action #22: ''DOT, through the National Highway Traffic Safety Administration, will adopt test procedures and new DOT rules requiring tire manufacturers to test and label (for fuel economy based on rolling resistance). DOT will also create a consumer-focused publicity program and a monitoring program in order to realize maximum benefits. The Administration is proposing to obligate $0.3 million in FY 1995 for this action and $2 million through 2000.''

[2] Peak traction is the primary traction force in anti-lock braking systems in which maximum braking action is obtained while the tire is still rolling.

Rulemaking (NPRM) on May 24, 1995 (60 FR 27472), with a comment closing date of July 10, 1995.

(1) *Treadwear.* The agency proposed to freeze the BCWR of the CMTs used in treadwear grading at its then-current value of 1.47 MPTM in an attempt to reduce treadwear grade creep.

The agency explained in the NPRM that it had considered many possible explanations for the consistent decrease in the BCWR of the CMTs, such as differences in climatic variations, changes in course severity, non-uniformity of wear rates among tires in the same lot, effects of aging and storage of CMTs, and errors in the BCWR calculation. To minimize the aging/storage factor, the agency now wraps CMTs in polyethylene bags for storage in a facility in which, although not temperature controlled, the temperature varies only between 50° and 90° Fahrenheit throughout the year. The agency then proposed fixing the BCWR at 1.47 MPTM to address the possibility of an error in the BCWR calculation. The agency believed that in addition to reducing, if not eliminating, the treadwear grade inflation, fixing the BCWR at a single figure would eliminate the time and expenditure of scarce resources required for operating test convoys for each new lot of CMTs, as well as eliminating the environmental impacts of operating those convoys.

(2) *Traction.* The agency further proposed to create a traction grade of ''AA'' to distinguish those tires with superior traction characteristics from those with lower traction performance characteristics.

NHTSA noted in the NPRM that analysis of traction data since 1989 revealed that traction performance has improved to the extent that the current grading system does not adequately differentiate between tires with varying levels of traction performance, particularly the tires showing the highest levels of traction performance. To address that situation, the agency solicited comments in the Request for Comments on whether the traction grading rules should be amended to differentiate more clearly between the highest performing tires. After considering the responses to the Request for Comments, NHTSA proposed to establish a new traction grading category of ''AA'' for tires achieving traction coefficients of more than 0.54μ on wet asphalt and more than 0.41μ on wet concrete[3]. NHTSA stated that since the ''AA'' category would be optional, manufacturers would incur no additional costs beyond modifying paper labels and sales brochures to reflect 4 traction grades instead of three. On the other hand, an ''AA'' category might provide an incentive to manufacturers to improve the traction performance of their tire lines.

With respect to the peak traction data solicited in the Request for Comments, NHTSA decided, based on the comments received, not to propose inclusion of peak traction in the traction ratings at this time. NHTSA noted that the majority of vehicles currently on the road are not equipped with ABS. The significance of that fact is that those vehicles continue to depend on sliding traction rather than peak traction for maximum stopping action. In addition, several tire manufacturers commented that peak traction performance is highly correlated with sliding traction performance.

(3) *Fuel Economy.* The agency proposed in the NPRM to rescind the temperature resistance grade and substitute therefor a fuel economy rating based on low rolling resistance characteristics of the tire.

(4) *Comments.* The NPRM generated 120 comments, all of which addressed the fuel economy proposal, while 10 commented on the traction proposal and 12 on the treadwear proposal. Commenters to the fuel economy proposals included several members of the U.S. Congress; the Secretary of Energy; tire manufacturers, wholesalers, and retail dealers, including their foreign plants and subsidiaries; environmental, safety, and consumer advocates; educators; and members of the public. Except for a certain few tire manufacturers, the majority of the tire industry and certain members of Congress strongly opposed the fuel economy proposal. The Secretary of Energy, on the other hand, along with most advocacy groups and most members of the public, supported it.

In response to a number of requests, the agency extended the NPRM comment period to August 14, 1995 (60 FR 34961, July 5, 1995) and hosted a public meeting on the UTQGS proposals on July 28, 1995. Twenty-five representatives of the groups enumerated above made oral presentations at the meeting while a number of others, including several members of Congress, filed written submissions. Nearly all the statements presented at the meeting, whether oral or written, addressed the fuel economy issue, expressing positions on both sides of the issue. Thereafter, in response to further requests, the agency again extended the NPRM comment period to September 1, 1995 to permit participants at the public meeting an opportunity to file written responses to matters presented at the public meeting (60 FR 42496, August 16, 1995).

Although the comment period closed on September 1, 1995, NHTSA continued to receive correspondence on both sides of the rolling resistance issue, including letters from various members of the Congress.

(d) *DOT Appropriations Act of 1996.* In early November, 1995, while NHTSA was still evaluating the comments and data from the NPRM and the public meeting, the Transportation Appropriations Act for Fiscal Year 1996 was enacted. Amendment number 66 to that Act prohibited the obligation or expenditure of any funds

> [T]o plan, finalize, or implement any rulemaking to add to section 575.104 of title 49 of the Code of Federal Regulations any requirement pertaining to a grading standard that is different from the three grading standards (treadwear, traction, and temperature resistance) already in effect.

NHTSA discontinued rulemaking activity on the fuel economy issue, but continued to assess the comments on the treadwear and traction proposals. Accordingly, this final rule addresses only the latter two proposals.

(e) *Public Comments on the NPRM.*

(1) *Treadwear.* Some commenters supported the proposal to fix the BCWR at the current figure, others supported the proposal as better than nothing, and still others opposed it. Regardless of their support for fixing the BCWR at a single figure, all commented that the present treadwear test procedure is inadequate and a new test procedure should be devised.

Michelin, The Cooper Tire Company (Cooper), Continental General Tire, Inc. (CGT), and the Rubber Manufacturers Association (RMA) supported the proposal to fix the BCWR at its current value so that further grade inflation will not occur. RMA and CGT agreed that the BCWR should be fixed immediately at 1.34 to prevent any further deterioration of the treadwear grades. Bridgestone/Firestone, Inc. (BF) supported fixing the BCWR, although it regards the BCWR itself as invalid in view of the consistency of the quality of modern tires. Similarly, Hercules Tire and Rubber Company (Hercules) supported freezing the BCWR at its current value ''or simply scrapping the system and starting over.'' Goodyear commented that the treadwear grade itself should be removed from the UTQGS because as manufacturers' treadwear warranties continue to improve, the treadwear labels under the UTQGS become less

[3] The preamble in the NPRM erroneously discussed a traction coefficient value of 0.41μ for the wet concrete surface. The correct value should have been 0.38μ.

significant for tire consumers. If the grade is not eliminated, however, Goodyear supports freezing the BCWR at its current value. Nevertheless, the company, like some other commenters, believes the treadwear test to be unreliable, inaccurate, cumbersome, costly, and environmentally unfriendly.

The Kelly Springfield Tire Company (Kelly) and Multinational Business Services, Inc. (MBS) oppose fixing the BCWR at a single figure. The European Tyre and Rim Technical Organisation (ETRTO) stated that changing the BCWR would be misleading to consumers because too many factors have an influence on the test results. Kelly stated that the treadwear grade should be eliminated and that freezing the BCWR would not make the treadwear rating any less confusing to consumers. Advocates for Highway and Auto Safety (Advocates), MTS Systems Corporation (MTS), and Herzlich Consulting, Inc. (Herzlich) expressed no opinion on freezing the BCWR, but commented at length on the inadequacy of the treadwear test. Advocates stated that using CMTs to determine the treadlife of all candidate tires creates test conditions that are arguably much less demanding than actual operating conditions on the road. MTS stated that the treadwear test should be conducted in an indoor test lab under controlled, repeatable conditions.

(2) *Traction.* Ten commenters, including 8 tire manufacturers, submitted comments on the ''AA'' traction proposal. Two supported the proposal, while the rest opposed it.

In support of the proposal, Michelin stated that creation of an additional traction grade would provide more differentiation between tires with superior traction characteristics without having to redefine the current A, B, and C levels. ETRTO stated that the present traction grades are generally acceptable and should be maintained, but if NHTSA wants to add a grade to indicate higher traction characteristics, ETRTO would prefer to maintain the present grades as they are and add an ''AA'' grade.

In opposing the addition of an ''AA'' grade to the traction category, Goodyear, Cooper, Dunlop, and CGT all stated that the traction test procedures were flawed and should be revised to reflect more accurately the true traction characteristics of tires. Goodyear, Dunlop and Kelly stated that the test procedure does not allow tires designed for hydroplane resistance to demonstrate that feature. Goodyear asserted that the average water depth of 0.02 inches used in the UTQGS test procedure is less than half the industry standard depth of 0.05 inches. Thus, the water depth used in traction grading favors tires with less void area. Dunlop suggested that a hydroplaning test be conducted in water depths of up to 15 millimeters (0.6 inches). Finally, Goodyear repeated its assertion made in earlier comments that the new test pads used at the UTQGTF caused traction grades to go down, and adding an ''AA'' grade would only accentuate the flaws in the test procedure.

Cooper asserted that the current test procedure is not repeatable or sensitive enough to detect the real differences between tires. For example, the ASTM ''standard'' tire is a straight-ribbed bias tire designed to be specially sensitive to differences in road surfaces, while candidate tires are commercial radial tires designed to yield good traction performance over a wide range of road surfaces and weather conditions.

Dunlop stated that the traction test is an insufficient basis for a traction grade because it is only a straight-ahead test on a damp surface. Dunlop and CGT suggested that, to be more accurate, the test should include accelerating traction, cornering traction, and traction testing under varying ambient conditions. Dunlop also suggested that if the current traction test procedures were not eliminated, a wet lateral braking test should be conducted over 2 different friction surfaces where deceleration Gs are measured and stopping distances calculated. Finally, Dunlop suggested adding the word ''wet'' to traction labels because the current straight-ahead test renders the traction rating ''inconclusive'' as a benefit to consumers whose vehicles are equipped with ABS.

MBS stated that the traction rating, based solely on sliding traction, is not helpful because it indicates nothing about other traction characteristics. MBS asserted that the traction rating should include peak traction performance for consumers with vehicles equipped with ABS. Kelly, however, stated that although there is a correlation between peak and sliding traction and that both values can be considered for grading purposes, the results are dependent on the differences among the various types of ABS systems. Thus, since a significant majority of vehicles in service are not equipped with ABS, sliding traction values rather than peak traction values should be retained for the traction ratings.

MBS and Dunlop argued that adding an AA grade could confuse consumers and mislead them because straight-ahead, sliding traction may not be best for ABS-equipped vehicles. Kelly stated that consumers could be confused by the limited amount of differentiation within the AA category. MBS and Cooper stated that the traction test should be redesigned and improved to be repeatable, sensitive, and relevant, and that research and testing should be conducted to ascertain the correlations among the different tire traction characteristics.

Advocates strongly opposed adding an AA rating to the UTQGS. Rather, Advocates favored increasing the minimum requirements for the existing grades. Advocates argued that adding an AA grade would not be as much of an incentive for tire manufacturers to improve the traction characteristics of their tires as would increasing minimum grade requirements. Advocates further asserted that adding an AA grade would only give manufacturers an excuse to charge higher prices for more highly-rated tires, thereby providing them larger profits.

Finally, Kelly stated that although the cost of tire mold reworking would be minimal, the costs associated with the proposed change would not be insignificant. Kelly stated that the 6,750 paper labels used in the Kelly production scheme would have to be changed to reflect the 4-grade traction rating system when only a very small number of higher grade changes would occur. Kelly asserted that the cost of changing those labels would be significant due to the necessity for new artwork, production of new labels, and subsequent destruction or other disposal of obsolete labels. CGT estimated that adding an AA grade would incur costs of $48,000 for new labels and required point-of-sale information. Like Kelly, Dean Tire & Rubber Company argued that adding an AA rating to the UTQGS would increase costs with no commensurate benefit.

III. Agency Decision

(a) *Treadwear.* NHTSA does not disagree that the treadwear grading procedure could be further improved. NHTSA does disagree, however, with Goodyear and Kelly that the treadwear grade should be eliminated. As the agency noted in the NPRM, 74 percent of consumers are familiar with the treadwear rating and 29 percent consider it in purchasing tires. Thus, the solution is not to eliminate the treadwear rating, but to improve the grading procedure to make the rating as meaningful and helpful as possible to the tire-buying public.

As stated above, when the NPRM was published on May 24, 1995, the then-current BCWR was 1.47 MPTM. Since that time, a new lot of CMTs was

procured and calibrated with a BCWR of 1.34. Thus, the BCWR continues its steady decline. To control that decline, this final rule announces the freezing of the BCWR at 1.34. Nothing in the comments has dissuaded NHTSA from believing that freezing the BCWR at 1.34 will significantly reduce, if not eliminate altogether, any variation in the grading results between lots. The agency also believes that the use of ASTM-specification tires with strict quality control will also contribute to controlling any lot-to-lot variations. NHTSA notes that the changes in the BCWRs have been consistently in the downward direction. If tire performance were changing appreciably due to production variables, the BCWR could be expected to change randomly in either direction.

NHTSA also disagrees with the commenters that stated that manufacturers' treadwear warranties have progressed to the point that they can supplant the UTQGS treadwear ratings. One manufacturer acknowledged that manufacturers' treadwear warranties are not always based on test results. Further, not all tires carry manufacturers' warranties and the terms of such warranties are not uniform. Accordingly, NHTSA believes that the UTQGS treadwear ratings are more accurate, consistent, and meaningful to consumers than manufacturers' warranties because the UTQGS ratings are based on uniformly applicable criteria.

The commenters' suggestions for changing the treadwear grading procedure fall into 2 basic categories: Revising the road test and developing a laboratory test. The commenters favoring the revised road test stated that the San Angelo test course is too mild and that, with the great improvement in treadwear in recent years, a test of only 6,400 miles does not provide sufficient tread wear on which to base reliable projections to wearout. The commenters that favored the laboratory test argued that a lab test would eliminate the need for CMTs and test convoys and would provide consistent, repeatable test results. In neither case did commenters suggest any specific test procedures nor offer any data that could form the basis for development of revised tests. NHTSA believes that adoption of either of these alternatives could entail considerable expenditure of funds and resources. Expansion of the road test to more closely approximate full-life testing of treadwear would increase the test duration and significantly increase costs and environmental impact. NHTSA's experience has shown that laboratory test machines lose repeatability because the abrasive surfaces of the test wheels tend to fill up with rubber particles. Accordingly, NHTSA does not believe that either of these alternatives is practicable at this time. The agency has, however, requested the assistance of the ASTM F9 committee in devising a better treadwear test. In addition, the agency intends to request data on the effects of aging on treadwear performance and storage procedures to reduce aging in a future Federal Register notice.

NHTSA believes, therefore, that until a better treadwear grading procedure can be devised, the BCWR should be fixed at its present value of 1.34 MPTM. The establishment of a BCWR for a new lot of CMTs does not normally need to be promulgated by rulemaking action published in the Federal Register. In this case, however, since the agency solicited public comment on its proposal to change the procedure for calculating the BCWR by fixing it at a permanent value, the agency deems it appropriate to announce this decision in the Federal Register.

(b) *Traction.* As noted above, Goodyear again commented that the new skid pads at the UTQGTF are more severe than the old pads in traction rating. NHTSA notes that the skid pads were changed in December 1991, and acknowledges that there may be a statistical difference in test results between the new pads and the old pads. Since the old pads no longer exist, however, the agency is not able to make a comparison for the purpose of devising a possible correction factor. Nevertheless, the agency believes that any differences in the test results do not significantly affect the traction ratings of tire lines and in any case, new tire lines should by now, after nearly 5 years, have replaced those tested on the old skid pads. Thus, most tires should by now be graded on a common basis.

Several commenters proposed other types of traction testing, including the testing of hydroplaning, cornering, acceleration, and peak traction characteristics, and testing in various water depths, ambient conditions, and road surfaces. While the agency regards these suggestions as worthy of consideration, they go beyond the scope of the proposals in the NPRM. Those traction factors could, however, be the subject of future agency research.

While Dunlop's suggestion that the traction grade be labeled ''wet traction'' on the tire sidewall and on other required labels may be somewhat more informative to the public, such a change would require the modification of tire molds, tread labels, and point-of-sale brochures. NHTSA believes that the costs associated with such a subtle change could not be justified by any perceived benefit.

NHTSA does not agree with Advocates' suggestion for raising the cutoff values for the existing traction grades rather than establishing a new grading category. The agency believes that considerable public confusion could be generated during the transition to the higher cutoff values where tires bearing the same grade but with significantly different traction characteristics are available side-by-side on store shelves. Such a transition could be lengthy because changing tire molds could take as long as 2 to 3 years and some tires may remain in dealers' stocks for a year or more. Further, since the UTQGS are only consumer information and do not establish minimum traction performance levels, the agency believes that simply adding an ''AA'' grade to the UTQGS traction ratings is the simplest, least confusing, least burdensome, and most cost effective way of differentiating between those few tire lines with the highest traction performance characteristics and those tire lines with lower levels of performance.

Advocates expressed concern that manufacturers would increase their prices for AA rated tires to the detriment of consumers. NHTSA acknowledges that manufacturers may choose to increase the prices of their AA traction-rated tires. However, the agency regards that as the type of marketing decision that manufacturers, distributors, and dealers are free to make in response to any product rating program. NHTSA believes that a tire rated AA for traction identifies that tire as one with superior traction performance and even if it costs slightly more, the consumer is advised of the specific characteristics of the tire from which he or she can make an informed purchasing decision.

NHTSA believes that while there may be some costs associated with the preparation and printing of tread labels and point-of-sale brochures, such costs can be minimized with adequate lead time. Manufacturers typically revise their labels and brochures annually, presumably not printing them in unlimited quantities. Thus, a lead time of 18 months should permit new labels and brochures to be prepared and printed in accordance with the normal business cycle, without undue scrappage of obsolete material. With respect to changing tire molds, the agency notes that since an AA rating is optional, tire manufacturers have an unlimited time in which to change molds on qualifying tire lines, if they decide to rate their tires with a traction

grade of AA at all. Accordingly, NHTSA believes that the minor costs associated with this rulemaking are well justified by the value of this rulemaking to consumers (see detailed discussion of costs and benefits in Section IV, below).

The agency proposed the AA rating criteria in the NPRM based on the statistical distribution of traction test results of 254 tire lines tested on the new skid pads at the UTQGTF. The distribution of the traction coefficients of the tested tires showed a mean, or average, value of 0.516 on wet asphalt and 0.364 on wet concrete, with a standard deviation of 0.029 on the wet asphalt and 0.017 on the wet concrete. Since those calculations were made, NHTSA has tested 40 additional tire lines. The mean plus one standard deviation for the entire population of 294 tires is 0.548 for asphalt and 0.387 for concrete. This compares to the values of the mean minus one standard deviation of 0.484 for asphalt and 0.341 for concrete, which are close to the current threshold values for the A grade. The agency believes that the proposed AA traction grade threshold is statistically compatible with the ranges for the A grade and the combined ranges of the B and C grades since, of the 294 tires tested, only 34 (12 percent) would qualify for the AA traction grade while 213 (72 percent) would qualify for the A grade. Thus, there should be approximately the same number of tire lines graded AA as are graded B and C.

IV. Cost/Benefit Analysis

(a) *Treadwear.* The fixing of the BCWR at a permanent value of 1.34 MPTM will not cause the Federal government or tire manufacturers to incur any additional costs. Instead, it will substantially reduce the cost of CMTs to tire testers and remove the necessity for the government to contract for one test convoy each year.

Tire manufacturers routinely purchase CMTs from lots procured by the government for testing of their tire lines. Prior to September 1, 1995, NHTSA charged $304.50 per tire. A DOT Inspector General audit, however, concluded that NHTSA was not recovering the full cost of purchasing, storing, and testing the CMTs. By final rule published on August 2, 1995 (60 FR 39269) NHTSA started charging $379.00 per tire, effective September 1, 1995. That charge included the government's purchase price of $250.00, $45.00 in testing costs to establish the BCWR, $34.00 for storage costs, and $50.00 for general facility costs and related salaries.

NHTSA estimates that fixing the BCWR at a permanent value will eliminate the need to calibrate new lots of CMTs, perhaps even eliminating the need for the government to purchase and store CMTs for resale. The savings to the government realized by not having to procure and store CMTs for resale and by not having to operate at least one test convoy per year is difficult to quantify. However, manufacturers purchasing CMTs from the government, even though they would no longer need to, could realize savings of from $45.00 to $95.00 per tire. At least the $45.00 testing cost could be saved, as well as perhaps some or all of the storage and/or facility costs.

Although the specific benefits of this change are also difficult to quantify, it is expected to reduce or eliminate the treadwear grade inflation experienced in the past, thereby relieving manufacturers of the possible need to retest certain tire lines and providing consumers more consistent and reliable treadwear grade information.

(b) *Traction.* The addition of an AA traction grade will not require any additional testing by manufacturers. Further, as previously noted, the assessing of an AA traction grade is optional for manufacturers. Accordingly, any costs associated with changing tire molds to show an AA grade can be phased in at the manufacturers' convenience and during the regular course of reworking the molds for their tire lines. In any case, only a very few tire lines will be affected. Accordingly, NHTSA estimates that there should be no additional mold or testing costs to manufacturers as a result of this change.

The only additional costs required by this change will be to indicate the existence of a new traction grade on tread labels and point-of-sale brochures. CGT estimated this cost to be $48,000. Pirelli estimated the cost of new artwork for labels to be $12,000 and the cost of brochures and dealer price books at $104,000. Kelly stated that 6,750 label designs would need to be changed, but gave no cost figure. Goodyear estimated that it would cost $26,000 for new labels and $120,000 for new point-of-sale brochures. MBS estimated that the costs of new labels and brochures would be $15 million for the tire industry.

None of the commenters specified whether the costs they quoted were additional annual costs or whether those were one-time costs associated with adding a description of the AA grade for the first time. Tire manufacturers update and reissue their labels and brochures periodically, normally annually, to account for new tire lines and improvements or changes in existing tire lines. It follows, therefore, that once a description of the AA grade is printed on/in the labels and brochures, that description can be repeated without change on subsequent labels and brochures without adding any additional costs to those printings. Accordingly, the agency assumes the figures quoted above are one-time costs only.

The MBS estimate of $15 million appears to be very high, compared to the figures estimated by the manufacturers themselves. Even so, NHTSA regards $15 million as a maximum figure applicable to the entire tire industry that, as previously pointed out, would be a one-time expenditure only.

This change will substantially benefit consumers by allowing them to identify those tire lines with the highest traction performance characteristics, thereby providing them even greater tire selectivity and allowing them to make even more-informed choices. In addition, NHTSA believes that introduction of an AA traction rating will provide an incentive to tire manufacturers to improve the traction performance of new tire lines, thereby contributing to motor vehicle safety.

V. Rulemaking Analyses and Notices

(a) Executive Order No. 12866 and DOT Regulatory Policies and Procedures

This document was reviewed under Executive Order No. 12866, *Regulatory Planning and Review.* NHTSA has analyzed the impact of this rulemaking action and has determined that it is ''significant'' under the DOT's regulatory policies and procedures because the proposal which preceded it contained an issue of substantial public and congressional interest. That issue, the substitution of a fuel economy grade for the existing temperature resistance grade, is not addressed in this final rule.

The Preliminary Regulatory Evaluation prepared by this agency for the 1995 NPRM remains valid as to the amendments adopted in this final rule. See section IV, Cost/Benefit Analysis, above for a full discussion of cost savings, additional costs, and proposed anticipated benefits of this rulemaking.

(b) Regulatory Flexibility Act

NHTSA has considered the effects of this rulemaking action under the Regulatory Flexibility Act. I hereby certify that the amendments promulgated by this final rule will not have a significant impact on a substantial number of small entities. Accordingly, a regulatory flexibility analysis has not been prepared.

The agency believes that few, if any, tire manufacturers qualify as small

businesses. Small businesses, small organizations, and small governmental units may be affected by this rulemaking action only to the extent that they could possibly pay slightly more for tires that are graded AA for traction performance characteristics.

(c) Executive Order 12612, Federalism

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

(d) National Environmental Policy Act

NHTSA has analyzed this rulemaking action for the purposes of the National Environmental Policy Act and has determined that implementation of this rulemaking action will not have any significant impact on the quality of the human environment.

(e) Paperwork Reduction Act

The provisions of this final rule requiring manufacturers to mold certain information into or onto the sidewalls of tires and to affix labels to tires explaining the tire quality grades for the benefit of consumers are considered to be third-party information collection requirements as defined by the Office of Management and Budget (OMB) in 5 CFR part 1320. The information collection requirements for 49 CFR 575.104 have been submitted to and approved by OMB pursuant to the provisions of the Paperwork Reduction Act, 44 U.S.C. § 3501, *et seq.* This collection of information authority has been assigned OMB control number 2127–0519, *Uniform Tire Quality Grading Standards, 49 CFR Part 575.104,* and has been approved for use through September 30, 1998.

(f) Civil Justice Reform

This final rule does not have any retroactive effect. Under 49 U.S.C. 30103(b), whenever a Federal motor vehicle safety standard is in effect, a state or political subdivision thereof may prescribe or continue in effect a standard applicable to the same aspect of performance of a motor vehicle only if the standard is identical to the Federal standard. However, a state may prescribe a standard for a motor vehicle or equipment obtained for its own use that imposes a higher performance requirement than the Federal standard. 49 U.S.C. § 30161 sets forth a procedure for judicial review of final rules establishing, amending or revoking Federal motor vehicle safety standards. A petition for reconsideration or other administrative proceedings is not required before parties may file suit in court.

List of Subjects in 49 CFR Part 575

Consumer protection, Motor vehicle safety, Reporting and recordkeeping, Tires.

In consideration of the foregoing, 49 CFR part 575 is amended as follows:

PART 575—CONSUMER INFORMATION REGULATIONS

1. The authority citation for Part 575 continues to read as follows:

Authority: 49 U.S.C. §§ 322, 30111, 30115, 30117, and 30166; delegation of authority at 49 CFR 1.50.

2. Section 575.104 is amended by revising paragraph (d)(1)(i)(B); (d)(1)(iii); (d)(2)(i); the introductory text of (d)(2)(ii); (e)(2)(ix)(C); Figure 1; Part I and the introductory text of Part II of Figure 2; and the paragraph entitled ''Traction'' in Part II of Figure 2; by adding paragaph (d)(2)(ii)(D); and by removing paragraphs (i), (j), (k), and (1), to read as follows:

§ 575.104 Uniform Tire Quality Grading Standards.

* * * * *

(d) *Requirements*—(1) *Information.*

(i) * * *

(A) * * *

(B) Each tire manufactured on and after the effective date of these amendments, other than a tire sold as original equipment on a new vehicle, shall have affixed to its tread surface so as not to be easily removable a label or labels containing its grades and other information in the form illustrated in Figure 2, Parts I and II. The treadwear grade attributed to the tire shall be either imprinted or indelibly stamped on the label containing the material in Part I of Figure 2, directly to the right of or below the word ''TREADWEAR.'' The traction grade attributed to the tire shall be indelibly circled in an array of the potential grade letters AA, A, B, or C, directly to the right of or below the word ''TRACTION'' in Part I of Figure 2. The temperature resistance grade attributed to the tire shall be indelibly circled in an array of the potential grade letters A, B, or C, directly to the right of or below the word ''TEMPERATURE'' in Part I of Figure 2. The words ''TREADWEAR,'' ''TRACTION,'' AND ''TEMPERATURE,'' in that order, may be laid out vertically or horizontally. The text of Part II of Figure 2 may be printed in capital letters. The text of Part I and the text of Part II of Figure 2 need not appear on the same label, but the edges of the two texts must be positioned on the tire tread so as to be separated by a distance of no more than one inch. If the text of Part I and the text of Part II of Figure 2 are placed on separate labels, the notation ''See EXPLANATION OF DOT QUALITY GRADES'' shall be added to the bottom of the Part I text, and the words ''EXPLANATION OF DOT QUALITY GRADES'' shall appear at the top of the Part II text. The text of Figure 2 shall be oriented on the tire tread surface with lines of type running perpendicular to the tread circumference. If a label bearing a tire size designation is attached to the tire tread surface and the tire size designation is oriented with lines type running perpendicular to the tread circumference, the text of Figure 2 shall read in the same direction as the tire size designation.

* * * * *

(iii) In the case of information required in accordance with § 575.6(a) to be furnished to the first purchaser of a new motor vehicle, each manufacturer of motor vehicles shall, as part of the required information, list all possible grades for traction and temperature resistance and restate verbatim the explanation for each performance area specified in Figure 2. The information need not be in the format of Figure 2, but it must contain a statement referring the reader to the tire sidewall for the specific tire grades for the tires with which the vehicle is equipped.

(2) *Performance.*—(i) *Treadwear.* Each tire shall be graded for treadwear performance with the word ''TREADWEAR'' followed by a number of two or three digits representing the tire's grade for treadwear, expressed as a percentage of the NHTSA nominal treadwear value, when tested in accordance with the conditions and procedures specified in paragraph (e) of this section. Treadwear grades shall be expressed in multiples of 20 (for example, 80, 120, 160).

(ii) *Traction.* Each tire shall be graded for traction performance with the word ''TRACTION,'' followed by the symbols AA, A, B, or C, when the tire is tested in accordance with the conditions and procedures specified in paragraph (f) of this section.

* * * * *

(D) The tire may be graded AA only when its adjusted traction coefficient is both:

(*1*) More than 0.54μ when tested in accordance with paragraph (f)(2) of this section on the asphalt surface specified in paragraph (f)(1)(i) of this section; and

(*2*) More than 0.38μ when tested in accordance with paragraph (f)(2) of this

section on the concrete surface specified in paragraph (f)(1)(i) of this section.

* * * * *

(e) * * *

(2) * * *

(ix) * * *

(C) Determine the course severity adjustment factor by assigning a base course wear rate of 1.34 to the course monitoring tires and dividing that rate by the average wear rate for the four course monitoring tires.

* * * * *

(i) Removed.

(j) Removed.

(k) Removed.

(l) Removed.

* * * * *

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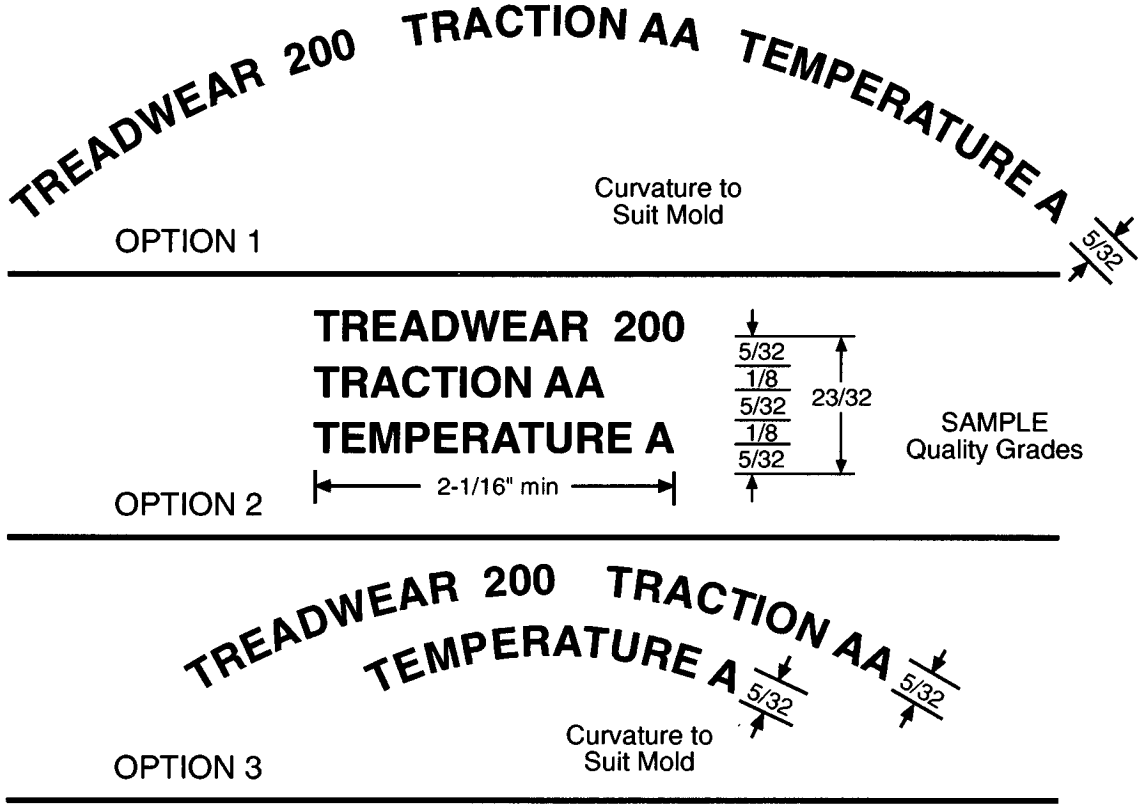

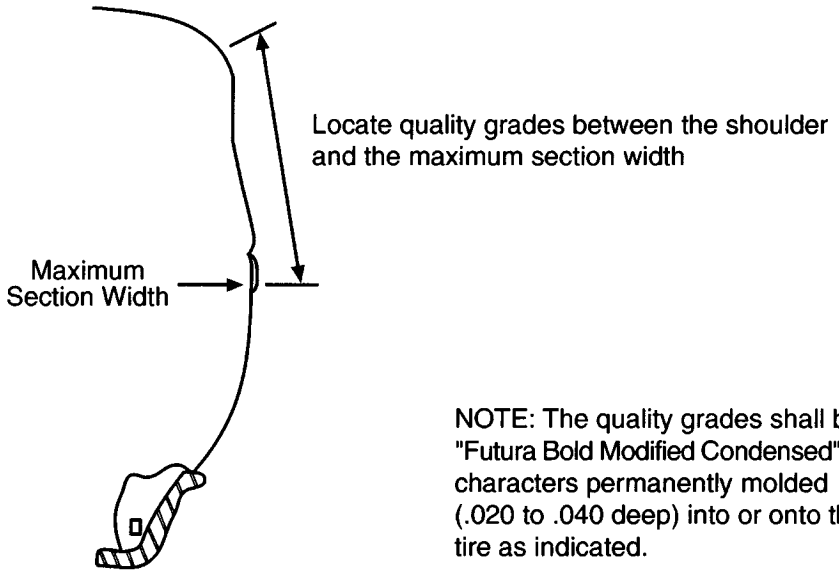

NOTE: The quality grades shall be in "Futura Bold Modified Condensed" or "Gothic" characters permanently molded (.020 to .040 deep) into or onto the tire as indicated.

Figure 1

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Figure 2—[Part I]—DOT QUALITY GRADES

TREADWEAR

TRACTION AA A B C

TEMPERATURE A B C

(Part II) All Passenger Car Tires Must Conform to Federal Safety Requirements In Addition To These Grades

* * * * *

TRACTION

The traction grades, from highest to lowest, are AA, A, B, and C. Those grades represent the tire's ability to stop on wet pavement as measured under controlled conditions on specified government test surfaces of asphalt and concrete. A tire marked C may have poor traction performance. Warning: The traction grade assigned to this tire is based on straight-ahead braking traction tests, and does not include acceleration, cornering, hydroplaning, or peak traction characteristics.

* * * * *

Issued on August 30, 1996.

Ricardo Martinez,

Administrator.

[FR Doc. 96–22761 Filed 9–6–96; 8:45 am]

BILLING CODE 4910–59–P

Surface Transportation Board

49 CFR Part 1039

[Ex Parte No. 346 (Sub-No. 35)]

Rail General Exemption Authority—Exemption of Ferrous Recyclables

AGENCY: Surface Transportation Board.

ACTION: Final rule.

SUMMARY: Pursuant to its authority under 49 U.S.C. 10502, the Surface Transportation Board is exempting from regulation the transportation by rail of blast furnace, open hearth, rolling mill or coke oven products, NEC (STCC Commodity Group No. 33–119). This commodity group is added to the list of exempt commodities, as set forth below, and is intended to eliminate unnecessary regulation.

EFFECTIVE DATE: October 9, 1996.

FOR FURTHER INFORMATION CONTACT: Beryl Gordon, (202) 927–5660. [TDD for the hearing impaired: (202) 927–5721.]

SUPPLEMENTARY INFORMATION: Since the Interstate Commerce Commission's [1] decision of May 16, 1995 (60 FR 26839, May 19, 1995), in this proceeding, which refrained from exempting commodities in STCC Commodity Group No. 33–119 because it included certain recyclable materials deemed to be nonferrous, Congress has passed the ICCTA. The ICCTA repealed the special statutory protections for transportation of nonferrous recyclable commodities. As a consequence, because regulation of the rail transportation of commodities in STCC Commodity Group No. 33–119 is not necessary, rather than distinguishing between ferrous and nonferrous commodities within the commodity group, we will exempt the entire five-digit commodity group.

Regulatory Flexibility Act

The Board certifies that this exemption will not have a significant economic impact on a substantial number of small entities within the meaning of the Regulatory Flexibility Act. This exemption will reduce regulation; it imposes no new reporting or other requirements directly or indirectly on small entities.

Environment and Energy

This action will not significantly affect either the quality of the human environment or the conservation of energy resources.

List of Subjects in 49 CFR Part 1039

Intramodal transportation, Manufactured commodities, Railroads.

Decided: August 27, 1996.

By the Board, Chairman Morgan, Vice Chairman Simmons, and Commissioner Owen.

Vernon A. Williams,

Secretary.

For the reasons set forth in the preamble, title 49, chapter X, part 1039 of the Code of Federal Regulations is amended as follows:

PART 1039—EXEMPTIONS

1. The authority citation for part 1039 is revised to read as follows:

Authority: 5 U.S.C. 553; 49 U.S.C. 10502 and 13301.

2. Section 1039.11, paragraph (a), is amended by adding the following new entry to the end of table:

§ 1039.11 Miscellaneous commodities exemptions.

(a) * * *

STCC No.	STCC tariff	Commodity
*	*	* * *
33 119	6001–X, eff. 1–11–96	Blast furnace, open hearth, rolling mill or coke oven products, NEC.

* * * * *

[FR Doc. 96–22916 Filed 9–6–96; 8:45 am]

BILLING CODE 4915–00–P

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

50 CFR Part 622

[Docket No. 960409106–6207–02; I.D. 031196A]

RIN 0648–AG26

Fisheries of the Caribbean, Gulf of Mexico, and South Atlantic; Shrimp Fishery Off the Southern Atlantic States; Amendment 1

AGENCY: National Marine Fisheries Service (NMFS), National Oceanic and Atmospheric Administration (NOAA), Commerce.

ACTION: Final rule.

SUMMARY: NMFS issues this final rule to implement Amendment 1 to the Fishery Management Plan for the Shrimp Fishery of the South Atlantic Region (FMP). This rule prohibits trawling for rock shrimp in an area off the Florida east coast; requires permits for dealers and vessels in the rock shrimp fishery off the southern Atlantic states; requires dealers to report information needed to monitor the fishery; and requires that the initial sale, trade, barter, or transfer of rock shrimp harvested from the exclusive economic zone (EEZ) off the southern Atlantic states occur only between permitted dealers and permitted vessels. In addition, NMFS informs the public of the approval by the Office of Management and Budget (OMB) of the collection-of-information requirements contained in this rule. The intended effect is to protect critical habitat and conserve and manage the rock shrimp fishery.

EFFECTIVE DATES: October 9, 1996; except that the amendments to §§ 622.4, 622.5, and 622.45 are effective November 1, 1996.

ADDRESSES: Requests for copies of the final regulatory flexibility analysis (FRFA) should be sent to Peter J. Eldridge, Southeast Regional Office,

[1] The ICC Termination Act of 1995, Pub. L. No. 104–88, 109 Stat. 803 (ICCTA), which was enacted on December 29, 1995, and took effect on January 1, 1996, abolished the Interstate Commerce Commission (ICC) and transferred certain functions to the Surface Transportation Board (Board). This decision relates to a proceeding that was pending with the ICC prior to January 1, 1996, and to functions that are subject to Board jurisdiction pursuant to 49 U.S.C. 10701 *et seq.* Citations are to the current sections of the statute.

NMFS, 9721 Executive Center Drive N., St. Petersburg, FL 33702.

Comments regarding the collection-of-information requirements contained in this rule should be sent to Edward E. Burgess, Southeast Regional Office, NMFS, 9721 Executive Center Drive N., St. Petersburg, FL 33702, and to the Office of Information and Regulatory Affairs, OMB, Washington, DC 20503 (Attention: NOAA Desk Officer).

FOR FURTHER INFORMATION CONTACT: Peter J. Eldridge, 813–570–5305.

SUPPLEMENTARY INFORMATION: The FMP was prepared by the South Atlantic Fishery Management Council (Council) under the authority of the Magnuson Fishery Conservation and Management Act (Magnuson Act). The background and rationale for the measures in Amendment 1, and the rationale for NMFS's disapproval, based on a preliminary evaluation of Amendment 1, of a measure that would have required vessel operator permits, were contained in the preamble to the proposed rule (61 FR 17866, April 23, 1996) and are not repeated here.

Comments and Responses

Comment: One fisherman commented that the area being closed to trawling is too large. He believes the outer or offshore edge of the closed area should be moved shoreward from the proposed 100–fathom (183–m) depth contour to the offshore edge of the Oculina Bank Habitat Area of Particular Concern (HAPC). He states that this will allow fishermen to continue their harvest of pink and rock shrimp in this area. In addition, he recommends delaying implementation of Amendment 1 until after the 1996 rock shrimp season (July through October).

Response: Amendment 1 specifically addresses the need to minimize impacts of the rock shrimp fishery on essential bottom habitat. Amendment 1 will extend protection of the valuable *Oculina* coral species and its existing habitat to the north and east of the existing HAPC. Amendment 1 recognizes and analyzes the adverse economic impacts of displacing fishermen from the area in which trawling would be prohibited. The Council concluded that the potential long-term economic benefits of the closed area would outweigh the short-term adverse effects. NMFS concurs with that conclusion. Thus, NMFS does not support moving the outer boundary of the proposed no-trawling area shoreward to the edge of the HAPC. Also, because of documented damage to *Oculina* habitat from trawling, to the detriment of the important species dependent on that habitat, it is not wise or prudent to delay implementation of approved Amendment 1.

Changes from the Proposed Rule

Since the proposed rule was published, NMFS has consolidated most of its fishery regulations for the Southeast Region into one set of regulations at 50 CFR part 622 (published on July 3, 1996, 61 FR 34930). Accordingly, the implementing regulations for Amendment 1 in this final rule are amendments to part 622 in lieu of amendments to the south Atlantic shrimp regulations, previously contained in part 659. Part 622 contains general provisions common to all federally managed fisheries (e.g., permit application procedures, vessel and gear identification requirements, and prohibitions). Therefore, such general provisions that appeared in the proposed rule are not included in this final rule. Minor changes in language have been made to conform to the standards in part 622. The proposed rule would have required the owner or operator of a permitted vessel or a permitted dealer to notify the Director, Southeast Region, NMFS (RD) within 15 days after any change in the information previously submitted on the permit application. To conform with the standard in other fisheries permitted by the RD, as it exists in part 622, the time frame for that notification is changed to 30 days.

Effective Dates

To allow time to publicize the requirements for vessel and dealer permits, distribute applications for such permits, receive and process applications, and issue permits, NMFS makes the provisions of this final rule that require permits, or that are dependent on the possession of a permit, effective November 1, 1996.

Classification

The RD determined that Amendment 1 is necessary for the conservation and management of the shrimp fishery off the southern Atlantic states and that it is consistent with the Magnuson Act and other applicable law, with the exception of the measure that was previously disapproved. See the proposed rule for a discussion of the disapproved measure.

This action has been determined to be not significant for purposes of E.O. 12866.

NMFS prepared a final regulatory flexibility analysis (FRFA) that indicates this final rule is necessary to minimize the impacts of rock shrimp trawling on important coral and coral reef resources and on live- and hard-bottom habitats within and adjacent to the HAPC off the east coast of Florida. Minimizing habitat damage will enhance survival of juvenile rock shrimp and snapper-grouper species dependent upon this habitat. Also this rule will allow NMFS to collect fishery and biological information necessary to improve the management program and to ensure attainment of optimum yield over the long-term. The one public comment received on the proposed rule indicated that the area closed to shrimp trawling is too large and should be reduced to minimize lost pink and rock shrimp harvest. The Council had already assessed this option in the initial regulatory flexibility analysis (IRFA) and related analyses of management options supporting its preferred measures in Amendment 1; it concluded that a smaller closed area would not offer sufficient habitat protection (see comments and responses above). Accordingly, this comment did not result in changes to the conclusions of the IRFA.

The FRFA indicates that this rule will result in significant economic impacts on between 65 and 108 vessels and 12 dealers; all of these vessels and dealers are considered small entities for purposes of the Regulatory Flexibility Act. The magnitude of the impacts per small entity were difficult to quantify because rock shrimp landings vary considerably from year to year and rock shrimp exhibit considerable geographic movement and could move from areas closed to trawling to open areas and, thus, be harvested. The principal adverse impacts will result from prohibiting shrimp trawling in the closed area. Assuming that the affected vessels cannot redirect their fishing effort to other areas, and assuming continuation of recent harvest rates, affected vessels may lose approximately $41,000 each the first year. It is likely, however, that most vessels will be able to shift their effort to other areas or to other fisheries and these losses are not projected for the long-term. The extent to which vessels are able to shift to open areas or to other fisheries will determine how well they can minimize reduced rock shrimp catches and revenues; this extent cannot be estimated at this time. It is possible that some vessels may not demonstrate reduced net revenues if, by switching to other fishing areas, they can harvest larger sized shrimp that bring a significantly higher price per pound.

This final rule contains new collection-of-information requirements including: Vessel permit applications; dealer permit applications; dealer

reports regarding rock shrimp receipts; and vessel identification requirements. These requirements will affect vessel owners or operators who choose to participate in the rock shrimp fishery and dealers who intend to purchase rock shrimp from permitted vessels. The professional skills necessary for complying with these information collection requirements are the same as required by the vessel owners/operators and dealers permitted in other federally managed fisheries of the south Atlantic area; these skills include the ability to understand, fill out, and submit to NMFS necessary application forms for vessel or dealer permits and for reporting landings and ex-vessel prices.

In trying to minimize significant economic impacts on small entities, the Council and NMFS considered numerous management alternatives in selecting the preferred management measures regarding addition of rock shrimp to the FMP management unit, habitat and shrimp resource protection, and permitting and reporting requirements. In general, some of the management options considered and rejected would have had less of a short-term impact on rock shrimp fishermen but the long-term damage to essential habitat and resource productivity would have been greater. Regarding the management unit measure, the FRFA indicates that a management unit with a smaller geographic range would not provide management authority for future, timely regulatory actions necessary to protect shrimp and habitat resources beyond the Oculina HAPC. Regarding the extent of the area closed to shrimp trawling, the area chosen was proposed by the industry as representing an acceptable balance between protecting critical shrimp and habitat resources and minimizing adverse, regulatory impacts. Rock shrimp fishing in the area to be closed has occurred only in recent years and the catch has consisted mainly of very small rock shrimp, which are intercepted before they reach traditional fishing grounds. The trawling closure area may result in higher fishery yields and revenues over the long-term, in part because small shrimp, otherwise harvested, will be allowed to reach a larger size and command a higher market price per pound. Regarding permitting and reporting and recordkeeping requirements, the Council deliberately chose an approach that would minimize burdens on reporting entities while still providing the information on actual landings and harvest locations necessary for management. While permits are required for vessels and dealers, only the dealers are required to submit reports on landings. The Council decided that this approach would minimize burdens on the individual fisherman (e.g., no mandatory log book system required). Also, the Council encouraged NMFS to use information from state fisheries agencies, particularly from Florida where most landings occur, to minimize additional reporting burdens on dealers. Refer to the FRFA for further details (see **ADDRESSES**). Notwithstanding any other provision of law, no person is required to respond to nor shall a person be subject to a penalty for failure to comply with a collection of information subject to the requirements of the Paperwork Reduction Act (PRA) unless that collection of information displays a currently valid OMB control number.

This rule contains new collection-of-information requirements subject to the PRA for vessels and dealers in the rock shrimp fishery—namely, vessel permit applications, dealer permit applications, dealer reports regarding rock shrimp receipts, and vessel identification requirements. The existing vessel identification requirements contained in 50 CFR 622.6(a)(1)(i) and (a)(2) are made applicable to a vessel in the rock shrimp fishery by requiring such vessel to obtain a permit—each vessel for which a permit has been issued under 50 CFR 622.4 is required to comply with those requirements. These collections of information have been approved by OMB under OMB control numbers 0648–0205, 0648–0205, 0648–0013, and 0648–0306, respectively. The public reporting burdens for these collections are estimated to average 20, 5, 15, and 45 minutes per response, respectively, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collections of information. Send comments regarding any of these reporting burden estimates, or any other aspect of the collections of information, including suggestions for reducing the burdens, to NMFS and OMB (see **ADDRESSES**).

List of Subjects in 50 CFR Part 622

Fisheries, Fishing, Puerto Rico, Reporting and recordkeeping requirements, Virgin Islands.

Dated: September 3, 1996.

N. Foster,

Deputy Assistant Administrator for Fisheries, National Marine Fisheries Service.

For the reasons set out in the preamble, 50 CFR Part 622 is amended as follows:

PART 622—FISHERIES OF THE CARIBBEAN, GULF AND SOUTH ATLANTIC

1. The authority citation for part 622 continues to read as follows:

Authority: 16 U.S.C. 1801 *et seq.*

2. In § 622.2, the definition of ''Dealer'' is added, in alphabetical order, to read as follows:

§ 622.2 Definitions and acronyms.

* * * * *

Dealer, in addition to the definition specified in § 600.15 of this chapter, means the person who first receives rock shrimp harvested from the EEZ upon transfer ashore.

* * * * *

3. In § 622.4, effective November 1, 1996, paragraph (a)(2)(viii) is added and the first sentence of paragraph (a)(4) is revised to read as follows:

§ 622.4 Permits and fees.

(a) * * *

(2) * * *

(viii) *South Atlantic rock shrimp*. For a person aboard a vessel to fish for rock shrimp in the South Atlantic EEZ or possess rock shrimp in or from the South Atlantic EEZ, a commercial vessel permit for rock shrimp must be issued to the vessel and must be on board.

* * * * *

(4) * * * For a dealer to receive Gulf reef fish, golden crab harvested from the South Atlantic EEZ, South Atlantic snapper-grouper, rock shrimp harvested from the South Atlantic EEZ, or wreckfish, a dealer permit for Gulf reef fish, golden crab, South Atlantic snapper-grouper, rock shrimp, or wreckfish, respectively, must be issued to the dealer. * * *

* * * * *

4. In § 622.5, effective November 1, 1996, paragraph (c)(7) is added to read as follows:

§ 622.5 Recordkeeping and reporting.

(c) * * *

(7) *South Atlantic rock shrimp*. (i) A dealer who has been issued a permit for rock shrimp, as required under § 622.4(a)(4), and who is selected by the SRD must provide information on receipts of rock shrimp and prices paid on forms available from the SRD. The required information must be submitted to the SRD at monthly intervals postmarked not later than 5 days after the end of each month. Reporting frequencies and reporting deadlines may be modified upon notification by the SRD.

(ii) On demand, a dealer who has been issued a dealer permit for rock

shrimp, as required under § 622.4(a)(4), must make available to an authorized officer all records of offloadings, purchases, or sales of rock shrimp.

* * * * *

5. In § 622.35, paragraph (g) is added to read as follows:

§ 622.35 South Atlantic EEZ seasonal and/or area closures.

* * * * *

(g) *Rock shrimp closed area*. No person may trawl for rock shrimp in the area east of 80°00′ W. long. between 27°30′ N. lat. and 28°30′ N. lat. shoreward of the 100–fathom (183–m) contour, as shown on the latest edition of NOAA chart 11460; and no person may possess rock shrimp in or from this area on board a fishing vessel.

6. In § 622.45, effective November 1, 1996, paragraph (g) is added to read as follows:

§ 622.45 Restrictions on sale/purchase.

* * * * *

(g) *South Atlantic rock shrimp*. (1) Rock shrimp harvested in the South Atlantic EEZ on board a vessel that does not have a valid commercial permit for rock shrimp, as required under § 622.4(a)(2)(viii), may not be transferred, received, sold, or purchased.

(2) Rock shrimp harvested on board a vessel that has a valid commercial permit for rock shrimp may be transferred or sold only to a dealer who has a valid permit for rock shrimp, as required under § 622.4(a)(4).

(3) Rock shrimp harvested in the South Atlantic EEZ may be received or purchased by a dealer who has a valid permit for rock shrimp, as required under § 622.4(a)(4), only from a vessel that has a valid commercial permit for rock shrimp.

[FR Doc. 96–22958 Filed 9–6–96; 8:45 am]

BILLING CODE 3510–22–F

Proposed Rules

Federal Register
Vol. 61, No. 175
Monday, September 9, 1996

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.

OFFICE OF PERSONNEL MANAGEMENT

5 CFR Part 316

RIN 3206–AH47

Temporary and Term Employment

AGENCY: Office of Personnel Management.

ACTION: Proposed regulations.

SUMMARY: The Office of Personnel Management (OPM) proposes to revise regulations on nonpermanent employment as part of continuing efforts to streamline the appointing system. The proposal would eliminate the authority for temporary appointments pending the establishment of a register (TAPER) as well as the ''outside-the-register authority'' for term appointments. The proposal would give OPM authority to extend the length of term appointments when justified, clarify the crediting of prior service for the required trial period, and allow certain excepted service employees whose positions are brought into the competitive service to serve the full 4-year period allowed for term appointment. The proposal would also add four categories of individuals to the list of those eligible for noncompetitive temporary and term appointments on the basis that they are currently eligible for permanent appointment and would clarify the conditions for making nonpermanent appointments based on a veteran's eligibility for a veterans readjustment appointment (VRA). To help agencies control the costs of workers' compensation by returning more injured employees to duty, the proposal would permit the reappointment of injured temporaries to any position for which qualified. Finally, the proposal would eliminate references to the former Federal Personnel Manual.

DATES: Comments must be received on or before November 8, 1996.

ADDRESSES: Send or deliver written comments to Mary Lou Lindholm, Associate Director for Employment, Office of Personnel Management, Room 6F08, 1900 E Street NW., Washington, DC 20415.

FOR FURTHER INFORMATION CONTACT: Ellen Russell or Karen Jacobs on 202–606–0830, FAX 202–606–2329, or TDD 202–606–0023.

SUPPLEMENTARY INFORMATION:

Length of Term Appointments

Agencies were authorized in 1962 to use term appointments of up to 4 years for project work with prior approval of the Civil Service Commission. A few years later, the Commission delegated full authority to agencies. On January 13, 1995, OPM broadened the conditions under which agencies could make term appointments to include nonpermanent situations other than project work. See § 316.301.

Some agencies have questioned whether they could make a second term appointment of an individual to the same position when the need for the employee continued beyond the 4-year limit. The appropriate procedure would be for the agency to document the reasons for the continued need of the individual and seek OPM approval to extend the term appointment. Although the current regulations do not prohibit consecutive term appointments as long as the agency follows appropriate competitive hiring procedures, the need for more than one term appointment suggests that a permanent appointment may be more appropriate.

This proposal would allow OPM, where clearly justified, to authorize extensions beyond the 4-year limit, including extensions in advance. Currently, OPM permits agencies to extend term appointments under certain conditions by issuing a variation to the regulations under § 5.1. The proposed regulatory provision permitting OPM to authorize extensions would change the form, not the substance, of the procedure in order to reduce paperwork.

We also propose to clarify that agencies may make term appointments in any increments so long as the appointment is for more than 1 year and no more than 4 years. For example, when an agency makes a term appointment for 13 months, the agency may extend that appointment up to the 4-year limit in as many increments as the agency chooses. The vacancy announcement for a term appointment of less than 4 years should make clear the possibility of extension up to the 4-year limit.

Eliminating Outside-the-Register Mechanism for Term Appointments

The proposal would eliminate the outside-the-register hiring mechanism for term appointments. In the past when OPM (or agencies under delegated examining) maintained standing registers, it was appropriate for the register-holding office to authorize outside-the-register appointments when those registers did not have candidates available for certification. However, as delegation of examining increased, OPM authorized fewer outside-the-register authorities. At this point, totally eliminating term appointments outside-the-register would be consistent with the new face of competitive examining. Now that OPM has delegated full examining authority to agencies, the outside-the-register mechanism is not necessary for term appointments. Agencies are in full control of the examining process and can announce individual vacancies as they occur. Also, since term appointees may serve for long periods of time and since they have benefits similar to permanent employees, it is appropriate that term and permanent employees be appointed in the same manner.

Trial Period for Term Appointment

The proposal would require crediting prior service toward the trial period required for term appointment in the same way that prior service is credited for probation, i.e., same agency, same line of work, and no more than a single break in service not exceeding 30 days. See § 315.802.

Crediting Excepted Service Toward Time Limit for Term Appointment

The proposal would allow former excepted employees whose positions were brought into the competitive service when OPM revoked an excepted authority to serve up to the full 4-year period for term appointment rather than have the amount of their prior time-limited excepted service subtracted from the maximum time limit for term appointment. This change in § 316.702 would give agencies more flexibility without harming employees who are already eligible for benefits.

Categories Eligible for Noncompetitive Term and Temporary Appointments

The current regulations indicate the categories of individuals eligible for noncompetitive term and temporary appointments based on their eligibility for permanent appointment under various authorities. In this proposal, we would add that appointments under 5 U.S.C. 3304(c), commonly referred to as Ramspeck appointments, can no longer be made after December 18, 1997, as provided by Pub. L. 104–65, the Lobbying Disclosure Act of 1995. We would also clarify that noncompetitive term and temporary appointments based on an individual's eligibility for a veterans readjustment appointment (VRA) are permitted only at the grade levels authorized for VRA appointments but that the temporary or term appointments are not VRA appointments themselves and do not lead to conversion to career-conditional. (This longstanding policy was stated in the former Federal Personnel Manual.)

The proposal would also add four categories of individuals to the list of those eligible for noncompetitive temporary and term appointments on the basis that they are currently eligible for permanent appointment. The categories are: current and former General Accounting Office employees (31 U.S.C. 732[g]); current and former employees of the Administrative Office of the U.S. Courts (Pub. L. 101–474); disabled veterans who have completed training prescribed by the VA under title 38 (5 CFR 315.604); and readers, interpreters, and personal assistants whose employment under Schedule A is no longer necessary (5 CFR 315.711).

We did not include other categories of individuals eligible for noncompetitive appointment under authorities that specifically require no break in service, e.g. current Postal employees because in such situations, an employee who took a temporary or term appointment would lose his or her eligibility for a permanent appointment.

Selecting Term Employees for Permanent Positions

We have received questions about the current regulation § 315.703 that permits the conversion of term appointees to permanent appointment under very limited conditions. Conversion is possible only when all the conditions of § 315.703 are met including the requirement that the term employee must have been within reach for permanent appointment. In this context, within reach means that the term employee could have been selected for a permanent position that was actually announced and filled. It is not sufficient for the vacancy announcement to have stated that positions could be filled by term or permanent appointment or that an individual selected for a term appointment might later be converted to a permanent appointment without further competition.

Temporary Employees Injured on the Job

The proposal would permit agencies to reappoint noncompetitively former temporary employees who were injured on the job to any position for which they qualify if their injury disqualified them for reappointment to their original position or one with the same qualification requirements. Time under the initial appointment and reappointment must adhere to the limits for temporary appointments, but time spent on workers' compensation does not count toward any time limit. For example, a temporary employee who worked for 8 months before being injured on the job spent 3 years on workers' compensation. If the individual recovered to some degree, the agency could reappoint the individual for the remaining 4 months of the temporary appointment and then, if warranted, extend the temporary appointment for up to another year. Reappointments of other former temporary employees, i.e., those who were *not* injured on the job, may be reappointed only to the same position or one with the same qualification requirements.

Temporary Appointments of Persons With Disabilities

Agencies may appoint qualified eligibles on a time-limited basis under § 213.3102(t) or (u), or § 213.3202(k), as appropriate. The time-limited appointment gives the individuals the opportunity to demonstrate their potential for successful performance, with or without reasonable accommodation. After determining that the appointees have successfully demonstrated their abilities, the agency may remove the time limitation on the appointment. This is important because the requirements for conversion of employees under 213.3102(t) and (u) to career or career-conditional appointment under § 315.709 include 2 or more years of satisfactory service under *nontemporary* Schedule A appointment. There is no conversion authority for individuals under 213.3202(k).

Eliminating the TAPER Authority

Our proposal would eliminate the TAPER (temporary appointments pending establishment of a register) authority for the reasons already discussed in connection with our proposal to eliminate the outside-the-register mechanism for term appointments. When OPM publishes final regulations eliminating the TAPER authority, agencies will have to examine competitively for positions, most notably Worker-Trainee (GS–1 and WG–1 and –2), that have been filled under the TAPER authority since 1979. In commenting on a draft of this proposal, a few agencies requested continuation of the TAPER authority for Worker Trainees on the basis that a simpler and more flexible examining process was required for individuals with limited education and experience. Such a process can be devised by agencies under their delegated authority to examine. According to the FY 95 Central Personnel Data File, agencies made only 97 Worker Trainee appointments. Thus there no longer appears to be a justification to continue a process solely for filling this type of position.

Individuals serving on TAPER appointments on the date OPM publishes final regulations eliminating the TAPER authority will not be affected. However, as required by § 315.704, TAPER employees who complete 3 years of qualifying service must have their appointments converted to career appointments or separated. TAPER employees who complete 3 years of qualifying service but do not meet the other conditions and requirements for conversion, must be separated no later than 90 calendar days following the day on which they met the service requirement for conversion.

Editorial

The proposal would also delete a section relating to the eligibility of certain term employees for within-grade increases. The section duplicates material already in subpart D of 5 CFR part 531, and employees would continue to be eligible.

Regulatory Flexibility Act

I certify that these regulations will not have a significant economic impact on a substantial number of small entities because the regulation pertains only to Federal employees and agencies.

List of Subjects in 5 CFR Part 316

Government employees.

U.S. Office of Personnel Management.

James B. King,

Director.

Accordingly, OPM proposes to amend part 316 of title 5, Code of Federal Regulations, as follows:

PART 316—TEMPORARY AND TERM EMPLOYMENT

1. The authority citation for part 316 is revised to read as follows:

Authority: 5 U.S.C., 3301; E.O. 10577, 3 CFR, 1954–1958 Comp., page 218.

Subpart B—[Removed]

2. Subpart B consisting of §§ 316.201 and 316.202 is removed and reserved.

3. In § 316.301, the existing text is designated as paragraph (a) and revised, and paragraph (b) is added, to read as follows:

§ 316.301 Purpose and duration of term appointments.

(a) An agency may make a term appointment for a period of more than 1 year but not more then 4 years to positions where the need for an employee's services is not permanent. Reasons for making a term appointment include, but are not limited to: project work; extraordinary workload; scheduled abolishment, reorganization, or contracting out of the function; uncertainty of future funding; or the need to maintain permanent positions for placement of employees who would otherwise be displaced from other parts of the organization. Agencies may extend appointments made for more than 1 year but less than 4 years up to the 4-year limit in increments determined by the agency. The vacancy announcement should state that the agency has the option of extending a term appointment up to the 4-year limit.

(b) At the request of an agency head (or designee), OPM may approve an exception to the time limits for term appointment when the extension is clearly justified to enable the agency to address a need more effectively and is consistent with applicable statutory provisions. Send requests to the Associate Director for Employment, Office of Personnel Management, Room 6F08, 1900 E Street NW., Washington, DC 20415.

4. Section 316.302 is revised to read as follows:

§ 316.302 Selection of term employees.

(a) Competitive term appointment. An agency may make a term appointment under 5 CFR part 332 competitive procedures.

(b) Noncompetitive term appointment. An agency may give a noncompetitive term appointment, without regard to the requirements of parts 332 and 333, to an individual who is qualified for the position and who is eligible for:

(1) Reinstatement under § 315.401;

(2) Veterans readjustment appointment (VRA) under § 307.103. Term appointments under this section are permitted only at the grade levels authorized for VRA appointments. Such appointment are not VRA appointments and do not lead to conversion to career-conditional appointment.

(3) Career-conditional appointment under §§ 315.601, 315.604, 315.605, 315.606, 315.607, 315.608, 315.609, 315.703, or 315.711 of this chapter;

(4) Appointment under 5 U.S.C. 3112 (veterans with compensable service-connected disability of 30% or more). The disability must be documented by a notice of retirement of discharge due to service-connected disability from active military service dated at any time, or by a notice of compensable disability rating from the Department of Veterans Affairs, dated within the last 12 months.

(5) Career appointment under 5 U.S.C. 3304(c) (''Ramspeck appointments'') but appointments must be effective no later than December 18, 1997. A term appointment under this section does not provide competitive status and does not extend or terminate an individual's eligibility for career appointment under 5 U.S.C. 3304(c).

(6) Appointment under 31 U.S.C. 732(g) for current and former employees of the General Accounting Office;

(7) Appointment under Pub. L. 101–474 for current and former employees of the Administrative Office of the U.S. Courts;

(8) Reappointment on the basis of having left a term appointment prior to serving the maximum amount of time allowed under the appointment. Reappointment must be to a position in the same agency appropriate for filling under term appointment and for which the individual qualifies. Combined service under the original term appointment and reappointment must not exceed the time limits in § 316.301.

(9) Conversion in the same agency from a current temporary appointment when the employee is or was within reach on a certificate of eligibles for term appointment *at any time during service in the temporary position.* Within reach means that the person could have been selected for the position under competitive hiring procedures, including veterans' preference. The certificate must have been actually used for term or permanent appointment. The person must have been continuously employed in the position from the date found within reach to the date converted to a term appointment.

(c) Term employees are eligible for an extension of their appointment in accordance with the time limits in § 316.301 even if their eligibility for noncompetitive appointment expires or is lost during the period they are serving under term employment.

5. In section 316.304 paragraph (a) is revised to read as follows:

§ 316.304 Trial period.

(a) The 1st year of service of a term employee is a trial period regardless of the method of appointment. Prior Federal civilian service is credited toward completion of the required trial period in the same manner as prescribed by § 315.802 of this chapter.

* * * * *

§ 316.305 [Removed]

6. Section 316.305 is removed.

7. Section 316.402 is revised to read as follows:

§ 316.402 Procedures for making temporary appointments.

(a) Competitive temporary appointments. In accordance with the time limits in § 316.401, an agency may make a temporary appointment under 5 CFR part 332 competitive procedures or under 5 CFR part 333 ''outside-the register'' procedures.

(b) Noncompetitive temporary appointments. In accordance with the time limits in § 316.401, an agency may give a noncompetitive temporary appointment, without regard to the requirements of parts 332 and 333, to an individual who is qualified for the position and who is eligible for:

(1) Reinstatement under § 315.401;

(2) Veterans readjustment appointment under § 307.103. Temporary limited appointments under this section are permitted only at the grade levels authorized for VRA appointments. Such appointments are not VRA appointments and do not lead to conversion to career-conditional appointment;

(3) Career-conditional appointment under §§ 315.601, 315.604, 315.605, 315.606, 315.607, 315.608, 315,609, or 315.711 of this chapter;

(4) Appointment under 5 U.S.C. 3112 (veterans with compensable service-connected disability of 30% or more). The disability must be documented by a notice of retirement of discharge due to service-connected disability from active military service dated at any time, or by a notice of compensable disability rating from the Department of Veterans Affairs, dated within the last 12 months;

(5) Career appointment under 5 U.S.C. 3304(c) (''Ramspeck appointments'') but appointments must be effective no later than December 19, 1997. A temporary appointment under this section does not provide competitive status and does not extend or terminate an individual's eligibility for career appointment under 5 U.S.C. 3304(c);

(6) Appointment under 31 U.S.C. 732(g) for current and former employees of the General Accounting Office;

(7) Appointment under Pub. L. 101–474 for current and former employees of the Administrative Office of the U.S. Courts;

(8) Reappointment on the basis of being a former temporary employee of the agency who was originally appointed from a certificate of eligibles or under the provisions of part 333 of this chapter. An agency may not reappoint a former temporary employee if the individual has already served the maximum time allowed in § 316.401 or if the position has been filled under temporary appointment for the maximum time allowed in § 316.401. Reappointment must be to the same position or another position appropriate for temporary appointment with the same qualification requirements;

(9) Reappointment on the basis of being a former temporary who was originally appointed from a certificate of eligibles or under the provisions of part 333 of this chapter and who sustained a compensable injury while serving on the temporary appointment. Reappointment must be to the same position or another position appropriate for temporary appointment with the same qualification requirements. If the compensable injury disqualifies the former individual from performing such a position, reappointment may be to any position for which the individual is qualified.

(c) An individual who receives a valid temporary appointment will be eligible for an extension in accordance with § 316.401 even if his or her eligibility for noncompetitive appointment expires or is lost during the authorized period of temporary employment.

8. In § 316.702 paragraph (d) is revised to read as follows:

§ 316.702 Excepted positions brought into the competitive service.

* * * * *

(d) An employee who was serving under an excepted appointment with a definite time limit longer than 1 year may be retained under a term appointment. The term appointment is subject to all conditions and time limits applicable to term appointments.

Subpart H—[Removed]

9. Subpart H consisting of § 316.801 is removed and reserved.

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DEPARTMENT OF AGRICULTURE

Food Safety and Inspection Service

9 CFR Parts 319 and 381

[Docket No. 95–051A]

RIN 0583–AC01

Meat and Poultry Standards of Identity and Composition

AGENCY: Food Safety and Inspection Service, USDA.

ACTION: Advance notice of proposed rulemaking; request for comments.

SUMMARY: The Food Safety and Inspection Service (FSIS) is reviewing the standards of identity and composition established over the years for meat and poultry food products. These standards define particular products or product categories in terms of specified meat or poultry contents or other characteristics. As part of its regulatory review initiatives, the Agency is considering whether to modify or eliminate specific standards, or to modify its overall regulatory approach to standardized meat and poultry products. Because of new technologies, changing lifestyles, changed consumer expectations, and the information now available to consumers through ingredient and nutrition labeling, the relevance and general usefulness of standards are in question.

FSIS recognizes that some of the current standards may impede innovation, or slow the introduction into the marketplace of products with reductions in certain constituents of health concern to some people. The Agency is soliciting information from the public on what direction further reform of food standards should take, including suggestions on whether to alter, or eliminate entirely, the regulations on standardized meat and poultry products. The Agency would like to know how product definitions and standards, if needed, can provide consumer protection, while at the same time granting the flexibility necessary for timely development and marketing of meat and poultry products that meet consumer needs. This review responds in part to President Clinton's memorandum to heads of departments and agencies, titled ''Regulatory Reinvention Initiative,'' dated March 4, 1995.

DATES: Comments must be received on or before November 25, 1996.

ADDRESSES: Please send an original and two copies of written comments to Docket Clerk, Room 4352 South Building, Food Safety and Inspection Service, U.S. Department of Agriculture, Washington, DC 20250. Copies of reports and handbooks cited in this notice are available for review in the FSIS Docket Room.

FOR FURTHER INFORMATION CONTACT: Mr. Robert Post, Chief, Food Standards and Ingredients Branch, Product Assessment Division, Regulatory Programs, at (202) 254–2588.

SUPPLEMENTARY INFORMATION:

Background

The Federal Meat Inspection Act (FMIA) and the Poultry Products Inspection Act (PPIA) prohibit the preparation for, and the sale or transportation, in commerce, of meat and poultry products that are adulterated or misbranded (21 U.S.C. 610; 21 U.S.C. 458).

These prohibitions apply to interstate and foreign commerce. They also apply to commerce solely within designated states by establishments that operate solely within a designated state. A state is designated if it does not have or is not effectively enforcing requirements at least equal to Title I and IV of the FMIA, and specified provisions of the PPIA. Once a state is designated, the inspection requirements of the FMIA and PPIA apply to establishments that slaughter livestock and poultry and/or prepare or process meat and/or poultry products therefrom, solely for distribution within the state.

A meat or poultry product may be considered misbranded if it falsely purports to be or falsely represents itself to be a food for which a standard of identity or composition has been prescribed by regulation, or if its label fails to bear the name of the food specified in the standard and, if required, the common or usual names of optional ingredients, except for certain specified optional ingredients (21 U.S.C. 601(n)(7); 21 U.S.C. 453(h)(7)).

FSIS has prescribed by regulation 60 meat and poultry standards of identity and composition (9 CFR §§ 319 and 381, Subpart P, for meat and poultry products, respectively), under its statutory authorities set forth in 21 U.S.C. 607(c) and 457(b). These sections permit the Secretary of Agriculture, whenever the Secretary determines such action is necessary for the protection of the public, to prescribe definitions and

standards of identity or composition for meat and poultry products. The Agency enforces the regulations concerning the standards through prior labeling approval, in-plant inspection, and compliance monitoring of products in commercial channels. Further, numerous informal standards for meat and poultry products are contained in the FSIS Standards and Labeling Policy Book.

The standards have been established to prescribe: (1) Minimum meat or poultry contents; (2) maximum fat and water contents; (3) methods of processing, cooking, and preparation; (4) permitted safe and suitable ingredients; and/or (5) expected or characterizing ingredients. Generally speaking, a standard of identity is like a recipe, requiring the presence of certain expected ingredients in a food product and/or mandating the way the product is formulated and prepared. A standard of composition generally specifies the minimum or maximum amount of ingredients in a product.

Standards of Identity and Composition and Regulatory Reform

FSIS has begun a comprehensive review of its regulatory procedures and requirements, including those for standards of identity and composition, to determine whether any are still needed and, if so, which ought to be modified or streamlined. This review is an integral part of the FSIS initiative to improve the safety of meat and poultry products by modernizing the Agency's system of food safety regulation. This review expands upon the page-by-page review of FSIS's regulations carried out earlier this year under the President's Reinvention of Government Initiative. This initiative directed departments and agencies to conduct a page-by-page review of all of their regulations and to eliminate or revise those that were outdated or otherwise in need of reform. For ones that FSIS determines need simplification or modification, FSIS is examining how it can make these regulations easier to understand and use, while still maintaining the protection they provide for consumers.

History of the Standards

From its early years, USDA has been concerned with food purity and compositional integrity. Beginning in the 1880's, Departmental scientists undertook systematic studies of food adulteration with a view toward its prevention, and published their results in numerous bulletins. By 1906, when the Meat Inspection Act and the Food and Drugs Act were passed, the Department had published, in circulars, about 200 standards of purity for food products, including meat and meat products.

The 1906 Meat Inspection Act and regulations subsequently enacted thereunder, prohibited the marketing of meat products that were misbranded or adulterated. Early inspection program directives and regulations listed permissible ingredients and coloring agents for meat products that corresponded to lists prepared by the Department's Bureau of Chemistry (predecessor of the Food and Drug Administration [FDA]). To assure that labels were truthful and not misleading, the directives listed basic requirements for products that were to bear a certain name. Thus, ''potted'' or ''deviled'' ham could be so named only if the product were made of ham or ham trimmings; if other pork was used, the mixture was required to be called ''pork meats'' or ''potted meats.'' A product called ''pork sausage'' could be made only from pork. ''Leaf lard'' had to be made only from the leaf fat of hogs.

The meat inspection regulations published in 1914 and 1922 prescribed product composition standards for products containing more than one ingredient. Thus, a pork sausage with beef added could be called a ''pork sausage'' only if it contained at least 50-percent pork and had to be labeled ''pork sausage, beef added.'' The meat portion of veal loaf had to be 100-percent veal. A 20-percent limit was imposed on the use of meat byproducts in products bearing a species name, such as ''beef,'' ''pork,'' or ''veal,'' along with the requirement that the presence of the byproducts be indicated in the product name. Percentage limitations on the use of ''cereals'' in sausage products were also prescribed.

The Department maintained such requirements for meat products in the meat regulations with minor modifications through the 1920's and 1930's. As the mandatory meat inspection program grew, more policies and standards were established for assuring accurate and consistent product identity. During the 1940's the Department developed policies and standards to prevent economic deception, that is, to protect consumers from receiving meat products that did not meet their expectations, such as debased food products in which fillers had been substituted for more valuable constituents.

Under the Agricultural Marketing Act of 1946, the Agency also promulgated poultry standards to ensure that poultry products would meet the expectations of consumers. During this period, the policies applied to poultry products were similar to those applied to meat products.

During the 1950's and 1960's, about a dozen prepared meat and poultry frozen dinners were marketed, all essentially similar and with simple formulations. Among the first regulatory standards of identity and composition for a ''further-processed'' poultry product, originating in the mid-1950's under the voluntary poultry inspection program, was the one specifying the minimum poultry meat content for poultry pies, such as ''turkey pies.''

Since standards for meat and poultry products have been developed over time in response to market trends, industry and consumer needs, and other developments, such as the advent of new methods of processing to yield traditional products, they are diverse in regard to their areas of coverage. Some standards define products or specify product characteristics and/or contents; others set forth methods of processing, preparation, and cooking. Not all of these elements are included in every standard.

Product Definitions, Contents, and Characteristics

Some standards define meat or poultry terms. For example, the standards for kinds and classes and cuts of raw poultry (§ 381.170) identify a Rock Cornish game hen or Cornish game hen as ''a young immature chicken (usually 5 to 6 weeks of age) weighing not more than 2 pounds ready-to-cook weight, which was prepared from a Cornish chicken or the progeny of a Cornish chicken crossed with another breed of chicken.''

Other standards require that certain products contain specific amounts and/or types of meat or poultry. For example, the standards for poultry dishes and specialty items in § 381.167 of the regulations require specific, minimum poultry content, calculated on a ready-to-eat basis, for certain products: ''Turkey a la King,'' for example, must contain 20 percent turkey meat, ''Chicken Tetrazzini'' must contain 15 percent chicken meat, and ''Chicken Stew'' must contain 12 percent chicken meat. There are similar standards for some meat products. For example, the regulations in § 319.304 require that meat stews, such as ''Beef Stew,'' contain no less than 25% meat of the species named on the label, computed on the weight of the fresh meat. Product identified as ''Corned Beef'' must, among other requirements, be prepared from beef briskets, navels, clods, middle ribs, rounds, rumps, or similar cuts (§ 319.100).

The use of safe and suitable ingredients, such as those additives specifically classified as extenders, binders, emulsifiers, coloring agents, antioxidants, flavoring agents, and tenderizing agents are frequently referenced in standards for meat or poultry products. The use of additives in meat and poultry products is essentially controlled by the regulations for standards, e.g., §§ 319 and 381 Subpart P, and those that directly address the use of safe and suitable ingredients, e.g., §§ 318.7 and 381.147.

Some meat and poultry standards specifically reference these safe and suitable ingredient regulations when identifying what can and cannot be included in a specific standardized product. For example, standards for cured meat or cured poultry products contain provisions for allowable curing ingredients that have been declared safe and suitable at restricted levels (§ 318.7 and 381.147). A product identified as ''Breakfast Sausage'' (§ 319.143) can only contain certain kinds of meat ingredients, and has limits on added water, fat content of the finished product, and binders or extenders that are to be added in accordance with § 318.7(c)(4). The kinds of binders and extenders allowed in meat and poultry products and their use restrictions can be found in the Tables of Approved Substances (§§ 318.7(c)(4) and 381.147(f)(4)) under ''Class of Substance, Binders and Extenders.'' Many other standards also reference the Tables of Approved Substances in regard to use of certain ingredients in the standardized product.

When appropriate, characterizing ingredients are also included as part of a product standard. For example, the regulations in § 319.145 require that a product identified as ''Italian Sausage'' contain salt, pepper, and either fennel or anise, or a combination of fennel and anise. The standard also requires that ''Italian Sausage'' contain at least 85-percent meat, or a combination of meat and fat, with the total fat content constituting not more than 35-percent of the finished product, as well as optional ingredients.

Methods of Processing, Preparation, and Cookery

Some standards include processing, preparation, or cooking criteria, some of which are relevant to ensuring product safety. For instance, the standard for ''Country Ham'' and ''Dry Cured Ham'' products (§ 319.106) specifies not only the kind of anatomical pork cut that is to be used as the starting material, but also requires the dry application of salt or salt and optional curing agents. It also specifies the length of time required for the salt penetration, the finished product weight, and the internal salt content or water activity level that must be met. All of these requirements help ensure product safety and shelf-stability. The presence and quantity of curing agents and salt, for example, and limits on water activity, help inhibit microbial growth.

Other standards specify cooking or processing requirements that were developed to ensure that consumer expectations about the nature of a product are met. For example, ''Barbecued Chicken'' (§ 381.165) must be cooked in dry heat and basted with a seasoned sauce. The standard for ''Barbecued Beef'' (§ 319.80) requires dry heat cooking by burning hardwood or hot coals therefrom, and a finished product with a brown crust and a yield of not more than 70 percent of the weight of the fresh uncooked meat.

Mechanically Separated (Species)

Most meat product and poultry food product standards identify a finished product, such as a ''Turkey Ham'' or ''Chili with Meat.'' However, the standard for mechanically separated species (MS(S)), such as that in § 319.6 for mechanically separated beef or pork, is somewhat different because it defines a meat ingredient that can be used with some restrictions in formulating other meat products. MS(S) is an ingredient that can be used in certain standardized meat food products, such as hot dogs, frankfurters, bologna (§ 319.180), meat stews (§ 319.304), spaghetti with meatballs (§ 319.306), pizza (§ 319.600), and tamales (§ 319.305). The level of its use, which is restricted, is specifically cited as part of its food product standard.

Current Concerns and Need for Review

The meat and poultry food product standards have provided a framework for identifying products and helping to ensure that products meet consumer expectations regarding product composition and characteristics. In certain instances, standards also have helped to ensure product safety. For example, the FSIS policy guide in the Standards and Labeling Policy Book for dry, fermented sausages prescribes moisture/protein ratios (MPR) that limit moisture content in these products, which, in turn, inhibits microbial growth.

Some manufacturers have complained that standards are too restrictive, stifle innovation, and prevent market acceptability of products, because they restrict the use of commonly understood product names familiar to consumers. Some manufacturers believe that the nutrition and ingredient information provided in labeling is adequate to enable consumers to distinguish among meat and poultry products and make informed choices.

Many proponents of standards reform contend that a product name has little relevance in today's market, which is becoming more and more diverse, with the increased manufacturing of new and nontraditional products. Because of changing market trends and public perceptions, some food manufacturers also believe that prescriptive standards of identity and composition impede the introduction of new, innovative, and possibly less expensive, products.

For example, food manufacturers have pointed out that restaurants market meatless pizzas consisting of a bread-type product topped with fruit or vegetables, olive oil, and seasonings. However, if an FSIS inspected establishment wants to prepare and market a nontraditional pizza that includes a meat topping of sausage but not cheese, it would be in conflict with FSIS's established standards for pizza products containing meat. The standard for ''pizza with sausage'' (§ 319.600(b)), for instance, requires that a product identified as ''Sausage Pizza'' be a bread-based meat food product with tomato sauce, cheese, and meat topping containing not less than 12 percent cooked sausage or 10 percent dry sausage (pepperoni).

Consumer expectations regarding the nutritional composition of foods have also changed in recent years. Health-conscious consumers looking for convenience and nutritional quality in their food purchases have come to play a decisive role in the marketplace. A growing body of scientific evidence that links dietary intake to health supports the concerns of these consumers, who demand products based upon traditional recipes which have been modified to have lower amounts of constituents with negative health implications, such as saturated fat and cholesterol. Meat and poultry food processors have striven to meet this demand by formulating products that resemble traditional products but that contain less fat and associated cholesterol.

In some circumstances, current standards inhibit the marketing of products lower in such constituents, because of limits on the types of ingredients permitted. FSIS has attempted to ease some of the restrictions posed by the existing standards by developing labeling approaches to identify the differences between traditional products and the

newer versions. Consequently, some products currently bear health-related nutrient content claims on their labels, such as, ''low-fat'' and ''reduced fat.''

Consumers' nutritional and health concerns indicate a need to review the basis for traditional standards of identity and composition, to question the justification for the establishment of new prescriptive standards, and to consider the elimination or modification of these standards. In fact, the public health rationale for doing so is underscored by a 1990 report by the Institute of Medicine, National Academy of Sciences (NAS). The report, ''Nutrition Labeling: Issues and Directions for the 1990's,'' argues for reexamining and changing any system ''that significantly impedes the marketing of reduced-, low-, and non- or no-fat substitutes.''

To begin to address this concern, FSIS has proposed in a separate document, ''Food Standards: Requirements for Processed Meat and Poultry Products Named by Use of an Expressed Nutrient Content Claim and a Standardized Term (60 FR 67474),'' to establish a general standard of identity for modified meat and poultry food products that would facilitate the development and marketing of, among other things, reduced fat substitutes for products currently subject to an FSIS standard of identity. The general standard of identity proposed would require that a modified meat or poultry product: (1) Not be nutritionally inferior to the traditional standardized food that it resembles and for which it substitutes, (2) possess performance characteristics that are generally similar to the traditional standardized food, (3) contain the same amount of any mandatory ingredient (i.e., meat or poultry) that is required to be in the traditional standardized food, and (4) not contain an ingredient that is prohibited in the traditional standardized food. The proposed standard (§§ 319.10 and 381.172, as proposed) also would allow safe and suitable ingredients, not specifically provided for in the standard or in excess of that provided for in the traditional food, in order that the product's makeup is consistent with the nutrient content claim made about the product.

In light of current budget constraints and the need to address high priority food safety concerns and redeploy Agency resources, FSIS is examining whether any of the Agency's approaches to regulating meat and poultry products for economic adulteration and mislabeling should be changed. Thus, FSIS is examining whether the current approach to promote fair competition and prevent misbranding and economic adulteration through developing and enforcing meat and poultry product standards continues to be appropriate.

Many of the standards are based on industry standards and were originally suggested by, and in many cases are still supported by, industry. Such standards not only reflect consumer expectations, but also serve to promote fair competition among manufacturers producing similar products. The FMIA, in fact, states that regulation of meat products is important, since ''* * * mislabeled, or deceptively packaged articles can be sold at lower prices and compete unfairly with the wholesome, not adulterated, and properly labeled and packaged articles, to the detriment of consumers and the public generally (21 U.S.C. 602).'' The PPIA also contains a similar provision which recognizes that unwholesome, adulterated, or misbranded poultry products destroy markets for wholesome, not adulterated, and properly marked, labeled, and packaged poultry products (21 U.S.C. 451).

FSIS is undertaking this comprehensive review of all of its existing product standards to determine whether in their present form they continue to play a useful role in serving the needs of industry and consumers. FSIS is exploring whether alternative approaches could be more effective in ensuring that consumers are adequately informed about the products they are purchasing and receive what they believe they are paying for, while ensuring fair competition. Any alternative approach or combination of approaches chosen would of course have to comply with the statutory mandates of the FMIA and PPIA with respect to misbranding (false or misleading labeling) and economic adulteration, provide industry greater flexibility to innovate, and expand consumer choices in the marketplace.

Issues for Public Comment

As part of its comprehensive standards review, FSIS is soliciting comments on the following issues, as well as any other comments that would assist the Agency in fulfilling its mission to protect the interest of consumers by helping to ensure that meat and poultry products are correctly labeled and are not adulterated. FSIS requests comments from any interested parties such as food manufacturers and distributors, including importers and exporters, individuals and consumer groups, academia, State and local governments, and the international community.

1. Utility of the System

a. In general, how do consumers and the regulated industry view the Agency's role in developing food standards? How would major changes in standards of identity affect consumers, producers, and manufacturers?

b. As discussed above, there are different types of standards. Are some more meaningful or useful than others? Could the objectives of meat and poultry standards, designed to ensure that products are correctly labeled and not economically adulterated, as well as help ensure fair competition and market stability for wholesome, properly labeled products, be accomplished by other more effective means? If so, how could they be accomplished within the limits of current and anticipated FSIS resources?

c. Do standards of identity for meat and poultry products actually protect the integrity of the food supply? Are there any data that indicate consumers are aware of or rely upon the current standards? If so, do consumers find the current system of standards meaningful and understandable? Would alteration of the standards significantly affect consumers' ideas about the integrity of meat and poultry products?

d. Does the industry need compositional standards for the orderly marketing of foods? Are food standards needed to control the composition of fabricated foods such as hot dogs, bologna, pepperoni, and potted meats? Depending on the extent of any standards reform, what market impact would result if manufacturers were allowed to decrease the amounts of meat or poultry used in products?

e. As previously discussed, some standards contain processing and other requirements relevant to food safety. Could food safety objectives be achieved by other means?

f. Are food standards an effective means of ensuring that only safe and suitable additives and ingredients are used in the formulation of products?

2. Flexibility

If FSIS continues to maintain a system of standards of identity and composition, how could current and future standards be made more flexible, to accomodate the needs of industry in a changing market, without compromising the Agency's efforts to ensure that meat and poultry products are neither misbranded nor economically adulterated?

3. Product Identity

a. Food standards of identity are a means of defining the composition of a

food that is marketed under a designated common or usual name. What criteria should be used for determining when a food standard is appropriate? Should evidence of the existence of consumer confusion or dissatisfaction be required as a precondition before FSIS undertakes a standards setting process?

b. How should FSIS address differences between the standards of identity established for similar meat and poultry products, such as those established for ham and turkey ham products, which allow for different levels of moisture content? What purpose do such differences serve and how do they affect consumers, producers, and processors? Also, FSIS requires establishments to indicate through labeling the presence of meat byproducts in all processed meat products. Should FSIS require disclosure of the presence of detached skin, even in natural proportions, in the ingredients statement of processed poultry products?

c. Consumers desire both product consistency and variety among products. Given this, how would revision or elimination of the standards of identity affect consumers? For which products or characteristics is consistency, or standardization, most important to consumers?

d. If there were no meat or poultry product standards, what criteria could be used to define ''imitation'' products?

e. If there were no standards, how would consumers, industry, and FSIS judge when a product is identified, by labeling, in a misleading way?

4. Federal Preemption: Impact on State Jurisdiction

a. FSIS specifically requests comments on the preemption aspects of Federal standards of identity. If Federal standards of identity were discontinued and the preemptive provisions of the FMIA and the PPIA for labeling were amended, would the States establish their own compositional requirements in the absence of a Federal meat and poultry standards program? Would a diverse, multi-State food standards program be desirable? What would be the costs and benefits?

b. If it is not deemed to be in the interest of the public to retain Federal food standards for meat and poultry products, what changes should be considered in the FMIA and PPIA? Comments should be supported by data where possible relating to the economics of production and marketing of commodities currently covered by food standards, including the costs and benefits to consumers, industry, and international trade.

5. Impact on Domestic and International Trade

a. How are current FSIS standards related to international meat and poultry standards and what would be the economic impact of standards reform on product development in the United States and international markets?

b. Would there be significant costs for industry if Federal meat and poultry standards of identity were conformed to international standards for these products, where possible? Also, what would be the costs for industry if states were permitted to enforce any type of standard requirements that were different from Federal and international standards?

c. In recommending an alternative to the current system of standards of identity and common or usual name designation for food, commenters should take into account the impact of the alternative on FSIS's ability to participate in the development and harmonization of international standards.

The United States participates in the Codex Alimentarius Commission (Codex) and its food standards program. Codex is sponsored jointly by the United Nations' Food and Agriculture Organization (FAO) and World Health Organization (WHO). Its goal is to promote the health and economic interests of consumers, while encouraging fair international trade in food. All food standards adopted by Codex must be reviewed by the FDA (in consultation with FSIS when appropriate) and be accepted without change, accepted with change, or not accepted. Procedures regarding Codex standard adoption are codified in 21 CFR 130.6.

U.S. food standards provide an important point of reference when international standards are established. How effective would U.S. delegates be in debating the merits of specific provisions in Codex food standards if the Federal government had no comparable standards? How important is it to exporters and importers that the compositional provisions of the Federal meat and poultry standards be reflected in international standards such as those established by the Codex Alimentarius?

6. FSIS and FDA Uniformity and Standards Systems

The FMIA (section 7(c)(2))(21 U.S.C. 607(c)(2)) and the PPIA (section 8(b)(2))(21 U.S.C. 457(b)(2)) provide that the Secretary of Agriculture may prescribe definitions and standards of identity or composition; that they not be inconsistent with any such standards established under the Federal Food, Drug, and Cosmetic Act; and that inconsistencies between Federal and State standards be avoided, insofar as feasible. To what extent should FSIS harmonize its approach to standards reform with FDA?

On December 29, 1995, FDA published an Advance Notice of Public Rulemaking, ''Food Standards of Identity, Quality and Fill of Container; Common or Usual Name Regulations; Request for Comment on Existing Regulations'' (60 FR 67490). FSIS encourages commenters to read the FDA document because it provides useful background information on similar FDA standards' issues. A thorough understanding of both agencies' food standards programs will help commenters in providing comments that will facilitate uniform food standards reform. Commenters should submit separate comments to each agency.

7. Agency Budget Constraints and Regulatory Compliance

Current and anticipated budget constraints compel FSIS to alter the way it allocates resources. The Agency must give priority to programs affecting food safety and public health, while seeking means to continue meeting its responsibilities concerning issues of economic adulteration and misbranding. Thus, comments supporting continuance of the existing food standards program should discuss possible sources of new or additional resources for the program. Further, in light of budget constraints, how should the Agency verify compliance with the standards in the future? What should be the FSIS inspector's role in a modified or streamlined system of standards?

8. Policy Guides

The Agency has developed policy guides for standards which are identified in the Standards and Labeling Policy Book. The Standards and Labeling Policy Book serves, in part, to guide industry regarding product names, composition, characterizing ingredients, methods of preparation related to product names, and such. Do the policy guides as embodied in the Standards and Labeling Policy Book, serve a useful purpose? If these policy guides serve a useful purpose, do they need revision? If so, what revisions are necessary and what data are available to support revision?

9. Standards and Substitute, Modified Meat and Poultry Products

a. To what extent do FSIS requirements for minimum meat and poultry content in the standards impede the development of reduced fat and other modified products that can assist consumers in meeting dietary needs?

b. Is there any point at which consumers would feel that ''substitute, modified foods,'' (i.e., standardized foods with a reduction in constituents of concern to consumers) are no longer similar to the standardized foods they are intended to resemble and are merely imitations of these foods? For further information about ''substitute, modified foods'' see FSIS's proposed rule, ''Food Standards: Requirements for Processed Meat and Poultry Products Named by Use of an Expressed Nutrient Content Claim and a Standardized Term'' (60 FR 67474).

10. Grandfather or Sunset Provisions

Is there a need to ''grandfather'' or ''sunset'' current regulatory requirements or policy guides?

11. Cost and Benefits to Consumers and Industry

The Agency is particularly interested in the cost/benefit aspects of food standards. It would appreciate receiving comments in response to the following questions: Do the benefits of standards to consumers and to the regulated industry outweigh the costs of such regulations?; What factors affect the benefits and costs of food standards?; How can FSIS best estimate the benefits and costs of particular standards?; Which standards are particularly beneficial or costly, and why?; and If the existing programs need to be restructured, how should this be accomplished, and how would such a change affect the costs and benefits to consumers?

Alternatives Considered

FSIS is considering adopting one or more of the following alternative approaches, should it continue meat and poultry standards in any form. FSIS believes that these approaches increase the flexibility of the meat and poultry product standards, while ensuring that meat and poultry products are identified in a non-misleading manner, and contain only safe and suitable ingredients.

1. Use of Percentage Declaration of Meat and/or Poultry Content in Conjunction with Standardized Names

One approach the Agency is considering would provide greater flexibility than currently allowed in the formulation of standardized products required to contain a specified minimum amount of meat or poultry. FSIS could permit the use of a lesser amount of meat and/or poultry in these standardized products, provided the product's label contained a declaration of the percentage of the meat or poultry content in the product. For example, the standard of identity for meat stews, such as ''Beef Stew'' (§ 319.304), currently requires the product contain ''not less than 25-percent of meat'' of the species named on the label.

Under current FSIS regulations and policy guides, products containing less than the prescribed amount of meat or poultry for a standardized product may be marketed (1) under names that indicate that the product is an ''imitation'' of the standardized food; (2) under names that distinguish the product from the standardized product, e.g., using a descriptive name such as ''gravy, vegetables, and beef,'' for a product that does not meet the ''Beef Stew'' standard; or (3) with labels that use a comparative, educational statement in addition to a standardized name to reflect the difference in meat or poultry contents, when the substitute product is nutritionally equivalent. For example, a pizza that contains only 5 percent sausage may be identified as ''Pizza with Sausage'' as long as a statement is included on the label that indicates the product ''contains 5 percent sausage, whereas the standard for 'Pizza with Sausage' requires 12 percent sausage.''

Under one alternative approach, a manufacturer might produce a ''Beef Stew'' containing a lesser amount of beef than prescribed in the standard, provided the principal display panel of the label bears, in conjunction with the name of the food, a declaration of the percentage of beef contained in the product, e.g., ''Beef Stew, Contains 10% Beef.'' Another option would be to provide the percentage declaration in conjunction with the ingredient list on the label.

Key advantages of such alternatives are that they would expand the flexibility available to companies in formulating products bearing the standardized name while still providing the consumers with important information about the meat or poultry content of the product, that is both factual and non-misleading. Information about the percentage of meat or poultry in a product, in combination with the nutrition information and ingredient labeling provided on labels, would give consumers valuable information upon which they could rely in making a food choice.

In considering such alternatives, FSIS recognizes that there may be some products that contain such a small amount of meat or poultry that the use of a standardized name, even if used in conjunction with a statement that indicates the percentage of meat and poultry in the product, may not be justified. FSIS will be considering whether products that contain an insignificant amount of meat or poultry should be permitted to use as standardized name as part of its labeling. FSIS would like comments on this issue.

The Agency has reviewed numerous meat and poultry standards to identify categories that may be good candidates for this alternative declaration-of-percentage approach to product identity. Obviously, candidates include standards that contain a minimum meat, meat food product, meat byproduct, and/or poultry content requirement. Such standards, found in 9 CFR Part 319 and 381, Subpart P, include scrapple (§ 319.280); chili con carne (§ 319.300); chili con carne with beans (§ 319.301); hash (§ 319.302); corned beef hash (319.303); meat stews (319.304); tamales (§ 319.305); spaghetti with meatballs and sauce—spaghetti with meat and sauce, and similar products (§ 319.309); spaghetti sauce with meat (§ 319.307); beans with frankfurters in sauce, sauerkraut with wieners and juice, and similar products (§ 319.306); lima beans with ham in sauce, beans with ham in sauce, beans with bacon in sauce and similar products (§ 319.310) chow mein vegetables with meat, and chop suey vegetables with meat (§ 310.311); pork with barbecue sauce and beef with barbecue sauce (§ 319.312); tongue spread and similar products (§ 319.762); liver meat food products (§ 319.881); poultry dinners (frozen) and pies (§ 381.158); and ''other poultry dishes and specialty items'' (§ 381.167).

2. Develop a General Standard of Identity for All Meat and Poultry Food Products

The Agency could propose to establish a general standard of identity for the 60 meat and poultry products defined by standards in the current regulations. This general standard of identity approach would provide for deviations from current ingredient allowances and restrictions. The deviations would be highlighted in the ingredient statement of the product. This labeling requirement would inform consumers of the difference between the standardized products and the ''modified'' version of the product.

For example, the current standard for ''Chili Con Carne'' (§ 319.300) requires

this product to contain no less than 40-percent meat computed on the weight of the fresh meat; allows the use of MS(S) in accordance with § 319.6; restricts head meat, cheek meat, and heart meat exclusive of the heart cap to no more than 25 percent of the meat ingredients under specific declaration on the label; and allows binders and extenders as provided in § 318.7(c)(4). Under a general standard of identity, a new, ''modified'' ''Chili con carne'' product might contain 40 percent cheek meat, as long as the ingredients statement highlighted this deviation. If the meat component were reduced from 40 percent to 20 percent, or if the product contained 40 percent textured vegetable protein as well as meat, these deviations also would need to be highlighted in the ingredients statement.

FSIS would like to receive comments on whether this approach could provide the flexibility desired by manufacturers, while protecting the integrity of the food supply by ensuring that consumers receive meat and poultry products labeled in an truthful and non-misleading manner.

3. Recommended Meat and Poultry Contents

Another approach would be to establish categories of meat or poultry products, and corresponding recommendations for expected meat and poultry contents. For example, FSIS could recommend that ''Beef Burgundy'' contain 50-percent beef, that ''Beef Stroganoff'' contain 30 percent cooked beef, and so forth. Under this approach, establishments could deviate from the recommended meat and poultry content. It would be expected that the difference be conveyed to the consumer through labeling. Recommended amounts of meat and poultry content in products would reflect consumer expectations, and, therefore, would serve as guidance for food manufacturers.

FSIS requests public comment on this alternative approach to establishing content standards, and would welcome other suggestions for establishing product categories, or determining what the meat and/or poultry content should be for the various categories. FSIS also requests comments on how other requirements in the current standards, such as those concerning additives, non-meat ingredients, or processing, would be affected by meat and poultry content recommendations for the various meat and poultry categories?

4. Private Certification of Food Products

Provided that amendments are made to the FMIA and PPIA, it may be possible for private organizations to certify that meat and poultry products meet consumer expectations. These organizations would establish criteria for product content and characteristics associated with product names.

FSIS would like to receive comments on the issue of eliminating standards of identity and composition including comments in response to the following questions: Could national associations that promote or address marketing issues for specific products or commodities, such as the National Food Processors Association and the National Frozen Pizza Association, or other recognized authorities, such as culinary societies, schools, or institutes, establish meaningful meat or poultry product standards?; How would the fact that products met such standards be conveyed in labeling?; Would a labeling statement, such as ''Meets standards established by the National Chili Society,'' have meaning in labeling?; How would the truthfulness or the accuracy for the statement be verified?; How would the credibility or authenticity of the certifying body be established?; Which characteristics of meat or poultry food products are most amenable to certification by private organizations rather than by local, State, or Federal government?; and Which factors render private certification impractical or inappropriate?

5. Elimination of the Standards of Identity and Composition

The FMIA and PPIA provide that USDA may promulgate definitions and standards of identity and composition for meat and poultry products whenever it determines such action is necessary for the protection of the public (21 U.S.C. 607(c), 457(b)). These Acts do not require, however, that USDA promulgate standards. Therefore, one option for the Agency is to eliminate regulations for standards of identity and composition and then to discontinue any programs related to the standards.

FSIS would like to receive comments on the issue of eliminating standards of identity and composition including comments in response to the following questions: In general, what would be the advantages and disadvantages to industry and consumers of eliminating the standards of identity and composition?; What would be the impact on domestic and foreign commerce, and food safety?; How would labeling requirements need to be revised if standards of identity were eliminated?; and In the absence of standards of identity, should labels specify percentages of ingredients?

Additionally, some standards include processing, preparation, or specific cooking requirements that are related to ensuring product safety and shelf-stability, such as the standard for ''Country Ham'' and ''Dry Cured Ham'' products (§ 319.106). FSIS would like comments on this issue including responses to the following questions: If such standards were eliminated, would remaining regulations be sufficient to assure the safety of these products?; and Should the safety provisions of these standards be included in other regulations?

Executive Order 12866

This advance notice of proposed rulemaking has been reviewed under Executive Order 12866. This rule has been determined to be significant for the purposes of Executive Order 12866 and, therefore, has been reviewed by the Office of Management and Budget.

FSIS is seeking the data necessary to assess how the regulatory changes discussed in this document might affect various sectors of the meat and poultry industries. Therefore, the Agency invites comment on potential effects, including economic costs or benefits.

Done, at Washington, D.C., on: September 3, 1996.

Michael R. Taylor,

Acting Under Secretary for Food Safety.

[FR Doc. 96–22956 Filed 9–6–96; 8:45 am]

BILLING CODE 3410–DM–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 39

[Docket No. 93–NM–194–AD]

RIN 2120–AA64

Airworthiness Directives; de Havilland, Inc., Model DHC–8–100 and –300 Series Airplanes

AGENCY: Federal Aviation Administration, DOT.

ACTION: Supplemental notice of proposed rulemaking; reopening of comment period.

SUMMARY: This document revises an earlier proposed airworthiness directive (AD), applicable to de Havilland Model DHC–8–100 and –300 series airplanes. That proposal would have superseded a previously-issued AD that currently requires repetitive inspections to detect cracks of the upper drag strut trunnion fittings of the nose landing gear and to verify tightness of the fitting attachment bolts. It also would have required the

installation of a modification to terminate the repetitive inspections. This new action revises the proposed rule by proposing to require a different terminating modification.

This action is prompted by data indicating that the previously proposed terminating modification is not effective.

The actions specified by the proposed AD are intended to prevent failure of the upper drag strut trunnion fittings of the nose landing gear, which could lead to collapse of the nose landing gear.

DATES: Comments must be received by September 30, 1996.

ADDRESSES: Submit comments in triplicate to the Federal Aviation Administration (FAA), Transport Airplane Directorate, ANM–103, Attention: Rules Docket No. 93–NM–194–AD, 1601 Lind Avenue, SW., Renton, Washington 98055–4056. Comments may be inspected at this location between 9:00 a.m. and 3:00 p.m., Monday through Friday, except Federal holidays.

The service information referenced in the proposed rule may be obtained from Bombardier, Inc., Bombardier Regional Aircraft Division, Garratt Boulevard, Downsview, Ontario M3K 1Y5, Canada. This information may be examined at the FAA, Transport Airplane Directorate, 1601 Lind Avenue, SW., Renton, Washington.

FOR FURTHER INFORMATION CONTACT: Jon Hjelm, Aerospace Engineer, Airframe Branch, ANE–172, FAA, Engine and Propeller Directorate, New York Aircraft Certification Office, 181 South Franklin Avenue, Room 202, Valley Stream, New York 11581; telephone (516) 256–7523; fax (516) 568–2716.

SUPPLEMENTARY INFORMATION:

Comments Invited

Interested persons are invited to participate in the making of the proposed rule by submitting such written data, views, or arguments as they may desire. Communications shall identify the Rules Docket number and be submitted in triplicate to the address specified above. All communications received on or before the closing date for comments, specified above, will be considered before taking action on the proposed rule. The proposals contained in this notice may be changed in light of the comments received.

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

Commenters wishing the FAA to acknowledge receipt of their comments submitted in response to this notice must submit a self-addressed, stamped postcard on which the following statement is made: ''Comments to Docket Number 93–NM–194–AD.'' The postcard will be date stamped and returned to the commenter.

Availability of NPRMs

Any person may obtain a copy of this NPRM by submitting a request to the FAA, Transport Airplane Directorate, ANM–103, Attention: Rules Docket No. 93–NM–194–AD, 1601 Lind Avenue, SW., Renton, Washington 98055–4056.

Discussion

A proposal to amend part 39 of the Federal Aviation Regulations (14 CFR part 39) to add an airworthiness directive (AD), applicable to certain de Havilland Model DHC–8–100 and –300 series airplanes, was published as a notice of proposed rulemaking (NPRM) in the Federal Register on February 7, 1994 (59 FR 5554). That NPRM would have superseded AD 93–08–03, amendment 39–8550 (58 FR 25549, April 27, 1993), which currently requires repetitive inspections to detect cracks of the upper drag strut trunnion fittings of the nose landing gear and to verify tightness of the fitting attachment bolts. It also requires replacement of the fittings or fasteners, if necessary. AD 93–08–03 was prompted by reports of cracks detected in two trunnion fittings which retain and support the nose landing gear upper drag link. The requirements of AD 93–08–03 are intended to prevent failure of the upper drag strut trunnion fittings of the nose landing gear, which could lead to collapse of the nose landing gear.

The NPRM would have added a requirement to the AD to modify the upper drag strut trunnion fittings and fasteners of the nose landing gear. Once the modification was installed, the repetitive inspections could be terminated.

Actions Since Issuance of Previous Proposal

Since the issuance of that NPRM, Transport Canada Aviation, which is the airworthiness authority for Canada, has advised the FAA that the modification proposed as terminating action for AD 93–08–03 has been determined to be ineffective. Data indicate that installation of Modification 8/1880, which is described in de Havilland Service Bulletin S.B. 8–53–45, dated July 12, 1993, may recreate the original problem that the AD intends to correct.

Explanation of New Relevant Service Information

De Havilland has issued Service Bulletin S.B. 8–53–49, dated June 30, 1995, that describes procedures for installing Modification 8/2139. This modification entails the installation of strengthened drag link trunnion fittings and adjacent right-angled support fittings, both of which will reduce premature fatigue. Additionally, the modification involves the installation of fasteners with larger diameters to attach the fittings, and installation of a new sensor support bracket.

Transport Canada Aviation approved the technical content of this service bulletin and issued Revision 3 of Canadian airworthiness directive CF–92–18, dated August 2, 1995, in order to assure the continued airworthiness of these airplanes in Canada. That revised Canadian airworthiness directive specifies that Modification 8/2139 is an optional terminating action for the repetitive inspections required of the drag strut trunnion fittings (required by the original issue of CF–92–18).

Additionally, de Havilland has issued Revision ''D'' of Service Bulletin S.B. A8–53–40, dated June 30, 1995. This revision is essentially identical in its technical content to the previous revisions of the service bulletin, but contains updated effectivity information and new references to Modification 8/2139.

FAA's Conclusions

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

Explanation of the New Proposed Requirements of the Rule

Since an unsafe condition has been identified that is likely to exist or develop on other airplanes of the same type design registered in the United States, this new proposed AD would

supersede AD 93–08–03 to continue to require inspection to detect cracks of the upper drag strut trunnion fittings of the nose landing gear, inspection to verify tightness of the fitting attachment bolts, and replacement of the fittings or fasteners, if necessary. Additionally, this new proposed AD would require the installation of Modification 8/2139. When accomplished, this modification would terminate the need for the currently required inspections. The modification would be required to be accomplished in accordance with de Havilland Service Bulletin S.B. 8–53–49, described previously.

The proposed AD also would limit the applicability of the rule to exclude those airplanes on which Modification 8/2139 has been installed previously. The manufacturer has installed Modification 8/2139 prior to delivery of airplanes having serial numbers 396 and subsequent. Airplanes so modified are not subject to the unsafe condition addressed by this proposed AD.

Paragraph (a) of the proposed AD has been revised to reference Revision ''D'' of de Havilland Service Bulletin S.B. A8 53–40, dated June 30, 1995, as an additional appropriate source of service information.

Differences Between the Proposed Rule and Related Canadian AD

Operators should note that, whereas the Canadian AD allows installation of Modification 8/2139 as an optional action, this proposed AD would mandate its installation as terminating action. The FAA has determined that long term continued operational safety will be better assured by modifications or design changes to remove the source of the problem, rather than by repetitive inspections. Long term inspections may not be providing the degree of safety assurance necessary for the transport airplane fleet. This, coupled with a better understanding of the human factors associated with numerous repetitive inspections, has led the FAA to consider placing less emphasis on special procedures and more emphasis on design improvements. The proposed modification requirement is in consonance with these considerations.

Reopening of Period for Public Comment

Since the changes made to this proposal expand the scope of the originally proposed rule, the FAA has determined that it is necessary to reopen the comment period to provide additional opportunity for public comment.

Cost Impact

The FAA estimates that 146 airplanes of U.S. registry would be affected by this proposed AD.

Accomplishment of the currently required inspections takes approximately 1 work hour per airplane, at an average labor rate of $60 per hour. Based on these figures, the cost impact of the currently required inspection actions on U.S. operators is estimated to be $8,760, or $60 per airplane, per inspection.

The proposed modification action would take approximately 18 work hours per airplane to accomplish the proposed actions, at an average labor rate of $60 per work hour. Required parts would cost approximately $3,325 per airplane. Based on these figures, the cost impact of the proposed AD on U.S. operators is estimated to be $638,725, or $4,405 per airplane.

The cost impact figures discussed above are based on assumptions that no operator has yet accomplished any of the proposed requirements of this AD action, and that no operator would accomplish those actions in the future if this AD were not adopted. However, based on the effective date and compliance time of AD 93–08–03, it can be reasonably assumed that the majority of affected U.S. operators already have initiated and are currently conducting the inspections required by that AD.

Regulatory Impact

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

For the reasons discussed above, I certify that this proposed regulation (1) is not a ''significant regulatory action'' under Executive Order 12866; (2) is not a ''significant rule'' under the DOT Regulatory Policies and Procedures (44 FR 11034, February 26, 1979); and (3) if promulgated, will not have a significant economic impact, positive or negative, on a substantial number of small entities under the criteria of the Regulatory Flexibility Act. A copy of the draft regulatory evaluation prepared for this action is contained in the Rules Docket. A copy of it may be obtained by contacting the Rules Docket at the location provided under the caption **ADDRESSES.**

List of Subjects in 14 CFR Part 39

Air transportation, Aircraft, Aviation safety, Safety.

The Proposed Amendment

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

PART 39—AIRWORTHINESS DIRECTIVES

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

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

§ 39.13 [Amended]

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

De Havilland, Inc.: Docket 93–NM–194–AD. Supersedes AD 93–08–03, amendment 39–8550.

Applicability: Model DHC–8–102, –103, –301, –311, and –314 series airplanes; having serial numbers 003 through 395, inclusive, but excluding serial numbers 011, 362, and 391; on which Modification 8/2139 (as described in de Havilland Service Bulletin S.B. 8–53–49, dated June 30, 1995) has not been accomplished; certificated in any category.

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

Compliance: Required as indicated, unless accomplished previously.

To prevent failure of the upper drag strut trunnion fittings of the nose landing gear, which could lead to collapse of the nose landing gear, accomplish the following:

(a) Within 500 landings after May 27, 1993 (the effective date of AD 93–08–03, Amendment 39–8550), unless accomplished within the last 500 landings, conduct a visual inspection of both upper drag strut trunnion fittings of the nose landing gear to detect cracks; and conduct an inspection of the fitting attachment bolts to verify tightness; in accordance with de Havilland DHC–8 Alert Service Bulletin S.B. A8–53–40, Revision 'A', dated June 12, 1992; or Revision 'B', dated February 24, 1993; or Revision 'D', dated June 30, 1995.

(1) If no crack is detected in the upper drag strut trunnion fittings of the nose landing

gear, and no looseness is detected in the fitting attachment bolts, repeat the inspections at intervals not to exceed 1,000 landings until the modification required by paragraph (b) of this AD is accomplished.

(2) If any crack is detected on either fitting, prior to further flight, replace both fittings with confirmed crack-free fittings in accordance with the service bulletin. After such replacement, the inspections required by this paragraph must continue at intervals not to exceed 1,000 landings until the modification required by paragraph (b) of this AD is accomplished.

(3) If any fitting attachment bolt is found to be loose during the initial inspection, prior to further flight, replace the fasteners (nut, washer, and bolt) that secure the fitting, in accordance with the service bulletin. After such replacement, the inspections required by this paragraph must continue at intervals not to exceed 1,000 landings until the modification required by paragraph (b) of this AD is accomplished.

(4) If any fastener is found to be loose during any repetitive inspection required by this AD, prior to further flight, tighten the bolt to the value specified in the service bulletin.

(b) Within 6 months after the effective date of this AD, install Modification 8/2139 in accordance with de Havilland Service Bulletin S.B. 8–53–49, dated June 30, 1995. Installation of this modification constitutes terminating action for the inspection requirements of this AD.

(c) Installation of Modification 8/2139, in accordance with de Havilland Service Bulletin S.B. 8–53–49, dated June 30, 1995, constitutes terminating action for the inspections required by this AD.

(d) An alternative method of compliance or adjustment of the compliance time that provides an acceptable level of safety may be used if approved by the Manager, New York Aircraft Certification Office (ACO), ANE–170, FAA, Engine and Propeller Directorate. Operators shall submit their requests through an appropriate FAA Principal Maintenance Inspector, who may add comments and then send it to the Manager, New York ACO.

Note 2: Information concerning the existence of approved alternative methods of compliance with this AD, if any, may be obtained from the New York ACO.

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

Issued in Renton, Washington, on September 3, 1996.

Darrell M. Pederson,

Acting Manager, Transport Airplane Directorate, Aircraft Certification Service.

[FR Doc. 96–22919 Filed 9–6–96; 8:45 am]

BILLING CODE 4910–13–U

14 CFR Part 39

[Docket No. 93–NM–193–AD]

RIN 2120–AA64

Airworthiness Directives; Fokker Model F28 Mark 0100 Series Airplanes

AGENCY: Federal Aviation Administration, DOT.

ACTION: Supplemental notice of proposed rulemaking; reopening of comment period.

SUMMARY: This document revises an earlier proposed airworthiness directive (AD) that is applicable to certain Fokker Model F28 Mark 0100 series airplanes. That proposal would have required repetitive inspections to detect corrosion in the wheel axles of the main landing gear (MLG) sliding members; and rework of any corroded areas, an inspection to detect cracks in the wheel axles, and replacement of any cracked sliding member. That proposal was prompted by a report of failure of a MLG wheel axle during push back of an in-service airplane from the terminal. This action revises the proposed rule by providing for interim actions that may be accomplished in lieu of the repetitive inspections. This action also revises the proposed rule by requiring eventual modifications of the main wheel brake units and the MLG sliding members; when accomplished, these modifications terminate the repetitive inspections and interim actions. The actions specified by this proposed AD are intended to prevent failure of the MLG wheel axle due to problems associated with corrosion and cracking.

DATES: Comments must be received by October 3, 1996.

ADDRESSES: Submit comments in triplicate to the Federal Aviation Administration (FAA), Transport Airplane Directorate, ANM–103, Attention: Rules Docket No. 93–NM–193–AD, 1601 Lind Avenue, SW., Renton, Washington 98055–4056. Comments may be inspected at this location between 9:00 a.m. and 3:00 p.m., Monday through Friday, except Federal holidays.

The service information referenced in the proposed rule may be obtained from Fokker Aircraft USA, Inc., 1199 North Fairfax Street, Alexandria, Virginia 22314. This information may be examined at the FAA, Transport Airplane Directorate, 1601 Lind Avenue, SW., Renton, Washington.

FOR FURTHER INFORMATION CONTACT: Ruth E. Harder, Aerospace Engineer, Standardization Branch, ANM–113, FAA, Transport Airplane Directorate, 1601 Lind Avenue, SW., Renton, Washington 98055–4056; telephone (206) 227–1721; fax (206) 227–1149.

SUPPLEMENTARY INFORMATION:

Comments Invited

Interested persons are invited to participate in the making of the proposed rule by submitting such written data, views, or arguments as they may desire. Communications shall identify the Rules Docket number and be submitted in triplicate to the address specified above. All communications received on or before the closing date for comments, specified above, will be considered before taking action on the proposed rule. The proposals contained in this notice may be changed in light of the comments received.

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

Commenters wishing the FAA to acknowledge receipt of their comments submitted in response to this notice must submit a self-addressed, stamped postcard on which the following statement is made: ''Comments to Docket Number 93–NM–193–AD.'' The postcard will be date stamped and returned to the commenter.

Availability of NPRMs

Any person may obtain a copy of this NPRM by submitting a request to the FAA, Transport Airplane Directorate, ANM–103, Attention: Rules Docket No. 93–NM–193–AD, 1601 Lind Avenue, SW., Renton, Washington 98055–4056.

Discussion

A proposal to amend part 39 of the Federal Aviation Regulations (14 CFR part 39) to add an airworthiness directive (AD), applicable to certain Fokker Model F28 Mark 0100 series airplanes, was published as a notice of proposed rulemaking (NPRM) in the Federal Register on February 2, 1994 (59 FR 4875). That NPRM would have required repetitive inspections to detect corrosion in the wheel axles of the main landing gear (MLG) sliding members; and rework of any corroded areas, an inspection to detect cracks in the wheel axles, and replacement of any cracked sliding member. That NPRM was prompted by a report that a MLG wheel axle failed during push back of an in-

service airplane from the terminal. That condition, if not corrected, could result in failure of the MLG wheel axle due to the problems associated with corrosion and cracking.

Actions Since Issuance of Previous Proposal

Since the issuance of the NPRM, three new or revised service bulletins have been released. These service bulletins are described below.

1. Dowty Aerospace has issued Service Bulletin F100–32–64, Revision 1, dated February 18, 1994. The original issue of this service bulletin was cited in the NPRM as an appropriate source of service information for accomplishment of repetitive visual inspections to detect corrosion in the wheel axles of the MLG sliding members. Although Revision 1 is essentially the same as the original issue, it contains certain editorial changes; the technical content of the service bulletin has not been changed.

2. Fokker has issued Service Bulletin SBF100–32–083, dated March 23, 1994. This service bulletin describes procedures for interim actions that may be accomplished in lieu of the repetitive inspections described in Fokker Service Bulletin SBF100–32–080. Accomplishment of these interim actions would allow an operator to increase the repetitive inspection interval for its fleet from 3 months to one year until terminating modifications are accomplished. The interim actions include:

—Installation of main wheel brake units with chamfered and cadmium-plated inboard bushings;
—Restoration of the protection scheme of the sliding members; and
—Inspections (also referred to as a ''sampling program'') to detect corrosion in the wheel axles of the MLG sliding members.

This service bulletin recommends that if any sampling is unsatisfactory, the repetitive inspections described in Fokker Service Bulletin SBF100–32–080 should be resumed. (Additionally, this service bulletin references Part B of the Dowty service bulletin described previously as an additional source of service information for accomplishment of the interim actions.)

3. Fokker also has issued Service Bulletin SBF100–32–081, dated March 23, 1994, which describes procedures for modifications of the main wheel brake units and the MLG sliding members. These modifications entail installing the main wheel brake units with chamfered and cadmium-plated inboard bushings, and installing landing gears with chromium or nickel plating on the brake abutment flange of the sliding member and restored cadmium plating and paint in the radius of the sliding member. Accomplishment of these modifications will prevent the development of corrosion in the radii of the wheel axles of the MLG sliding members. Accomplishment of the modifications eliminates the need for the repetitive inspections and the interim actions. (Additionally, the Fokker service bulletin references Part C of the Dowty service bulletin described previously as an additional source of service information for accomplishment of the modifications.)

Related Action by the Netherlands Authorities

The Rijksluchtvaartdienst (RLD), which is the airworthiness authority for the Netherlands, has approved the Fokker service bulletins, and issued Netherlands airworthiness directive (BLA) 93–108/3 (A), dated April 29, 1994, in order to assure the continued airworthiness of these airplanes in the Netherlands.

The BLA requires the accomplishment of either the repetitive visual inspections for corrosion, or the interim actions (including the 'sampling program'' inspections).

FAA's Findings; New Proposed Requirements

The FAA examined the findings of the RLD, and reviewed the latest service information. The FAA finds that the previously issued NPRM must be revised to provide for interim actions that may be accomplished in lieu of the repetitive inspections, and to require the accomplishment of the modifications of the main wheel brake units and the MLG sliding members specified in Fokker Service Bulletin SBF100–32–081, dated March 23, 1994. Two new paragraphs have been added to this supplemental NPRM to provide for these interim actions and to require the modifications that constitute terminating action for the inspections.

The FAA also has revised the NPRM to cite the latest service bulletin revisions as the appropriate sources of service information.

Differences Between Proposed Rule and Netherlands Directive

Although the Netherlands BLA does not mandate the accomplishment of the modifications, this proposed AD would require that those modifications be accomplished. The FAA has determined that long term continued operational safety will be better assured by design changes to remove the source of the problem, rather than by repetitive inspections. Long term inspections may not be providing the degree of safety assurance necessary for the transport airplane fleet. This, coupled with a better understanding of the human factors associated with numerous continual inspections, has led the FAA to consider placing less emphasis on inspections and more emphasis on design improvements. The proposed modification requirement is in consonance with these considerations.

Conclusion

Since these changes expand the scope of the originally proposed rule, the FAA has determined that it is necessary to reopen the comment period to provide additional opportunity for public comment.

Cost Impact

The cost impact information specified in the NPRM indicated that 100 airplanes of U.S. registry would be affected by this proposed AD. The FAA has updated that information, below, to indicate that 125 airplanes would be affected.

In addition, the FAA has recently reviewed the figures it has used over the past several years in calculating the economic impact of AD activity. In order to account for various inflationary costs in the airline industry, the FAA has determined that it is necessary to increase the labor rate used in these calculations from $55 per work hour to $60 per work hour. The cost impact information also has been revised to reflect this increase in the specified hourly labor rate.

The FAA estimates that 125 airplanes of U.S. registry would be affected by this proposed AD, that it would take approximately 14 work hours per airplane to accomplish the proposed visual inspections, and that the average labor rate is $60 per work hour. Based on these figures, the cost impact of the initial visual inspection of this proposed AD on U.S. operators is estimated to be $105,000, or $840 per airplane.

The FAA estimates that it would take approximately 66 work hours per airplane to accomplished the proposed terminating modifications, at an average labor rate of $60 per work hour. The cost for required parts would be approximately $865 per airplane. Based on these figures, the cost impact of the proposed terminating action on U.S. operators is estimated to be $603,125, or $4,825 per airplane.

The cost impact figures discussed above are based on assumptions that no operator has yet accomplished any of the proposed requirements of this AD

action, and that no operator would accomplish those actions in the future if this AD were not adopted.

Should an operator elect to accomplish the repetitive visual inspections that would be provided by this AD action, it would take approximately 14 work hours to accomplish each repetitive inspection, at an average labor rate of $60 per work hour. The FAA estimates that these inspections would be accomplished four times per year. Based on these figures, the cost impact of the repetitive inspections on U.S. operators is estimated to be $3,360 per airplane, per year.

Should an operator elect to accomplish the interim actions that would be provided by this AD action, it would take approximately 26 work hours for the rework, and 26 work hours per airplane for the brake unit replacement. It would take between 28–168 work hours per year for the sampling program, depending on the size of an operator's fleet. The average labor rate is $60 per work hour. The cost for required parts would be approximately $865 per airplane. Additionally, once these interim actions are accomplished, the cost impact of the terminating modifications discussed previously would be reduced by $2,400 per airplane.

Regulatory Impact

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

For the reasons discussed above, I certify that this proposed regulation (1) is not a ''significant regulatory action'' under Executive Order 12866; (2) is not a ''significant rule'' under the DOT Regulatory Policies and Procedures (44 FR 11034, February 26, 1979); and (3) if promulgated, will not have a significant economic impact, positive or negative, on a substantial number of small entities under the criteria of the Regulatory Flexibility Act. A copy of the draft regulatory evaluation prepared for this action is contained in the Rules Docket. A copy of it may be obtained by contacting the Rules Docket at the location provided under the caption **ADDRESSES.**

List of Subjects in 14 CFR Part 39

Air transportation, Aircraft, Aviation safety, Safety.

The Proposed Amendment

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

PART 39—AIRWORTHINESS DIRECTIVES

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

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

§ 39.13 [Amended]

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

Fokker: Docket 93–NM–193–AD.

Applicability: Model F28 Mark 0100 series airplanes equipped with Dowty Aerospace main landing gear (MLG) part number 201072011, 201072012, 201072013, 201072014, 201072015, or 201072016; certificated in any category.

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

Compliance: Required as indicated, unless accomplished previously.

To prevent failure of the MLG wheel axle due to problems associated with corrosion and cracking, accomplish the following:

(a) Within 30 days after the effective date of this AD, remove the MLG wheels and brakes and perform a visual inspection to detect corrosion and cracking in the wheel axles of the MLG sliding members in accordance with Fokker Service Bulletin F100–32–079, Revision 1, dated October 4, 1993, and paragraph 2.A. of the Accomplishment Instructions of Dowty Aerospace Service Bulletin F100–32–63, Revision 2, dated September 23, 1993.

(b) Following accomplishment of the inspection required by paragraph (a) of this AD, accomplish either paragraph (b)(1) or (b)(2) of this AD.

(1) Repeat the inspection required by paragraph (a) of this AD thereafter at intervals not to exceed 3 months in accordance with Fokker Service Bulletin SBF100–32–080, dated October 4, 1993, and Dowty Aerospace Service Bulletin F100–32–64, Revision 1, dated February 18, 1994, until the actions required by paragraph (e) of this AD are accomplished. Or

(2) Accomplish paragraphs (b)(2)(i), (b)(2)(ii), and (b)(2)(iii) of this AD at the times specified in those paragraphs in accordance with Fokker Service Bulletin SBF100–32–083, dated March 23, 1994.

(i) Within 3 months after the accomplishment of an inspection required by paragraph (a) or (b)(1) of this AD: Rework the axles in accordance with Part 2 of the Accomplishment Instructions of the service bulletin. Repeat this rework thereafter at intervals not to exceed 12 months or 2,200 landings, whichever occurs first. And

(ii) Prior to or concurrent with accomplishing the initial rework specified in paragraph (b)(2)(i) of this AD: Replace the main wheel brake units in accordance with Part 1 of the Accomplishment Instructions of the service bulletin. And

(iii) Within 3 months after the first accomplishment of the rework required by paragraph (b)(2)(i) of this AD: Begin performing interim inspections (''sampling program'') to detect corrosion and cracking in the wheel axles of the MLG sliding members, in accordance with Part 3 of the Accomplishment Instructions of the service bulletin. Perform these inspections at the intervals specified in the service bulletin until the actions required by paragraph (e) of this AD are accomplished.

(c) If any corrosion is found during any inspection required by this AD, prior to further flight, rework the affected area and perform a non-destructive testing (NDT) inspection to detect cracks in the MLG wheel axles, in accordance with Appendix A of Dowty Aerospace Service Bulletin F100–32–63, Revision 2, dated September 23, 1993 (if corrosion is found during the initial inspection required by this AD); or Dowty Aerospace Service Bulletin F100–32–64, Revision 1, dated February 18, 1994 (if corrosion is found during a repetitive inspection required by this AD); as applicable. After rework, perform repetitive inspections of the affected area in accordance with paragraph (b)(1) of this AD until the actions required by paragraph (e) of this AD are accomplished.

(d) If any crack is found during any inspection required by this AD, prior to further flight, replace the affected sliding member with a serviceable sliding member in accordance with Dowty Aerospace Service Bulletin F100–32–63, Revision 2, dated September 23, 1993 (if any crack is found during the initial inspection required by this AD); or Dowty Aerospace Service Bulletin F100–32–64, Revision 1, dated February 18, 1994 (if any crack is found during a repetitive inspection required by this AD); as applicable. After replacement of the affected sliding member, perform the repetitive inspections in accordance with paragraph (b)(1) of this AD until the actions required by paragraph (e) of this AD are accomplished.

(e) At the next major gear overhaul, or within 4,400 landings after accomplishment of the initial inspection required by paragraph (a) of this AD, whichever occurs first: Rework the sliding member, and replace the main wheel brake units in accordance

with the Accomplishment Instructions of Fokker Service Bulletin SBF100–32–081, dated March 23, 1994. Accomplishment of these actions constitutes terminating action for the repetitive inspections and the interim actions specified in paragraph (b) of this AD.

Note 2: Fokker Service Bulletin SBF100–32–081 references Dowty Aerospace Service Bulletin F100–32–64, Revision 1, dated February 18, 1994, as an additional source of service information for accomplishment of the rework and replacement.

(f) As of the effective date of this AD, no person shall install a Dowty Aerospace MLG, part number 201072011, 201072012, 201072013, 201072014, 201072015, or 201072016, on any airplane unless the requirements of this AD have been accomplished on that MLG. Following its installation, the repetitive inspections required by paragraph (b) of this AD shall be accomplished on that MLG.

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

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

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

Issued in Renton, Washington, on September 3, 1996.

Darrell M. Pederson,

Acting Manager, Transport Airplane Directorate, Aircraft Certification Service.

[FR Doc. 96–22920 Filed 9–6–96; 8:45 am]

BILLING CODE 4910–13–U

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14 CFR Part 71

[Airspace Docket No. 96–ANM–23]

Proposed Removal of Class D Airspace and Establishment of Class E Airspace; Coeur d'Alene, Idaho

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Notice of proposed rulemaking.

SUMMARY: This notice proposes to remove Class D Airspace and establish Class E Airspace at Coeur d'Alene, Idaho. This action is the result of decommissioning the air traffic control tower at Coeur d'Alene Air Terminal, Idaho. The area would be depicted on aeronautical charts for pilot reference.

DATES: Comments must be received on or before October 15, 1996.

ADDRESSES: Send comments on the proposal in triplicate to: Manager, Operation Branch, ANM–530, Federal Aviation Administration, Docket No. 96–ANM–23, 1601 Lind Avenue S.W., Renton, Washington 98055–4056.

The official docket may be examined at the same address.

An informal docket may also be examined during normal business hours at the address listed above.

FOR FURTHER INFORMATION CONTACT: James Riley, ANM–532.2, Federal Aviation Administration, Docket No. 96–ANM–23, 1601 Lind Avenue S.W., Renton, Washington 98055–4056; telephone number: (206) 227–2537.

SUPPLEMENTARY INFORMATION:

Comments Invited

Interested parties are invited to participate in this proposed rulemaking by submitting such written data, views, or arguments as they may desire. Comments that provide the factual basis supporting the views and suggestions presented are particularly helpful in developing reasoned regulatory decisions on the proposal. Comments are specifically invited on the overall regulatory, aeronautical, economic, environmental, and energy related aspects of the proposal. Communications should identify the airspace docket number and be submitted in triplicate to the address listed above. Commenters wishing the FAA to acknowledge receipt of their comments on this notice must submit with those comments a self-addressed, stamped postcard on which the following statement is made: ''Comments to Airspace Docket No. 96–ANM–23.'' The postcard will be date/time stamped and returned to the commenter. All communications received on or before the specified closing date for comments will be considered before taking action on the proposed rule. The proposal contained in this notice may be changed in the light of comments received. All comments submitted will be available for examination at the address listed above both before and after the closing date for comments. A report summarizing each substantive public contact with FAA personnel concerned with this rulemaking will be filed in the docket.

Availability of NPRM's

Any person may obtain a copy of this Notice of Proposed Rulemaking (NPRM) by submitting a request to the Federal Aviation Administration, Operations Branch, ANM–530, 1601 Lind Avenue S.W., Renton, Washington 98055–4056. Communications must identify the notice number of this NPRM. Persons interested in being placed on a mailing list for future NPRM's should also request a copy of Advisory Circular No. 11–2A, which describes the application procedure.

The Proposal

The FAA is considering an amendment to part 71 of the Federal Aviation Regulations (14 CFR part 71) to remove Class D airspace and establish Class E airspace at Coeur d'Alene, Idaho. This action is the result of decommissioning the air traffic control tower at Coeur d'Alene Air Terminal, Idaho. The area would be depicted on aeronautical charts for pilot reference. Class D and Class E airspace areas are published in Paragraphs 5000 and 6002 respectively, of FAA Order 7400.9C dated August 17, 1995, and effective September 16, 1995, which is incorporated by reference in 14 CFR 71.1. The Class E airspace designation listed in this document would be published subsequently in the Order.

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

List of Subjects in 14 CFR Part 71

Airspace, Incorporation by reference, Navigation (air).

The Proposed Amendment

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

PART 71—[AMENDED]

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

Authority: 49 U.S.C. 106(g), 40103, 40113, 40120; E.O. 10854, 24 FR 9565, 3 CFR, 1959–1963 Comp., p. 389; 14 CFR 11.69.

§ 71.1 [Amended]

2. The incorporation by reference in 14 CFR 71.1 of the Federal Aviation Administration Order 7400.9B, Airspace Designations and Reporting Points, dated August 17, 1995, and effective September 18, 1995, is amended as follows:

Paragraph 5000 Class D airspace.

* * * * *

ANM ID D Coeur d'Alene, ID [Removed]

* * * * *

Paragraph 6002 Class E airspace areas designated as a surface area for an airport.

* * * * *

ANM ID E2 Coeur d'Alene, ID [New]

Coeur d'Alene Air Terminal, ID
(Lat. 47°46′28″ N, long. 116°49′11″ W)

That airspace extending upward from the surface to and including 4,800 feet MSL within a 4.4 mile radius of the Coeur d'Alene Air Terminal.

* * * * *

Issued in Seattle, Washington, on August 21, 1996.

Glenn A. Adams,

Assistant Manager, Air Traffic Division, Northwest Mountain Region.

[FR Doc. 96–22944 Filed 9–6–96; 8:45 am]

BILLING CODE 4910–13–M

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14 CFR Part 71

[Airspace Docket No. 96–AGL–10]

Establishment of Class E Airspace; Hazen, ND

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Notice of proposing rulemaking.

SUMMARY: This notice proposes to establish Class E5 airspace at Mercer County Regional Airport, Hazen, ND, to accommodate a Non-Directional Radio Beacon (NDB) for Runway 32, Global Positioning System (GPS) Runway 32 and GPS Runway 14. Controlled airspace extending upward from 700 to 1200 feet above ground level (AGL) is needed to contain aircraft executing the approach. The intended affect of this proposal is to provide segregation of aircraft using instrument approach procedures in instrument conditions from other aircraft operating in visual weather conditions.

DATES: Comments must be received on or before October 18, 1996.

ADDRESSES: Send comments on the proposal in triplicate to: Federal Aviation Administration, Office of the Assistant Chief Counsel, AGL–7, Rules Docket No. 96–AGL–10, 2300 East Devon Avenue, Des Plaines, Illinois 60018.

The official docket may be examined in the Office of the Assistant Chief Counsel, Federal Aviation Administration, 2300 East Devon Avenue, Des Plaines, Illinois. An informal docket may also be examined during normal business hours at the Air Traffic Division, Operations Branch, Federal Aviation Administration, 2300 East Devon Avenue, Des Plaines, Illinois.

FOR FURTHER INFORMATION CONTACT: John A. Clayton, Air Traffic Division, Operations Branch, AGL–530, Federal Aviation Administration, 2300 East Devon Avenue, Des Plaines, Illinois 60018, telephone (847) 294–7568.

SUPPLEMENTARY INFORMATION:

Comments Invited

Interested parties are invited to participate in this proposed rulemaking by submitting such written data, views, or arguments as they may desire. Comments that provide the factual basis supporting the views and suggestions presented are particularly helpful in developing reasoned regulatory decisions on the proposal. Comments are specifically invited on the overall regulatory, aeronautical, economic, environmental, and energy-related aspects of the proposal. Communications should identify the airspace docket number and be submitted in triplicate to the address listed above. Commenters wishing the FAA to acknowledge receipt of their comments on this notice must submit with those comments a self-addressed, stamped postcard on which the following statement is made: ''Comments to Airspace Docket No. 96–AGL–10.'' The postcard will be date/time stamped and returned to the commenter. All communications received on or before the specified closing date for comments will be considered before taking action on the proposed rule. The proposal contained in this notice may be changed in light of comments received. All comments submitted will be available for examination in the Rules Docket, FAA, Great Lakes Region, Office of the Assistant Chief Counsel, 2300 East Devon Avenue, Des Plaines, Illinois, both before and after the closing date for comments. A report summarizing each substantive public contact with FAA personnel concerned with this rulemaking will be filed in the docket.

Availability of NPRM's

Any person may obtain a copy of the Notice of Proposed Rulemaking (NPRM) by submitting a request to the Federal Aviation Administration, Office of Public Affairs, Attention: Public Inquiry Center, APA–230, 800 Independence Avenue, S.W., Washington, DC 20591, or by calling (202) 267–3484. Communications must identify the notice number of this NPRM. Persons interested in being placed on a mailing list for future NPRM's should also request a copy of Advisory Circular No. 11–2A, which describes the application procedure.

The Proposal

The FAA is considering an amendment to part 71 of the Federal Aviation Regulations (14 CFR part 71) to establish Class E5 airspace at Mercer County Regional Airport, Hazen, ND, to accommodate a Non-Directional Radio Beacon (NDB) for Runway 32, Global Positioning System (GPS) Runway 32 and GPS Runway 14. Controlled airspace extending upward from 700 to 1200 feet AGL is needed to contain aircraft executing the approach. The intended affect of this action is to provide segregation of aircraft using instrument approach procedures in instrument conditions from other aircraft operating in visual weather conditions. The area would be depicted on appropriate aeronautical charts thereby enabling pilots to circumnavigate the area or otherwise comply with IFR procedures. Class E airspace designations for airspace areas extending upward from 700 feet or more above the surface of the earth are published in paragraph 6005 of FAA Order 7400.9C dated August 17, 1995, and effective September 16, 1995, which is incorporated by reference in 14 CFR 71.1 The Class E airspace designation listed in this document would be published subsequently in the Order.

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

List of Subjects in 14 CFR Part 71

Airspace, Incorporation by reference, Navigation (air).

The Proposed Amendment

Accordingly, pursuant to the authority delegated to me, the Federal Aviation Administration proposes to amend part 71 of the Federal Aviation Regulations (14 CFR part 71) as follows:

PART 71—[AMENDED]

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

Authority: 49 U.S.C. 106(g), 40103, 40113, 40120; E.O. 10854, 24 FR 9565, 3 CFR, 1959–1963 Comp., p. 389; 14 CFR 11.69.

§ 71.1 [Amended]

2. The incorporation by reference in 14 CFR 71.1 of the Federal Aviation Administration Order 7400.9C, Airspace Designations and Reporting Points, dated August 17, 1995, and effective September 16, 1995, is amended as follows:

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

* * * * *

AGL ND E5 Hazen, ND [New]

Mercer County Regional Airport, ND
(Lat. 47°17′23″ N., long. 101°34′50″ W.)
Dickinson VORTAC
(Lat. 46°51′36″ N., long. 102°46′25″ W.)
Minot Air Force Base
(Lat. 48°24′56″ N., long. 101°21′27″ W.)
Bismarck VOR/DME
(Lat. 46°45′43″ N., long. 100°39′55″ W.)

That airspace extending upward from 700 feet above the surface within a 5.8-mile radius of the Mercer County Regional Airport, and that airspace extending upward from 1,200 feet above the surface bounded on the northwest by V–491, on the south by V–510, on the east V–15, on the southwest by the 25.2-mile arc of the Dickinson VORTAC, on the north by the 47-mile radius of the Minot AFB, and on the southeast by the 36-mile arc of the Bismarck VOR/DME.

* * * * *

Issued in Des Plaines, Illinois on August 26, 1996.

Peter H. Salmon,

Acting Manager, Air Traffic Division.

[FR Doc. 96–22946 Filed 9–6–96; 8:45 am]

BILLING CODE 4910–13–M

DEPARTMENT OF DEFENSE

Defense Special Weapons Agency

32 CFR Part 318

[DSWA Instruction 5400.11B]

Privacy Program

AGENCY: Defense Special Weapons Agency, DOD.

ACTION: Proposed rule.

SUMMARY: As of June 26, 1996, the Defense Nuclear Agency is known as the Defense Special Weapons Agency (DSWA). The Defense Special Weapons Agency (DSWA) is revising its procedural and exemptions rules for the DSWA Privacy Program. DSWA is updating the procedures for accessing information contained in DSWA systems of records, and for contesting contents and appealing initial agency determinations.

DATES: Comments must be received on or before November 8, 1996, to be considered by the agency.

ADDRESSES: Send comments regarding this proposed rule to the General Counsel, Defense Special Weapons Agency, 6801 Telegraph Road, Alexandria, VA 22310–3398.

FOR FURTHER INFORMATION CONTACT: Mrs. Sandy Barker at (703) 325–7681.

SUPPLEMENTARY INFORMATION: Executive Order 12866. The Director, Administration and Management, Office of the Secretary of Defense has determined that this Privacy Act rule for the Department of Defense does not constitute 'significant regulatory action'. Analysis of the rule indicates that it does not have an annual effect on the economy of $100 million or more; does not create a serious inconsistency or otherwise interfere with an action taken or planned by another agency; does not materially alter the budgetary impact of entitlements, grants, user fees, or loan programs or the rights and obligations of recipients thereof; does not raise novel legal or policy issues arising out of legal mandates, the President's priorities, or the principles set forth in Executive Order 12866 (1993).

Regulatory Flexibility Act of 1980. The Director, Administration and Management, Office of the Secretary of Defense certifies that this Privacy Act rule for the Department of Defense does not have significant economic impact on a substantial number of small entities because it is concerned only with the administration of Privacy Act systems of records within the Department of Defense.

Paperwork Reduction Act. The Director, Administration and Management, Office of the Secretary of Defense certifies that this Privacy Act rule for the Department of Defense imposes no information requirements beyond the Department of Defense and that the information collected within the Department of Defense is necessary and consistent with 5 U.S.C. 552a, known as the Privacy Act of 1974.

As of June 26, 1996, the Defense Nuclear Agency is known as the Defense Special Weapons Agency (DSWA). The Defense Special Weapons Agency is revising its procedural and exemptions rules for the DSWA Privacy Program. DSWA is updating the procedures for accessing information contained in DSWA systems of records, and for contesting contents and appealing initial agency determinations.

List of Subjects in 32 CFR Part 318

Privacy.

Accordingly, the Defense Special Weapons Agency amends 32 CFR part 318 as follows:

Part 318 is proposed to be revised to read as follows:

PART 318–DEFENSE SPECIAL WEAPONS AGENCY PRIVACY PROGRAM

Sec.

318.1 Purpose and scope.
318.2 Applicability.
318.3 Designations and responsibilities.
318.4 Procedures for requests pertaining to individual records in a record system.
318.5 Disclosure of requested information to individuals.
318.6 Request for correction or amendment to a record.
318.7 Agency review of request for correction or amendment of record.
318.8 Appeal of initial adverse Agency determination for access, correction or amendment.
318.9 Exemption rules.

Authority: Pub. L. 93–579, 88 Stat. 1896 (5 U.S.C. 552a).

§ 318.1 Purpose and scope.

(a) This rule implements the provisions of the Privacy Act of 1974, as amended, and adopts the policies and procedures as set forth by the Department of Defense Privacy Program, 32 CFR part 310.

(b) This rule establishes procedures whereby individuals can:

(1) Request notification of whether Defense Special Weapons Agency (DSWA) maintains or has disclosed a record pertaining to them in any nonexempt system of records;

(2) Request a copy or other access to such a record or to an accounting of its disclosure;

(3) Request that the record be amended; and

(4) Appeal any initial adverse determination of any such request.

(c) Specifies those system of records which the Director, Headquarters, Defense Special Weapons Agency has determined to be exempt from the procedures established by this rule and by certain provisions of the Privacy Act.

(d) DSWA policy encompasses the safeguarding of individual privacy from any misuse of DSWA records and the

provides the fullest access practicable by individuals to DSWA records concerning them.

§ 318.2 Applicability.

The provisions of this rule apply to Headquarters, Defense Special Weapons Agency (HQ DSWA), and Field Command, Defense Special Weapons Agency (FC DSWA).

§ 318.3 Designations and responsibilities.

(a) The General Counsel, Headquarters, Defense Special Weapons Agency, is designated as the Agency Privacy Act Officer.

(1) The Privacy Act Officer is the principal point of contact for privacy matters and is the Agency Initial Denial Authority.

(2) The Privacy Act Officer is responsible for monitoring and ensuring Agency compliance with the DoD Privacy Program in accordance with 32 CFR part 310.

(b) The Director, DSWA, is the Agency Appellate Authority.

(c) The Director, DSWA is responsible for implementing the Agency Privacy Act Program in accordance with the specific requirements of 32 CFR part 310.

(d) Agency component and element responsibilities are set forth in DSWA Instruction 5400.11B,[1] January 12, 1995.

§ 318.4 Procedures for requests pertaining to individual records in a record system.

(a) An individual seeking notification of whether a system of records, maintained by the Defense Special Weapons Agency, contains a record pertaining to himself/herself and who desires to review, have copies made of such records, or to be provided an accounting of disclosures from such records, shall submit his or her request in writing. Requesters are encourage to review the systems of records notices published by the Agency so as to specifically identify the particular record system(s) of interest to be accessed.

(b) In addition to meeting the requirements set forth in section 318.4 of this part, the individual seeking notification, review or copies, and an accounting of disclosures will provide in writing his or her full name, address, Social Security Number, and a telephone number where the requester can be contacted should questions arise concerning the request. This information will be used only for the purpose of identifying relevant records in response to an individual's inquiry. It is further recommended that individuals indicate any present or past relationship or affiliations, if any, with the Agency and the appropriate dates in order to facilitate a more thorough search. A notarized statement or an unsworn declaration in accordance with 28 U.S.C. 1746 may also be required.

(c) An individual who wishes to be accompanied by another individual when reviewing his or her records, must provide the Agency with written consent authorizing the Agency to disclose or discuss such records in the presence of the accompanying individual.

(d) Individuals should mail their written request to the Office of General Counsel, Defense Special Weapons Agency, 6801 Telegraph Road, Alexandria, VA 22310–3398 or to the office designated in the system notice and indicate clearly on the outer envelope 'Privacy Act Request'.

§ 318.5 Disclosure of requested information to individuals.

(a) The Defense Special Weapons Agency, upon receiving a request for notification of the existence of a record or for access to a record, shall acknowledge receipt of the request within 10 working days.

(b) Determine whether or not such record exists.

(c) Determine whether or not such request for access is available under the Privacy Act.

(d) Notify requester of determinations within 30 working days after receipt of such request.

(e) Provide access to information pertaining to that person which has been determined to be available within 30 working days.

(f) Notify the individual if fees will be assessed for reproducing copies of the records. Fee schedule and rules for assessing fees are contained in section 318.11 of this part.

§ 318.6 Request for correction or amendment to a record.

(a) An individual may request that the Defense Special Weapons Agency correct, amend, or expunge any record, or portions thereof, pertaining to the requester that he/she believe to be inaccurate, irrelevant, untimely, or incomplete.

(b) Such requests shall specify the particular portions of the records in question, be in writing and should be mailed to the Office of General Counsel, Defense Special Weapons Agency, 6801 Telegraph Road, Alexandria, VA 22310–3398.

(c) The requester shall provide sufficient information to identify the record and furnish material to substantiate the reasons for requesting corrections, amendments, or expurgation.

§ 318.7 Agency review of request for correction or amendment of record.

(a) The Agency will acknowledge a request for correction or amendment within 10 working days of receipt. The acknowledgment will be in writing and will indicate the date by which the Agency expects to make its initial determination.

(b) The Agency shall complete its consideration of requests to correct or amend records within 30 working days, and inform the requester of its initial determination.

(c) If it is determined that records should be corrected or amended in whole or in part, the Agency shall advise the requester in writing of its determination; and correct or amend the records accordingly. The Agency shall then advise prior recipients of the records of the fact that a correction or amendment was made and provide the substance of the change.

(d) If the Agency determines that a record should not be corrected or amended, in whole or in part, as requested by the individual, the Agency shall advise the requester in writing of its refusal to correct or amend the records and the reasons therefor. The notification will inform the requester that the refusal may be appealed administratively and will advise the individual of the procedures for such appeals.

§ 318.8 Appeal of initial adverse Agency determination for access, correction or amendment.

(a) An individual who disagrees with the denial or partial denial of his or her request for access, correction, or amendment of Agency records pertaining the himself/herself, may file a request for administrative review of such refusal within 30 days after the date of notification of the denial or partial denial.

(b) Such requests shall be made in writing and mailed to the Office of the General Counsel, Defense Special Weapons Agency, 6801 Telegraph Road, Alexandria, VA 22310–3398.

(c) The requester shall provide a brief written statement setting for the reasons for his or her disagreement with the initial determination and provide such additional supporting material as the individual feels necessary to justify the appeal.

[1] Copies may be obtained from Office of General Counsel, Headquarters, Defense Special Weapons Agency, Washington, DC 20305–1000.

(d) Within 30 working days of receipt of the request for review, the Agency shall advise the individual of the final disposition of the request.

(e) In those cases where the initial determination is reversed, the individual will be so informed and the Agency will take appropriate action.

(f) In those cases where the initial determination is sustained, the individual shall be advised:

(1) In the case of a request for access to a record, of the individual's right to seek judicial review of the Agency refusal for access.

(2) In the case of a request to correct or amend the record:

(i) Of the individual's right to file a concise statement of his or her reasons for disagreeing with the Agency's decision in the record,

(ii) Of the procedures for filing a statement of the disagreement, and

(iii) Of the individual's right to seek judicial review of the Agency's refusal to correct or amend a record.

§ 318.9 Exemption rules.

(a) *Exemption for classified material.* All systems of records maintained by the Defense Special Weapons Agency shall be exempt under section (k)(1) of 5 U.S.C. 552a, to the extent that the systems contain any information properly classified under E.O. 12598 and that is required by that E.O. to be kept secret in the interest of national defense or foreign policy. This exemption is applicable to parts of all systems of records including those not otherwise specifically designated for exemptions herein which contain isolated items of properly classified information.

(b) *System identifier and name:* HDSWA 007, Security Operations.

(1) *Exemption.* Portions of this system of records may be exempt from the provisions of 5 U.S.C. 552a(c)(3), (d)(1) through (d)(4), (e)(1), (e)(4)(G), (H), (I), and (f).

(2) *Authority.* 5 U.S.C. 552a(k)(5).

(3) *Reasons.* (i) From subsection (c)(3) because it will enable DSWA to safeguard certain investigations and relay law enforcement information without compromise of the information, and protect the identities of confidential sources who might not otherwise come forward and who have furnished information under an express promise that the sources' identity would be held in confidence (or prior to the effective date of the Act, under an implied promise.)

(ii) From subsection (d)(1) through (d)(4) and (f) because providing access to records of a civil investigation and the right to contest the contents of those records and force changes to be made to the information contained therein would seriously interfere with and thwart the orderly and unbiased conduct of security investigations. Providing access rights normally afforded under the Privacy Act would provide the subject with valuable information that would allow interference with or compromise of witnesses or render witnesses reluctant to cooperate; lead to suppression, alteration, or destruction of evidence; and result in the secreting of or other disposition of assets that would make them difficult or impossible to reach in order to satisfy any Government claim growing out of the investigation or proceeding.

(iii) From subsection (e)(1), (e)(4)(G), (H), (I) because it will provide protection against notification of investigatory material including certain reciprocal investigations and counterintelligence information, which might alert a subject to the fact that an investigation of that individual is taking place, and the disclosure of which would weaken the on-going investigation, reveal investigatory techniques, and place confidential informants in jeopardy who furnished information; under an express promise that the sources' identity would be held in confidence (or prior to the effective date of the Act, under an implied promise.)

(d) *System identifier and name:* HDSWA 011, Inspector General Investigation Files.

(1) *Exemption.* Portions of this system of records may be exempt from the provisions of 5 U.S.C. 552a(c)(3); (d)(1) through (4); (e)(1); (e)(4)(G), (H), and (I); and (f).

(2) *Authority:* 5 U.S.C. 552a (k)(2).

(3) *Reasons.* (i) From subsection (c)(3) because it will enable DSWA to conduct certain investigations and relay law enforcement information without compromise of the information, protection of investigative techniques and efforts employed, and identities of confidential sources who might not otherwise come forward and who furnished information under an express promise that the sources' identity would be held in confidence (or prior to the effective date of the Act, under an implied promise.)

(ii) From subsection (d)(1) through (d)(4) and (f) because providing access to records of a civil investigation and the right to contest the contents of those records and force changes to be made to the information contained therein would seriously interfere with and thwart the orderly and unbiased conduct of the investigation and impede case preparation. Providing access rights normally afforded under the Privacy Act would provide the subject with valuable information that would allow interference with or compromise of witnesses or render witnesses reluctant to cooperate; lead to suppression, alteration, or destruction of evidence; and result in the secreting of or other disposition of assets that would make them difficult or impossible to reach in order to satisfy any Government claim growing out of the investigation or proceeding.

(iii) From subsection (e)(1), (e)(4)(G), (H), and (I) because it will provide protection against notification of investigatory material including certain reciprocal investigations and counterintelligence information, which might alert a subject to the fact that an investigation of that individual is taking place, and the disclosure of which would weaken the on-going investigation, reveal investigatory techniques, and place confidential informants in jeopardy who furnished information under an express promise that the sources' identity would be held in confidence (or prior to the effective date of the Act, under an implied promise).

Dated: August 30, 1996.

Patricia L. Toppings,

Alternate OSD Federal Register Liaison Officer, Department of Defense.

[FR Doc. 96–22855 Filed 9–6–96; 8:45 am]

BILLING CODE 5000–04–F

DEPARTMENT OF VETERANS AFFAIRS

38 CFR Part 16

RIN 2900–AH68

Treatment of Research-Related Injuries to Human Subjects

AGENCY: Department of Veterans Affairs.

ACTION: Proposed rule.

SUMMARY: The Department of Veterans Affairs (VA) proposes to amend its regulations to provide (or to pay for the provision of) necessary medical treatment to human subjects injured as a result of participation in VA research. All participants in research approved by a VA Research and Development Committee (regardless of source of funding) and conducted by a VA employee would be eligible for such treatment. Experience suggests the

incidence of research-related injury is low and, therefore, the additional costs of this policy will be minimal.

DATES: Comments must be received on or before November 8, 1996.

ADDRESSES: Mail or hand deliver written comments to: Director, Office of Regulations Management (02D), Department of Veterans Affairs, 810 Vermont Ave., NW, Room 1154, Washington, DC 20420. Comments should indicate that they are submitted in response to ''RIN 2900–AH68''. All written comments will be available for public inspection at the above address in the Office of Regulations Management, Room 1158, between the hours of 8:00 a.m. and 4:30 p.m., Monday through Friday (except holidays).

FOR FURTHER INFORMATION CONTACT: Theodore W. Lorei, (202) 273–8285.

SUPPLEMENTARY INFORMATION: It is a commonly accepted ethical position that research subjects deserve to receive free medical treatment if their participation in the research results in unforeseen adverse health effects. Although current VA regulations are silent regarding this policy, the acceptance of this right in practice is suggested by the inclusion of the following statement on the research consent form (VA Form 10–1086): ''If any medical problems occur in connection with this study, VA will provide emergency care''. It is important to clarify this issue in regulation so that research participants can be confidently informed of their rights and research administrators can take appropriate action to provide such benefits when appropriate.

The Secretary hereby certifies that this rule will not have a significant economic impact on a substantial number of small entities as they are defined in the Regulatory Flexibility Act, 5 U.S.C. 601–612.

There is no Catalog of Federal Domestic Assistance Program Number.

List of Subjects in 38 CFR Part 16

Human research subjects, reporting and record keeping requirements.

Approved: May 28, 1996.

Jesse Brown,

Secretary of Veterans Affairs.

For the reasons set out in the preamble, 38 CFR part 16 is proposed to be amended as set forth below:

PART 16—PROTECTION OF HUMAN SUBJECTS

1. The authority citation for part 16 continues to read as follows:

Authority: 5 U.S.C. 301; 38 U.S.C. 501, 7331,7334; 42 U.S.C. 300v–1(b).

2. Section 16.125 is added to read as follows:

§ 16.125 Treatment of research-related injuries to human subjects.

(a) VA medical facilities shall provide necessary medical treatment to research subjects who are injured as a result of participation in a research project approved by a VA Research and Development Committee and conducted by VA employees. This regulation does not apply to:

(1) Treatment for injuries due to noncompliance by a subject with study procedures, or

(2) Research conducted for VA under a contract with a non-VA institution.

Note: Veterans who are injured as a result of participation in such research may be eligible for care from VA under other provisions of this part.

(b) Except in the following situations, care for VA research subjects under this regulation shall be provided in VA medical facilities:

(1) If VA medical facilities are not capable of furnishing economical care or are not capable of furnishing the care or services required, VA medical facility directors shall contract for the needed care.

(2) If inpatient care must be provided to a non-veteran under this policy, VA medical facility directors may contract for such care.

(3) If a research subject needs treatment in a medical emergency for a condition covered by this policy, VA medical facility directors shall provide reasonable reimbursement for the emergency treatment in a non-VA facility.

(Authority: 38 U.S.C. 501)

[FR Doc. 96–22591 Filed 9–6–96; 8:45 am]

BILLING CODE 8320–01–P

FEDERAL COMMUNICATIONS COMMISSION

47 CFR Part 73

[MM Docket No. 96–174, RM–8849]

Radio Broadcasting Services; Thomaston, AL

AGENCY: Federal Communications Commission.

ACTION: Proposed rule.

SUMMARY: This document requests comments on a petition for rule making filed by Andrea Reynolds, requesting the allotment of FM Channel 249A to Thomaston, Alabama, as that community's first local aural transmission service. Coordinates used for this proposal are 32–14–11 North Latitude and 87–40–46 West Longitude.

DATES: Comments must be filed on or before October 15, 1996, and reply comments on or before October 30, 1996.

ADDRESSES: Secretary, Federal Communications Commission, Washington, DC 20554. In addition to filing comments with the FCC, interested parties should serve the petitioner, as follows: Andrea Reynolds, 2501 - 15th Street E, #214, Tuscaloosa, AL 35404.

FOR FURTHER INFORMATION CONTACT: Nancy Joyner, Mass Media Bureau, (202) 418–2180.

SUPPLEMENTARY INFORMATION: This is a synopsis of the Commission's *Notice of Proposed Rule Making,* MM Docket No. 96–174, adopted August 16, 1996, and released August 23, 1996. The full text of this Commission decision is available for inspection and copying during normal business hours in the FCC's Reference Center (Room 239), 1919 M Street, NW., Washington, DC. The complete text of this decision may also be purchased from the Commission's copy contractors, International Transcription Service, Inc., (202) 857–3800, 2100 M Street, NW., Suite 140, Washington, DC 20037.

Provisions of the Regulatory Flexibility Act of l980 do not apply to this proceeding.

Members of the public should note that from the time a Notice of Proposed Rule Making is issued until the matter is no longer subject to Commission consideration or court review, all *ex parte* contacts are prohibited in Commission proceedings, such as this one, which involve channel allotments. See 47 CFR 1.1204(b) for rules governing permissible *ex parte* contacts.

For information regarding proper filing procedures for comments, See 47 CFR 1.415 and 1.420.

List of Subjects in 47 CFR Part 73

Radio broadcasting.

Federal Communications Commission.

John A. Karousos,

Chief, Allocations Branch, Policy and Rules Division, Mass Media Bureau.

[FR Doc. 96–22840 Filed 9–6–96; 8:45 am]

BILLING CODE 6712–01–F

47 CFR Part 73

[MM Docket No. 96–176, RM–8851]

Radio Broadcasting Services; Greensboro, AL

AGENCY: Federal Communications Commission.

ACTION: Proposed rule.

SUMMARY: This document requests comments on a petition for rule making filed by Autaugaville Radio, requesting the allotment of FM Channel 256A to Greensboro, Alabama, as that community's first local aural transmission service. Coordinates used for this proposal are 32–47–22 North Latitude and 87–34–39 West Longitude.

DATES: Comments must be filed on or before October 21, 1996, and reply comments on or before November 5, 1996.

ADDRESSES: Secretary, Federal Communications Commission, Washington, DC 20554. In addition to filing comments with the FCC, interested parties should serve the petitioner, as follows: Autaugaville Radio, Inc., Attn: Roscoe J. Miller, Manningham Road at I–65, P.O. Box 369, Greenville, AL 36037.

FOR FURTHER INFORMATION CONTACT: Nancy Joyner, Mass Media Bureau, (202) 418–2180.

SUPPLEMENTARY INFORMATION: This is a synopsis of the Commission's *Notice of Proposed Rule Making,* MM Docket No. 96–176, adopted August 23, 1996, and released August 30, 1996. The full text of this Commission decision is available for inspection and copying during normal business hours in the FCC's Reference Center (Room 239), 1919 M Street, NW., Washington, DC. The complete text of this decision may also be purchased from the Commission's copy contractors, International Transcription Service, Inc., (202) 857–3800, 2100 M Street, NW., Suite 140, Washington, DC 20037.

Provisions of the Regulatory Flexibility Act of l980 do not apply to this proceeding.

Members of the public should note that from the time a Notice of Proposed Rule Making is issued until the matter is no longer subject to Commission consideration or court review, all *ex parte* contacts are prohibited in Commission proceedings, such as this one, which involve channel allotments. See 47 CFR 1.1204(b) for rules governing permissible *ex parte* contacts.

For information regarding proper filing procedures for comments, See 47 CFR 1.415 and 1.420.

List of Subjects in 47 CFR Part 73

Radio broadcasting.

Federal Communications Commission.

John A. Karousos,

Chief, Allocations Branch, Policy and Rules Division, Mass Media Bureau.

[FR Doc. 96–22848 Filed 9–6–96; 8:45 am]

BILLING CODE 6712–01–F

47 CFR Part 73

[MM Docket No. 96–177, RM–8853]

Radio Broadcasting Services; Galena, KS

AGENCY: Federal Communications Commission.

ACTION: Proposed rule.

SUMMARY: The Commission requests comments on a petition by Acorn Broadcasting Company requesting the allotment of Channel 282A at Galena, Kansas, as the community's first local aural transmission service. Channel 282A can be allotted to Galena in compliance with the Commission's minimum distance separation requirements with a site restriction of 6.5 kilometers (4.0 miles) west to avoid short-spacing conflicts with the licensed sites of Station KBCN(FM), Channel 282C, Marshall, Arkansas, Station KBEQ(FM), Channel 282C, Kansas City, Missouri, and with Station KQMO(FM)'s construction permit, Channel 281C3, Ash Grove, Missouri. The coordinates for Channel 282A at Galena are 37–03–24 and 94–42–11.

DATES: Comments must be filed on or before October 21, 1996, and reply comments on or before November 5, 1996.

ADDRESSES: Federal Communications Commission, Washington, DC 20554. In addition to filing comments with the FCC, interested parties should serve the petitioner, or its counsel or consultant, as follows: J. Richard Guest, President, Acorn Broadcasting Company, 3001 West 13th Street, Joplin, Missouri 64801 (petitioner).

FOR FURTHER INFORMATION CONTACT: Pam Blumenthal, Mass Media Bureau, (202) 418–2180.

SUPPLEMENTARY INFORMATION: This is a synopsis of the Commission's *Notice of Proposed Rule Making,* MM Docket No. 96–177, adopted August 23, 1996 and released August 30, 1996. The full text of this Commission decision is available for inspection and copying during normal business hours in the FCC's Reference Center (Room 239), 1919 M Street, NW., Washington, DC. The complete text of this decision may also be purchased from the Commission's copy contractor, ITS, Inc., (202) 857–3800, 2100 M Street, NW., Suite 140, Washington, DC 20037.

Provisions of the Regulatory Flexibility Act of 1980 do not apply to this proceeding.

Members of the public should note that from the time a Notice of Proposed Rule Making is issued until the matter is no longer subject to Commission consideration or court review, all *ex parte* contacts are prohibited in Commission proceedings, such as this one, which involve channel allotments. See 47 CFR 1.1204(b) for rules governing permissible *ex parte* contacts.

For information regarding proper filing procedures for comments, see 47 CFR 1.415 and 1.420.

List of Subjects in 47 CFR Part 73

Radio broadcasting.

Federal Communications Commission.

John A. Karousos,

Chief, Allocations Branch, Policy and Rules Division, Mass Media Bureau.

[FR Doc. 96–22849 Filed 9–6–96; 8:45 am]

BILLING CODE 6712–01–F

47 CFR Part 73

[MM Docket No. 96–175; RM–8850]

Radio Broadcasting Services; Strasburg, CO

AGENCY: Federal Communications Commission.

ACTION: Proposed rule.

SUMMARY: This document requests comments on a petition for rule making filed by J.P.I. Radio, Inc. requesting the allotment of FM Channel 249C3 to Strasburg, Colorado, as that community's second local aural transmission service, and its reservation for noncommercial educational use. Coordinates utilized for this proposal are 39–43–13 North Latitude and 104–11–58 West Longitude. See Supplementary Information, *infra.*

DATES: Comments must be filed on or before October 21, 1996, and reply comments on or before November 5, 1996.

ADDRESSES: Secretary, Federal Communications Commission, Washington, DC 20554. In addition to filing comments with the FCC, interested parties should serve the petitioner, as follows: J.P.I. Radio, Inc., Attn: Jarel L. Pittman, 12104 Old Highway 169, Hibbing, MN 55746.

FOR FURTHER INFORMATION CONTACT: Nancy Joyner, Mass Media Bureau, (202) 418–2180.

SUPPLEMENTARY INFORMATION: This is a synopsis of the Commission's *Notice of Proposed Rule Making,* MM Docket No. 96–175, adopted August 23, 1996, and released August 30, 1996. The full text of this Commission decision is available for inspection and copying during normal business hours in the FCC's Reference Center (Room 239), 1919 M Street, NW., Washington, DC. The complete text of this decision may also be purchased from the Commission's copy contractors, International Transcription Service, Inc., (202) 857–3800, 2100 M Street, NW., Suite 140, Washington, DC 20037.

Channel 272A was allotted to Strasburg, Colorado, in MM Docket No. 89–61. See *Report and Order,* 4 FCC Rcd 7570 (1989), 54 FR 45735, October 31, 1989. However, Channel 272A at Strasburg, Colorado, does not appear in 47 CFR 73.202(b), the Table of Allotments. Therefore, as announced in the *Notice* in this proceeding, we will make an editorial amendment to the FM Table of Allotments to include Channel 272A at Strasburg, Colorado, at the conclusion of the instant rule making proceeding.

Provisions of the Regulatory Flexibility Act of l980 do not apply to this proceeding.

Members of the public should note that from the time a Notice of Proposed Rule Making is issued until the matter is no longer subject to Commission consideration or court review, all *ex parte* contacts are prohibited in Commission proceedings, such as this one, which involve channel allotments. See 47 CFR 1.1204(b) for rules governing permissible *ex parte* contacts.

For information regarding proper filing procedures for comments, See 47 CFR 1.415 and 1.420.

List of Subjects in 47 CFR Part 73

Radio broadcasting.

Federal Communications Commission.

John A. Karousos,

Chief, Allocations Branch, Policy and Rules Division, Mass Media Bureau.

[FR Doc. 96–22842 Filed 9–6–96; 8:45 am]

BILLING CODE 6712–01–F

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47 CFR Part 73

[MM Docket No. 96–53; RM–8767]

Radio Broadcasting Services; Marinette, WI

AGENCY: Federal Communications Commission.

ACTION: Proposed rule; dismissal.

SUMMARY: This document dismisses a *Notice of Proposed Rule Making* issued in response to a petition filed by Douglas A. Maszka d/b/a Tri-City Television Company requesting the allotment of Channel 25 to Marinette, Wisconsin. *See* 61 FR 14043, March 29, 1996. On August 7, 1996, Tri-City filed comments withdrawing its interest in the allotment at Marinette. As stated in the *Notice,* a showing of continuing interest is required before a channel will be allotted, and absent such an expression of interest, it is the Commission's policy to refrain from allotting a channel. Due to a lack of interest in Channel 25 at Marinette, we shall dismiss the proposal. With this action, this proceeding is terminated.

FOR FURTHER INFORMATION CONTACT: Kathleen Scheuerle, Mass Media Bureau, (202) 418–2180.

SUPPLEMENTARY INFORMATION: This is a summary of the Commission's *Report and Order,* MM Docket No. 96–53, adopted August 23, 1996, and released August 30, 1996. The full text of this Commission decision is available for inspection and copying during normal business hours in the Commission's Reference Center (Room 239), 1919 M Street, NW., Washington, DC. The complete text of this decision may also be purchased from the Commission's copy contractors, International Transcription Services, Inc., 2100 M Street, NW., Suite 140, Washington, DC 20037, (202) 857–3800.

List of Subjects in 47 CFR Part 73

Radio broadcasting.

Federal Communications Commission.

John A. Karousos,

Chief, Allocations Branch, Policy and Rules Division, Mass Media Bureau.

[FR Doc. 96–22844 Filed 9–6–96; 8:45 am]

BILLING CODE 6712–01–F

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

50 CFR Part 648

[I.D. 090396C]

New England Fishery Management Council; Meeting

AGENCY: National Marine Fisheries Service (NMFS), National Oceanic and Atmospheric Administration (NOAA), Commerce.

ACTION: Public meeting.

SUMMARY: The New England Fishery Management Council (Council) will hold a special 1-day meeting to consider actions affecting New England fisheries in the exclusive economic zone.

DATES: The meeting is scheduled for Monday, September 9, 1996, at 9 a.m.

ADDRESSES: The meeting will be held at the Holiday Inn, One Newbury Street, Peabody, MA; telephone (508) 535–4600. Requests for special accommodations should be addressed to the New England Fishery Management Council, 5 Broadway, Saugus, MA 01906–1097; telephone: (617) 231–0422.

FOR FURTHER INFORMATION CONTACT: Christopher B. Kellogg, Acting Executive Director, New England Fishery Management Council (617) 231–0422.

SUPPLEMENTARY INFORMATION: The September 9, 1996, meeting is being convened specifically to consider final action on several pending framework adjustments to the Northeast Multispecies Fishery Management Plan (FMP).

The Council will consider final action on Framework Adjustments 18 and 19 to the FMP under the framework for abbreviated rulemaking procedure contained in 50 CFR 648.90. If approved, Framework Adjustment 18 would allow herring and mackerel fishing with pelagic mid-water trawls in areas of Georges Bank now closed to all gear capable of catching groundfish. Framework Adjustment 19, would replace the Gulf of Maine area closures now in place to enhance groundfish conservation with alternatives that may alleviate some of the economic burden to fishermen without compromising the objectives of the FMP.

The Council considers public comments at a minimum of two Council meetings prior to making final recommendations to the Director, Northeast Region, NMFS, (Regional Director) under the provisions for abbreviated rulemaking, cited above. If the Regional Director concurs with the measures proposed by the Council, he will publish them as a final rule in the Federal Register.

There will be a discussion of an experimental fishery to assess the selectivity of longline gear. The Regional Director is considering an experimental fishery for a vessel involved in a Saltonstall/Kennedy Grant awarded to the New England Aquarium and entitled ''Selectivity and Survival of Atlantic Cod (*Gadus morhua*) and Haddock (*Melanogrammus aeglefinus*) in a Northwest Atlantic Longline Fishery.'' The Massachusetts Division of Marine Fisheries (MADMF) is assisting in the project and would assist in the completion of the experimental fishery. The objective of the project is to assess

the selectivity of bottom longlines currently in use in the fishing industry and to attempt to improve the selectivity of longline gear. The experimental fishery would involve the use of longline gear equivalent to current commercial longline gear as well as experimental hooks, bait, and other control gears to compare results. The New England Aquarium and the MADMF have received funding for and conducted similar selectivity and survival experimental fisheries in the past.

Special Accommodations

This meeting is physically accessible to people with disabilities. Requests for sign language interpretation or other auxiliary aids should be directed to Christopher B. Kellogg at the Council (see **ADDRESSES**).

Authority: 16 U.S.C. 1801 *et seq.*

Dated: September 4, 1996.

Gary Matlock,

Director, Office of Sustainable Fisheries, National Marine Fisheries Service.

[FR Doc. 96–22957 Filed 9–4–96; 3:10 pm]

BILLING CODE 3510–22–F

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50 CFR Part 648

[Docket No. 960830238–6239–3802; I.D. 081496C]

RIN 0648–AJ07

Fisheries of the Northeastern United States; Northeast Multispecies Fishery; Control Date

AGENCY: National Marine Fisheries Service (NMFS), National Oceanic and Atmospheric Administration (NOAA), Commerce.

ACTION: Advance notice of proposed rulemaking; consideration of a control date.

SUMMARY: NMFS announces that the New England Fishery Management Council (Council) is considering limiting future access to anyone not in possession of a current multispecies limited access multispecies permit who enters the fisheries for silver hake (*Merluccis bilinearis*), black-eye whiting (offshore hake) (*Merluccis albibus*), ocean pout (*Macrozoarces americanus*), and red hake (*Urophycis chuss*) after September 9, 1996 (control date). Consideration of a control date is intended to discourage new entry into the fishery based on economic speculation during the Council's deliberation on the issue.

DATES: Comments must be submitted by October 7, 1996.

ADDRESSES: Comments should be directed to: Douglas Marshall, Executive Director, New England Fishery Management Council, 5 Broadway, Saugus, MA 01906.

FOR FURTHER INFORMATION CONTACT: Susan A. Murphy, NMFS, Fishery Policy Analyst, 508–281–9252.

SUPPLEMENTARY INFORMATION: The Council manages multispecies under the Northeast Multispecies Fishery Management Plan (FMP). Amendment 4 to the FMP, effective June 27, 1991, included fisheries for silver hake, red hake and ocean pout, but did not include any specific measures to manage these species. On March 1, 1994, Amendment 5 to the FMP established a limited access permit program for regulated multispecies and retained an open-access permit category for the nonregulated multispecies—whiting, red hake, and ocean pout.

A definition for ''nonregulated species'' pertaining to the Northeast multispecies fishery was established by a final rule published on July 31, 1996, at 61 FR 39909. That definition contains the following species: Whiting, red hake, and ocean pout. The term ''nonregulated species'' in this action refers to whiting, red hake, ocean pout, and black-eye whiting. Black-eye whiting has historically not been distinguished from whiting, but the Council has recently requested information regarding biology and fishery economics from NMFS, because it may be prudent to monitor and manage the species separately.

On February 5, 1996, the Council submitted Amendment 7 to the FMP to NMFS and, after a preliminary evaluation, three measures in the amendment were disapproved on February 14, 1996, including the establishment of a limited access category for qualified vessels that fished in the open access possession limit category under Amendment 5. Pursuant to section 304(b)(3)(A) of the Magnuson Fishery Conservation and Management Act (Magnuson Act), the Council resubmitted the measure that would implement a possession limit permit category by revising it to allow any vessel of the United States to obtain the permit and fish for and possess nonregulated multispecies. NMFS approved this resubmitted measure on July 19, 1996, and implemented it by a final rule on July 31, 1996 (61 FR 39909). The rule established an open access permit category named the ''open access nonregulated multispecies permit.''

The Council currently manages fisheries for silver hake, ocean pout, and red hake under the FMP, and it is gathering information necessary to consider the inclusion of black-eye whiting in the FMP in a plan amendment now under development. One of the impacts of the regulated species effort reduction program under Amendments 5 and 7 is that vessels are seeking alternative fisheries, including nonregulated multispecies fisheries. As markets develop, additional participants may enter these fisheries with potentially negative impacts on the health of the resource. Of the nonregulated multispecies, NMFS scientists have indicated one of the two stocks of silver hake is probably overexploited and the other is fully exploited, ocean pout is fully exploited, and red hake is underexploited.

Future access to these resources (the nonregulated species) in the exclusive economic zone will not be assured beyond the control date if a management regime that limits the number of participants in the fishery is developed and implemented under the Magnuson Act. The Council has indicated its intent to qualify vessels that hold a valid limited access multispecies permit for any limited access system that may be implemented for these species. The potential eligibility criteria may be based on current eligibility for limited access multispecies permits, as well as on historical participation, defined as any number of trips having any documented amount of any of these species. This document, therefore, gives the public, particularly those not in possession of a limited access multispecies permit, notice that they should locate and preserve records that substantiate and verify their participation in the fisheries for these species.

The control date will help to distinguish currently established multispecies fishermen from speculative entrants to the fisheries while management measures are being developed. Fishermen not in possession of a current limited access multispecies permit are notified that entering the fisheries after the control date may not qualify as previous participation, should such a criterion be the basis for future access to the silver hake, red hake, ocean pout, or black-eye whiting resources. Furthermore, additional and/or other qualifying criteria also may be applied. The Council may choose different and variably weighted methods to qualify fishermen, based on the type and length of participation in the fishery or on the quantity of landings. The Council may also decide not to limit entry into these fisheries after a

consideration of all reasonable alternatives for their management.

Authority: 16 U.S.C. 1801 *et seq.*

Dated: September 3, 1996.

N. Foster,

Deputy Assistant Administrator for Fisheries, National Marine Fisheries Service.

[FR Doc. 96–22953 Filed 9–6–96; 8:45 am]

BILLING CODE 3510–22–F

Notices

Federal Register
Vol. 61, No. 175
Monday, September 9, 1996

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

Secretary of Agriculture's Special Cotton Import Quota Announcement Number 1

AGENCY: Office of the Secretary, USDA.

ACTION: Notice.

SUMMARY: A special import quota for upland cotton equal to 43,370,449 kilograms (95,615,552 pounds) is established in accordance with section 136(b) of the Federal Agriculture Improvement and Reform Act of 1996 (the 1996 Act) under Presidential Proclamation 6301 of June 7, 1991. The quota is referenced as the Secretary of Agriculture's Special Cotton Import Quota Announcement Number 1, effective July 22, 1996, and is set forth in subheading 9903.52.01, subchapter III, chapter 99 of the Harmonized Tariff Schedule of the United States (HTS).

DATES: The quota is effective as of July 22, 1996, and applies to upland cotton purchased not later than October 19, 1996 (90 days from the date the quota was established), and entered into the United States not later than January 17, 1997 (180 days from the date the quota was established).

FOR FURTHER INFORMATION CONTACT: Janise Zygmont, Farm Service Agency, United States Department of Agriculture, Stop 0515, P.O. Box 2415, Washington, DC 20013–2415 or call (202) 720–8841.

SUPPLEMENTARY INFORMATION: The 1996 Act requires that a special import quota for upland cotton be determined and announced immediately if, for any consecutive 10-week period, the Friday through Thursday average price quotation for the lowest-priced U.S. growth, as quoted for Middling 1 3/32 inch cotton, C.I.F. northern Europe (U.S. Northern Europe price), adjusted for the value of any cotton user marketing certificates issued, exceeds the Northern Europe price by more than 1.25 cents per pound. This condition was met during the consecutive 10-week period that ended June 6, 1996. Therefore, a quota referenced as the Secretary of Agriculture's Special Cotton Import Quota Announcement Number 1, effective July 22, 1996, is hereby established.

Because there are only 20 subheadings available for designating upland cotton special import quotas in subchapter III of chapter 99 of the HTS, only 20 such quotas can be in effect at one time. Each subheading corresponds to a Secretary of Agriculture's Special Cotton Import Quota Announcement specifying that a particular amount of upland cotton may be imported during a particular 180-day period. The special import quota described in this notice cannot take effect until HTS subheading 9903.52.01 becomes available upon the expiration of the Secretary of Agriculture's Special Cotton Import Quota Announcement Number 1, effective January 24, 1996, through July 21, 1996. Therefore, the special import quota described in this notice opens on July 22, 1996, the day after the previous special import quota 1 ends.

The quota amount, 43,370,449 kilograms (95,615,552 pounds), is equal to 1 week's consumption of upland cotton by domestic mills at the seasonally-adjusted average rate of the most recent 3 months for which data are available—February 1996 through April 1996. The special import quota identifies a quantity of imports that is not subject to the over-quota tariff rate of a tariff-rate quota. The quota is not divided by staple length or by country of origin. The quota does not affect existing tariff rates or phytosanitary regulations. The quota does not apply to Extra Long Staple cotton.

Authority: Sec. 136, P.L. 104–127 and U.S. Note 6(a), Subchapter III, Chapter 99 of the HTS.

Signed at Washington, D.C., on Agusut 23, 1996.

Dan Glickman,

Secretary.

[FR Doc. 96–22885 Filed 9–06–96; 8:45 am]

BILLING CODE 3410–05–P

Secretary of Agriculture's Special Cotton Import Quota Announcement Number 2

AGENCY: Office of the Secretary, USDA.

ACTION: Notice.

SUMMARY: A special import quota for upland cotton equal to 43,370,449 kilograms (95,615,552 pounds) is established in accordance with section 136(b) of the Federal Agriculture Improvement and Reform Act of 1996 (the 1996 Act) under Presidential Proclamation 6301 of June 7, 1991. The quota is referenced as the Secretary of Agriculture's Special Cotton Import Quota Announcement Number 2, effective July 29, 1996, and is set forth in subheading 9903.52.02, subchapter III, chapter 99 of the Harmonized Tariff Schedule of the United States (HTS).

DATES: The quota is effective as of July 29, 1996, and applies to upland cotton purchased not later than October 26, 1996 (90 days from the date the quota was established), and entered into the United States not later than January 24, 1997 (180 days from the date the quota was established).

FOR FURTHER INFORMATION CONTACT: Janise Zygmont, Farm Service Agency, United States Department of Agriculture, Stop 0515, P.O. Box 2415, Washington, DC 20013–2415 or call (202) 720–8841.

SUPPLEMENTARY INFORMATION: The 1996 Act requires that a special import quota for upland cotton be determined and announced immediately if, for any consecutive 10-week period, the Friday through Thursday average price quotation for the lowest-priced U.S. growth, as quoted for Middling 1 3/32 inch cotton, C.I.F. northern Europe (U.S. Northern Europe price), adjusted for the value of any cotton user marketing certificates issued, exceeds the Northern Europe price by more than 1.25 cents per pound. This condition was met during the consecutive 10-week period that ended June 13, 1996. Therefore, a quota referenced as the Secretary of Agriculture's Special Cotton Import Quota Announcement Number 2, effective July 29, 1996, is hereby established.

Because there are only 20 subheadings available for designating upland cotton special import quotas in subchapter III of chapter 99 of the HTS, only 20 such quotas can be in effect at one time. Each subheading corresponds to a Secretary of Agriculture's Special Cotton Import Quota Announcement specifying that a particular amount of upland cotton may be imported during a particular 180-day period. The special import quota described in this notice

cannot take effect until HTS subheading 9903.52.02 becomes available upon the expiration of the Secretary of Agriculture's Special Cotton Import Quota Announcement Number 2, effective January 31, 1996, through July 28, 1996. Therefore, the special import quota described in this notice opens on July 29, 1996, the day after the previous special import quota 2 ends.

The quota amount, 43,370,449 kilograms (95,615,552 pounds), is equal to 1 week's consumption of upland cotton by domestic mills at the seasonally-adjusted average rate of the most recent 3 months for which data are available—February 1996 through April 1996. The special import quota identifies a quantity of imports that is not subject to the over-quota tariff rate of a tariff-rate quota. The quota is not divided by staple length or by country of origin. The quota does not affect existing tariff rates or phytosanitary regulations. The quota does not apply to Extra Long Staple cotton.

Authority: Sec. 136, Pub. L. 104–127 and U.S. Note 6(a), Subchapter III, Chapter 99 of the HTS.

Signed at Washington, DC, on August 23, 1996.

Dan Glickman,

Secretary.

[FR Doc. 96–22886 Filed 9–6–96; 8:45 am]

BILLING CODE 3410–05–P

Secretary of Agriculture's Special Cotton Import Quota Announcement Number 3

AGENCY: Office of the Secretary, USDA.

ACTION: Notice.

SUMMARY: A special import quota for upland cotton equal to 43,370,449 kilograms (95,615,552 pounds) is established in accordance with section 136(b) of the Federal Agriculture Improvement and Reform Act of 1996 (the 1996 Act) under Presidential Proclamation 6301 of June 7, 1991. The quota is referenced as the Secretary of Agriculture's Special Cotton Import Quota Announcement Number 3, effective August 5, 1996, and is set forth in subheading 9903.52.03, subchapter III, chapter 99 of the Harmonized Tariff Schedule of the United States (HTS).

DATES: The quota is effective as of August 5, 1996, and applies to upland cotton purchased not later than November 2, 1996 (90 days from the date the quota was established), and entered into the United States not later than January 31, 1997 (180 days from the date the quota was established).

FOR FURTHER INFORMATION CONTACT: Janise Zygmont, Farm Service Agency, United States Department of Agriculture, Stop 0515, P.O. Box 2415, Washington, DC 20013–2415 or call (202) 720–8841.

SUPPLEMENTARY INFORMATION: The 1996 Act requires that a special import quota for upland cotton be determined and announced immediately if, for any consecutive 10-week period, the Friday through Thursday average price quotation for the lowest-priced U.S. growth, as quoted for Middling 1 3/32 inch cotton, C.I.F. northern Europe (U.S. Northern Europe price), adjusted for the value of any cotton user marketing certificates issued, exceeds the Northern Europe price by more than 1.25 cents per pound. This condition was met during the consecutive 10-week period that ended June 20, 1996. Therefore, a quota referenced as the Secretary of Agriculture's Special Cotton Import Quota Announcement Number 3, effective August 5, 1996, is hereby established.

Because there are only 20 subheadings available for designating upland cotton special import quotas in subchapter III of chapter 99 of the HTS, only 20 such quotas can be in effect at one time. Each subheading corresponds to a Secretary of Agriculture's Special Cotton Import Quota Announcement specifying that a particular amount of upland cotton may be imported during a particular 180-day period. The special import quota described in this notice cannot take effect until HTS subheading 9903.52.03 becomes available upon the expiration of the Secretary of Agriculture's Special Cotton Import Quota Announcement Number 3, effective February 7, 1996, through August 4, 1996. Therefore, the special import quota described in this notice opens on August 5, 1996, the day after the previous special import quota 3 ends.

The quota amount, 43,370,449 kilograms (95,615,552 pounds), is equal to 1 week's consumption of upland cotton by domestic mills at the seasonally-adjusted average rate of the most recent 3 months for which data are available—February 1996 through April 1996. The special import quota identifies a quantity of imports that is not subject to the over-quota tariff rate of a tariff-rate quota. The quota is not divided by staple length or by country of origin. The quota does not affect existing tariff rates or phytosanitary regulations. The quota does not apply to Extra Long Staple cotton.

Authority: Sec. 136, P.L. 104–127 and U.S. Note 6(a), Subchapter III, Chapter 99 of the HTS.

Signed at Washington, D.C., on August 23, 1996.

Dan Glickman,

Secretary.

[FR Doc. 96–22887 Filed 9–6–96; 8:45 am]

BILLING CODE 3410–05–P

Secretary of Agriculture's Special Cotton Import Quota Announcement Number 4

AGENCY: Office of the Secretary, USDA.

ACTION: Notice.

SUMMARY: A special import quota for upland cotton equal to 43,827,535 kilograms (96,623,255 pounds) is established in accordance with section 136(b) of the Federal Agriculture Improvement and Reform Act of 1996 (the 1996 Act) under Presidential Proclamation 6301 of June 7, 1991. The quota is referenced as the Secretary of Agriculture's Special Cotton Import Quota Announcement Number 4, effective August 12, 1996, and is set forth in subheading 9903.52.04, subchapter III, chapter 99 of the Harmonized Tariff Schedule of the United States (HTS).

DATES: The quota is effective as of August 12, 1996, and applies to upland cotton purchased not later than November 9, 1996 (90 days from the date the quota was established), and entered into the United States not later than February 7, 1997 (180 days from the date the quota was established).

FOR FURTHER INFORMATION CONTACT: Janise Zygmont, Farm Service Agency, United States Department of Agriculture, Stop 0515, P.O. Box 2415, Washington, DC 20013–2415 or call (202) 720–8841.

SUPPLEMENTARY INFORMATION: The 1996 Act requires that a special import quota for upland cotton be determined and announced immediately if, for any consecutive 10-week period, the Friday through Thursday average price quotation for the lowest-priced U.S. growth, as quoted for Middling 1 3/32 inch cotton, C.I.F. northern Europe (U.S. Northern Europe price), adjusted for the value of any cotton user marketing certificates issued, exceeds the Northern Europe price by more than 1.25 cents per pound. This condition was met during the consecutive 10-week period that ended June 27, 1996. Therefore, a quota referenced as the Secretary of Agriculture's Special Cotton Import Quota Announcement Number 4, effective August 12, 1996, is hereby established.

Because there are only 20 subheadings available for designating upland cotton special import quotas in

subchapter III of chapter 99 of the HTS, only 20 such quotas can be in effect at one time. Each subheading corresponds to a Secretary of Agriculture's Special Cotton Import Quota Announcement specifying that a particular amount of upland cotton may be imported during a particular 180-day period. The special import quota described in this notice cannot take effect until HTS subheading 9903.52.04 becomes available upon the expiration of the Secretary of Agriculture's Special Cotton Import Quota Announcement Number 4, effective February 14, 1996, through August 11, 1996. Therefore, the special import quota described in this notice opens on August 12, 1996, the day after the previous special import quota 4 ends.

The quota amount, 43,827,535 kilograms (96,623,255 pounds), is equal to 1 week's consumption of upland cotton by domestic mills at the seasonally-adjusted average rate of the most recent 3 months for which data are available—March 1996 through May 1996. The special import quota identifies a quantity of imports that is not subject to the over-quota tariff rate of a tariff-rate quota. The quota is not divided by staple length or by country of origin. The quota does not affect existing tariff rates or phytosanitary regulations. The quota does not apply to Extra Long Staple cotton.

Authority: Sec. 136, Pub.L. 104–127 and U.S. Note 6(a), Subchapter III, Chapter 99 of the HTS.

Signed at Washington, D.C., on August 23, 1996.

Dan Glickman,

Secretary.

[FR Doc. 96–22888 Filed 9–6–96; 8:45 am]

BILLING CODE 3410–05–P

Secretary of Agriculture's Special Cotton Import Quota Announcement Number 5

AGENCY: Office of the Secretary, USDA.

ACTION: Notice.

SUMMARY: A special import quota for upland cotton equal to 43,827,535 kilograms (96,623,255 pounds) is established in accordance with section 136(b) of the Federal Agriculture Improvement and Reform Act of 1996 (the 1996 Act) under Presidential Proclamation 6301 of June 7, 1991. The quota is referenced as the Secretary of Agriculture's Special Cotton Import Quota Announcement Number 5, effective August 19, 1996, and is set forth in subheading 9903.52.05, subchapter III, chapter 99 of the Harmonized Tariff Schedule of the United States (HTS).

DATES: The quota is effective as of August 19, 1996, and applies to upland cotton purchased not later than November 16, 1996 (90 days from the date the quota was established), and entered into the United States not later than February 14, 1997 (180 days from the date the quota was established).

FOR FURTHER INFORMATION CONTACT: Janise Zygmont, Farm Service Agency, United States Department of Agriculture, Stop 0515, P.O. Box 2415, Washington, DC 20013–2415 or call (202) 720–8841.

SUPPLEMENTARY INFORMATION: The 1996 Act requires that a special import quota for upland cotton be determined and announced immediately if, for any consecutive 10-week period, the Friday through Thursday average price quotation for the lowest-priced U.S. growth, as quoted for Middling 1 3/32 inch cotton, C.I.F. northern Europe (U.S. Northern Europe price), adjusted for the value of any cotton user marketing certificates issued, exceeds the Northern Europe price by more than 1.25 cents per pound. This condition was met during the consecutive 10-week period that ended July 4, 1996. Therefore, a quota referenced as the Secretary of Agriculture's Special Cotton Import Quota Announcement Number 5, effective August 19, 1996, is hereby established.

Because there are only 20 subheadings available for designating upland cotton special import quotas in subchapter III of chapter 99 of the HTS, only 20 such quotas can be in effect at one time. Each subheading corresponds to a Secretary of Agriculture's Special Cotton Import Quota Announcement specifying that a particular amount of upland cotton may be imported during a particular 180-day period. The special import quota described in this notice cannot take effect until HTS subheading 9903.52.05 becomes available upon the expiration of the Secretary of Agriculture's Special Cotton Import Quota Announcement Number 5, effective February 21, 1996, through August 18, 1996. Therefore, the special import quota described in this notice opens on August 19, 1996, the day after the previous special import quota 5 ends.

The quota amount, 43,827,535 kilograms (96,623,255 pounds), is equal to 1 week's consumption of upland cotton by domestic mills at the seasonally-adjusted average rate of the most recent 3 months for which data are available—March 1996 through May 1996. The special import quota identifies a quantity of imports that is not subject to the over-quota tariff rate of a tariff-rate quota. The quota is not divided by staple length or by country of origin. The quota does not affect existing tariff rates or phytosanitary regulations. The quota does not apply to Extra Long Staple cotton.

Authority: Sec. 136, Pub.L. 104–127 and U.S. Note 6(a), Subchapter III, Chapter 99 of the HTS.

Signed at Washington, D.C., on Augsut 23, 1996.

Dan Glickman,

Secretary.

[FR Doc. 96–22889 Filed 9–6–96; 8:45 am]

BILLING CODE 3410–05–P

Secretary of Agriculture's Special Cotton Import Quota Announcement Number 6

AGENCY: Office of the Secretary, USDA.

ACTION: Notice.

SUMMARY: A special import quota for upland cotton equal to 43,827,535 kilograms (96,623,255 pounds) is established in accordance with section 136(b) of the Federal Agriculture Improvement and Reform Act of 1996 (the 1996 Act) under Presidential Proclamation 6301 of June 7, 1991. The quota is referenced as the Secretary of Agriculture's Special Cotton Import Quota Announcement Number 6, effective August 26, 1996, and is set forth in subheading 9903.52.06, subchapter III, chapter 99 of the Harmonized Tariff Schedule of the United States (HTS).

DATES: The quota is effective as of August 26, 1996, and applies to upland cotton purchased not later than November 23, 1996 (90 days from the date the quota was established), and entered into the United States not later than February 21, 1997 (180 days from the date the quota was established).

FOR FURTHER INFORMATION CONTACT: Janise Zygmont, Farm Service Agency, United States Department of Agriculture, Stop 0515, P.O. Box 2415, Washington, DC 20013–2415 or call (202) 720–8841.

SUPPLEMENTARY INFORMATION: The 1996 Act requires that a special import quota for upland cotton be determined and announced immediately if, for any consecutive 10-week period, the Friday through Thursday average price quotation for the lowest-priced U.S. growth, as quoted for Middling 1 3/32 inch cotton, C.I.F. northern Europe (U.S. Northern Europe price), adjusted for the value of any cotton user marketing certificates issued, exceeds the Northern

Europe price by more than 1.25 cents per pound. This condition was met during the consecutive 10-week period that ended July 11, 1996. Therefore, a quota referenced as the Secretary of Agriculture's Special Cotton Import Quota Announcement Number 6, effective August 26, 1996, is hereby established.

Because there are only 20 subheadings available for designating upland cotton special import quotas in subchapter III of chapter 99 of the HTS, only 20 such quotas can be in effect at one time. Each subheading corresponds to a Secretary of Agriculture's Special Cotton Import Quota Announcement specifying that a particular amount of upland cotton may be imported during a particular 180-day period. The special import quota described in this notice cannot take effect until HTS subheading 9903.52.06 becomes available upon the expiration of the Secretary of Agriculture's Special Cotton Import Quota Announcement Number 6, effective February 28, 1996, through August 25, 1996. Therefore, the special import quota described in this notice opens on August 26, 1996, the day after the previous special import quota 6 ends.

The quota amount, 43,827,535 kilograms (96,623,255 pounds), is equal to 1 week's consumption of upland cotton by domestic mills at the seasonally-adjusted average rate of the most recent 3 months for which data are available—March 1996 through May 1996. The special import quota identifies a quantity of imports that is not subject to the over-quota tariff rate of a tariff-rate quota. The quota is not divided by staple length or by country of origin. The quota does not affect existing tariff rates or phytosanitary regulations. The quota does not apply to Extra Long Staple cotton.

Authority: Sec. 136, Pub.L. 104–127 and U.S. Note 6(a), Subchapter III, Chapter 99 of the HTS.

Signed at Washington, D.C., on August 23, 1996.

Dan Glickman,

Secretary.

[FR Doc. 96–22890 Filed 9–6–96; 8:45 am]

BILLING CODE 3410–05–P

Secretary of Agriculture's Special Cotton Import Quota Announcement Number 7

AGENCY: Office of the Secretary, USDA.

ACTION: Notice.

SUMMARY: A special import quota for upland cotton equal to 43,827,535 kilograms (96,623,255 pounds) is established in accordance with section 136(b) of the Federal Agriculture Improvement and Reform Act of 1996 (the 1996 Act) under Presidential Proclamation 6301 of June 7, 1991. The quota is referenced as the Secretary of Agriculture's Special Cotton Import Quota Announcement Number 7, effective September 2, 1996, and is set forth in subheading 9903.52.07, subchapter III, chapter 99 of the Harmonized Tariff Schedule of the United States (HTS).

DATES: The quota is effective as of September 2, 1996, and applies to upland cotton purchased not later than November 30, 1996 (90 days from the date the quota was established), and entered into the United States not later than February 28, 1997 (180 days from the date the quota was established).

FOR FURTHER INFORMATION CONTACT: Janise Zygmont, Farm Service Agency, United States Department of Agriculture, Stop 0515, P.O. Box 2415, Washington, DC 20013–2415 or call (202) 720–8841.

SUPPLEMENTARY INFORMATION: The 1996 Act requires that a special import quota for upland cotton be determined and announced immediately if, for any consecutive 10-week period, the Friday through Thursday average price quotation for the lowest-priced U.S. growth, as quoted for Middling 1–3/32 inch cotton, C.I.F. northern Europe (U.S. Northern Europe price), adjusted for the value of any cotton user marketing certificates issued, exceeds the Northern Europe price by more than 1.25 cents per pound. This condition was met during the consecutive 10-week period that ended July 18, 1996. Therefore, a quota referenced as the Secretary of Agriculture's Special Cotton Import Quota Announcement Number 7, effective September 2, 1996, is hereby established.

Because there are only 20 subheadings available for designating upland cotton special import quotas in subchapter III of chapter 99 of the HTS, only 20 such quotas can be in effect at one time. Each subheading corresponds to a Secretary of Agriculture's Special Cotton Import Quota Announcement specifying that a particular amount of upland cotton may be imported during a particular 180-day period. The special import quota described in this notice cannot take effect until HTS subheading 9903.52.07 becomes available upon the expiration of the Secretary of Agriculture's Special Cotton Import Quota Announcement Number 7, effective March 6, 1996, through September 1, 1996. Therefore, the special import quota described in this notice opens on September 2, 1996, the day after the previous special import quota 7 ends.

The quota amount, 43,827,535 kilograms (96,623,255 pounds), is equal to 1 week's consumption of upland cotton by domestic mills at the seasonally-adjusted average rate of the most recent 3 months for which data are available—March 1996 through May 1996. The special import quota identifies a quantity of imports that is not subject to the over-quota tariff rate of a tariff-rate quota. The quota is not divided by staple length or by country of origin. The quota does not affect existing tariff rates or phytosanitary regulations. The quota does not apply to Extra Long Staple cotton.

Authority: Sec. 136, Pub.L. 104–127 and U.S. Note 6(a), Subchapter III, Chapter 99 of the HTS.

Signed at Washington, D.C., on August 23, 1996.

Dan Glickman,

Secretary.

[FR Doc. 96–22891 Filed 9–6–96; 8:45 am]

BILLING CODE 3410–05–P

Secretary of Agriculture's Special Cotton Import Quota Announcement Number 8

AGENCY: Office of the Secretary, USDA.

ACTION: Notice.

SUMMARY: A special import quota for upland cotton equal to 44,368,028 kilograms (97,814,838 pounds) is established in accordance with section 136(b) of the Federal Agriculture Improvement and Reform Act of 1996 (the 1996 Act) under Presidential Proclamation 6301 of June 7, 1991. The quota is referenced as the Secretary of Agriculture's Special Cotton Import Quota Announcement Number 8, effective September 9, 1996, and is set forth in subheading 9903.52.08, subchapter III, chapter 99 of the Harmonized Tariff Schedule of the United States (HTS).

DATES: The quota is effective as of September 9, 1996, and applies to upland cotton purchased not later than December 7, 1996 (90 days from the date the quota was established), and entered into the United States not later than March 7, 1997 (180 days from the date the quota was established).

FOR FURTHER INFORMATION CONTACT: Janise Zygmont, Farm Service Agency, United States Department of Agriculture, Stop 0515, P.O. Box 2415, Washington, DC 20013–2415 or call (202) 720–8841.

SUPPLEMENTARY INFORMATION: The 1996 Act requires that a special import quota for upland cotton be determined and announced immediately if, for any consecutive 10-week period, the Friday through Thursday average price quotation for the lowest-priced U.S. growth, as quoted for Middling 1 3/32 inch cotton, C.I.F. northern Europe (U.S. Northern Europe price), adjusted for the value of any cotton user marketing certificates issued, exceeds the Northern Europe price by more than 1.25 cents per pound. This condition was met during the consecutive 10-week period that ended July 25, 1996. Therefore, a quota referenced as the Secretary of Agriculture's Special Cotton Import Quota Announcement Number 8, effective September 9, 1996, is hereby established.

Because there are only 20 subheadings available for designating upland cotton special import quotas in subchapter III of chapter 99 of the HTS, only 20 such quotas can be in effect at one time. Each subheading corresponds to a Secretary of Agriculture's Special Cotton Import Quota Announcement specifying that a particular amount of upland cotton may be imported during a particular 180-day period. The special import quota described in this notice cannot take effect until HTS subheading 9903.52.08 becomes available upon the expiration of the Secretary of Agriculture's Special Cotton Import Quota Announcement Number 8, effective March 13, 1996, through September 8, 1996. Therefore, the special import quota described in this notice opens on September 9, 1996, the day after the previous special import quota 8 ends.

The quota amount, 44,368,028 kilograms (97,814,838 pounds), is equal to 1 week's consumption of upland cotton by domestic mills at the seasonally-adjusted average rate of the most recent 3 months for which data are available—April 1996 through June 1996. The special import quota identifies a quantity of imports that is not subject to the over-quota tariff rate of a tariff-rate quota. The quota is not divided by staple length or by country of origin. The quota does not affect existing tariff rates or phytosanitary regulations. The quota does not apply to Extra Long Staple cotton.

Authority: Sec. 136, Pub. L. 104–127 and U.S. Note 6(a), Subchapter III, Chapter 99 of the HTS.

Signed at Washington, D.C., on August 23, 1996.

Dan Glickman,

Secretary.

[FR Doc. 96–22892 Filed 9–6–96; 8:45 am]

BILLING CODE 3410–05–P

Rural Housing Service

Farm Service Agency

Notice of Request for Extension of a Currently Approved Information Collection

AGENCY: Rural Housing Service and Farm Service Agency, USDA.

ACTION: Proposed collection; comments request.

SUMMARY: In accordance with the Paperwork Reduction Act of 1995 (Pub. L. 104–13), this notice announces the Rural Housing Service (RHS) and Farm Service Agency's (FSA) intention to request an extension for an information collection currently approved for the agencies account servicing policies for programs formerly administered by the United States Department of Agriculture, Farmers Home Administration. These regulations are published under the authority of the Consolidated Farm and Rural Development Act (CONACT), as amended.

DATES: Comments on this notice must be received on or before November 8, 1996 to be assured of consideration.

FOR FURTHER INFORMATION CONTACT: William D. Cobb, Senior Loan Officer, Loan Servicing and Property Management Division, Farm Service Agency, USDA/FSA/LSPMD/ Stop 0523, P.O. Box 2415, Washington, DC 20013–2415; Telephone (202) 720–1059.

SUPPLEMENTARY INFORMATION:

Title: Account Servicing Policies.

OMB Number: 0575–0075.

Expiration Date of Approval: March 31, 1997.

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

Abstract: The information collected under Office of Management and Budget (OMB) Number 0575–0075, as identified above, is needed to enable RHS and FSA to effectively collect on loans made under programs formerly administered by the Farmers Home Administration (FmHA). Under the provisions of the Department of Agriculture Reorganization Act of 1994, FmHA loan programs where transferred to either Rural Development, which includes RHS, the Rural Business-Cooperative Service, and the Rural Utilities Service; or the Farm Service Agency. RHS provides supervised credit in the form of Single Family Housing loans and grants, Multi-Family Housing loans and grants, and Community Facility loans and grants. FSA's Farm Credit Program provides supervised credit in the form of loans to family farmers and ranchers to purchase farm land and finance agricultural production. This regulation sets forth the policies and procedures regarding the application of payments on loans made under the RHS and FSA mission areas.

When loans are paid in full, the agencies Finance Office will automatically refund an overpayment of $10.00 or more. It is not cost efficient for the agencies to process refunds of overpayments of less than $10.00; therefore, these will be credited to the borrower's account unless a written request for a refund is submitted by the borrower.

Promissory notes evidencing a debt which has been reduced to a judgment are a part of the court record and ordinarily cannot be withdrawn and returned to the debtor, even after satisfaction of the debt. Therefore, no effort will be made to return these notes unless a written request is received from the borrower or their legal representative.

Estimate of Burden: Pubic reporting burden for this collection of information is estimated to average .25 hours per response.

Respondents: Individuals or households, farms, businesses or other for-profit, small businesses or organizations.

Estimated Number of Respondents: 10.

Estimated Number of Responses per Respondent: 1.

Estimated Total Annual Burden on Respondents: 3 hours.

Copies of the information collection can be obtained from Barbara Williams, Regulations and Paperwork Management Division, at (202) 720–9734.

Comments

Comments are invited on: (a) Whether the proposed collection of information is necessary for the proper performance of the agencies, including whether the information will have practical utility; (b) the accuracy of the Agencies estimate of the burden of the proposed collection of information including the validity of the methodology and assumption used; (c) ways to enhance the quality, utility and clarity of the information to be collected; and (d) ways to minimize the burden of the

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 Barbara Williams, Regulations and Paperwork Management Division, U.S. Department of Agriculture, Rural Development, Stop 0743, Washington, DC 20250–0743. 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.

Dated: August 28, 1996.

Bruce R. Weber,

Acting Administrator, Farm Service Agency.

Maureen Kennedy,

Administrator, Rural Housing Service.

[FR Doc. 96–22884 Filed 9–6–96; 8:45 am]

BILLING CODE 3410–07–M

Natural Resources Conservation Service

McKinney-Buzzard Creek Watershed, OK; Notice of Intent To Deauthorize Federal Funding

SUMMARY: Pursuant to the Watershed Protection and Flood Prevention Act, Public Law 83–566, and the Natural Resources Conservation Service Guidelines (7 CFR 622), the Natural Resources Conservation Service gives notice of the intent to deauthorize Federal funding for the McKinney-Buzzard Creek Watershed project (McCurtain County, Oklahoma).

FOR FURTHER INFORMATION CONTACT: Ronnie L. Clark, State Conservationist, Natural Resources Conservation Service, 100 USDA, Suite 203, Stillwater, Oklahoma 74074–2655. Telephone: (405) 742–1204.

McKinney Buzzard Creek Watershed, Oklahoma

Notice of Intent To Deauthorize Federal Funding

SUPPLEMENTARY INFORMATION: A determination had been made by Ronnie L. Clark that the proposed works of improvement for the McKinney-Buzzard Creek project will not be installed. The sponsoring local organizations have concurred in this determination and agree that Federal funding should be deauthorized for the project. Information regarding this determination may be obtained from Ronnie L. Clark, State Conservationist, at the above address and telephone number.

No administrative action on implementation of the proposed deauthorization will be taken until 60 days after the date of this publication in the Federal Register.

Dated: August 26, 1996.

Ronnie L. Clark,

State Conservationist.

(Catalog of Federal Domestic Assistance Program No. 10.904, Watershed Protection and Flood Prevention. Office of Management and Budget Circular A–95 regarding State and local clearinghouse review of Federal and federally assisted programs and projects is applicable)

[FR Doc. 96–22858 Filed 9–6–96; 8:45 am]

BILLING CODE 3410–16–M

Starkweather Watershed, ND; Notice of Deauthorization of Federal Funding

SUMMARY: Pursuant to the Watershed Protection Act, Public Law 83–566, and the Natural Resources Conservation Service Guidelines (7 CFR 622), the Natural Resources Conservation Service gives notice of the deauthorization of Federal funding for the Starkweather Watershed project, Cavalier and Ramsey Counties, North Dakota, effective on August 30, 1996.

FOR FURTHER INFORMATION CONTACT: Scott Hoag, Jr., State Conservationist, Natural Resources Conservation Service, 220 E. Rosser Avenue, P.O. Box 1458, Bismarck, North Dakota, 58502–1458. Telephone number: 701–250–4441.

Dated: August 30, 1996.

Ronald D. Sando,

Acting State Conservationist.

(Catalog of Federal Domestic Assistance Program No. 10.904, Watershed Protection and Flood Prevention. Office of Management and Budget Circular No. A–95 regarding State and local clearinghouse review of Federal and federally assisted programs and projects is applicable)

[FR Doc. 96–22857 Filed 9–6–96; 8:45 am]

BILLING CODE 3410–16–M

ASSASSINATION RECORDS REVIEW BOARD

Sunshine Act Meeting

TIME AND DATE: 10:00 a.m., September 17, 1996.

PLACE: Board of Education, District Board Room H–160, 450 North Grand, Los Angeles, CA 90051.

STATUS: Public Hearing.

MATTERS TO BE CONSIDERED: Testimony on Assassination Records.

A list of witnesses will be available from the Review Board by September 12, 1996. Due to time constraints, the Board will not be able to accept unscheduled testimony. The record of this hearing will be kept open until October 11, 1996, for those who wish to submit written comments.

CONTACT PERSON FOR MORE INFORMATION: Thomas Samoluk, Associate Director for Communications, 600 E Street, NW, Second Floor, Washington, DC 20530. Telephone: (202) 724–0088; Fax: (202) 724–0457.

David G. Marwell,

Executive Director.

[FR Doc. 96–23089 Filed 9–5–96; 2:48 pm]

BILLING CODE 6118–01–P

DEPARTMENT OF COMMERCE

Submission For OMB Review; Comment Request

The Department of Commerce (DOC) has submitted to the Office of Management and Budget (OMB) for clearance the following proposal for collection of information under the provisions of the Paperwork Reduction Act (44 U.S.C. Chapter 35).

Agency: Bureau of the Census.

Title: 1996 Community Census – Integrated Coverage Measurement (ICM) Activities (CAPI Person Interview, CAPI Person QA Interview, Outmover Tracing, and Dual System Estimation Follow up).

Form Number(s): CAPI Person Interview, CAPI Person QA Interview, DT–1301, DT–1301A, DT–1340, DT–1309(L), DT–31.

Agency Approval Number: None.

Type of Request: New collection.

Burden: 4,903 hours.

Number of Respondents: 12,000 housing units and 120 persons.

Avg Hours Per Response: 18 and ½ minutes.

Needs and Uses: The Census Bureau requests OMB approval of the activities and instruments associated with conducting the interviewing and follow up phases of ICM research in the 1996 Community Census. Prompted by the need to improve statistical methodology for estimating population coverage during the decennial census, the Bureau of the Census developed the ICM approach. In ICM, census blocks are separately enumerated to obtain an independent roster. The independent roster is then compared to the census results to measure coverage of housing units and of persons in missed housing units and coverage of persons in housing units included in the census. The ICM approach was first tested in the 1995 Census Test. ICM Research in the 1996 Community Census will expand

upon results from that earlier test. The activities and forms for the initial stages of ICM research during the 1996 Community Census (independent listing and reconciliation follow up) were approved previously by OMB.

Affected Public: Individuals or households.

Frequency: One–time.

Respondent's Obligation: Mandatory.

Legal Authority: Title 13 USC, Sections 141, 193, and 221.

OMB Desk Officer: Jerry Coffey, (202) 395–7314.

Copies of the above information collection proposal can be obtained by calling or writing Linda Engelmeier, Acting DOC Forms Clearance Officer, (202) 482–3272, Department of Commerce, Room 5312, 14th and Constitution Avenue, NW, Washington, DC 20230.

Written comments and recommendations for the proposed information collection should be sent within 30 days of publication of this notice to Jerry Coffey, OMB Desk Officer, Room 10201, New Executive Office Building, Washington, DC 20503.

Dated: August 30, 1996.

Linda Engelmeier,

Acting Departmental Forms Clearance Officer, Office of Management and Organization.

[FR Doc. 96–22893 Filed 9–6–96; 8:45 am]

BILLING CODE 3510–07–F

Economics and Statistics Administration

Performance Review Board Membership

Below is a listing of individuals who are eligible to serve on the Performance Review Board in accordance with the Economics and Statistics Administration Senior Executive Service (SES) Performance Appraisal System:

Lewis S. Alexander
Frederick T. Alt
Betty L. Barker
O. Bryant Benton
Cynthia Z.F. Clark
Gerald F. Donahoe
Nancy M. Gordon
Arnold A. Jackson
Frederick T. Knickerbocker
Hugh W. Knox
John S. Landefeld
Paul A. London
Robert W. Marx
Gerald A. Pollack
Nancy A. Potok
Marvin D. Raines
Martha Farnsworth Riche
Paula J. Schneider
Katherine K. Wallman
James K. White

James K. White,

Executive Director, Performance Review Board.

[FR Doc. 96–23083 Filed 9–6–96; 8:45 am]

BILLING CODE 3510–BS–M

CORPORATION FOR NATIONAL AND COMMUNITY SERVICE

Proposed Information Collection Activity

AGENCY: Corporation for National and Community Service.

ACTION: Notice of 60-day review and comment on the proposed AmeriCorps Member Application and AmeriCorps Referral Card Information Collection Activity.

SUMMARY: The Office of Recruitment announces a 60-day review and comment period during which the public is encouraged to submit comments on suggested revisions to the AmeriCorps Member Application and AmeriCorps Referral Card.

DATES: The Corporation For National and Community Service, Recruitment Unit will consider written comments on the AmeriCorps Member Application and AmeriCorps Referral Card received on or before November 8, 1996.

ADDRESSES: Send comments to Margaret McLaughlin, Corporation for National and Community Service, 1201 New York Avenue, Washington, DC 20525.

FOR FURTHER INFORMATION CONTACT: Margaret McLaughlin, (202) 606–5000, ext. 269.

SUPPLEMENTARY INFORMATION: This notice proposes collection of information and solicit comments to:

1. 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;

2. Evaluate the accuracy of the agency's estimate of the burden of proposed collection of information, including validity of the methodology and assumption used:

3. Enhance the quality, utility, and clarity of the information to be collected; and

4. 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.

Dated: August 27, 1996.

Margaret McLaughlin,

Acting Director of Recruitment, Office of AmeriCorps Recruitment.

[FR Doc. 96–22862 Filed 9–6–96; 8:45 am]

BILLING CODE 6050–28–M

Revision of the National Senior Service Corps' Project Grant Application

AGENCY: Corporation for National and Community Service.

ACTION: Notice of 30-day OMB review of Project Grant Application.

SUMMARY: On July 1, the National Senior Service Corps (NSSC) announced a 60-day review and comment period, ending August 30, 1996, during which project sponsors and the public were encouraged to submit comments suggesting revisions to the NSSC Project Grant Application (424–NSSC). The Project Grant Application is submitted by prospective grantees to apply for or renew sponsorship of projects under the Retired and Senior Volunteer Program (RSVP), Foster Grandparent Program (FGP), and Senior Companion Program (SCP), collectively known as the National Senior Service Corps. Completion of the application is required to obtain or retain sponsorship.

In the July 1 announcement, comments were invited on (1) Whether the existing Grant Application collects appropriate information to allow agency decision-makers to fully assess applicant capabilities and plans for quality sponsorship; (2) ways to enhance the utility and clarity of the Project Grant Application; (3) accuracy of agency estimates of reporting burden; and (4) ways to further reduce burden on respondents.

NSSC is requesting extension of the authorization to use the Project Grant Application in its current form with grants funded in 1997. However, revising and phasing in of a new form in conjunction with planned implementation of the impact programming initiative is anticipated for grants funded in 1998 and beyond.

DATES: The National Senior Service Corps and the Office of Management and Budget will consider written comments on the Project Grant Application and recordkeeping requirements which are received on or before October 9, 1996.

Addresses to send comments to both:

Janice Forney Fisher, NSSC, Rm. 9403A, Corp. for National Service, 1201 New York Avenue, NW., Washington, DC 20525.

Deborah Bonds, Office of Info. & Regulatory Affairs, Office of

Management and Budget, Attn: Desk Officer for CNS, Washington, DC 20503.

Estimated Annual Reporting or Disclosure Burden: 19,398 hours (1,220 annual respondents at an average 15.9 hours burden per respondent).

FOR FURTHER INFORMATION CONTACT: Janice Forney Fisher (202) 606–5000 ext. 275.

* This document will be made available in alternate format upon request. TDD (202) 606–5000 ext. 164.

Regulatory Authority: National Service Trust Act of 1993.

Dated: September 4, 1996.

Thomas E. Endres,

Deputy Director, National Senior Service Corps.

[FR Doc. 96–22955 Filed 9–6–96; 8:45 am]

BILLING CODE 6050–28–M

DEPARTMENT OF DEFENSE

Office of the Secretary

Public Information Collection Requirement Submitted to the Office of Management and Budget (OMB) for Review

ACTION: Notice.

The Department of Defense has submitted to OMB for clearance, the following proposal for collection of information under the provisions of the Paperwork Reduction Act (44 U.S.C. Chapter 35).

Title, Applicable Form, and OMB Control Number: Oceanic Sounding Report; DMS Form 8053–1; OMB Number 0704–0208.

Type of Request: Reinstatement, without change.

Number of Respondents: 30.

Responses Per Respondent: 1.

Annual Responses: 30.

Average Burden Per Response: 3 hours.

Annual Burden Hours: 90.

Needs and Uses: Respondents to this information collection are mariners and navigators of merchant ships and vessels. The information collected hereby, is used to improve maritime safety. The navigational data provided updates the Department of Defense Bathymetric Data Base, and is used in the construction and correction of safe nautical charts.

Affected Public: Business or other for-profit.

Frequency: On occasion.

Respondent's Obligation: Voluntary.

OMB Desk Officer: Mr. Edward C. Springer.

Written comments and recommendations on the proposed information collection should be sent to Mr. Springer at the Office of Management and Budget, Desk Officer for DoD, Room 10236, New Executive Office Building, Washington, DC 20503.

DOD Clearance Officer: Mr. William Pearce.

Written requests for copies of the information collection proposal should be sent to Mr. Pearce, WHS/DIOR, 1215 Jefferson Davis Highway, Suite 1204, Arlington, VA 22202–4302.

Dated: August 30, 1996.

Patricia L. Toppings,

Alternate OSD Federal Register Liaison Officer, Department of Defense.

[FR Doc. 96–22859 Filed 9–6–96; 8:45 am]

BILLING CODE 5000–04–M

Public Information Collection Requirement Submitted to the Office of Management and Budget (OMB) for Review

ACTION: Notice.

The Department of Defense has submitted to OMB for clearance, the following proposal for collection of information under the provisions of the Paperwork Reduction Act (44 U.S.C. Chapter 35).

Title, Applicable Form, and OMB Control Number: DMA Port Information Report; DMA Form 8330–1; OMB Number 0704–0210.

Type of Request: Reinstatement, without change.

Number of Respondents: 100.

Responses Per Respondent: 2.

Annual Responses: 200.

Average Burden Per Response: 30 minutes.

Annual Burden Hours: 100.

Needs and Uses: Respondents to this information collection are mariners and navigators of merchant ships and vessels while the vessel is actually in the port. The information collected hereby, serves to prevent potential Maritime disasters, particularly in port areas. It is used by personnel of the Navigation Information and Services Department to update existing date and to provide better quality and more current charts, publications, and services pertaining to ports and port safety.

Affected Public: Business or other for-profit.

Frequency: On occasion.

Respondent's Obligation: Voluntary.

OMB Desk Officer: Mr. Edward C. Springer.

Written comments and recommendations on the proposed information collection should be sent to Mr. Springer at the Office of Management and Budget, Desk Officer for DoD, Room 10236, New Executive Office Building, Washington, DC 20503.

DOD Clearance Officer: Mr. William Pearce.

Written requests for copies of the information collection proposal should be sent to Mr. Pearce, WHS/DIOR, 1215 Jefferson Davis Highway, Suite 1204, Arlington, VA 22202–4302.

Dated: August 30, 1996.

Patricia L. Toppings,

Alternate OSD Federal Register Liaison Officer, Department of Defense.

[FR Doc. 96–22860 Filed 9–6–96; 8:45 am]

BILLING CODE 5000–04–M

Public Information Collection Requirement Submitted to the Office of Management and Budget (OMB) for Review

ACTION: Notice.

The Department of Defense has submitted to OMB for clearance, the following proposal for collection of information under the provisions of the Paperwork Reduction Act (44 U.S.C. Chapter 35).

Title, Applicable Form, and OMB Control Number: Notice to Mariners Information and Suggestion Sheet; DMA 8260–3; OMB Number 0704–0211.

Type of Request: Reinstatement, without change.

Number of Respondents: 520.

Responses Per Respondent: 1.

Annual Responses: 520.

Average Burden Per Response: 15 minutes.

Annual Burden Hours: 130.

Needs and Uses: Respondents to this information collection are mariners and navigators of merchant ships and vessels. The information collected hereby, is used to improve maritime safety. The identification or inconsistencies, discrepancies, and inadequacies of present nautical products enables personnel of the Navigation Information and Services Department in constructing and correcting safe navigational charts, publications, and services.

Affected Public: Business or other for-profit.

Frequency: On occasion.

Responent's Obligation: Voluntary.

OMB Desk Officer: Mr. Edward C. Springer.

Written comments and recommendations on the proposed information collection should be sent to Mr. Springer at the Office of Management and Budget, Desk Officer for DoD, Room 10236, New Executive Office Building, Washington, DC 20503.

Dod Clearance Officer: Mr. William Pearce.

Written requests for copies of the information collection proposal should be sent to Mr. Pearce, WHS/DIOR, 1215 Jefferson Davis Highway, Suite 1204, Arlington, VA 22202–4302.

Dated: August 30, 1996.

Patricia L. Toppings,

Alternate OSD Federal Register Liaison Officer, Department of Defense.

[FR Doc. 96–22861 Filed 9–6–96; 8:45 am]

BILLING CODE 5000–04–M

Public Information Collection Requirement Submitted to the Office of Management and Budget (OMB) for Review

ACTION: Notice.

The Department of Defense has submitted to OMB for clearance, the following proposal for collection of information under the provisions of the Paperwork Reduction Act (44 U.S.C. Chapter 35).

Title, Applicable Form, and OMB Control Number: Professional Qualification, Medical and Peer Reviewers; CHAMPUS Form 780; OMB Number 0720–0005.

Type of Request: Reinstatement, without change.

Number of Respondents: 20.

Responses Per Respondent: 1.

Annual Responses: 20.

Average Burden Per Response: 30 minutes.

Annual Burden Hours: 10.

Needs and Uses: The information collected hereby, is used as evidence of the qualifications of the medical professionals who provide medical and peer review in the CHAMPUS appeal and hearing process. Respondents to this information collection are the reviewing medical professionals, and the information provided is maintained in the respective appeal or hearing case file.

Affected Public: Business of other for-profit; Individuals or households.

Frequency: On occasion.

Respondent's Obligation: Voluntary.

OMB Desk Officer: Ms. Allison Eydt.

Written comments and recommendations on the proposed information collection should be sent to Ms. Eydt at the Office of Management and Budget, Desk Officer to DoD, Room 10235, New Executive Office Building, Washington, DC 20503.

DOD Clearance Officer: Mr. William Pearce.

Written requests for copies of the information collection proposal should be sent to Mr. Pearce, WHS/DIOR, 1215 Jefferson Davis Highway, Suite 1204, Arlington, VA 22202–4302.

Dated: September 3, 1996.

Patricia L. Toppings,

Alternate OSD Federal Register Liaison Officer, Department of Defense.

[FR Doc. 96–22863 Filed 9–6–96; 8:45 am]

BILLING CODE 5000–04–M

Department of the Navy

Privacy Act of 1974; Amend Record Systems

AGENCY: Department of the Navy, DOD.

ACTION: Amend Record Systems.

SUMMARY: The Department of the Navy proposes to amend twenty systems of records notice in its inventory of record systems subject to the Privacy Act of 1974 (5 U.S.C. 552a), as amended.

DATES: The amendments will be effective on October 9, 1996, unless comments are received that would result in a contrary determination.

ADDRESSES: Send comments to the Department of the Navy, PA/FOIA Policy Branch, Chief of Naval Operations (N09B30), 2000 Navy Pentagon, Washington, DC 20350–2000.

FOR FURTHER INFORMATION CONTACT: Mrs. Doris Lama at (202) 685–6545 or DSN 325–6545.

SUPPLEMENTARY INFORMATION: The Department of the Navy's record system notices for records systems subject to the Privacy Act of 1974 (5 U.S.C. 552a), as amended, have been published in the Federal Register and are available from the address above.

The Department of the Navy proposes to amend twenty systems of records notice in its inventory of record systems subject to the Privacy Act of 1974 (5 U.S.C. 552a), as amended.

The specific changes to the system of records are set forth below followed by the system of records notice published in its entirety, as amended. The amendments are not within the purview of subsection (r) of the Privacy Act of 1974 (5 U.S.C. 552a), as amended, which requires the submission of new or altered systems reports.

Dated: August 30, 1996.

Patricia L. Toppings,

Alternate OSD Federal Register Liaison Officer, Department of Defense.

N01070–3

SYSTEM NAME:

Navy Personnel Records System *(September 29, 1994, 59 FR 49648).*

CHANGES:

* * * * *

RETENTION AND DISPOSAL:

At end of entry add 'An exception is made for copies of officer fitness reports, enlisted evaluations, and officer and enlisted counseling forms which may be maintained by the member's commanding officer or command for a period not to exceed five years.'

* * * * *

N01070–3

SYSTEM NAME:

Navy Personnel Records System.

SYSTEM LOCATION:

Active duty records are located at the Bureau of Naval Personnel, 2 Navy Annex, Washington, DC 20370–5001; Naval Reserve Personnel Center, New Orleans, LA 70149–7800; and local activity to which individual is assigned. Official mailing addresses are published as an appendix to the Navy's compilation of system of record notices.

Secondary systems are located at the Department of the Navy Activities in the chain of command between the local activity and the headquarters level; Federal Records Storage Centers; National Archives. Official mailing addresses are published as an appendix to the Navy's compilation of system of record notices.

CATEGORIES OF INDIVIDUALS COVERED BY THE SYSTEM:

All Navy military personnel: officers, enlisted, active, inactive, reserve, fleet reserve, retired, midshipmen, officer candidates, and Naval Reserve Officer Training Corps personnel.

CATEGORIES OF RECORDS IN THE SYSTEM:

Personnel service jackets and service records, correspondence and records in both automated and non-automated form concerning classification, assignment, distribution, promotion, advancement, performance, recruiting, retention, reenlistment, separation, training, education, morale, personal affairs, benefits, entitlements, discipline and administration of naval personnel.

AUTHORITY FOR MAINTENANCE OF THE SYSTEM:

5 U.S.C. 301, Departmental Regulations and E.O. 9397.

PURPOSE(S):

To assist officials and employees of the Navy in the management, supervision and administration of Navy personnel (officer and enlisted) and the operations of related personnel affairs and functions.

ROUTINE USES OF RECORDS MAINTAINED IN THE SYSTEM, INCLUDING CATEGORIES OF USERS AND THE PURPOSES OF SUCH USES:

In addition to those disclosures generally permitted under 5 U.S.C. 552a(b) of the Privacy Act, these records or information contained therein may specifically be disclosed outside the DoD as a routine use pursuant to 5 U.S.C. 552a(b)(3) as follows:

To officials and employees of the National Research Council in Cooperative Studies of the National History of Disease; of Prognosis and of Epidemiology. Each study in which the records of members and former members of the naval service are used must be approved by the Chief of Naval Personnel.

To officials and employees of the Department of Health and Human Services, Department of Veteran Affairs, and Selective Service Administration in the performance of their official duties related to eligibility, notification and assistance in obtaining benefits by members and former members of the Navy.

To officials and employees of the Department of Veteran Affairs in the performance of their duties relating to approved research projects.

To officials and employees of Navy Relief and the American Red Cross in the performance of their duties relating to the assistance of the members and their dependents and relatives, or related to assistance previously furnished such individuals, without regard to whether the individual assisted or his/her sponsor continues to be a member of the Navy.

To duly appointed Family Ombudsmen in the performance of their duties related to the assistance of the members and their families.

To state and local agencies in the performance of their official duties related to verification of status for determination of eligibility for Veterans Bonuses and other benefits and entitlements.

To officials and employees of the Office of the Sergeant at Arms of the United States House of Representatives in the performance of their official duties related to the verification of the active duty naval service of Members of Congress.

Information as to current military addresses and assignments may be provided to military banking facilities who provide banking services overseas and who are reimbursed by the Government for certain checking and loan losses. For personnel separated, discharged or retired from the Armed Forces information as to last known residential or home of record address may be provided to the military banking facility upon certification by a banking facility officer that the facility has a returned or dishonored check negotiated by the individual or the individual has defaulted on a loan and that if restitution is not made by the individual the United States Government will be liable for the losses the facility may incur.

To federal, state, local, and foreign (within Status of Forces agreements) law enforcement agencies or their authorized representatives in connection with litigation, law enforcement, or other matters under the jurisdiction of such agencies.

Information relating to professional qualifications of chaplains may be provided to civilian certification boards and committees, including, but not limited to, state and federal licensing authorities and ecclesiastical endorsing organizations.

The 'Blanket Routine Uses' that appear at the beginning of the Navy's compilation of system of record notices also apply to this system.

POLICIES AND PRACTICES FOR STORING, RETRIEVING, ACCESSING, RETAINING, AND DISPOSING OF RECORDS IN THE SYSTEM:

STORAGE:

Automated records may be stored on magnetic tapes, disc, and drums. Manual records may be stored in paper file folders, microfiche or microfilm.

RETRIEVABILITY:

Automated records may be retrieved by name and Social Security Number. Manual records may be retrieved by name, Social Security Number, enlisted service number, or officer file number.

SAFEGUARDS:

Computer facilities and terminals are located in restricted areas accessible only to authorized persons that are properly screened, cleared and trained. Manual records and computer printouts are available only to authorized personnel having a need-to-know.

RETENTION AND DISPOSAL:

Records are retained one year past retirement, removal, or resignation of the member and then transferred to the National Personnel Records Center (Military Personnel Records), 9700 Page Avenue, St. Louis, MO 63132–5101 for permanent retention. An exception is made for copies of officer fitness reports, enlisted evaluations, and officer and enlisted counseling forms which may be maintained by the member's commanding officer or command for a period not to exceed five years.

SYSTEM MANAGER(S) AND ADDRESS:

Chief of Naval Personnel (Pers 06), Bureau of Naval Personnel, 2 Navy Annex, Washington, DC 20370–5001; Commanding Officers, Officers in Charge, and Heads of Department of the Navy activities. Official mailing addresses are published as an appendix to the Navy's compilation of system of record notices.

NOTIFICATION PROCEDURE:

Individuals seeking to determine whether this system of records contains information about themselves should address written inquiries to the Chief of Naval Personnel (Pers 06), Bureau of Naval Personnel, 2 Navy Annex, Washington, DC 20370–5001, or contact the personnel officer where assigned. Official mailing addresses are published as an appendix to the Navy's compilation of system of record notices.

The letter should contain full name, Social Security Number (and/or enlisted service number/officer file number), rank/rate, designator, military status, address, and signature of the requester.

The individual may visit the Chief of Naval Personnel, Bureau of Naval Personnel, 2 Navy Annex, Washington, DC 20370–5001, for assistance with records located in that building; or the individual may visit the local activity to which attached for access to locally maintained records. Proof of identification will consist of Military Identification Card for persons having such cards, or other picture-bearing identification.

RECORD ACCESS PROCEDURES:

Individuals seeking access to records about themselves contained in this system of records should address written inquiries to the Chief of Naval Personnel (Pers 06), Bureau of Naval Personnel, 2 Navy Annex, Washington, DC 20370–5001, or contact the personnel officer where assigned. Official mailing addresses are published as an appendix to the Navy's compilation of system of records notices.

The letter should contain full name, Social Security Number (and/or enlisted service number/officer file number), rank/rate, designator, military status, address, and signature of the requester.

The individual may visit the Chief of Naval Personnel (Pers 06), Bureau of Naval Personnel, 2 Navy Annex, Washington, DC 20370–5001, for assistance with records located in that building; or the individual may visit the local activity to which attached for access to locally maintained records. Proof of identification will consist of Military Identification Card for persons

having such cards, or other picture-bearing identification.

CONTESTING RECORD PROCEDURES:

The Navy's rules for accessing records, and for contesting contents and appealing initial agency determinations are published in Secretary of the Navy Instruction 5211.5; 32 CFR part 701; or may be obtained from the system manager.

RECORD SOURCE CATEGORIES:

Correspondence; educational institutions; federal, state, and local court documents; civilian and military investigatory reports; general correspondence concerning the individual; official records of professional qualifications; Navy Relief and American Red Cross requests for verification of status.

EXEMPTIONS CLAIMED FOR THE SYSTEM:

None.

N01080–1

SYSTEM NAME:

Enlisted Master File Automated System *(February 22, 1993, 58 FR 10705).*

* * * * *

SYSTEM LOCATION:

Delete entry and replace with 'Bureau of Naval Personnel, 2 Navy Annex, Washington, DC 20370–5001;

Enlisted Personnel Management Information Center, New Orleans, LA 70159–7800;

Naval Reserve Personnel Center, New Orleans, LA 70149–7800.'

* * * * *

RETENTION AND DISPOSAL:

Delete entry and replace with 'Permanent. Annually transferred to the National Archives under Group 24, Records of the Bureau of Naval Personnel.'

* * * * *

N01080–1

SYSTEM NAME:

Enlisted Master File Automated System.

SYSTEM LOCATION:

Bureau of Naval Personnel, 2 Navy Annex, Washington, DC 20370–5001;

Enlisted Personnel Management Information Center, New Orleans, LA 70159–7800;

Naval Reserve Personnel Center, New Orleans, LA 70149–7800.

CATEGORIES OF INDIVIDUALS COVERED BY THE SYSTEM:

All Navy enlisted personnel: active and inactive.

CATEGORIES OF RECORDS IN THE SYSTEM:

System contains information related to enlisted assignment, planning, programming, accounting, promotions, career development, procurement, education, training, retirement, performance, security, personal data, qualifications, programming, and enlisted reserve drill data. The system also contains Activity Personnel Diaries, personnel accounting documents, Reserve Unit Drill reports, and other personnel transaction documents necessary to maintain file accuracy and currency; and, all computer extracts, microform, and printed reports.

AUTHORITY FOR MAINTENANCE OF THE SYSTEM:

5 U.S.C. 301, Departmental Regulations and E.O. 9397.

PURPOSE(S):

To assist in the administration, management, and supervision of Navy enlisted personnel and the operation of personnel affairs and functions.

ROUTINE USES OF RECORDS MAINTAINED IN THE SYSTEM, INCLUDING CATEGORIES OF USERS AND THE PURPOSES OF SUCH USES:

In addition to those disclosures generally permitted under 5 U.S.C. 552a(b) of the Privacy Act, these records or information contained therein may specifically be disclosed outside the DoD as a routine use pursuant to 5 U.S.C. 552a(b)(3) as follows:

The 'Blanket Routine Uses' that appear at the beginning of the Navy's compilation of system of record notices apply to this system.

POLICIES AND PRACTICES FOR STORING, RETRIEVING, ACCESSING, RETAINING, AND DISPOSING OF RECORDS IN THE SYSTEM:

STORAGE:

Automated records are stored on magnetic tapes, disks, and drums. Printed reports and other related documents supporting the system are stored in authorized areas only.

RETRIEVABILITY:

Name and Social Security Number.

SAFEGUARDS:

Within the computer center, controls have been established to disseminate computer output over the counter only to authorized users. Specific procedures are also in force for the disposal of computer output. Output material in the sensitive category, i.e., inadvertent or unauthorized disclosure that may result in harm, embarrassment, inconvenience or unfairness to the individual, will be shredded. Computer files are kept in a secure, continuously manned area and are accessible only to authorized computer operators, programmers, enlisted management, placement, and distributing personnel who are directed to respond to valid official requests for data. These accesses are controlled and monitored by the security system.

RETENTION AND DISPOSAL:

Permanent. Annually transferred to the National Archives under Group 24, Records of the Bureau of Naval Personnel.

SYSTEM MANAGER(S) AND ADDRESS:

Chief of Naval Personnel, Navy Department, Washington, DC 20370–5000.

NOTIFICATION PROCEDURE:

Active duty enlisted personnel seeking to determine whether this system of records contains information about themselves should address written inquiries to the Chief of Naval Personnel (Pers 06), 2 Navy Annex, Washington, DC 20370–5001.

Inactive duty and reserve personnel seeking to determine whether this system of records contains information about themselves shall address written inquiries to the Commanding Officer, Naval Reserve Personnel Center (ATTN: Privacy Act Coordinator), New Orleans, LA 70149–7800.

Written request should contain full name, Social Security Number, rank, status, and signature of requester.

RECORD ACCESS PROCEDURES:

Individuals seeking access to records about themselves contained in this system of records should address written inquiries to the Chief of Naval Personnel (Pers 06), 2 Navy Annex, Washington, DC 20370–5001.

Inactive duty and reserve personnel seeking to determine whether this system of records contains information about themselves shall address written inquiries to the Commanding Officer, Naval Reserve Personnel Center (ATTN: Privacy Act Coordinator), New Orleans, LA 70149–7800.

Written request should contain full name, Social Security Number, rank, status, and signature of requester.

CONTESTING RECORD PROCEDURES:

The Navy's rules for accessing records, and for contesting contents and appealing initial agency determinations are published in Secretary of the Navy Instruction 5211.5; 32 CFR Part 701; or may be obtained from the system manager.

RECORD SOURCE CATEGORIES:

Official records, correspondence, and educational institutions.

EXEMPTIONS CLAIMED FOR THE SYSTEM:

None.

N01531–1

SYSTEM NAME:

USNA Applicants, Candidates, and Midshipmen Records *(September 20, 1993, 58 FR 48855).*

CHANGES:

* * * * *

SYSTEM LOCATION:

Delete entry and replace with 'U.S. Naval Academy, 117 Decatur Road, Annapolis, MD 21402–5017.

* * * * *

CATEGORIES OF RECORDS IN THE SYSTEM:

Add new paragraph 'Midshipmen separation files; midshipmen military justice files; midshipmen JAGMAN investigations; midshipmen personnel claim files; and midshipmen honor records.'

* * * * *

ROUTINE USES OF RECORDS MAINTAINED IN THE SYSTEM, INCLUDING CATEGORIES OF USERS AND THE PURPOSES OF SUCH USES:

Replace second paragraph with 'Parents and legal guardians of midshipmen for the limited purpose of counseling midshipmen who encounter academic, performance and/or disciplinary difficulties, as well as health and welfare issues.

At the end of the fourth paragraph, add the following, 'and for the purpose of supporting its activities related to the mission of the Naval Academy.'

* * * * *

RETENTION AND DISPOSAL:

In paragraph three, line four, delete 'copy;', and replace with 'copy. A tape is sent to the National Archives two years after class graduates to be stored as a national disaster recovery measure.'

* * * * *

N01531–1

SYSTEM NAME:

USNA Applicants, Candidates, and Midshipmen Records.

SYSTEM LOCATION:

U.S. Naval Academy, 117 Decatur Road, Annapolis, MD 21402–5017.

CATEGORIES OF INDIVIDUALS COVERED BY THE SYSTEM:

Applicants and candidates for admission and Naval Academy Midshipmen.

CATEGORIES OF RECORDS IN THE SYSTEM:

Admissions records contain pre-candidate questionnaires concerning educational background, personal data, physical data, extracurricular activities, and employment; personal data; personal statements; transcripts from previously attended academic institutions; admission tests results; physical aptitude exam results; recommendation letters from school officials and others; professional development tests; interest inventory; extracurricular activities reports; reports of officer interviews; records of prior military service; and, Privacy Act disclosure forms. Nomination and appointment records include all card files of congressional offices and the names of persons whom each congressman appointed; files of candidates nominated for the following academic year; status cards, indexed by nominating source of all candidates appointed, admitted, and graduated, or resigned prior to graduation. Similar files are separately kept on foreign candidates.

Performance jackets and academic records include performance aptitude evaluations, performance grades, personal history, autobiography, record of emergency data, aptitude history, review boards records, medical excuse from duty forms, conduct records and grades, professional development tests, counseling and guidance development tests, counseling and guidance interview sheets and data forms, academic grades, class rankings, letters of commendation, training records, Oath of Office, Agreement to Serve, Privacy Act disclosure forms and other such records and information relative to the midshipmen.

Midshipmen separation files; midshipmen military justice files; midshipmen JAGMAN investigations; midshipmen personnel claim files; and midshipmen honor records.

AUTHORITY FOR MAINTENANCE OF THE SYSTEM:

5 U.S.C. 301, Departmental Regulations; 10 U.S.C. 6956, 6957, 6958, 6962, and 6963; 44 U.S.C. 3101; and E.O. 9397.

PURPOSE(S):

To establish an audit trail of files which contains information on individuals as they progress from the application stage, through the admissions process, to disenrollment or graduation from the Naval Academy. Applicant's files contain information which is used to evaluate and to determine competitive standing and eligibility for appointments to the Naval Academy. Successful applicants become candidates whose files contain information to evaluate further each candidate's eligibility. Candidates' files are also used to identify candidates profiles for initiation of formal officer accession programs in conjunction with the Naval Academy admission process. Successful candidates who accept appointments become midshipmen. Midshipmen records contain personal, academic, and professional background information and are used for the management, supervision, administration, counseling, and discipline of midshipmen.

ROUTINE USES OF RECORDS MAINTAINED IN THE SYSTEM, INCLUDING CATEGORIES OF USERS AND THE PURPOSES OF SUCH USES:

In addition to those disclosures generally permitted under 5 U.S.C. 552a(b) of the Privacy Act, these records or information contained therein may specifically be disclosed outside the DoD as a routine use pursuant to 5 U.S.C. 552a(b)(3) as follows:

Parents and legal guardians of midshipmen for the limited purpose of counseling midshipmen who encounter academic, performance and/or disciplinary difficulties, as well as health and welfare issues.

The United States Naval Institute for the limited purpose of notifying midshipmen and their parents about benefits and opportunities provided by the United States Naval Institute.

The Naval Academy Athletic Association for the limited purpose of promoting and funding the Naval Academy Intercollegiate Athletic Program and for the purpose of supporting its activities related to the mission of the Naval Academy.

The United States Naval Academy Foundation for the limited purpose of sponsoring midshipmen candidates who were not admitted in previous years.

The United States Naval Academy Alumni Association for the limited purpose of supporting its activities related to the mission of the Naval Academy.

The Contract Tailor Shop for the limited purpose of scheduling appointments as required for uniform fittings.

The 'Blanket Routine Uses' that appear at the beginning of the Navy's compilation of systems of records notices apply to this system.

POLICIES AND PRACTICES FOR STORING, RETRIEVING, ACCESSING, RETAINING, AND DISPOSING OF RECORDS IN THE SYSTEM:

STORAGE:

All hard copy records are kept in file folders in secure rooms or in locked cabinets.

On-line storage is maintained on the Honeywell DPS8 mainframe in Computer Services, with line networking to VACs and interfacing with microcomputers and dial-up lines.

Off-line storage is kept on disks.

Records on magnetic tapes and hard copy data are kept in secured rooms or in locked cabinets for operator access and user pickup.

Backup magnetic tapes are kept in a vault.

RETRIEVABILITY:

Records are kept alphabetically by Company and Class. Records can be retrieved from data base by selection of any data element, i.e., name, address, alpha code, six digit candidate number, or Social Security Number, etc.

SAFEGUARDS:

Visitor control. Records are kept in locked cabinets or in secured rooms. Computer records are safeguarded through selective file access, signing of Privacy Act forms, passwords, RAM systems, program passwords, user controls, encoding and port controls. Disk and tape storage is in a secure room. Backup systems on magnetic tapes are secured in fire proof vault in Ward Hall.

RETENTION AND DISPOSAL:

On-line computer records are destroyed one year after the midshipman's class graduates or the midshipman is separated.

Performance records are retained by the Performance Officer for two years after the midshipman's class graduates, and then destroyed. Backup systems on magnetic tapes and disks are kept in secure storage and destroyed two years after the midshipman's class graduates. Files relative to midshipmen separated involuntarily, including by qualified resignation, are retained for two years after the midshipman's class graduates, or three years from the date of separation, whichever date is later, and then destroyed.

Official transcripts and records files are kept indefinitely by the Registrar on microfilm, computer files, magnetic tapes, and hard copy. A tape is sent to the National Archives two years after class graduates to be stored as a national disaster recovery measure. Admission records of unsuccessful candidates are properly destroyed after one year. Counseling and Guidance Research data are kept by the Professional Development Research Coordinator indefinitely. Nomination and appointment files are retained for varying lengths of time.

SYSTEM MANAGER(S) AND ADDRESS:

Superintendent, U.S. Naval Academy, 121 Blake Road, Annapolis, MD 21402–5000.

NOTIFICATION PROCEDURE:

Individuals seeking to determine whether information about themselves is contained in this system should address written inquiries to the Superintendent, U.S. Naval Academy, 121 Blake Road, Annapolis, MD 21402–5000.

Written requests should contain full name, company, class, and any personal identifier, such as a Social Security Number.

RECORD ACCESS PROCEDURES:

Individuals seeking access to information about themselves contained in this system should address written inquiries to the Superintendent, U.S. Naval Academy, 121 Blake Road, Annapolis, MD 21402–5000.

Written requests should contain full name, company, class, and any personal identifier, such as a Social Security Number.

CONTESTING RECORD PROCEDURES:

The Navy's rules for accessing records, and for contesting contents and appealing initial agency determinations are published in Secretary of the Navy Instruction 5211.5; 32 CFR part 701; or may be obtained from the system manager.

RECORD SOURCE CATEGORIES:

Individuals, midshipman, supervisors, Registrar, instructors, professors, officers, midshipman personal history/performance record, midshipman autobiography, Record of Emergency Data (NAVPERS 601–2), Statement of Personal History (DD Form 398), Aptitude History Record (Form 1610–105), Midshipman Summary Sheet, Certificate of Release or Discharge From Active Duty (DD Form 214), Military Performance Board Results, Letters of Probation, Midshipmen Performance Evaluation Reports (Form 54A), Medical Reports, Clinical Psychologist Reports, Excused Squad Chits (Form 6320/20), Conduct Card (Form 1690/91C), Letters of Commendation, Counseling and Guidance Interview and Data Records, Letters of Congressmen, parents, etc., and copies of replies thereto, transcripts from high school or prior college, Review Board Records, and Record of Disclosure (Privacy Act).

EXEMPTIONS CLAIMED FOR THE SYSTEM:

None.

N01710–1

SYSTEM NAME:

Special Membership Listing of the Organizational Recreation Association *(February 22, 1993, 58 FR 10721).*

CHANGES:

* * * * *

SYSTEM NAME:

Delete entry and replace with 'Recreation Association Membership Files.'

* * * * *

CATEGORIES OF INDIVIDUALS COVERED BY THE SYSTEM:

Delete entry and replace with 'Name, rank, Social Security Number, room and telephone number, membership card number and dates purchased.'

* * * * *

STORAGE:

Delete entry and replace with 'File folders, card files, magnetic tape, personal computer.'

* * * * *

SAFEGUARDS:

Delete entry and replace with 'Password control system, file, and element access based on predefined need-to-know. Physical access is controlled by locked terminals and rooms, guards, personnel screening and visitor control.'

RETENTION AND DISPOSAL:

Delete entry and replace with 'Records are destroyed one year after individual terminates membership.'

SYSTEM MANAGER(S) AND ADDRESS:

Delete entry and replace with 'Policy Official: Chief of Naval Personnel (Pers-06), Bureau of Naval Personnel, 2 Navy Annex, Washington, DC 20370–5001.

System Manager: Commanding officer of the activity in question. Official mailing addresses are published as an appendix to the Navy's compilation of systems of records notices.'

* * * * *

RECORD SOURCE CATEGORIES:

Delete entry and replace with 'Individual.'

* * * * *

N01710–1

SYSTEM NAME:

Recreation Association Membership Files.

SYSTEM LOCATION:

Organizational elements of the Department of the Navy. Official mailing addresses are published as an appendix to the Navy's compilation of systems of records notices.

CATEGORIES OF INDIVIDUALS COVERED BY THE SYSTEM:

Name, rank, social security number, room and telephone number,

membership card number and dates purchased.

CATEGORIES OF RECORDS IN THE SYSTEM:

This record lists the names, internal codes, room and telephone numbers of each membership card and dates purchased.

AUTHORITY FOR MAINTENANCE OF THE SYSTEM:

5 U.S.C. 301, Departmental Regulations and E.O. 9397.

PURPOSE(S):

To indicate income from sale of membership cards; to provide an audit trial for the auditors; and to confirm memberships, upon request.

ROUTINE USES OF RECORDS MAINTAINED IN THE SYSTEM, INCLUDING CATEGORIES OF USERS AND THE PURPOSES OF SUCH USES:

In addition to those disclosures generally permitted under 5 U.S.C. 552a(b) of the Privacy Act, these records or information contained therein may specifically be disclosed outside the DoD as a routine use pursuant to 5 U.S.C. 552a(b)(3) as follows:

The 'Blanket Routine Uses' that appear at the beginning of the Navy's compilation of systems of records notices apply to this system.

POLICIES AND PRACTICES FOR STORING, RETRIEVING, ACCESSING, RETAINING, AND DISPOSING OF RECORDS IN THE SYSTEM:

STORAGE:

File folders, card files, magnetic tape, personal computer.

RETRIEVABILITY:

Name, Social Security Number, Case number, organization.

SAFEGUARDS:

Password control system, file, and element access based on predefined need-to-know. Physical access is controlled by locked terminals and rooms, guards, personnel screening and visitor control.

RETENTION AND DISPOSAL:

Records are destroyed one year after individual terminates membership.

SYSTEM MANAGER(S) AND ADDRESS:

Policy Official: Chief of Naval Personnel (Pers-06), Bureau of Naval Personnel, 2 Navy Annex, Washington, DC 20370–5001.

System Manager: Commanding officer of the activity in question. Official mailing addresses are published as an appendix to the Navy's compilation of systems of records notices.

NOTIFICATION PROCEDURE:

Individuals seeking to determine whether information about themselves is contained in this system should address written inquiries to the Commanding officer of the activity in question. Official mailing addresses are published as an appendix to the Navy's compilation of systems of records notices.

RECORD ACCESS PROCEDURES:

Individuals seeking access to information about themselves contained in this system should address written inquiries to the Commanding officer of the activity in question. Official mailing addresses are published as an appendix to the Navy's compilation of systems of records notices.

CONTESTING RECORD PROCEDURES:

The Navy's rules for accessing records, and for contesting contents and appealing initial agency determinations are published in Secretary of the Navy Instruction 5211.5; 32 CFR part 701; or may be obtained from the system manager.

RECORD SOURCE CATEGORIES:

Individual.

EXEMPTIONS CLAIMED FOR THE SYSTEM:

None.

N01770–3

SYSTEM NAME:

Naval Academy Cemetery and Columbarium Records *(September 20, 1993, 58 FR 48857).*

CHANGES:

* * * * *

SYSTEM LOCATION:

Delete entry and replace with, 'Security Department and Public Works Department, U.S. Naval Academy, 257 Longshaw Road, Annapolis, MD 21402–5036.'

* * * * *

N01770–3

SYSTEM NAME:

Naval Academy Cemetery and Columbarium Records.

SYSTEM LOCATION:

Security Department and Public Works Department, U.S. Naval Academy, 257 Longshaw Road, Annapolis, MD 21402–5036.

CATEGORIES OF INDIVIDUALS COVERED BY THE SYSTEM:

Those eligible to reserve a lot for future burial in the Naval Academy Cemetery. Deceased individuals interred/inured in the Naval Academy Cemetery/Columbarium.

CATEGORIES OF RECORDS IN THE SYSTEM:

State Burial Transit Permit, Application for Reimbursement of Headstone or Marker Expenses (VA Form 21–8834), Application of Standard Government Headstone or Marker for Installation in a Private or Local Cemetery (VA Form 40–1330), Lot Marker (NDW–USNA–DMC–1170/08), Columbarium Niche Cover Inscription (NDW–USNA–DMC–5370/42), U.S. Naval Academy Internment/Inurement Record (NDW–USNA–DMC–5360/43), U.S. Naval Academy Cemetery Record (NDW–USNA–DMC–1170/46), Naval Academy Foundation Order (NDW–USNA–DMC–5360/09), and correspondence to and from individuals. Specifically, information contained on the forms or correspondence may be: Full name, home address, rank, service, Social Security Number, date and place of birth, date and place of death, marital status, name of father and mother, name of next of kin and their address, telephone number, date of birth and date of death (if applicable), date and place of burial, lot number and other information relating to burial arrangements.

AUTHORITY FOR MAINTENANCE OF THE SYSTEM:

5 U.S.C. 301, Departmental Regulations; 10 U.S.C. 1481–1488; 44 U.S.C. 3101; and E.O. 9397.

PURPOSE(S):

To maintain official records of individuals holding grave site reservations and/or individuals interred/inured in the Naval Academy Cemetery or Columbarium. Records are used to respond to general inquiries from individuals holding grave site reservations, to verify eligibility of spouses of an officer or enlisted person of the Navy or Marine Corps who is interred/inured in the Naval Academy Cemetery or Columbarium.

ROUTINE USES OF RECORDS MAINTAINED IN THE SYSTEM, INCLUDING CATEGORIES OF USERS AND THE PURPOSES OF SUCH USES:

In addition to those disclosures generally permitted under 5 U.S.C. 552a(b) of the Privacy Act, these records or information contained therein may specifically be disclosed outside the DoD as a routine use pursuant to 5 U.S.C. 552a(b)(3) as follows:

The 'Blanket Routine Uses' that appear at the beginning of the Navy's compilation of systems of records notices apply to this system.

POLICIES AND PRACTICES FOR STORING, RETRIEVING, ACCESSING, RETAINING, AND DISPOSING OF RECORDS IN THE SYSTEM:

STORAGE:

Paper records in file folders and microfiche.

RETRIEVABILITY:

Alphabetically by last name and numerically by lot number.

SAFEGUARDS:

Records are kept in a building not open to general visiting and are maintained in an area accessible only to authorized personnel. Building is under surveillance of security personnel during non-working hours. Microfiche records are kept in the Naval Academy Archives which is not open to general visiting and is locked during non-working hours.

RETENTION AND DISPOSAL:

Records are permanent. They are retained after the individual is deceased.

SYSTEM MANAGER(S) AND ADDRESS:

Superintendent, U.S. Naval Academy, 121 Blake Road, Annapolis, MD 21402–5000.

NOTIFICATION PROCEDURE:

Individuals seeking to determine whether information about themselves is contained in this system should address written inquiries to the Superintendent, U.S. Naval Academy, 121 Blake Road, Annapolis, MD 21402–5000. Requests should contain name and Social Security Number of the individual concerned.

RECORD ACCESS PROCEDURES:

Individuals seeking access to information about themselves contained in this system should address written inquiries to the Superintendent, U.S. Naval Academy, 121 Blake Road, Annapolis, MD 21402–5000.

CONTESTING RECORD PROCEDURES:

The Navy's rules for accessing records, and for contesting contents and appealing initial agency determinations are published in Secretary of the Navy Instruction 5211.5; 32 CFR part 701; or may be obtained from the system manager.

RECORD SOURCE CATEGORIES:

Information in this system comes from the individual to whom it applies, the next of kin, and from the Register of the Alumni.

EXEMPTIONS CLAIMED FOR THE SYSTEM:

None.

N01900–2

SYSTEM NAME:

Navy Individual Service Review Board (ISRB) Proceedings Application File *(November 10, 1993, 58 FR 59712).*

CHANGES:

* * * * *

STORAGE:

Delete entry and replace with 'Paper records in file folders.'

* * * * *

SAFEGUARDS:

In lines three and six, delete the word 'Command' and replace with 'Bureau'.

RETENTION AND DISPOSAL:

Delete entry and replace with 'Applications which are approved will necessitate creation of a service record which is part of the Navy Personnel Records System. Remaining records are retained in the Bureau of Naval Personnel for two years and then destroyed.'

* * * * *

N01900–2

SYSTEM NAME:

Navy Individual Service Review Board (ISRB) Proceedings Application File.

SYSTEM LOCATION:

Bureau of Naval Personnel (Pers 324), 2 Navy Annex, Washington, DC 20370–3240.

CATEGORIES OF INDIVIDUALS COVERED BY THE SYSTEM:

Individuals who have applied for military status and subsequent discharge from the United States Navy because they claim membership in a group which has been determined to have performed active military service with the United States Navy.

CATEGORIES OF RECORDS IN THE SYSTEM:

Application for discharge, supporting documentation, copies of correspondence between the individual and the Navy ISRB and other correspondence concerning the case.

AUTHORITY FOR MAINTENANCE OF THE SYSTEM:

Pub.L. 95–202 and E.O. 9397.

PURPOSE(S):

To consider the individual's application for military status and discharge.

ROUTINE USES OF RECORDS MAINTAINED IN THE SYSTEM, INCLUDING CATEGORIES OF USERS AND THE PURPOSES OF SUCH USES:

In addition to those disclosures generally permitted under 5 U.S.C. 552a(b) of the Privacy Act, these records or information contained therein may specifically be disclosed outside the DoD as a routine use pursuant to 5 U.S.C. 552a(b)(3) as follows:

The 'Blanket Routine Uses' that appear at the beginning of the Navy's compilation of systems of records notices apply to this system.

POLICIES AND PRACTICES FOR STORING, RETRIEVING, ACCESSING, RETAINING, AND DISPOSING OF RECORDS IN THE SYSTEM:

STORAGE:

Paper records in file folders.

RETRIEVABILITY:

Name and Social Security Number.

SAFEGUARDS:

The files are kept within the Bureau of Naval Personnel offices. Access during business hours is controlled by Bureau personnel. Records not in use are maintained in a room which is locked during non-duty hours. The Bureau is secured at the close of business and the building in which the command is located has limited access controlled by security guards.

RETENTION AND DISPOSAL:

Applications which are approved will necessitate creation of a service record which is part of the Navy Personnel Records System. Remaining records are retained in the Bureau of Naval Personnel for two years and then destroyed.

SYSTEM MANAGER(S) AND ADDRESS:

Chief of Naval Personnel (Pers 324), Bureau of Naval Personnel, 2 Navy Annex, Washington, DC 20370–3240.

NOTIFICATION PROCEDURE:

Individuals seeking to determine whether information about themselves is contained in this system should address written inquiries to the Chief of Naval Personnel (Code Pers 324), Bureau of Naval Personnel, 2 Navy Annex, Washington, DC 20370–3240.

RECORD ACCESS PROCEDURES:

Individuals seeking access to information about themselves contained in this system should address written inquiries to the Chief of Naval Personnel (Code Pers 324), Bureau of Naval Personnel, 2 Navy Annex, Washington, DC 20370–3240.

CONTESTING RECORD PROCEDURES:

The Navy's rules for accessing records, and for contesting contents and appealing initial agency determinations are published in Secretary of the Navy Instruction 5211.5; 32 CFR part 701; or may be obtained from the system manager.

RECORD SOURCE CATEGORIES:

Information contained in the files is obtained from the individual or those acting on the individual's behalf, from other military records and from the Department of Defense Civilian/Military Service Review Board.

EXEMPTIONS CLAIMED FOR THE SYSTEM:

None.

N04064–1

SYSTEM NAME:

USNA Laundry and Drycleaning Charge Account *(September 20, 1993, 58 FR 48861).*

CHANGES:

* * * * *

SYSTEM LOCATION:

Delete entry and replace with 'Laundry and Drycleaning Plant, U.S. Naval Academy, 580 Kingwood Street, Annapolis, MD 21402–5052.'

* * * * *

SYSTEM MANAGER(S) AND ADDRESS:

Delete entry and replace with 'Head, Laundry and Drycleaning Plant, U.S. Naval Academy, 580 Kingwood Street, Annapolis, MD 21402–5052.'

* * * * *

N04064–1

SYSTEM NAME:

USNA Laundry and Drycleaning Charge Account.

SYSTEM LOCATION:

Laundry and Drycleaning Plant, U.S. Naval Academy, 580 Kingwood Street, Annapolis, MD 21402–5052.

CATEGORIES OF INDIVIDUALS COVERED BY THE SYSTEM:

Individuals who have applied for a charge account with the Naval Academy Laundry and Drycleaning Plant.

CATEGORIES OF RECORDS IN THE SYSTEM:

Information is collected on Form NDW-USNA-DMH–4064/14 and includes applicant's name; Social Security Number; rank (if applicable); branch of service; home and work addresses and telephone numbers. Information required to maintain the charge account records is obtained from and/or recorded on accounts receivable ledgers, journals, charge tickets and check listings.

AUTHORITY FOR MAINTENANCE OF THE SYSTEM:

5 U.S.C. 301, Departmental Regulations; 44 U.S.C. 3101; and E.O. 9397.

PURPOSE(S):

To establish a charge account at the Naval Academy Laundry and Drycleaning Plant. Information will be used for billing purposes by the officials and employees of the Plant.

ROUTINE USES OF RECORDS MAINTAINED IN THE SYSTEM, INCLUDING CATEGORIES OF USERS AND THE PURPOSES OF SUCH USES:

In addition to those disclosures generally permitted under 5 U.S.C. 552a(b) of the Privacy Act, these records or information contained therein may specifically be disclosed outside the DoD as a routine use pursuant to 5 U.S.C. 552a(b)(3) as follows:

The 'Blanket Routine Uses' that appear at the beginning of the Navy's compilation of systems of records notices apply to this system.

POLICIES AND PRACTICES FOR STORING, RETRIEVING, ACCESSING, RETAINING, AND DISPOSING OF RECORDS IN THE SYSTEM:

STORAGE:

Hard copy and magnetic minicassette tape form.

RETRIEVABILITY:

Name.

SAFEGUARDS:

Access to building is restricted to authorized persons only. Record files are not available to personnel not requiring access in the performance of their official duties. This is routinely limited to the billing clerk processing the application and recording activity on the account. Records are secured within a locked office in a locked building on a military installation when not actually in use.

RETENTION AND DISPOSAL:

Hard copy records are retained in the current file area as long as the charge account is active. These records are then retired and kept in secured storage for two years and then destroyed. Cassette tape records are of two types, daily and journal (monthly recapitulation). These tapes are erased on a daily or monthly basis, respectively, during the preparation of the following day's or month's activity record.

SYSTEM MANAGER(S) AND ADDRESS:

Head, Laundry and Drycleaning Plant, U.S. Naval Academy, 580 Kingwood Street, Annapolis, MD 21402–5052.

NOTIFICATION PROCEDURE:

Individuals seeking to determine whether this system of records contains information about themselves should address written inquiries to the Head, Laundry and Drycleaning Plant, U.S. Naval Academy, 580 Kingwood Street, Annapolis, MD 21402–5052.

Requesting individuals should specify their full names. Visitors should be able to identify themselves by any commonly recognized evidence of identity. Written requests must be signed by the requesting individual.

RECORD ACCESS PROCEDURES:

Individuals seeking access to records about themselves should address written inquiries to the Head, Laundry and Drycleaning Plant, U.S. Naval Academy, 580 Kingwood Street, Annapolis, MD 21402–5052.

Requesting individuals should specify their full names. Visitors should be able to identify themselves by any commonly recognized evidence of identity. Written requests must be signed by the requesting individual.

CONTESTING RECORD PROCEDURES:

The Navy's rules for accessing records, and for contesting contents and appealing initial agency determinations are published in Secretary of the Navy Instruction 5211.5; 32 CFR part 701; or may be obtained from the system manager.

RECORD SOURCE CATEGORIES:

Information in this system comes from the individual applying for the charge account, from daily laundry and drycleaning will-call tickets (charges for goods and services provided) and from records of payment by charge account holders (check listings).

EXEMPTIONS CLAIMED FOR THE SYSTEM:

None.

N04064–2

SYSTEM NAME:

USNA Retail Customer Claim Record *(September 20, 1993, 58 FR 48861).*

CHANGES:

* * * * *

SYSTEM LOCATION:

Delete entry and replace with 'Laundry and Drycleaning Plant, U.S. Naval Academy, 580 Kingwood Street, Annapolis, MD 21402–5052.'

* * * * *

SYSTEM MANAGER(S) AND ADDRESS:

Delete entry and replace with 'Head, Laundry and Drycleaning Plant, U.S. Naval Academy, 580 Kingwood Street, Annapolis, MD 21402–5052.'

* * * * *

N04064–2

SYSTEM NAME:

USNA Retail Customer Claim Record.

SYSTEM LOCATION:

Laundry and Drycleaning Plant, U.S. Naval Academy, 580 Kingwood Street, Annapolis, MD 21402–5052.

CATEGORIES OF INDIVIDUALS COVERED BY THE SYSTEM:

Individuals who have filed claims against the Naval Academy Laundry and Drycleaning Plant and appropriation 17X4002 for cash or credit settlement for damaged or lost articles.

CATEGORIES OF RECORDS IN THE SYSTEM:

Information is collected on Form NDW-USNA-DMH–4064/15 and includes claimant's name; Social Security Number; rank (if applicable); home and work addresses and telephone numbers; description, original cost and date of purchase of item(s) for which claim is filed, and circumstances of loss or extent of damage; claim number, disposition, and remarks by approving authority.

AUTHORITY FOR MAINTENANCE OF THE SYSTEM:

5 U.S.C. 301, Departmental Regulations; 44 U.S.C. 3101; and E.O. 9397.

PURPOSE(S):

To investigate claims for cash or credit settlement for damaged or lost articles.

ROUTINE USES OF RECORDS MAINTAINED IN THE SYSTEM, INCLUDING CATEGORIES OF USERS AND THE PURPOSES OF SUCH USES:

In addition to those disclosures generally permitted under 5 U.S.C. 552a(b) of the Privacy Act, these records or information contained therein may specifically be disclosed outside the DoD as a routine use pursuant to 5 U.S.C. 552a(b)(3) as follows:

The 'Blanket Routine Uses' that appear at the beginning of the Navy's compilation of systems of records notices apply to this system.

POLICIES AND PRACTICES FOR STORING, RETRIEVING, ACCESSING, RETAINING, AND DISPOSING OF RECORDS IN THE SYSTEM:

STORAGE:

Hard copy form.

RETRIEVABILITY:

Name of customer and date laundry was turned in for cleaning.

SAFEGUARDS:

Access to building is restricted to authorized persons only. Record files are not available to personnel not requiring access in the performance of their official duties. This is limited to the official processing of the claim and the clerk who maintains the file and prepares the administrative paperwork. Records are secured within a locked office in a locked building on a military installation when not actually in use.

RETENTION AND DISPOSAL:

Retained in the current file area for one calendar year after the close of the individual's claim. The record is then stored for one more year and then destroyed.

SYSTEM MANAGER(S) AND ADDRESS:

Head, Laundry and Drycleaning Plant, U.S. Naval Academy, 580 Kingwood Street, Annapolis, MD 21402–5052.

NOTIFICATION PROCEDURE:

Individuals seeking to determine whether this system of records contains information about themselves should address written inquiries to the Head, Laundry and Drycleaning Plant, U.S. Naval Academy, 580 Kingwood Street, Annapolis, MD 21402–5052.

Requesting individuals should specify their full names. Visitors should be able to identify themselves by any commonly recognized evidence of identity. Written requests must be signed by the requesting individual.

RECORD ACCESS PROCEDURES:

Individuals seeking access to records about themselves should address written inquiries to the Head, Laundry and Drycleaning Plant, U.S. Naval Academy, 580 Kingwood Street, Annapolis, MD 21402–5052.

Requesting individuals should specify their full names. Visitors should be able to identify themselves by any commonly recognized evidence of identity. Written requests must be signed by the requesting individual.

CONTESTING RECORD PROCEDURES:

The Navy's rules for accessing records, and for contesting contents and appealing initial agency determinations are published in Secretary of the Navy Instruction 5211.5; 32 CFR part 701; or may be obtained from the system manager.

RECORD SOURCE CATEGORIES:

Individual who filed the claim and offices who are processing the claim.

EXEMPTIONS CLAIMED FOR THE SYSTEM:

None.

N04066–5

SYSTEM NAME:

NEXCOM Direct Mail List *(September 20, 1993, 58 FR 48866).*

CHANGES:

* * * * *

SYSTEM NAME:

Delete entry and replace with 'NEXCOM Direct Mail List/Patron Profile.'

* * * * *

CATEGORIES OF INDIVIDUALS COVERED BY THE SYSTEM:

Delete entry and replace with 'All authorized customers of military resale systems.'

CATEGORIES OF RECORDS IN THE SYSTEM:

Delete entry and replace with 'For each sponsor: Name, address, rank, branch of service, status (active, reserve, or retired), Social Security Number, pay grade, birth date, sex, race, names, birth dates, and Social Security Numbers of dependents, date of sign up, telephone number (if available), account number, rotation date (if available), mailings sent and responses (if available).

For all other authorized customers: Name, address, Social Security Number, birth date, sex, race, date of sign up, telephone number (if available), account number, mailings sent to customer and responses available, purchase history, preference and summary. Sponsor information (rank, branch of service, status (active, reserve or retired), Social Security Number, pay grade, birth date, sex, race, account number.)

PURPOSE(S):

In line 7, delete the words 'who sign up for the list in order'.

* * * * *

STORAGE:

Delete entry and replace with 'Electronic media.'

* * * * *

SAFEGUARDS:

At end of entry, add '/password protected.'

RETENTION AND DISPOSAL:

Delete lines 3 and 4 and replace with 'patron profiles are destroyed when no longer an authorized customer.'

SYSTEM MANAGER(S) AND ADDRESS:

In paragraph 2, delete 'Deputy Commander, Marketing Communications Division (MCD)' and replace with 'Director, Advertising,'.

* * * * *

RECORD SOURCE CATEGORIES:

Delete entry and replace with 'The individual authorized customer/sponsor, Department of Defense/Defense Enrollment Eligibility Reporting System and Defense Finance Accounting System.'

* * * * *

N04066–5

SYSTEM NAME:

NEXCOM Direct Mail List/Patron Profile.

SYSTEM LOCATION:

Navy Exchange Service Command, 3280 Virginia Beach Boulevard, Virginia Beach, VA 23452–5724.

CATEGORIES OF INDIVIDUALS COVERED BY THE SYSTEM:

All authorized customers of military resale systems.

CATEGORIES OF RECORDS IN THE SYSTEM:

For each sponsor: Name, address, rank, branch of service, status (active, reserve, or retired), Social Security Number, pay grade, birth date, sex, race, names, birth dates, and Social Security Numbers of dependents, date of sign up, telephone number (if available), account number, rotation date (if available), mailings sent and responses (if available).

For all other authorized customers: Name, address, Social Security Number, birth date, sex, race, date of sign up, telephone number (if available), account number, mailings sent to customer and responses available, purchase history, preference and summary. Sponsor information (rank, branch of service, status (active, reserve or retired), Social Security Number, pay grade, birth date, sex, race, account number.)

AUTHORITY FOR MAINTENANCE OF THE SYSTEM:

5 U.S.C. 301, Departmental Regulations; 10 U.S.C. 6011; and E.O. 9397.

PURPOSE(S):

To maintain a data base which will permit the Navy Exchange Program to mail sales promotional, informational and market research materials to those authorized customers who have requested receipt of materials. The data base will also be used to define target markets among the authorized customers to develop better merchandise assortments and services to meet the needs of the customers.

ROUTINE USES OF RECORDS MAINTAINED IN THE SYSTEM, INCLUDING CATEGORIES OF USERS AND THE PURPOSES OF SUCH USES:

In addition to those disclosures generally permitted under 5 U.S.C. 552a(b) of the Privacy Act, these records or information contained therein may specifically be disclosed outside the DoD as a routine use pursuant to 5 U.S.C. 552a(b)(3) as follows:

The 'Blanket Routine Uses' that appear at the beginning of the Navy's compilation of systems notices apply to this system.

POLICIES AND PRACTICES FOR STORING, RETRIEVING, ACCESSING, RETAINING, AND DISPOSING OF RECORDS IN THE SYSTEM:

STORAGE:

Electronic media.

RETRIEVABILITY:

Name, Social Security Number, address and account number.

SAFEGUARDS:

Secured and supervised facility; access restricted/password protected.

RETENTION AND DISPOSAL:

The records are retained as long as the customer wishes to receive the materials, then the patron profiles are destroyed when no longer an authorized customer.

SYSTEM MANAGER(S) AND ADDRESS:

Policy Official: Commander, Navy Exchange Service Command, 3280 Virginia Beach Boulevard, Virginia Beach, VA 23452–5724.

Record Holder Manager: Director, Advertising, Navy Exchange Service Command, 3280 Virginia Beach Boulevard, Virginia Beach, VA 23452–5724.

NOTIFICATION PROCEDURE:

Individuals seeking to determine whether this system of records contains information about themselves should address written inquiries to the Commander, Navy Exchange Service Command, 3280 Virginia Beach Boulevard, Virginia Beach, VA 23452–5724.

RECORD ACCESS PROCEDURES:

Individuals seeking access to records should address written inquiries to the Commander, Navy Exchange Service Command, 3280 Virginia Beach Boulevard, Virginia Beach, VA 23452–5724.

CONTESTING RECORD PROCEDURES:

The Navy's rules for accessing records, and for contesting contents and appealing initial agency determinations are published in Secretary of the Navy Instruction 5211.5; 32 CFR part 701; or may be obtained from the system manager.

RECORD SOURCE CATEGORIES:

The individual authorized customer/sponsor, Department of Defense/Defense Enrollment Eligibility Reporting System and Defense Finance Accounting System.

EXEMPTIONS CLAIMED FOR THE SYSTEM:

None.

N04650–1

SYSTEM NAME:

Personnel Transportation System *(March 24, 1994, 59 FR 13943).*

CHANGES:

* * * * *

PURPOSE(S):

At end of entry, add 'For audit or research purposes to obtain background information/data.'

ROUTINE USES OF RECORDS MAINTAINED IN THE SYSTEM, INCLUDING CATEGORIES OF USERS AND THE PURPOSES OF SUCH USES:

Delete paragraph two and replace with 'To officials and employees of other departments and agencies of the Executive Branch of government, upon request, in the performance of their official duties related to the provision of transportation; diplomatic, official, and other no-cost passports; and visas to subject individuals.'

* * * * *

N04650–1

SYSTEM NAME:

Personnel Transportation System.

SYSTEM LOCATION:

All Personnel Support Activity Detachments and Navy Passenger Transportation Offices Worldwide and Administrative Support Unit, Bahrain. Official mailing addresses are published as an appendix to the Navy's compilation of systems of records notices.

CATEGORIES OF INDIVIDUALS COVERED BY THE SYSTEM:

Navy military personnel (active and retired), civilian employees of the Navy, dependents, Midshipmen, and other individuals authorized through Navy commands to travel at Government expense.

CATEGORIES OF RECORDS IN THE SYSTEM:

Applications for travel and, where applicable, for passports and visas; requests for extension of time limit on travel by retired members to home of record; requests for exceptions of policies/procedures involving travel entitlements/eligibilities; supporting documents; correspondence, and approvals/disapprovals relating to the above records; travel arrangements in response to above applications.

AUTHORITY FOR MAINTENANCE OF THE SYSTEM:

5 U.S.C. 5701 et seq Travel, Transportation and Subsistence; 10 U.S.C. 2631–2635 and Chapter 7; 37 U.S.C. 404, Travel and Transportation Allowances-General; and E.O. 9397.

PURPOSE(S):

To provide official travel services; determine eligibility for transportation; to authorize or deny transportation; and otherwise manage the Navy-wide passenger transportation system. For audit or research purposes to obtain background information/data.

ROUTINE USES OF RECORDS MAINTAINED IN THE SYSTEM, INCLUDING CATEGORIES OF USERS AND THE PURPOSES OF SUCH USES:

In addition to those disclosures generally permitted under 5 U.S.C. 552a(b) of the Privacy Act, these records or information contained therein may specifically be disclosed outside the DoD as a routine use pursuant to 5 U.S.C. 552a(b)(3) as follows:

To officials and employees of other departments and agencies of the Executive Branch of government, upon request, in the performance of their official duties related to the provision of transportation; diplomatic, official, and other no-cost passports; and visas to subject individuals.

To Foreign embassies, legations, and consular offices--to determine eligibility for visas to respective countries, if visa is required.

To Commercial Carriers providing transportation to individuals whose applications are processed through this system of records.

When required by Federal statute, by Executive Order, or by treaty, personnel record information will be disclosed to the individual, organization, or governmental agency as necessary.

The 'Blanket Routine Uses' that appear at the beginning of the Navy's compilation of systems of records notices apply to this system.

POLICIES AND PRACTICES FOR STORING, RETRIEVING, ACCESSING, RETAINING, AND DISPOSING OF RECORDS IN THE SYSTEM:

STORAGE:

Automated records may be stored on magnetic tapes/disks. Manual records in file folders or file-card boxes, and microfiche or microfilm.

RETRIEVABILITY:

Automated records may be retrieved by Social Security Number and/or name. Manual records are normally filed alphabetically by name of applicant, month, and fiscal year; applications for dependents travel are filed under name of sponsor.

SAFEGUARDS:

Manual records are maintained in file cabinets under the control of authorized personnel during working hours. The office space in which the file cabinets are located is locked outside of official working hours. Computer terminals are located in supervised areas. Computer terminals are controlled by password or other user code system.

RETENTION AND DISPOSAL:

Records are retained for three years and then forwarded to the records center for retention for additional four years. After seven years, all records are destroyed.

SYSTEM MANAGER(S) AND ADDRESS:

Personnel Support Activity Detachments and Navy Passenger Transportation Offices Worldwide and Administrative Support Unit, Bahrain. Official mailing addresses are published as an appendix to the Navy's compilation of systems of records notices.

Policy Official: Chief of Naval Personnel, Bureau of Naval Personnel (Pers 332), 2 Navy Annex, Washington, DC 20370–3320.

NOTIFICATION PROCEDURE:

Individuals seeking to determine whether information about themselves is contained in this system should address written inquiries to the local activity where the request for transportation was initiated, and/or to intermediate activities (if applicable), or to the Chief of Naval Personnel (ATTN: Privacy Act Coordinator), Navy Department, Washington, DC 20370. Official mailing addresses are published as an appendix to the Navy's compilation of systems of records notices.

The letter should contain full name, Social Security Number, address and signature of the requester. The individual may visit the activities and commands listed under LOCATION for assistance with the records maintained at the respective locations. Proof of identification will consist of Military Identification Card for persons having such cards. Others must present other positive personal identification, preferably picture-bearing.

RECORD ACCESS PROCEDURES:

Individuals seeking access to information about themselves contained in this system should address written inquiries to the local activity where the request for transportation was initiated, and/or to intermediate activities (if applicable), or to the Chief of Naval Personnel (ATTN: Privacy Act Coordinator), Navy Department, Washington, DC 20370. Official mailing addresses are published as an appendix to the Navy's compilation of systems of records notices.

The letter should contain full name, Social Security Number, address and signature of the requester. The individual may visit the activities and commands listed under LOCATION for assistance with the records maintained at the respective locations. Proof of identification will consist of Military Identification Card for persons having such cards. Others must present other positive personal identification, preferably picture-bearing.

CONTESTING RECORD PROCEDURES:

The Navy's rules for accessing records, and for contesting contents and appealing initial agency determinations are published in Secretary of the Navy Instruction 5211.5; 32 CFR part 701; or may be obtained from the system manager.

RECORD SOURCE CATEGORIES:

Individual; member's service record/civilian personnel file; officials and employees of the Department of the Navy, Department of Defense, State Department; and other agencies of the Executive Branch and components thereof; foreign embassies, legations, and consular offices reporting approval/disapproval of visas; and carriers reporting on provision of transportation.

EXEMPTIONS CLAIMED FOR THE SYSTEM:

None.

N05101–1

SYSTEM NAME:

Safety Equipment Needs, Issues, Authorizations .

CHANGES:

SYSTEM IDENTIFIER:

Delete entry and replace with 'N05100–3'.

* * * * *

SAFEGUARDS:

Delete entry and replace with 'File areas are accessible only to authorized persons who are properly screened, cleared, and trained. Computer terminals/personal computers are password protected.'

RETENTION AND DISPOSAL:

Delete entry and replace with 'Destroy when equipment is returned or inventoried.'

* * * * *

N05100–3

SYSTEM NAME:

Safety Equipment Needs, Issues, Authorizations *(February 22, 1993, 58 FR 10747).*

SYSTEM LOCATION:

Organizational elements of the Department of the Navy. Official

mailing addresses are published as an appendix to the Navy's compilation of systems of records notices.

CATEGORIES OF INDIVIDUALS COVERED BY THE SYSTEM:

Personnel whose work requires them to wear, or are issued, protective clothing or equipment, including prescription safety lenses.

CATEGORIES OF RECORDS IN THE SYSTEM:

Listings, cards, and other records which list individuals requiring, authorized, or issued prescription or other safety equipment. Such listings may include name, Social Security Number, organization code, date equipment issued, date equipment returned, equipment I.D. number, etc.

AUTHORITY FOR MAINTENANCE OF THE SYSTEM:

5 U.S.C. 301, Departmental Regulations and E.O. 9397.

PURPOSE(S):

To determine who needs, is eligible, or has been authorized or issued prescription or other safety equipment for protection.

ROUTINE USES OF RECORDS MAINTAINED IN THE SYSTEM, INCLUDING CATEGORIES OF USERS AND THE PURPOSES OF SUCH USES:

In addition to those disclosures generally permitted under 5 U.S.C. 552a(b) of the Privacy Act, these records or information contained therein may specifically be disclosed outside the DoD as a routine use pursuant to 5 U.S.C. 552a(b)(3) as follows:

The 'Blanket Routine Uses' that appear at the beginning of the Navy's compilation of systems of records notices apply to this system.

POLICIES AND PRACTICES FOR STORING, RETRIEVING, ACCESSING, RETAINING, AND DISPOSING OF RECORDS IN THE SYSTEM:

STORAGE:

Paper and automated records.

RETRIEVABILITY:

Name, Social Security Number, or date equipment was issued.

SAFEGUARDS:

File areas are accessible only to authorized persons who are properly screened, cleared, and trained. Computer terminals/personal computers are password protected.

RETENTION AND DISPOSAL:

Destroy when equipment is returned or inventoried.

SYSTEM MANAGER(S) AND ADDRESS:

Commanding officer of the activity in question. Official mailing addresses are published as an appendix to the Navy's compilation of systems of records notices.

NOTIFICATION PROCEDURE:

Individuals seeking to determine whether this system of records contains information about themselves should address written inquiries to the commanding officer of the activity where assigned. Official mailing addresses are published as an appendix to the Navy's compilation of systems of records notices.

Requests should contain full name, Social Security Number, and date equipment was assigned (if known), and be signed.

RECORD ACCESS PROCEDURES:

Individuals seeking access to records about themselves contained in this system of records should address written inquiries to the commanding officer of the activity where assigned. Official mailing addresses are published as an appendix to the Navy's compilation of systems of records notices.

Requests should contain full name, Social Security Number, and date equipment was assigned (if known), and be signed.

CONTESTING RECORD PROCEDURES:

The Navy's rules for accessing records, and for contesting contents and appealing initial agency determinations are published in Secretary of the Navy Instruction 5211.5; 32 CFR part 701; or may be obtained from the system manager.

RECORD SOURCE CATEGORIES:

Individual.

EXEMPTIONS CLAIMED FOR THE SYSTEM:

None.

N05210–1

SYSTEM NAME:

General Correspondence Files *(February 22, 1993, 58 FR 10748).*

CHANGES:

SYSTEM IDENTIFIER:

Delete entry and replace with 'N05000–1.'

* * * * *

SYSTEM LOCATION:

Add two addresses 'Commander in Chief, U.S. Atlantic Command, 1562 Mitscher Avenue, Suite 200, Norfolk, VA 23551–2488 and Commander in Chief, U.S. Pacific Command, Building 1, Camp H. M. Smith, HI 96861–4028'

* * * * *

SAFEGUARDS:

Delete entry and replace with 'Access is provided on need-to-know basis only. Manual records are maintained in file cabinets under the control of authorized personnel during working hours. The office space in which the file cabinets are located is locked outside of official working hours. Computer terminals are located in supervised areas. Access to computerized data is controlled by password or other user code system.'

* * * * *

N05000–1

SYSTEM NAME:

General Correspondence Files.

SYSTEM LOCATION:

Organizational elements of the Department of the Navy. Official mailing addresses are published as an appendix to the Navy's compilation of system of records notices.

Commander in Chief, U.S. Atlantic Command, 1562 Mitscher Avenue, Suite 200, Norfolk, VA 23551–2488.

Commander in Chief, U.S. Pacific Command, Building 1, Camp H. M. Smith, HI 96861–4028.

CATEGORIES OF INDIVIDUALS COVERED BY THE SYSTEM:

Individuals who have initiated correspondence with the Department of the Navy.

CATEGORIES OF RECORDS IN THE SYSTEM:

Incoming correspondence which may include name, address, telephone number, organization, date of birth, and Social Security Number of correspondent and supporting documentation. Files also contain copy of response letter and documentation required to prepare the response.

AUTHORITY FOR MAINTENANCE OF THE SYSTEM:

5 U.S.C. 301, Departmental Regulations and E.O. 9397.

PURPOSE(S):

To maintain a record of correspondence received and responses made.

ROUTINE USES OF RECORDS MAINTAINED IN THE SYSTEM, INCLUDING CATEGORIES OF USERS AND THE PURPOSES OF SUCH USES:

In addition to those disclosures generally permitted under 5 U.S.C. 552a(b) of the Privacy Act, these records or information contained therein may specifically be disclosed outside the DoD as a routine use pursuant to 5 U.S.C. 552a(b)(3) as follows:

The 'Blanket Routine Uses' that appear at the beginning of the Navy's compilation of systems notices apply to this system.

POLICIES AND PRACTICES FOR STORING, RETRIEVING, ACCESSING, RETAINING, AND DISPOSING OF RECORDS:

STORAGE:

Paper and automated records.

RETRIEVABILITY:

Name, organization, and date of correspondence.

SAFEGUARDS:

Access is provided on need-to-know basis only. Manual records are maintained in file cabinets under the control of authorized personnel during working hours. The office space in which the file cabinets are located is locked outside of official working hours. Computer terminals are located in supervised areas. Access to computerized data is controlled by password or other user code system.

RETENTION AND DISPOSAL:

Retained for two years and then destroyed.

SYSTEM MANAGER(S) AND ADDRESS:

Commanding officer of the activity in question. Official mailing addresses are published as an appendix to the Navy's compilation of system of record notices.

NOTIFICATION PROCEDURE:

Individuals seeking to determine whether this system of records contains information about themselves should address written inquiries to the commanding officer of the activity in question. Official mailing addresses are published as an appendix to the Navy's compilation of system of records notices.

The request should contain full name and date individual wrote to the Navy or received a response. Request must be signed.

RECORD ACCESS PROCEDURES:

Individuals seeking access to records about themselves contained in this system of records should address written inquiries to the commanding officer of the activity in question. Official mailing addresses are published as an appendix to the Navy's compilation of system of record notices.

The request should contain full name and date individual wrote to the Navy or received a response. Request must be signed.

CONTESTING RECORD PROCEDURES:

The Navy's rules for accessing records, and for contesting contents and appealing initial agency determinations are published in Secretary of the Navy Instruction 5211.5; 32 CFR part 701; or may be obtained from the system manager.

RECORD SOURCE CATEGORIES:

Individual concerned and records collected by the activity to respond to the request.

EXEMPTIONS CLAIMED FOR THE SYSTEM:

None.

N05330–1

SYSTEM NAME:

Manhour Accounting System *(May 22, 1996, 61 FR 25640).*

CHANGES:

SYSTEM IDENTIFIER:

Delete entry and replace with 'N12610–1.'

SYSTEM NAME:

Delete entry and replace with 'Hours of Duty Records.'

* * * * *

STORAGE:

Delete entry and replace with 'Paper and computerized records.'

* * * * *

SAFEGUARDS:

Delete entry and replace with 'Access is provided on need-to-know basis only. Manual records are maintained in file cabinets under the control of authorized personnel during working hours. The office space in which the file cabinets are located is locked outside of official working hours. Computer terminals are located in supervised areas. Access to computerized data is controlled by password or other user code system.'

RETENTION AND DISPOSAL:

Delete entry and replace with 'Records are destroyed when three years old.'

* * * * *

N12610–1

SYSTEM NAME:

Hours of Duty Records.

SYSTEM LOCATION:

Organizational elements of the Department of the Navy. Official mailing addresses are published as an appendix to the Navy's compilation of systems of records notices.

CATEGORIES OF INDIVIDUALS COVERED BY THE SYSTEM:

Military and civilian personnel.

CATEGORIES OF RECORDS IN THE SYSTEM:

Record contains such information as name, grade/rate, Social Security Number, organizational code, work center code, grade code, pay rate, labor code, type transaction, hours assigned. Data base includes scheduling and assignment of work; skill level; tools issued; leave; temporary assignments to other areas.

AUTHORITY FOR MAINTENANCE OF THE SYSTEM:

5 U.S.C. 301, Departmental Regulations and E.O. 9397.

PURPOSE(S):

To effectively manage the work force.

ROUTINE USES OF RECORDS MAINTAINED IN THE SYSTEM, INCLUDING CATEGORIES OF USERS AND THE PURPOSES OF SUCH USES:

In addition to those disclosures generally permitted under 5 U.S.C. 552a(b) of the Privacy Act, these records or information contained therein may specifically be disclosed outside the DoD as a routine use pursuant to 5 U.S.C. 552a(b)(3) as follows:

The 'Blanket Routine Uses' that appear at the beginning of the Navy's compilation of systems of records notices apply to this system.

POLICIES AND PRACTICES FOR STORING, RETRIEVING, ACCESSING, RETAINING, AND DISPOSING OF RECORDS IN THE SYSTEM:

STORAGE:

Paper and computeruzed records.

RETRIEVABILITY:

Name, organization code, Social Security Number, and work center.

SAFEGUARDS:

Access is provided on need-to-know basis only. Manual records are maintained in file cabinets under the control of authorized personnel during working hours. The office space in which the file cabinets are located is locked outside of official working hours. Computer terminals are located in supervised areas. Access to computerized data is controlled by password or other user code system.

RETENTION AND DISPOSAL:

Records are destroyed when three years old.

SYSTEM MANAGER(S) AND ADDRESS:

The commanding officer of the activity in question. Official mailing addresses are published as an appendix to the Navy's compilation of systems of records notices.

NOTIFICATION PROCEDURE:

Individuals seeking to determine whether this system of records contains information about themselves should address written inquiries to the commanding officer of the naval activity where currently employed. Official mailing addresses are published as an appendix to the Navy's compilation of systems of records notices.

The request should include full name, Social Security Number, address of individual concerned, and should be signed.

RECORD ACCESS PROCEDURE:

Individuals seeking access to records about themselves contained in this system of records should address written inquiries to the commanding officer of the naval activity where currently employed. Official mailing addresses are published as an appendix to the Navy's compilation of systems of records notices.

The request should include full name, Social Security Number, address of individual concerned, and should be signed.

CONTESTING RECORD PROCEDURE:

The Navy's rules for accessing records, and for contesting contents and appealing determinations are published in Secretary of the Navy Instruction 5211.5; 32 CFR part 701; or may be obtained from the system manager.

RECORD SOURCE CATEGORIES:

Individual, correspondence, and personnel records.

EXEMPTIONS CLAIMED FOR THE SYSTEM:

None.

N05340–1

SYSTEM NAME:

Combined Federal Campaign/Navy Relief Society.

CHANGES:

SYSTEM IDENTIFIER:

Delete entry and replace with 'N05380–1'

* * * * *

AUTHORITY FOR MAINTENANCE OF THE SYSTEM:

Delete entry and replace with 'E.O.s 9397, 10927, and 12353.'

* * * * *

STORAGE:

Delete entry and replace with 'Manual and computerized records.'

* * * * *

SAFEGUARDS:

Delete entry and replace with 'Access is provided on need-to-know basis only. Manual records are maintained in file cabinets under the control of authorized personnel during working hours. The office space in which the file cabinets are located is locked outside of official working hours. Computer terminals are located in supervised areas. Access to computerized data is controlled by password or other user code system.'

* * * * *

RECORD SOURCE CATEGORIES:

Delete entry and replace with 'Individual; payroll files; personnel files.'

* * * * *

N05380–1

SYSTEM NAME:

Combined Federal Campaign/Navy Relief Society *(February 22, 1993, 58 FR 10754).*

SYSTEM LOCATION:

Organizational elements of the Department of the Navy. Official mailing addresses are published as an appendix to the Navy's compilation of systems of records notices.

CATEGORIES OF INDIVIDUALS COVERED BY THE SYSTEM:

All assigned personnel.

CATEGORIES OF RECORDS IN THE SYSTEM:

Names, addresses, Social Security Numbers, payroll identifying data, contributor cards and lists.

AUTHORITY FOR MAINTENANCE OF THE SYSTEM:

E.O.s 9397, 10927, and 12353.

PURPOSE(S):

To manage the Combined Federal Campaign and Navy Relief Society Fund drives and provide the respective campaign coordinator with necessary information.

ROUTINE USES OF RECORDS MAINTAINED IN THE SYSTEM, INCLUDING CATEGORIES OF USERS AND THE PURPOSES OF SUCH USES:

In addition to those disclosures generally permitted under 5 U.S.C. 552a(b) of the Privacy Act, these records or information contained therein may specifically be disclosed outside the DoD as a routine use pursuant to 5 U.S.C. 552a(b)(3) as follows:

The 'Blanket Routine Uses' that appear at the beginning of the Navy's compilation of systems of records notices apply to this system.

POLICIES AND PRACTICES FOR STORING, RETRIEVING, ACCESSING, RETAINING, AND DISPOSING OF RECORDS IN THE SYSTEM:

STORAGE:

Manual and computerized records.

RETRIEVABILITY:

Name, Social Security Number, and organization.

SAFEGUARDS:

Access is provided on need-to-know basis only. Manual records are maintained in file cabinets under the control of authorized personnel during working hours. The office space in which the file cabinets are located is locked outside of official working hours. Computer terminals are located in supervised areas. Access to computerized data is controlled by password or other user code system.

RETENTION AND DISPOSAL:

Records are maintained for one year or completion of next equivalent campaign and then destroyed.

SYSTEM MANAGER(S) AND ADDRESS:

Commanding officer of the activity in question. Official mailing addresses are published as an appendix to the Navy's compilation of systems of records notices.

NOTIFICATION PROCEDURE:

Individuals seeking to determine whether this system of records contains information about themselves should address written inquiries to the commanding officer of the naval activity where currently or previously employed. Official mailing addresses are published as an appendix to the Navy's compilation of systems of records notices.

The request should include full name, Social Security Number, address of the individual concerned, and should be signed.

RECORD ACCESS PROCEDURE:

Individuals seeking access to records about themselves contained in this system of records should address written inquiries to the commanding officer of the naval activity where currently or previously employed. Official mailing addresses are published as an appendix to the Navy's compilation of systems of records notices.

The request should include full name, Social Security Number, address of the individual concerned, and should be signed.

CONTESTING RECORD PROCEDURE:

The Navy's rules for accessing records, and for contesting contents and appealing determinations are published in Secretary of the Navy Instruction 5211.5; 32 CFR part 701; or may be obtained from the system manager.

RECORD SOURCE CATEGORIES:

Individual; payroll files; personnel files.

EXEMPTIONS CLAIMED FOR THE SYSTEM:

None.

N05350–1

SYSTEM NAME:

Navy Drug and Alcohol Program System *(February 22, 1993, 58 FR 10755).*

CHANGES:

* * * * *

SYSTEM LOCATION:

In paragraph 2, lines 5 and 6, delete the words 'Navy Alcohol and Drug Safety Action Program Offices' and replace with Personal Responsibility and Values Education and Training Program Offices,'.

CATEGORIES OF INDIVIDUALS COVERED BY THE SYSTEM:

In line 3, after the word 'abusers,' add 'or who are out of Navy body fat standards and may be obese/compulsive overeaters,'. In line 9, delete the words 'Navy Alcohol and Drug Safety Action Program' and replace with 'Personal Responsibility and Values Education and Training Program.'

* * * * *

PURPOSE(S):

At end of paragraph one, add the following 'and programs for those members who are obese/compulsive overeaters.'

ROUTINE USES OF RECORDS MAINTAINED IN THE SYSTEM, INCLUDING CATEGORIES OF USERS AND THE PURPOSES OF SUCH USES:

In paragraph 3, line 6, after the word 'abuse' add the following ', or obesity/compulsive overeating'.

In paragraph 3, line 14, delete '290dd-3 and 290ee-3' and replace with 290dd-2.'

* * * * *

RETENTION AND DISPOSAL:

Delete entry and replace with 'Manual records are maintained for two years (Level I/II) or three years (Level III) and then retired to the nearest Federal Records Center. Automated records are maintained indefinitely.'

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N05350–1

SYSTEM NAME:

Navy Drug and Alcohol Program System.

SYSTEM LOCATION:

Primary location: Bureau of Naval Personnel (Pers 63), 2 Navy Annex, Washington, DC 20370–5001.

Decentralized locations: Navy Alcohol Rehabilitation Centers, Navy Alcohol Rehabilitation Departments in Naval Hospitals, Counseling and Assistance Centers, Personal Responsibility and Values Education and Training Program Offices, Navy Drug Screening Laboratories, Bureau of Naval Personnel Detachment (Drug and Alcohol Program Management Activity), and local activities to which an individual is assigned. Addresses are contained in a directory which is available from the Chief of Naval Personnel (Pers 63), Bureau of Naval Personnel, 2 Navy Annex, Washington, DC 20370–5001.

CATEGORIES OF INDIVIDUALS COVERED BY THE SYSTEM:

Navy personnel (officers and enlisted) who have been identified as drug or alcohol abusers or who are out of Navy body fat standards and may be obese/compulsive overeaters, and who are subsequently screened or referred for remedial education, outpatient counseling, or residential rehabilitation; counselors, counselor interns, and counselor applicants; Navy personnel who attend the Personal Responsibility and Values Education and Training Program for preventive education; dependents and civilians, where authorized, who participate in preventive and remedial education programs, outpatient counseling, and residential rehabilitation; and officer, enlisted, and civilian staff members of facilities providing drug and alcohol education, screening, counseling, rehabilitation, and drug testing.

CATEGORIES OF RECORDS IN THE SYSTEM:

Documentation containing demographic data, screening and assessment information, progress notes, medical and laboratory data, narrative summaries of treatment, aftercare plans, and other information pertaining to a member's participation in substance abuse education, counseling, and rehabilitation programs.

AUTHORITY FOR MAINTENANCE OF THE SYSTEM:

5 U.S.C. 301, Departmental Regulations; 10 U.S.C. para 1090; 42 U.S.C. 290dd–2; and E.O. 9397.

PURPOSE(S):

To train, educate, identify, screen, counsel, rehabilitate, and monitor the progress of individuals in drug and alcohol abuse programs and programs for those members who are obese/compulsive overeaters.

Information is used to screen and evaluate the certified counselors, counselor interns, and counselor applicants throughout the course of their duties.

ROUTINE USES OF RECORDS MAINTAINED IN THE SYSTEM, INCLUDING CATEGORIES OF USERS AND THE PURPOSES OF SUCH USES:

In addition to those disclosures generally permitted under 5 U.S.C. 552a(b) of the Privacy Act, these records or information contained therein may specifically be disclosed outside the DoD as a routine use pursuant to 5 U.S.C. 552a(b)(3) as follows:

In order to comply with the provisions of 42 U.S.C. 290dd–2, the Navy's 'Blanket Routine Uses' do not apply to this system of records.

Specifically, records of the identity, diagnosis, prognosis, or treatment of any client/patient, irrespective of whether or when he/she ceases to be client/patient, maintained in connection with the performance of any alcohol or drug abuse or obesity/compulsive overeating prevention, education, training, treatment, rehabilitation, or research which is conducted, regulated, or directly or indirectly assisted by any department or agency of the United States, shall, except as provided therein, be confidential and be disclosed only for the purposes and under the circumstances expressly authorized in 42 U.S.C. 290dd–2. This statute takes precedence over the Privacy Act of 1974 in regard to accessibility of such records, except to the individual to whom the record pertains.

The content of any record may be disclosed in accordance with prior written consent of the patient with respect to whom such record is maintained, but only to such extent, under such circumstances, and for such purposes as may be allowed under such prescribed regulations.

Information from records may be released without the member's consent in the following situations:

To medical personnel to the extent necessary to meet a bona fide medical emergency.

To qualified personnel for the purpose of conducting scientific research, management audits, or program evaluation, but such personnel may not identify, directly or indirectly, any individual patient in any report of such research, audit or evaluation, or otherwise disclose patient identities in any manner.

If authorized by an appropriate order of a court of competent jurisdiction granted after application showing good case therefore. In accessing good cause, the court shall weigh the public interest and the need for disclosure against the injury to the patient, to the physician-patient relationship, and to the treatment services. Upon the granting of such order, the court, in determining the extent to which any disclosure of all or any part of any record is necessary, shall impose appropriate safeguards against unauthorized disclosures.

The above prohibitions do not apply to any interchange of records within the Armed Forces or within those components of the Department of Veterans Affairs furnishing health care to veterans or between such components and the Armed Forces.

POLICIES AND PRACTICES FOR STORING, RETRIEVING, ACCESSING, RETAINING, AND DISPOSING OF RECORDS:

STORAGE:

Automated records may be stored on computer disks (both hard drive and floppy), magnetic tapes, and drums.

Manual records may be stored in paper file folders, computer printouts, microfiche, or microfilm.

RETRIEVABILITY:

Name and Social Security Number.

SAFEGUARDS:

Computer facilities are located in restricted areas accessible only to authorized persons that are properly screened, cleared and trained.

Manual records and computer printouts are available only to authorized personnel having a need-to-know.

RETENTION AND DISPOSAL:

Manual records are maintained for two years (Level I/II) or three years (Level III) and then retired to the nearest Federal Records Center. Automated records are maintained indefinitely.

SYSTEM MANAGER(S) AND ADDRESS:

Chief of Naval Personnel (Pers 63), Bureau of Naval Personnel, 2 Navy Annex, Washington, DC 20370–5001.

NOTIFICATION PROCEDURE:

Individuals seeking to determine whether this system of records contains information about themselves should address written inquiries to the Chief of Naval Personnel (Pers 06), Bureau of Naval Personnel, 2 Navy Annex, Washington, DC 20370–5001, or to the naval activity providing treatment. Addresses are contained in a directory which is available from the Chief of Naval Personnel (Pers 63), Bureau of Naval Personnel, 2 Navy Annex, Washington, DC 20370–5001.

The letter should contain full name, Social Security Number, rank/rate, military status, and signature of the requester. The individual may visit the Bureau of Naval Personnel, 2 Navy Annex, Washington, DC 20370–5001, for assistance with records located in that building; or the individual may visit the local activity to which attached for access to locally maintained records. Proof of identification will consist of Military Identification Card for persons having such cards, or other picture-bearing identification.

RECORD ACCESS PROCEDURES:

Individuals seeking access to records about themselves contained in this system of records should address written inquiries to the Chief of Naval Personnel (Pers 06), Bureau of Naval Personnel, 2 Navy Annex, Washington, DC 20370–5001, or to the naval activity providing treatment. Addresses are contained in a directory which is available from the Chief of Naval Personnel (Pers 63), Bureau of Naval Personnel, 2 Navy Annex, Washington, DC 20370–5001.

The letter should contain full name, Social Security Number, rank/rate, military status, and signature of the requester. The individual may visit the Bureau of Naval Personnel, 2 Navy Annex, Washington, DC 20370–5001, for assistance with records located in that building; or the individual may visit the local activity to which attached for access to locally maintained records. Proof of identification will consist of Military Identification Card for persons having such cards, or other picture-bearing identification.

CONTESTING RECORD PROCEDURES:

The Navy's rules for accessing records, and for contesting contents and appealing initial agency determinations are published in Secretary of the Navy Instruction 5211.5; 32 CFR part 701; or may be obtained from the system manager.

RECORD SOURCE CATEGORIES:

DOD/DON officials; notes and documents from Service Jackets and Medical Records; and general correspondence concerning the individual.

EXEMPTIONS CLAIMED FOR THE SYSTEM:

None.

N05801–2

SYSTEM NAME:

Legal Assistance Management Information System *(February 22, 1993, 58 FR 10772).*

CHANGES:

* * * * *

STORAGE:

At end of entry add 'Electronic records are stored on computer disks.'

* * * * *

SAFEGUARDS:

Delete entry and replace with 'Cards, case files, and computer disks are maintained in metal filing cabinets or other storage devices under the control of authorized personnel during working hours. The office space in which the file cabinets and storage devices are located in locked outside normal working hours. The files are not accessible to the public or to persons within the command without an official need-to-know.'

RETENTION AND DISPOSAL:

Delete entry and replace with 'Most files are maintained for two years after the completion of the services and then destroyed. However, some files may be maintained indefinitely if a future legal dispute or inquiry about the matters addressed in the file is reasonably foreseeable.'

Files are maintained for two years after completion of the services and then destroyed.

* * * * *

N05801–2

SYSTEM NAME:

Legal Assistance Management Information System.

SYSTEM LOCATION:

Naval Legal Service Offices (NLSO) and NLSO detachments and other commands that provide legal assistance services under the auspices of the Navy's Legal Assistance Program through an assigned judge advocate or civilian attorney. Official mailing addresses are published as an appendix to the Navy's compilation of system of record notices.

CATEGORIES OF INDIVIDUALS COVERED BY THE SYSTEM:

Active duty military personnel, retirees, dependents, and authorized civilians who have been provided legal assistance.

CATEGORIES OF RECORDS IN THE SYSTEM:

Legal Assistance Card Files contain basic client identification information; e.g., name, address, duty station, telephone number(s), a brief description of the subject of the visit, name of the attorney assigned, and attorney time expended.

Legal Assistance Client Case Files contain personal and privileged information on the client and about the legal matter(s) for which the client is seeking assistance, including various documents related to the client's case, such as copies of client records provided to the attorney; memoranda of attorney-client interviews and attorney-client telephone conversations; memoranda of meetings and telephone conversations with relevant third parties; copies of statutes and case law relevant to the case; attorney research and notes; copies of all documents prepared, and of all correspondence sent or received, by the legal assistance provider; and a record of the results obtained.

AUTHORITY FOR MAINTENANCE OF THE SYSTEM:

5 U.S.C. 301, Departmental Regulations; 10 U.S.C. 1044; and 32 CFR part 727, Legal Assistance.

PURPOSE(S):

Data from the records is compiled for the purpose of generating periodic workload productivity and statistical reports, for internal management of the office, and for counsel assignment. To provide an administrative record for use by attorneys and clerical personnel directly involved in rendering legal assistance.

ROUTINE USES OF RECORDS MAINTAINED IN THE SYSTEM, INCLUDING CATEGORIES OF USERS AND THE PURPOSES OF SUCH USES:

In addition to those disclosures generally permitted under 5 U.S.C. 552a(b) of the Privacy Act, these records or information contained therein may specifically be disclosed outside the DoD as a routine use pursuant to 5 U.S.C. 552a(b)(3) as follows:

The 'Blanket Routine Uses' published at the beginning of the Navy's compilation do not apply to this system of records.

POLICIES AND PRACTICES FOR STORING, RETRIEVING, ACCESSING, RETAINING, AND DISPOSING OF RECORDS IN THE SYSTEM:

STORAGE:

Paper card and case files are stored in file cabinets. Electronic records are stored on computer disks.

RETRIEVABILITY:

Name of client.

SAFEGUARDS:

Cards, case files, and computer disks are maintained in metal filing cabinets or other storage devices under the control of authorized personnel during working hours. The office space in which the file cabinets and storage devices are located in locked outside normal working hours. The files are not accessible to the public or to persons within the command without an official need-to-know.

RETENTION AND DISPOSAL:

Most files are maintained for two years after the completion of the services and then destroyed. However, some files may be maintained indefinitely if a future legal dispute or inquiry about the matters addressed in the file is reasonably foreseeable.

Files are maintained for two years after completion of the services and then destroyed

SYSTEM MANAGER(S) AND ADDRESS:

Deputy Assistant Judge Advocate General (Legal Assistance), Office of the Judge Advocate General, Department of the Navy, 200 Stovall Street, Alexandria, VA 22332–2400.

NOTIFICATION PROCEDURE:

Individuals seeking to determine whether this system of records contains information about themselves should address written inquiries to the office providing the legal assistance or to the Deputy Assistant Judge Advocate General (Legal Assistance), Office of the Judge Advocate General, Department of the Navy, 200 Stovall Street, Alexandria, VA 22332–2400.

The written request should include full name and must be signed by the requesting individual.

RECORD ACCESS PROCEDURES:

Individuals seeking access to records about themselves contained in this system of records should address written inquiries to the office providing the legal assistance or to the Deputy Assistant Judge Advocate General (Legal Assistance), Office of the Judge Advocate General, Department of the Navy, 200 Stovall Street, Alexandria, VA 22332–2400.

The written request should include full name, address, and telephone number of the requester and must be signed by the requesting individual.

CONTESTING RECORD PROCEDURES:

The Navy's rules for accessing records, and for contesting contents and appealing initial agency determinations are published in Secretary of the Navy Instruction 5211.5; 32 CFR part 701; or may be obtained from the system manager.

RECORD SOURCE CATEGORIES:

Basic information is provided by the client. Additional information regarding the case, including actions taken and the ultimate disposition of the case, is provided by the attorney rendering the service.

EXEMPTIONS CLAIMED FOR THE SYSTEM:

None.

N05810–1

SYSTEM NAME:

Article 138 Complaint of Wrongs *(February 22, 1993, 58 FR 10773).*

CHANGES:

SYSTEM IDENTIFIER:

Delete entry and replace with 'N05819–4'.

SYSTEM NAME:

Delete entry and replace with 'Complaints of Wrong Under Article 138/Article 1150.'

* * * * *

CATEGORIES OF INDIVIDUALS COVERED BY THE SYSTEM:

Delete entry and replace with: 'Active duty Navy and Marine Corps personnel who have submitted complaints of wrong pursuant to Article 138, Uniform Code of Military Justice, or Article 1150, U. S. Navy Regulations, 1990 which have been forwarded to the Secretary of the Navy for final review of the proceedings.'

CATEGORIES OF RECORDS IN THE SYSTEM:

Delete entry and replace with 'Files consist of complaint or report, the investigations into the complaint or report, the action of the general court-martial authority, and action of the Secretary of the Navy accumulated at the Office of the Judge Advocate General.'

AUTHORITY FOR MAINTENANCE OF THE SYSTEM:

Delete entry and replace with 'Article 138, Uniform Code of Military Justice and Article 1150, U.S. Navy Regulations, 1990.'

PURPOSE(S):

In line 3, after the words, 'Article 138' add the words, 'and Article 1150'.

* * * * *

RETRIEVABILITY:

Delete entry and replace with 'Closed files are kept in alphabetical order according to the last name of the complainant. Active files are maintained chronologically by case number.'

* * * * *

RETENTION AND DISPOSAL:

Delete entry and replace with 'Permanent. Retire to Washington National Records Center when 3 years old. Transfer to NARA when 20 years old.'

* * * * *

RECORD SOURCE CATEGORIES:

Delete entry and replace with 'Complainant; investigatory files; individuals interviewed.'

* * * * *

N05819–4

SYSTEM NAME:

Complaints of Wrong Under Article 138/Article 1150.

SYSTEM LOCATION:

Office of the Judge Advocate General (Code 32), Department of the Navy, 200 Stovall Street, Alexandria, VA 22332–2400. Complaints, three years old or older, are stored at the Federal Records Center, Suitland, MD 20409.

CATEGORIES OF INDIVIDUALS COVERED BY THE SYSTEM:

Active duty Navy and Marine Corps personnel who have submitted complaints of wrong pursuant to Article 138, Uniform Code of Military Justice, or Article 1150 of the U. S. Navy Regulations (1990) which have been forwarded to the Secretary of the Navy for final review of the proceedings.

CATEGORIES OF RECORDS IN THE SYSTEM:

Files consist of complaint or report, the investigations into the complaint or report, the action of the general court-martial authority, and action of the Secretary of the Navy accumulated at the Office of the Judge Advocate General.

AUTHORITY FOR MAINTENANCE OF THE SYSTEM:

Article 138, Uniform Code of Military Justice and Article 1150 of the U.S. Navy Regulations (1990).

PURPOSE(S):

Used by JAG as a working file to review and make recommendations to the Secretary of the Navy on Article 138 and Article 1150 complaints.

ROUTINE USES OF RECORDS MAINTAINED IN THE SYSTEM, INCLUDING CATEGORIES OF USERS AND THE PURPOSES OF SUCH USES:

In addition to those disclosures generally permitted under 5 U.S.C. 552a(b) of the Privacy Act, these records or information contained therein may specifically be disclosed outside the DoD as a routine use pursuant to 5 U.S.C. 552a(b)(3) as follows:

The 'Blanket Routine Uses' that appear at the beginning of the Navy's compilation of systems notices apply to this system.

POLICIES AND PRACTICES FOR STORING, RETRIEVING, ACCESSING, RETAINING AND DISPOSING OF RECORDS IN THE SYSTEM:

STORAGE:

File folders.

RETRIEVABILITY:

Closed files are kept in alphabetical order according to the last name of the complainant. Active files are maintained chronologically by case number.

SAFEGUARDS:

Files are maintained in file cabinets and other storage devices under control of authorized personnel during working hours; the office spaces in which the file cabinets and storage devices are located is locked outside office working hours.

RETENTION AND DISPOSAL:

Permanent. Retire to Washington National Records Center when 3 years old. Transfer to NARA when 20 years old.

SYSTEM MANAGER(S) AND ADDRESS:

Deputy Assistant Judge Advocate General (Civil Affairs), Office of the Judge Advocate General, Department of the Navy, 200 Stovall Street, Alexandria, VA 22332–2400.

NOTIFICATION PROCEDURE:

Individuals seeking to determine whether this system of records contains information about themselves should address written inquiries to the Deputy Assistant Judge Advocate General (Civil Affairs), Office of the Judge Advocate General, Department of the Navy, 200 Stovall Street, Alexandria, VA 22332–2400.

The written request should contain full name and the approximate date the complaint was submitted for review if known. Written requests must be signed by the requesting individual. Personal visits may be made to the Civil Affairs Division, Office of the Judge Advocate General, Room 9N11, Hoffman Building II, 200 Stovall Street, Alexandria, VA 22332–2400. Individuals making such visits should be able to provide some acceptable identification, e.g. Armed Forces identification card, driver's license, etc.

RECORD ACCESS PROCEDURES:

Individuals seeking access to records about themselves contained in this system of records should address written inquiries to the Deputy Assistant Judge Advocate General (Civil Affairs), Office of the Judge Advocate General, Department of the Navy, 200 Stovall Street, Alexandria, VA 22332–2400.

The written request should contain full name and the approximate date the complaint was submitted for review if known. Written requests must be signed by the requesting individual. Personal visits may be made to the Civil Affairs Division, Office of the Judge Advocate General, Room 9N11, Hoffman Building II, 200 Stovall Street, Alexandria, VA 22332–2400. Individuals making such visits should be able to provide some acceptable identification, e.g. Armed Forces identification card, driver's license, etc. The agency's rules for access to records may be obtained from the system manager.

CONTESTING RECORD PROCEDURES:

The Navy's rules for accessing records, and for contesting contents and appealing initial agency determinations are published in Secretary of the Navy Instruction 5211.5; 32 CFR part 701; or may be obtained from the system manager.

RECORD SOURCE CATEGORIES:

Complainant; investigatory files; individuals interviewed.

EXEMPTIONS CLAIMED FOR THE SYSTEM:

None.

N06530–1

SYSTEM NAME:

Blood Donor Files *(February 22, 1993, 58 FR 10798).*

CHANGES:

* * * * *

SYSTEM IDENTIFIER:

Delete entry and replace with 'N06320–4'.

* * * * *

RETENTION AND DISPOSAL:

Delete entry and replace with 'Records are destroyed when three years old or discontinuance of function, whichever is earlier.'

SYSTEM MANAGER(S) AND ADDRESS:

In line 2, after the word 'Surgery' add ', 2300 E Street, NW'.

* * * * *

N06320–4

SYSTEM NAME:

Blood Donor Files.

SYSTEM LOCATION:

Organizational elements of the Department of the Navy. Official mailing addresses are published as an appendix to the Navy's compilation of systems of records notices.

CATEGORIES OF INDIVIDUALS COVERED BY THE SYSTEM:

Personnel donating blood or seeking replacement of blood.

CATEGORIES OF RECORDS IN THE SYSTEM:

Blood donation and blood replacement requirement records.

AUTHORITY FOR MAINTENANCE OF THE SYSTEM:

5 U.S.C. 301, Departmental Regulations; 21 U.S.C. 600–799; and E.O. 9397.

PURPOSE(S):

To record emergency blood requests by blood type, identify donors, replace blood provided to cover individuals, and to meet regulatory requirements imposed by the Food and Drug Administration.

ROUTINE USES OF RECORDS MAINTAINED IN THE SYSTEM, INCLUDING CATEGORIES OF USERS AND THE PURPOSES OF SUCH USES:

In addition to those disclosures generally permitted under 5 U.S.C. 552a(b) of the Privacy Act, these records

or information contained therein may specifically be disclosed outside the DoD as a routine use pursuant to 5 U.S.C. 552a(b)(3) as follows:

The 'Blanket Routine Uses' that appear at the beginning of the Navy's compilation of systems notices apply to this system.

POLICIES AND PRACTICES FOR STORING, RETRIEVING, ACCESSING, RETAINING, AND DISPOSING OF RECORDS IN THE SYSTEM:

STORAGE:

Computerized and paper records.

RETRIEVABILITY:

Name and Social Security Number.

SAFEGUARDS:

Access provided on a need-to-know basis only. Computerized information is password protected and maintained is a locked and/or guarded office.

RETENTION AND DISPOSAL:

Records are destroyed when three years old or discontinuance of function, whichever is earlier.

SYSTEM MANAGER(S) AND ADDRESS:

Policy Official: Chief, Bureau of Medicine and Surgery, 2300 E Street, NW, Washington, DC 20372–5300.

System manager: Commanding officer of the activity in question. Official mailing addresses are published as an appendix to the Navy's compilation of systems of records notices.

NOTIFICATION PROCEDURE:

Individuals seeking to determine whether this system of records contains information about themselves should address written inquiries to the commanding officer of the activity where assigned.

The request should contain full name, Social Security Number, and must be signed.

RECORD ACCESS PROCEDURES:

Individuals seeking access to records contained in this system of records should address written inquiries to the commanding officer of the activity where assigned.

The request should contain full name, Social Security Number, and must be signed.

CONTESTING RECORD PROCEDURES:

The Navy's rules for accessing records, and for contesting contents and appealing initial agency determinations are published in Secretary of the Navy Instruction 5211.5; 32 CFR part 701; or may be obtained from the system manager.

RECORD SOURCE CATEGORIES:

Individual, American Red Cross, blood donors, hospitals, persons seeking replacement of blood.

EXEMPTIONS CLAIMED FOR THE SYSTEM:

None.

N07320–1

SYSTEM NAME:

Property Accountability Records *(February 22, 1993, 58 FR 10808).*

CHANGES:

* * * * *

SYSTEM LOCATION:

Delete entry and replace with 'Organizational elements of the Department of the Navy. Official mailing addresses are published as an appendix to the Navy's compilation of systems of records notices.'

CATEGORIES OF INDIVIDUALS COVERED BY THE SYSTEM:

Delete entry and replace with 'Any individual who receives and signs for government property.'

* * * * *

STORAGE:

In line 4, after the word 'photographs' add ', computerized data base,'.

RETRIEVABILITY:

In line 2, after the word 'Name,' add 'Social Security Number'.

SAFEGUARDS:

Delete entry and replace with 'Access is limited and provided on a need-to-know basis only. Computerized data bases are password protected.'

RETENTION AND DISPOSAL:

Delete entry and replace with 'Property accounting records are destroyed when two years old. Custody receipts are destroyed when material or equipment is destroyed.'

* * * * *

N07320–1

SYSTEM NAME:

Property Accountability Records.

SYSTEM LOCATION:

Organizational elements of the Department of the Navy. Official mailing addresses are published as an appendix to the Navy's compilation of systems of records notices.

CATEGORIES OF INDIVIDUALS COVERED BY THE SYSTEM:

Any individual who receives and signs for government property.

CATEGORIES OF RECORDS IN THE SYSTEM:

The receipts maintained are any of the following: Logbooks, property passes, custody chits, charge tickets, sign out cards, tool tickets, sign out forms, photographs, charge cards, or any other statement of individual accountability for receipt of government property.

AUTHORITY FOR MAINTENANCE OF THE SYSTEM:

5 U.S.C. 301, Departmental Regulations and E.O. 9397.

PURPOSE(S):

To identify individuals to whom government property has been issued.

ROUTINE USES OF RECORDS MAINTAINED IN THE SYSTEM, INCLUDING CATEGORIES OF USERS AND THE PURPOSES OF SUCH USES:

In addition to those disclosures generally permitted under 5 U.S.C. 552a(b) of the Privacy Act, these records or information contained therein may specifically be disclosed outside the DoD as a routine use pursuant to 5 U.S.C. 552a(b)(3) as follows:

The 'Blanket Routine Uses' that appear at the beginning of the Navy's compilation of systems of records notices apply to this system.

POLICIES AND PRACTICES FOR STORING, RETRIEVING, ACCESSING, RETAINING, AND DISPOSING OF RECORDS IN THE SYSTEM:

STORAGE:

The receipts may be maintained in any of the following formats: Logbooks, property passes, custody chits, charge tickets, sign out cards, tool tickets, sign out forms, photographs, computerized data base, charge out cards or any other statement of individual accountability for receipt of government property.

RETRIEVABILITY:

Retrievability may be by any of the following: Name, Social Security Number, badge number, tool number, property serial number, or any other locally determined method of property receipt accountability.

SAFEGUARDS:

Access is limited and provided on a need-to-know basis only. Computerized data bases are password protected.

RETENTION AND DISPOSAL:

Property accounting records are destroyed when two years old. Custody receipts are destroyed when material or equipment is destroyed.

SYSTEM MANAGER(S) AND ADDRESS:

The system manager is the commanding officer or officer in charge of the activity where the property accountability records are maintained.

NOTIFICATION PROCEDURE:

Individuals seeking to determine whether system records contain information pertaining to them may do so by making application to the commanding officer or officer in charge of the activity where the receipts are located. Individuals making application must have a Department of the Navy approved identification card.

RECORD ACCESS PROCEDURES:

Individuals seeking access to information about themselves contained in this system should address written inquiries to the commanding officer or officer in charge of the activity where the receipts are located. Individuals making application must have a Department of the Navy approved identification card.

CONTESTING RECORD PROCEDURES:

The Navy's rules for accessing records, and for contesting contents and appealing initial agency determinations are published in Secretary of the Navy Instruction 5211.5; 32 CFR part 701; or may be obtained from the system manager.

RECORD SOURCE CATEGORIES:

Information is collected directly from the subject individual.

EXEMPTIONS CLAIMED FOR THE SYSTEM:

None.

MFD00003

SYSTEM NAME:

Joint Uniform Military Pay System/ Manpower Management System(JUMPS/MMS) *(February 22, 1993, 58 FR 10635).*

CHANGES:

* * * * *

SYSTEM NAME:

Delete entry and replace with 'Marine Corps Total Force System (MCTFS).'

SYSTEM LOCATION:

Delete entry and replace with 'Primary locations: Defense Mega-Center, St. Louis, MO 63120-1798.

Defense Finance and Accounting Service-Kansas City Center, 1500 East Bannister Road, Kansas City, MO 64197–0001. The Financial Systems Activity-Kansas City, 1500 East Bannister Road, Kansas City, MO 64197–0001.

Manpower Information Systems Support Activity, 1500 East Bannister Road, Kansas City, MO 64197–0001.

Decentralized segments: Manpower Information System Support Office-02, Marine Corps Base, Camp LeJeune NC 28542–5000.

Manpower Information System Support Office-03, Marine Corps Base, Camp Pendleton, CA 92055–5000.

Manpower Information System Support Office-06, Marine Corps Base, Hawaii, Kaneohe Bay, HI 96863–5000.

Manpower Information System Support Office-09, Headquarters, U.S. Marine Corps, Washington, DC 20380–1775.

Manpower Information System Support Office-16 and 17, Marine Corps Support Activity, Kansas City, MO 64197–0001.

Manpower Information System Support Office-11, Headquarters, Washington, DC 20380–1775.

Manpower Information System Support Office-27, Marine Corps Base, Camp S.D. Butler, Okinawa, JA, FPO AP 98773–5001.'

CATEGORIES OF INDIVIDUAL COVERED BY THE SYSTEM:

Delete entry and replace with 'Marine Corps Total Force System (MCTFS) contains the personnel records of all active, reserve and retired Marines. MCTFS also contains the pay records of active and reserve Marines.'

CATEGORIES OF RECORDS IN THE SYSTEM:

Delete entry and replace with 'File contains personnel and pay data which includes, but is not limited to Name, rank/grade, Social Security Number, date of birth, citizenship, marital status, home of record, dependents information including their Social Security Numbers, records of emergency data, enlistment contract or officer acceptance form identification, duty status, component code, population group, sex, ethnic group, duty information duty station/personnel assignment, unit information, security investigation date/ type, leave account information, separation document code, test scores/ information, language proficiency, military/civilian/off-duty education, training information to include marksmanship data, physical fitness data, swim qualifications, military occupational specialties, military skills and schools, awards, combat tour information, aviation/pilot/flying time data, reserve drill information, reserve unit information, lineal precedence number, limited duty officer/warrant officer footnote, TAD data, overseas deployment data, limited medical data, conduct and proficiency marks, years in service, promotional data, weight control and military appearance data, commanding officer assignment/relief data, joint MOS data, and related data. Pay data included leave and earnings statement which may include base pay, allowances, allotments, bond authorization, health care coverage, dental coverage (if applicable), special pay and bonus data, federal and state withholding/income tax data, FDIC contributions, Medicare, Social Security, SGLI deductions, leave account, wage and summaries, reserve drill pay, reserve AT pay, and other personnel/pay management data.'

* * * * *

PURPOSE(S):

Delete entry and replace with 'To maintain records of pay and personnel data on all active and reserve Marine Corps personnel, and to maintain personnel data from all retired Marine Corps personnel.'

* * * * *

STORAGE:

Delete entry and replace with 'Data is recorded on magnetic records and discs, computer printouts, microfilm, file folders, compact disc, electronic media and other documents.'

* * * * *

SAFEGUARDS:

Delete entry and replace with 'Building management employs security guards; building is locked nights and holidays. Authorized persons may enter and leave the building during nonworking hours but must sign in and out. Records maintained in areas assessable only to authorized personnel have a specific and recorded need-to-know. On-line data sets (both type and disc) pertaining to personnel information are password protected, areas are controlled and access lists are used. The files are also protected at a level appropriate to the type of information being processed.'

* * * * *

SYSTEM MANAGER(S) AND ADDRESS:

Delete entry and replace with 'The Commandant of the Marine Corps, (Code MIF), Headquarters. U.S. Marine Corps, Washington, DC 20380–1775.

Director, Defense Finance and Accounting Service - Kansas City Center, 1500 East Bannister Road, Kansas City, MO 64197–0001.'

NOTIFICATION PROCEDURE:

Delete entry and replace with 'Active Duty/Reserve Members seeking to determine whether pay information about themselves is contained in this system should address written inquiries to the member's local disbursing office.

Active Duty/Reserve Members seeking to determine whether pay information about themselves is contained in this system should address written inquiries

to the member's immediate commanding officer.

Retired Members seeking to determine whether personnel information about themselves is contained in this system should address written inquiries to the Commandant of the Marine Corps, (Code MIF), Headquarters. U.S. Marine Corps, Washington, DC 20380–1775.

Individual should provide their full name, Social Security Number, and the request must be signed.

In order to personally visit the above addresses and obtain information, individuals must present a military identification card, a driver's license, or other proof of identity.'

RECORDS ACCESS PROCEDURES:

Delete entry and replace with 'Active Duty/Reserve Members seeking to access pay information about themselves contained in this system should address written inquiries to the member's local disbursing office.

Active Duty/Reserve Members seeking access to pay information about themselves contained in this system should address written inquiries to the member's immediate commanding officer.

Retired Members seeking to access personnel information about themselves contained in this system should address written inquiries to the Commandant of the Marine Corps, (Code MIF), Headquarters. U.S. Marine Corps, Washington, DC 20380–1775.

Individual should provide their full name, Social Security Number, and the request must be signed.

In order to personally visit the above addresses and obtain information, individuals must present a military identification card, a driver's license, or other proof of identity.'

* * * * *

RECORD SOURCE CATEGORIES:

Delete entry and replace with 'Recruiting offices, disbursing offices, active and reserve Marine Corps unit administration offices, and the individual are the principle source of the information contained in the MCTFS record for that person.'

* * * * *

MFD00003

SYSTEM NAME:

Marine Corps Total Force System (MCTFS).

SYSTEM LOCATION:

Primary locations: Defense Mega-Center, St. Louis, MO 63120-1798.

Defense Finance and Accounting Service-Kansas City Center, 1500 East Bannister Road, Kansas City, MO 64197–0001. The Financial Systems Activity-Kansas City, 1500 East Bannister Road, Kansas City, MO 64197–0001.

Manpower Information Systems Support Activity, 1500 East Bannister Road, Kansas City, MO 64197–0001.

Decentralized segments:

Manpower Information System Support Office-02, Marine Corps Base, Camp LeJeune NC 28542–5000.

Manpower Information System Support Office-03, Marine Corps Base, Camp Pendleton, CA 92055–5000.

Manpower Information System Support Office-06, Marine Corps Base, Hawaii, Kaneohe Bay, HI 96863–5000.

Manpower Information System Support Office-09, Headquarters, U.S. Marine Corps, Washington, DC 20380–1775.

Manpower Information System Support Office-16 and 17, Marine Corps Support Activity, Kansas City, MO 64197–0001.

Manpower Information System Support Office-11, Headquarters, Washington, DC 20380–1775.

Manpower Information System Support Office-27, Marine Corps Base, Camp S.D. Butler, Okinawa, JA, FPO AP 98773–5001.

CATEGORIES OF INDIVIDUALS COVERED BY THE SYSTEM:

Marine Corps Total Force System (MCTFS) contains the personnel records of all active, reserve and retired Marines. MCTFS also contains the pay records of active and reserve Marines.

CATEGORIES OF RECORDS IN THE SYSTEM:

File contains personnel and pay data which includes, but is not limited to Name, rank/grade, Social Security Number, date of birth, citizenship, marital status, home of record, dependents information including their Social Security Numbers, records of emergency data, enlistment contract or officer acceptance form identification, duty status, component code, population group, sex, ethnic group, duty information duty station/personnel assignment, unit information, security investigation date/type, leave account information, separation document code, test scores/information, language proficiency, military/civilian/off-duty education, training information to include marksmanship data, physical fitness data, swim qualifications, military occupational specialties, military skills and schools, awards, combat tour information, aviation/pilot/flying time data, reserve drill information, reserve unit information, lineal precedence number, limited duty officer/warrant officer footnote, TAD data, overseas deployment data, limited medical data, conduct and proficiency marks, years in service, promotional data, weight control and military appearance data, commanding officer assignment/relief data, joint MOS data, and related data. Pay data included leave and earnings statement which may include base pay, allowances, allotments, bond authorization, health care coverage, dental coverage (if applicable), special pay and bonus data, federal and state withholding/income tax data, FDIC contributions, Medicare, Social Security, SGLI deductions, leave account, wage and summaries, reserve drill pay, reserve AT pay, and other personnel/pay management data.

AUTHORITY FOR MAINTENANCE OF THE SYSTEM:

10 U.S.C. 5013 and 37 U.S.C. 5031 and 5201.

PURPOSE(S):

To maintain records of pay and personnel data on all active and reserve Marine Corps personnel, and to maintain personnel data from all retired Marine Corps personnel.

ROUTINE USES OF RECORDS MAINTAINED IN THE SYSTEM, INCLUDING CATEGORIES OF USERS AND THE PURPOSES OF SUCH USES:

In addition to those disclosures generally permitted under 5 U.S.C. 552a(b) of the Privacy Act, these records or information contained therein may specifically be disclosed outside the DoD as a routine use pursuant to 5 U.S.C. 552a(b)(3) as follows:

The Attorney General of the U.S. - By officials and employees of the Attorney General in connection with litigation, law enforcement or other matters under the legal representative of the Executive Branch agencies.

By officials and employees of the American Red Cross and the Navy Relief Society in the performance of their duties. Access will be limited to those portions of the member's record required to effectively assist the member.

Federal, state and local government agencies - By officials and employees of federal, state and local government through Official request for information with respect to law enforcement, investigatory procedures, criminal prosecution, civil court action and regulatory order.

The 'Blanket Routine Uses' set forth at the beginning of the Marine Corp's compilation of systems of records notices apply to this system.

POLICIES AND PRACTICES FOR STORING, RETRIEVING, ACCESSING, RETAINING, AND DISPOSING OF RECORDS IN THE SYSTEM:

STORAGE:

Data is recorded on magnetic records and discs, computer printouts, microfilm, file folders, compact disc, electronic media and other documents.

RETRIEVABILITY:

The data contained in magnetic records can be displayed on cathode-ray tubes, it can be computer printed on paper, and it can be converted to microform for information retrieval; the data in the supporting file folders and other manual records is retrieved manually. Computerized and conventional indices are required to retrieve individual records from the system. Normally, all types of records are retrieved by Social Security Number and name.

SAFEGUARDS:

Building management employs security guards; building is locked nights and holidays. Authorized persons may enter and leave the building during nonworking hours but must sign in and out. Records maintained in areas assessable only to authorized personnel have a specific and recorded need-to-know. On-line data sets (both type and disc) pertaining to personnel information are password protected, areas are controlled and access lists are used. The files are also protected at a level appropriate to the type of information being processed.

RETENTION AND DISPOSAL:

Magnetic records are maintained on all military personnel and certain civilians while they are in service or employed by the service and for a period of 11 months after separation. Paper and film records are maintained for a period of 10 years after the final transaction, then they are destroyed. End calendar and fiscal year 'snapshots' of the MMS data base are maintained indefinitely in magnetic form at Headquarters, U.S. Marine Corps.

SYSTEM MANAGER(S) AND ADDRESS:

The Commandant of the Marine Corps, (Code MIF), Headquarters. U.S. Marine Corps, Washington, DC 20380–1775.

Director, Defense Finance and Accounting Service - Kansas City Center, 1500 East Bannister Road, Kansas City, MO 64197–0001

NOTIFICATION PROCEDURE:

Active Duty/Reserve Members seeking to determine whether pay information about themselves is contained in this system should address written inquiries to the member's local disbursing office.

Active Duty/Reserve Members seeking to determine whether pay information about themselves is contained in this system should address written inquiries to the member's immediate commanding officer.

Retired Members seeking to determine whether personnel information about themselves is contained in this system should address written inquiries to the Commandant of the Marine Corps, (Code MIF), Headquarters. U.S. Marine Corps, Washington, DC 20380–1775.

Individual should provide their full name, Social Security Number, and the request must be signed.

In order to personally visit the above addresses and obtain information, individuals must present a military identification card, a driver's license, or other proof of identity.

RECORDS ACCESS PROCEDURES:

Active Duty/Reserve Members seeking to access pay information about themselves contained in this system should address written inquiries to the member's local disbursing office.

Active Duty/Reserve Members seeking access to pay information about themselves contained in this system should address written inquiries to the member's immediate commanding officer.

Retired Members seeking to access personnel information about themselves contained in this system should address written inquiries to the Commandant of the Marine Corps, (Code MIF), Headquarters. U.S. Marine Corps, Washington, DC 20380–1775.

Individual should provide their full name, Social Security Number, and the request must be signed.

In order to personally visit the above addresses and obtain information, individuals must present a military identification card, a driver's license, or other proof of identity.

CONTESTING RECORD PROCEDURES:

The USMC rules for contesting contents and appealing initial agency determinations are published in Secretary of the Navy Instruction 5211.5; Marine Corps Order P5211.2; 32 CFR part 701; or may be obtained from the system manager.

RECORD SOURCE CATEGORIES:

Recruiting offices, disbursing offices, active and reserve Marine Corps unit administration offices, and the individual are the principle source of the information contained in the MCTFS record for that person.

EXEMPTIONS CLAIMED FOR THE SYSTEM:

None.

[FR Doc. 96–22856 Filed 9–6–96; 8:45 am]

BILLING CODE 5000–04–F

DEPARTMENT OF EDUCATION

Notice of Proposed Information Collection Requests

AGENCY: Department of Education.

ACTION: Submission for OMB review; comment request.

SUMMARY: The Director, Information Resources Group, 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 October 9, 1996.

ADDRESSES: Written comments should be addressed to the Office of Information and Regulatory Affairs, Attention: Wendy Taylor, Desk Officer, Department of Education, Office of Management and Budget, 725 17th Street, NW., Room 10235, New Executive Office Building, Washington, DC 20503. Requests for copies of the proposed information collection requests should be addressed to Patrick J. Sherrill, Department of Education, 600 Independence Avenue, S.W., Room 5624, Regional Office Building 3, Washington, DC 20202–4651.

FOR FURTHER INFORMATION CONTACT: Patrick J. Sherrill (202) 708–8196. Individuals who use a telecommunications device for the deaf (TDD) may call the Federal Information Relay Service (FIRS) at 1–800–877–8339 between 8 a.m. and 8 p.m., Eastern time, Monday through Friday.

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 Director of the Information Resources Group publishes this 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 at the address specified above. Copies of the requests are available from Patrick J. Sherrill at the address specified above.

Dated: September 3, 1996.

Gloria Parker,

Director, Information Resources Group.

Office of Educational Research and Improvement

Type of Review: Revision.

Title: Early Childhood Longitudinal Survey.

Frequency: One or two times.

Affected Public: Individuals or households; Not-for-profit institutions; State, local or Tribal Government, SEAs or LEAs.

Reporting and Recordkeeping Hour Burden:

Responses: 8,170.

Burden Hours: 7,500.

Abstract: The National Center for Education Statistics requests a 3-year generic clearance from the Office of Management and Budget to conduct developmental and design activities (i.e., field test) that will culminate in instruments that measure cognitive outcomes as well as the factors that affect learning outcomes in young children and to conduct the base year survey and assessment activities. Kindergarten enrollee cohorts are involved.

Office of Elementary and Secondary Education

Type of Review: New.

Title: Title VI Innovative Education Program Strategies.

Frequency: Biennially.

Affected Public: Federal Government, State, local or Tribal Gov't, SEAs and LEAs.

Reporting and Recordkeeping Hour Burden:

Responses: 16,052.

Burden Hours: 48,884.

Abstract: This form will be used by the Department as a means for collecting information on program effectiveness to report to Congress. This information will assure statutory mandates are followed.

[FR Doc. 96–22896 Filed 9–6–96; 8:45 am]

BILLING CODE 4000–01–P

DEPARTMENT OF ENERGY

Morgantown Energy Technology Center; Request for Financial Assistance Applications

AGENCY: U.S. Department of Energy, Morgantown Energy Technology Center.

ACTION: Notification of availability of a request for financial assistance applications.

SUMMARY: The Department of Energy is soliciting applications for the development of advanced drilling systems which will be capable of reducing overall systems costs, increasing rates of penetration, and that will allow economical development of remaining natural gas and oil resources in the United States.

DATES: The solicitation will be available on or about September 2, 1996, and applications will be accepted for a period of 30 days. The last date applications will be accepted will be noted in the solicitation.

FOR FURTHER INFORMATION CONTACT: The solicitation is available on the Internet at http://www.metc.doe.gov/business/solicita.html. Requests for information concerning the solicitation should be submitted in writing to the following address: U.S. Department of Energy, Attn: Thomas L. Martin, M.S. I07, Morgantown, WV 26507–0880. Requests may also be sent by FAX to (304) 285–4683, or by Internet to tmarti@metc.doe.gov.

SUPPLEMENTARY INFORMATION: Identification Number: DE-RP21–96MC33063.

Authority for Issuance: 10 CFR 600.

James J. Grabulis,

Director, Acquisition and Assistance Division.

[FR Doc. 96–22903 Filed 9–6–96; 8:45 am]

BILLING CODE 6450–01–P

Federal Energy Regulatory Commission

[FERC–597]

Proposed Information Collection and Request for Comments

AGENCY: Federal Energy Regulatory Commission.

ACTION: Notice of proposed information collection and request for comments.

SUMMARY: In compliance with the requirements of Section 3506(c)(2)(a) of the Paperwork Reduction Act of 1995 (Pub. L. No. 104–13), the Federal Energy Regulatory Commission (Commission) is soliciting public comment on the specific aspects of the information collection described below.

DATES: Consideration will be given to comments submitted on or before November 8, 1996.

ADDRESSES: Copies of the proposed collection of information can be obtained from and written comments may be submitted to the Federal Energy Regulatory Commission, Attn: Michael P. Miller, Information Services Division, ED–12.4 888 First Street, N.E., Washington, D.C., 20426.

FOR FURTHER INFORMATION CONTACT: Michael P. Miller may be reached by telephone at (202) 208–1415, by fax at (202) 237–0873, and by email at mmiller@.fercfed.us.

SUPPLEMENTARY INFORMATION: The information collected under the requests for FERC–597 ''Customer Satisfaction Survey'' (OMB No. 1902–0163) is used by the Commission's Public Reference and Files Maintenance Branch to evaluate the services performed in the Public Reference Room for the public. The survey is conducted on an annual basis and responses to the survey are voluntary.

Action: The Commission is requesting a three-year extension of the current expiration date, with no changes to the existing collection of data.

Burden Statement: Public reporting burden for this collection is estimated as:

Number of respondents annually (1)	Number of responses per respondent (2)	Average burden hours per response (3)	Total annual burden hours (1)×(2)×(3)
100	1	.15	15

Estimated cost burden to respondents: Because of the minimal amount of time necessary to conduct this survey (15 minutes), and the voluntary nature of response to this survey, the Commission estimates that the cost to respondents will be minimal.

The reporting burden includes the total time, effort, or financial resources expended to generate, maintain, retain, disclose, or provide the information

including: (1) Reviewing instructions; (2) developing, acquiring, installing, and utilizing technology, (where applicable) and systems for the purposes of collecting, validating, verifying, processing, maintaining, disclosing and providing information; (3) adjusting the existing ways to comply with any previously applicable instructions and requirements; (4) training personnel to respond to a collection of information (if applicable); (5) searching data sources; (6) completing and reviewing the collection of information; and (7) transmitting, or otherwise disclosing the information.

Generally, the estimate of cost for respondents is based upon salaries for professional and clerical support, as well as direct and indirect overhead costs. Direct costs include all costs directly attributable to providing this information, such as administrative costs and the cost for information technology. Indirect or overhead costs are costs incurred by an organization in support of its mission. These costs apply to activities which benefit the whole organization rather than any one particular function or activity.

Comments are invited on: (1) Whether the proposed collection of information is necessary for the proper performance of the functions of the Commission, including whether the information will have practical utility; (2) 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; (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 those who are to respond, including the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology *e.g.* permitting electronic submission of responses.

Lois D. Cashell,

Secretary.

[FR Doc. 96–22906 Filed 9–6–96; 8:45 am]

BILLING CODE 6717–01–M

[FERC Form No. 715]

Proposed Information Collection and Request for Comments

September 4, 1996.

AGENCY: Federal Energy Regulatory Commission.

ACTION: Notice of proposed information collection and request for comments.

SUMMARY: In compliance with the requirements of Section 3506(c)(2)(a) of the Paperwork Reduction Act of 1995 (Pub. L. No. 104–13), the Federal Energy Regulatory Commission (Commission) is soliciting public comment on the specific aspects of the information collection described below.

DATES: Consideration will be given to comments submitted on or before November 8, 1996.

ADDRESSES: Copies of the proposed collection of information can be obtained from and written comments may be submitted to the Federal Energy Regulatory Commission, Attn: Michael P. Miller, Information Services Division, ED–12.4, 888 First Street, N.E., Washington, D.C., 20426.

FOR FURTHER INFORMATION CONTACT: Michael P. Miller may be reached by telephone at (202) 208–1415, by fax at (202) 273–0873, and by email at mmiller@.fercfed.us.

SUPPLEMENTARY INFORMATION: The information collected under the requirements for FERC Form No. 715 ''Annual Transmission Planning and Evaluation Report'' (1902–0171) is used by the Commission to implement the statutory provisions of Section 213(b) of the Federal Power Act as created by the provisions of the Energy Policy Act of 1992. The information collected under FERC Form No. 715 is used to adequately inform potential transmission customers, State regulatory authorities, and the public of potentially available transmission capacity and constraints. In addition, the Commission will use the information as part of its efforts to encourage the sharing of information and to use in resolving disputes between all stakeholders within Regional Transmission Groups as well as disputes brought before it on transmission conflicts. The Commission also will review the current requirements for this form after full implementation of the Commission's OASIS rule pursuant to Order 889. The Commission implements these filing requirements in the Code of Federal Regulations (CFR) under 18 CFR Part 141.300.

Action: The Commission is requesting a three-year extension of the current expiration date with no changes to the existing collection of data.

Burden Statement: Public Reporting burden for this collection is estimated as:

Number of respondents annually (1)	Number of responses per respondent (2)	Average burden hours per response (3)	Total annual burden hours (1) × (2) × (3)
200	1	100	20,000

Estimated cost burden to respondents: 20,000 hours/2087 hours per year × $102,000 per year = $977,480.

The reporting burden includes the total time, effort, or financial resources expended to generate, maintain, retain, disclose, or provide the information including: (1) Reviewing instructions; (2) developing, acquiring, installing, and utilizing technology and systems for the purposes of collecting, validating, verifying, processing, maintaining, disclosing and providing information; (3) adjusting the existing ways to comply with any previously applicable instructions and requirements; (4) training personnel to respond to a collection of information; (5) searching data sources; (6) completing and reviewing the collection of information; and (7) transmitting, or otherwise disclosing the information.

The estimate of cost for respondents is based upon salaries for professional and clerical support, as well as direct and indirect overhead costs. Direct costs include all costs directly attributable to providing this information, such as administrative costs and the cost for information technology. Indirect or overhead costs are costs incurred by an organization in support of its mission. These costs apply to activities which benefit the whole organization rather than any one particular function or activity.

Comments are invited on: (1) Whether the proposed collection of information is necessary for the proper performance of the functions of the Commission, including whether the information will have practical utility; (2) 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; (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 those who are to respond, including the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology

e.g. permitting electronic submission of responses.

Lois D. Cashell,

Secretary.

[FR Doc. 96–22907 Filed 9–6–96; 8:45 am]

BILLING CODE 6717–01–M

[FERC Form No. 714]

Proposed Information Collection and Request for Comments

September 4, 1996.

AGENCY: Federal Energy Regulatory Commission, Energy.

ACTION: Notice of proposed information collection and request for comments.

SUMMARY: In compliance with the requirements of Section 3506(c)(2)(a) of the Paperwork Reduction Act of 1995 (Pub. L. No. 104–13), the Federal Energy Regulatory Commission (Commission) is soliciting public comment on the specific aspects of the information collection described below.

DATES: Consideration will be given to comments submitted by no later than November 8, 1996.

ADDRESSES: Copies of the proposed collection of information can be obtained from and written comments may be submitted to the Federal Energy Regulatory Commission, Attn: Michael P. Miller, Information Services Division, ED–12.4, 888 First Street, N.E., Washington, D.C. 20426.

FOR FURTHER INFORMATION CONTACT: Michael P. Miller may be reached by telephone at (202) 208–1415, by fax at (202) 273–0873, and by e-mail at mmiller@ferc.fed.us.

SUPPLEMENTARY INFORMATION: The information collected under the requirements for FERC Form No. 714 ''Annual Electric Control and Planning Area Report'' (OMB No. 1902–0140) is used by the Commission to implement the statutory provisions of Sections 202, 207, 210, 211–213 of the Federal Power Act (FPA), as amended (49 Stat. 838; 16 U.S.C. 791a–825r) and particularly Sections 304, 309 and 311. The Commission implements Form 714's filing requirements in the Code of Federal Regulations (CFR) under 18 CFR Part 141.51.

FERC Form No. 714 gathers basic utility operating and planning information, primarily on a control area basis, for the purpose of evaluating utility operations related to proposed mergers, interconnections, wholesale rate investigations, and wholesale market changes and trends under emerging competitive forces. Such evaluations are made to assess reliability, costs and other operating attributes.

Action: The Commission is requesting a three-year extension of the current expiration date, with no changes to the existing collection of data.

Burden Statement: Public reporting burden for this collection is estimated as:

Number of respondents annually (1)	Number of responses per respondent (2)	Average burden hours per response (3)	Total annual burden hours (1)×(2)×(3)
250	1	50	12,500

Estimated cost burden to respondents: 12,500 hours/2087 hours per year × $102,000 per year = $610,925. The reporting burden includes the total time, effort, or financial resources expended to generate, maintain, retain, disclose, or provide the information including: (1) Reviewing instructions; (2) developing, acquiring, installing, and utilizing technology and systems for the purposes of collecting, validating, verifying, processing, maintaining, disclosing and providing information; (3) adjusting the existing ways to comply with any previously applicable instructions and requirements; (4) training personnel to respond to a collection of information; (5) searching data sources; (6) completing and reviewing the collection of information; and (7) transmitting, or otherwise disclosing the information.

The estimate of cost for respondents is based upon salaries for professional and clerical support, as well as direct and indirect overhead costs. Direct costs include all costs directly attributable to providing this information, such as administrative costs and the cost for information technology. Indirect or overhead costs are costs incurred by an organization in support of its mission. These costs apply to activities which benefit the whole organization rather than any one particular function or activity.

Comments are invited on: (1) Whether the proposed collection of information is necessary for the proper performance of the functions of the Commission, including whether the information will have practical utility; (2) 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; (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 those who are to respond, including the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology *e.g.*, permitting electronic submission of responses.

Lois D. Cashell,

Secretary.

[FR Doc. 96–22908 Filed 9–6–96; 8:45 am]

BILLING CODE 6717–01–M

[Docket No. TM97–2–91–000]

ANR Storage Company; Notice of Proposed Changes in FERC Gas Tariff

September 3, 1996.

Take notice that on August 29, 1996, ANR Storage Company (ANR Storage) tendered for filing to become part of its FERC Gas Tariff, Original Volume No. 2, Eighth Revised Sheet No. 1(a), with a proposed effective date of October 1, 1996.

ANR Storage states that Eighth Revised Sheet No. 1(a) reflects the new ACA rate to be charged per the Annual Charge Adjustment clause provisions established by the Commission in Order No. 472, issued on May 29, 1987. The new ACA rate to be charged by ANR Storage will be effective October 1, 1996.

ANR Storage states that copies of the filing were served upon the company's Jurisdictional customers.

Any person desiring to be heard or to protest said filing should file a motion to intervene or protest with the Federal Energy Regulatory Commission, 888 First Street, NE., Washington, D.C. 20426, in accordance with 18 CFR 385.214 and 385.211 of the Commission's Rules and Regulations. All such motions or protests must be filed as provided in Section 154.210 of the Commission's Regulations. Protests will be considered by the Commission in determining the appropriate action to be taken, but will not serve to make protestants parties to the proceeding. Any person wishing to become a party must file a motion to intervene. Copies of this filing are on file with the Commission and are available for public

inspection in the Public Reference Room.

Lois D. Cashell,

Secretary.

[FR Doc. 96–22869 Filed 9–6–96; 8:45 am]

BILLING CODE 6717–01–M

[Docket No. TM97–1–91–000]

ANR Storage Company; Notice of Proposed Changes in FERC Gas Tariff

September 3, 1996.

Take notice that on August 29, 1996, ANR Storage Company (ANR Storage) tendered for filing to become part of its FERC Gas Tariff, Original Volume No. 1, Fourth Revised Sheet No. 5, with a proposed effective date of October 1, 1996.

ANR Storage states that Fourth Revised Sheet No. 5 reflects the new ACA rate to be charged per the Annual Charge Adjustment clause provisions established by the Commission in Order No. 472, issued on May 29, 1987. The new ACA rate to be charged by ANR Storage will be effective October 1, 1996.

ANR Storage states that copies of the filing were served upon the company's jurisdictional customers.

Any person desiring to be heard or to protest said filing should file a motion to intervene or protest with the Federal Energy Regulatory Commission, 888 First Street, N.E., Washington, D.C. 20426, in accordance with 18 CFR 385.214 and 385.211 of the Commission's Rules and Regulations. All such motions or protests must be filed as provided in Section 154.210 of the Commission's Regulations. Protests will be considered by the Commission in determining the appropriate action to be taken, but will not serve to make protestants parties to the proceeding. Any person wishing to become a party must file a motion to intervene. Copies of this filing are on file with the Commission and are available for public inspection in the Public Reference Room.

Lois D. Cashell,

Secretary.

[FR Doc. 96–22870 Filed 9–6–96; 8:45 am]

BILLING CODE 6717–01–M

Black Marlin Pipeline Company; Notice of Proposed Changes in FERC Gas Tariff

September 3, 1996.

Take notice that on August 29, 1996, Black Marlin Pipeline Company (Black Marlin) tendered for filing to become part of its FERC Gas Tariff, First Revised Volume No. 1, the following tariff sheet to be effective October 1, 1996:

Seventh Revised Sheet No. 4

Black Marlin states that the above-referenced tariff sheet is being filed pursuant to Section 18 of the General Terms and Conditions of Black Marlin's tariff to reflect the decrease of the ACA charge to 0.19¢/MMBtu based on the Commission's Annual Charge Billing for Fiscal Year 1996 and an average Btu content of 1.0436 MMBtu per Mcf.

Any person desiring to be heard or to protest said filing should file a motion to intervene or protest with the Federal Energy Regulatory Commission, 888 First Street, NE, Washington, DC, 20426, in accordance with Sections 385.211 and 385.214 of the Commission's Rules and Regulations. All such motions or protests must be filed as provided in Section 154.210 of the Commission's Regulations. Protests will be considered by the Commission in determining the appropriate action to be taken, but will not serve to make protestants parties to the proceeding. Any person wishing to become a party must file a motion to intervene. Copies of this filing are on file with the Commission and are available for public inspection in the Public Reference Room.

Lois D. Cashell,

Secretary.

[FR Doc. 96–22871 Filed 9–6–96; 8:45 am]

BILLING CODE 6717–01–M

[Docket No. TM97–1–112–000]

Blue Lake Gas Storage Company; Notice of Proposed Changes in FERC Gas Tariff

September 3, 1996.

Take notice that on August 29, 1996, Blue Lake Gas Storage Company (Blue Lake) tendered for filing to become part of its FERC Gas Tariff, First Revised Volume No. 1, Fourth Revised Sheet No. 5, with a proposed effective date of October 1, 1996.

Blue Lake states that Fourth Revised Sheet No. 5 reflects the new ACA rate to be charged per the Annual Charge Adjustment Clause provisions established by the Commission in Order No. 472, issued on May 29, 1987. The new ACA rate to be charged by Blue Lake will be effective October 1, 1996.

Blue Lake states that copies of the filing were served upon the company's jurisdictional customer.

Any person desiring to be heard or to protest said filing should file a motion to intervene or protest with the Federal Energy Regulatory Commission, 888 First Street, N.E., Washington, D.C. 20462, in accordance with 18 CFR 385.214 and 385.211 of the Commission's Rules and Regulations. All such motions or protests must be filed as provided in Section 154.210 of the Commission's Regulations. Protests will be considered by the Commission in determining the appropriate action to be taken, but will not serve to make protestants parties to the proceeding. Any person wishing to become a party must file a motion to intervene. Copies of this filing are on file with the Commission and are available for public inspection in the Public Reference Room.

Lois D. Cashell,

Secretary.

[FR Doc. 96–22866 Filed 9–6–96; 8:45 am]

BILLING CODE 6717–01–M

[Docket No. TM97–1–97–000]

Chandeleur Pipe Line Company; Notice of Proposed Changes in FERC Gas Tariff

September 3, 1996.

Take notice on August 29, 1996, Chandeleur Pipe Line Company (Chandeleur) submits for filing to become part of its FERC Gas Tariff, Second Revised Volume No. 1, the following tariff sheets to become effective October 1, 1996:

Fourth Revised Sheet No. 5

Chandeleur proposes to adjust its rates to reflect the Federal Energy Regulatory Commission's FY 1996 annual charge for natural gas pipeline companies of $0.0023 per MMBtu.

Any person desiring to be heard or to protest this filing should file a motion to intervene or protest with the Federal Energy Regulatory Commission, 888 First Street, NE., Washington, DC 20426, in accordance with 18 CFR 385.214 and 385.211. All such motions or protests must be filed as provided in Section 154.210 of the Commission's Regulations. Protests will be considered by the Commission in determining the appropriate action to be taken, but will not serve to make protestants parties of the proceeding. Any person wishing to become a party must file a motion to intervene. Copies of this filing are on file with the Commission and are available for public inspection in the Public Reference Room.

Lois D. Cashell,

Secretary.

[FR Doc. 96–22868 Filed 9–6–96; 8:45 am]

BILLING CODE 6717–01–M

[Docket No. TM97–1–34–001]

Florida Gas Transmission Company; Notice of Proposed Changes in FERC Gas Tariff

September 3, 1996.

Take notice that on August 29, 1996, Florida Gas Transmission Company (FGT) tendered for filing as part of its FERC Gas Tariff, Third Revised Volume No. 1, the following tariff sheets to become effective October 1, 1996.

Substitute Sixteenth Revised Sheet No. 8A
Substitute Ninth Revised Sheet No. 8A.01
Substitute Eighth Revised Sheet No. 8A.02
Substitute Fourteenth Revised Sheet No. 8B
Substitute Seventh Revised Sheet No. 8B.01

FGT states that the above referenced tariff sheets are being filed pursuant to Section 22 of the General Terms and Conditions (GTC) of FGT's tariff to reflect a decrease of the ACA charge to 0.19 ¢ per MMBtu based on the Commission's Annual Charge Billing for Fiscal Year 1996. FGT states that it is requesting these sheets be made effective in place of the corresponding tariff sheets filed August 21, 1996 in Docket No. TM97–1–34–000 which reflected the calculation of the ACA Charge from the wrong Unit Charge Factor.

Any person desiring to protest said filing should file a protest with the Federal Energy Regulatory Commission, 888 First Street, NE, Washington, DC 20426, in accordance with Section 385.211 of the Commission's Rules and Regulations. All such protests must be filed as provided in Section 154.210 of the Commission's Regulations. Protests will be considered by the Commission in determining the appropriate action to be taken, but will not serve to make protestants parties to the proceeding. Copies of this filing are on file with the Commission and are available for public inspection in the Public Reference Room.

Lois D. Cashell,

Secretary.

[FR Doc. 96–22877 Filed 9–6–96; 8:45 am]

BILLING CODE 6717–01–M

[Docket No. TM97–1–65–000]

Jupiter Energy Corporation; Notice of Proposed Changes in FERC Gas Tariff

September 3, 1996.

Take notice that on August 28, 1996 Jupiter Energy Corporation (Jupiter Energy), tendered for filing to become part of its FERC Gas Tariff, Original Volume No. 1, the following sheets, with a proposed effective date of October 1, 1996:

Tenth Revised Sheet No. 4A
Tenth Revised Sheet No. 5A
Tenth Revised Sheet No. 6A

Jupiter Energy states that the filed tariff sheets reflect, pursuant to Section 154.38(d)(6) of the Commission's regulations, the implementation of Jupiter Energy's Annual Charge Adjustment (ACA) surcharge. The proposed surcharge rate is 0.23¢ per Mcf.

Jupiter Energy states that copies of the filing have been served on the Company's jurisdictional customers.

Any person desiring to be heard or to protest said filing should file a motion to intervene or protest with the Federal Energy Regulatory Commission, 888 First Street, NE, Washington, DC 20426, in accordance with Rules 211 and 214 of the Commission's Rules of Practice and Procedure. All such motions or protests should be filed as provided in Section 154.210 of the Commission's Regulations. Protests will be considered by the Commission in determining the appropriate action to be taken, but will not serve to make protestants parties to the proceeding. Any person wishing to become a party must file a motion to intervene. Copies of Jupiter Energy's filing are on file with the Commission and are available for public inspection.

Lois D. Cashell,

Secretary.

[FR Doc. 96–22874 Filed 9–6–96; 8:45 am]

BILLING CODE 6717–01–M

[Docket No. RP96–350–000]

K N Interstate Gas Transmission Co.; Notice of Waiver Request

September 3, 1996.

Take notice that on August 28, 1996 K N Interstate Gas Transmission Co. (K N Interstate) filed a request for a one-time waiver of certain timing requirements of Section 18 of its FERC GAS Tariff, Volume No. I–B, relating to the Right of First Refusal process. K N Interstate requests a shortened time frame for the iterative bidding process, if applicable, and for tendering and execution of new service agreements.

K N Interstate states that copies of the filing have been served upon mainline transportation and storage shippers and affected state regulatory bodies.

Any person desiring to be heard or to make any protest with reference to this filing should file a motion to intervene or protest with the Federal Energy Regulatory Commission, 888 First Street, N.E., Washington, D.C. 20426, in accordance with Rules 211 and 214 of the Commission's Rules of Practice and Procedure (18 CFR 385.211, 385.214). All such motions or protests must be filed as provided in Section 154.210 of the Commission's Regulations. All protests filed with the Commission will be considered by it in determining the appropriate action to be taken, but will not serve to make the protestants parties to the proceeding. Any person wishing to become a party to a proceeding or to participate as a party in any hearing therein must file a petition to intervene in accordance with the Commission's Rules. Copies of this filing are on file with the Commission and are available for public inspection.

Lois D. Cashell,

Secretary.

[FR Doc. 96–22878 Filed 9–6–96; 8:45 am]

BILLING CODE 6717–01–M

[Docket No. TM97–1–47–000]

MIGC, Inc.; Notice of Proposed Changes in FERC Gas Tariff

September 3, 1996.

Take notice that on August 29, 1996, MIGC, Inc. (MIGC) tendered for filing to become part of its FERC Gas Tariff, First Revised Volume No. 1, Fourth Revised Sheet No. 4. This tariff sheet is proposed to become effective October 1, 1996.

MIGC states that the instant filing is being submitted to reflect Annual Charge Adjustment unit charges applicable to transportation services during the fiscal year commencing October 1, 1996.

Any person desiring to be heard or to protest said filing should file a petition to intervene or protest with the Federal Energy Regulatory Commission, 888 First Street, NE., Washington, D.C. 20426, in accordance with Rules 214 and 211 of the Commission's Rules of Practice and Procedure (18 CFR sections 385.214 and 385.211). All such petitions or protests must be filed as provided in section 154.210 of the Commission's Regulations. Protests will be considered by the Commission in determining appropriate action to be taken, but will not serve to make protestants parties to the proceedings. Any person wishing to become a party must file a petition to intervene. Copies of this filing are on file with the Commission and are available for public inspection.

Lois D. Cashell,

Secretary.

[FR Doc. 96–22875 Filed 9–6–96; 8:45 am]

BILLING CODE 6717–01–M

[Docket No. TM97–1–37–000]

Northwest Pipeline Corporation; Notice of Proposed Changes in FERC Gas Tariff

September 3, 1996.

Take notice that on August 29, 1996, Northwest Pipeline Corporation (Northwest) tendered for filing as part of its FERC Gas Tariff the following tariff sheets, to become effective October 1, 1996:

Third Revised Volume No. 1
Eighth Revised Sheet No. 5
Seventh Revised Sheet No. 8
Original Volume No. 2
Twenty-First Revised Sheet No. 2.2

Northwest states that the purpose of this filing is to update Northwest's tariff to reflect the Commission approved Annual Charge Adjustment (ACA) factor to be effective for the twelve-month period beginning October 1, 1996 pursuant to Section 154.402 of the Commission's regulations and Section 16 of the General Terms and Conditions of Northwest's tariff. Northwest states that its new ACA factor will be .20¢ per MMBtu, a reduction of .02¢ per MMBtu from its current ACA factor.

Any person desiring to be heard or protest this filing should file a motion to intervene or protest with the Federal Energy Regulatory Commission, 888 First Street, NE., Washington, DC 20426, in accordance with Sections 385.214 and 385.211 of the Commission's Rules and Regulations. All such motions or protests must be filed as provided in Section 154.210 of the Commission's Regulations. Protests will be considered by the Commission in determining the appropriate action to be taken, but will not serve to make protestants parties to the proceeding. Any person wishing to become a party must file a motion to intervene. Copies of this filing are on file with the Commission and are available for public inspection in the Public Reference Room.

Lois D. Cashell,
Secretary.

[FR Doc. 96–22876 Filed 9–6–96; 8:45 am]

BILLING CODE 6717–01–M

[Docket Nos. ER96–1663–000, EC96–19–000 and EL96–48–000]

Pacific Gas and Electric Company, San Diego Gas & Electric Company, Southern California Edison Company; Notice of Speakers and Panels for Technical Conference

August 30, 1996.

As previously announced (61 FR 42878 (Aug. 19, 1996)), the Commission Staff will convene a two-day technical conference in the captioned proceedings to be held on Thursday, September 12 and Friday, September 13, 1996, at the offices of the Federal Energy Regulatory Commission, 888 First Street, N.E., Washington, DC 20426. The technical conference will commence at 10:00 a.m. on Thursday, September 12, 1996. The starting time for the second day of the technical conference, Friday September 13, 1996, has been changed to 9:00 a.m. The technical conference will be open to all interested persons.

More interested persons desired to speak at the technical conference than the time allotted would have allowed. Therefore, based on the requests to participate, the Commission Staff has assembled panels of speakers representing a broad spectrum of interests and views for each panel. A list of the speakers and panels for the technical conference is contained in the Attachment.

For Further Information Contact:

Stephen T. Greenleaf, Office of Electric Power Regulation, Federal Energy Regulatory Commission, 888 First Street, N.E., Washington, DC 20426, (202) 208–0430

David E. Mead, Office of Economic Policy, Federal Energy Regulatory Commission, 888 First Street, N.E., Washington, DC 20426, (202) 208–0438

Lois D. Cashell,
Secretary.

Panels for Staff Conference on WEPEX

Each panelist should plan on a five minute presentation followed by questions from the Commission Staff.

Thursday, September 12, 1996 Agenda

Panel 1—Market Power

The panelists will discuss the market power analyses presented by the applicants, including related topics, such as the role of demand-side bidding; effect of any performance-based ratemaking; the role of the power exchange; the appropriate monitoring program; any mitigation measures that may be needed; and the effect of zones on market power; as well as other issues concerning market power that participants wish to address.

Joe D. Pace, for Pacific Gas & Electric Company
Paul Joskow, Elizabeth and James Killian, Professor of Economics and Management, Head, Department of Economics, Massachusetts Institute of Technology, for Southern California Edison Company
William Hieronymus, for San Diego Gas & Electric Company
Scott Hempling, Toward Utility Rate Normalization
Evelyn K. Elsesser, Energy Producers and Users Coalition
Dennis W. Carlton, for Sacramento Municipal Utility District
Sara D. Schotland, Electricity Consumers Resource Council

Lunch

Panel 2—Transmission Pricing

The panelists will discuss transmission pricing issues, including cost recovery and access charges; market efficiency, cost shifting; congestion management issues; ancillary services and losses issues; and the appropriate use of zones.

Stephen J. Metague, Manager of Grid Customer Services, Pacific Gas & Electric Company
Maureen Palmer, Bulk Power Special Projects, Los Angeles, Department of Water and Power
Barbara Barkovich, for California Large Energy Consumers' Association
Clifford B. Rochlin, Market Advisor, Southern California Gas Company
W. Kent Palmerton, Manager of Industry Restructuring Programs, Northern California Power Agency
Larry Klein, City and County of San Francisco, California

Friday, September 13, 1996 Agenda

Panel 3—Transmission Expansion and Transmission Rights/TCCs

The panelists will discuss transmission expansion issues, including who builds and pays for new facilities and the proper incentives to ensure that necessary new transmission facilities are constructed. The panelists will also discuss physical transmission rights and role of financial instruments, *i.e.*, Transmission Congestion Contracts (TCCs). The Commission staff is interested in comments addressing the interaction of proposed WEPEX transmission rights and TCCs with the Commission's pending CRT proposal.

Geoff Gaebe, Group Manager, San Diego Gas & Electric Company
Ron Nunnally, Manager of Grid Planning and Strategy, Southern California Edison Company
Jeffrey K. Hartman, Director, Wholesale, Cogeneration and UEG Segments, Southern California Gas Company
Robert A. Levin, Senior Vice-President of the New York Mercantile Exchange
Keith McCrea, California Manufacturers Association
W. Kent Palmerton, Manager of Industry Restructuring Programs, Northern California Power Agency

Panel 4—ISO Facilities and Operations

The panelists will discuss the transmission/distribution split; what control will be transferred from utilities to the ISO; the ISO's integration of national, regional and individual transmission owner operational criteria; and the incentives the ISO will have to achieve operational efficiency.

Dennis N. Benevides, Senior Transmission Planning Engineer, Pacific Gas & Electric Company

Sohrab A. Yari, Transmission Planning Supervisor, San Diego Gas & Electric Company

Armie Perez, Manager of Transmission Planning, Southern California Edison Company

Marcie Edwards, Director of Bulk Power, Los Angeles Department of Water and Power

Chris Kiriakou, Assistant General Manager of Energy Resources, Turlock Irrigation District

Jeffrey C. Miller, Supervisor of Transmission Planning for the Sacramento Municipal Utility District and Chairman of the Western Systems Coordinating Council (WSCC) Reliability Subcommittee

Lunch

Panel 5—Scheduling, Bidding, Settlements and the Role of Scheduling Coordinators

The panelists will discuss the integration of PX bidding and bilateral schedules; the types of information that should flow among the PX, ISO and scheduling coordinators; the advantages and disadvantages of ISO/PX separation; unit commitment decision making; ancillary services issues; must-run and overgeneration criteria.

John Ballance, Manager of Grid Dispatch, Southern California Edison Company

Susan J. Mara, Director of Transmission Policy and Pricing, Pacific Gas & Electric Company

Eric C. Woychik, Utility Consumers' Action Network

Jan Smutny-Jones, Executive Director, Independent Energy Producers Association

Thomas Beach, for Watson Cogeneration Company

Barbara Barkovich, for California Large Energy Consumers Association

[FR Doc. 96–22865 Filed 9–6–96; 8:45 am]

BILLING CODE 6717–01–M

[Docket No. TM97–1–111–000]

Steuben Gas Storage Company; Notice of Proposed Changes in FERC Gas Tariff

September 3, 1996.

Take notice that on August 29, 1996, Stueben Gas Storage Company (Steuben) tendered for filing to become part of its FERC Gas Tariff, Original Volume No. 2, Fourth Revised Sheet No. 1(A), with a proposed effective date of October 1, 1996.

Steuben states that Fourth Revised Sheet No. 1(A) reflects the new ACA rate to be charged per the Annual Charge Adjustment clause provisions established by the Commission in Order No. 472, issued on May 29, 1987. The new ACA rate to be charged by Steuben will be effective October 1, 1996.

Steuben states that copies of the filing were served upon the company's Jurisdictional customers.

Any person desiring to be heard or to protest said filing should file a motion to intervene or protest with the Federal Energy Regulatory Commission, 888 First Street, N.E., Washington, D.C. 20426, in accordance with 18 CFR 385.214 and 385.211 of the Commission's Rules and Regulations. All such motions or protests must be filed as provided in Section 154.210 of the Commission's Regulations. Protests will be considered by the Commission in determining the appropriate action to be taken, but will not serve to make protestants parties to the proceeding. Any person wishing to become a party must file a motion to intervene. Copies of this filing are on file with the Commission and are available for public inspection in the Public Reference Room.

Lois D. Cashell,

Secretary.

[FR Doc. 96–22867 Filed 9–6–96; 8:45 am]

BILLING CODE 6717–01–M

[Docket No. ER96–2524–000]

Symmetry Device Research, Inc.; Notice of Issuance of Order

September 4, 1996.

Symmetry Device Research, Inc. (SDRI) submitted for filing a rate schedule under which SDRI will engage in wholesale electric power and energy transactions as a marketer. SDRI also requested waiver of various Commission regulations. In particular, SDRI requested that the Commission grant blanket approval under 18 CFR Part 34 of all future issuances of securities and assumptions of liability by SDRI.

On August 22, 1996, pursuant to delegated authority, the Director, Division of Applications, Office of Electric Power Regulation, granted requests for blanket approval under Part 34, subject to the following:

Within thirty days of the date of the order, any person desiring to be heard or to protest the blanket approval of issuances of securities or assumptions of liability by SDRI should file a motion to intervene or protest with the Federal Energy Regulatory Commission, 888 First Street, N.E., Washington, D.C. 20426, in accordance with Rules 211 and 214 of the Commission's Rules of Practice and Procedure (18 CFR 385.211 and 385.214).

Absent a request for hearing within this period, SDRI 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 such issuance or assumption is for some lawful object within the corporate purposes of the applicant, and 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 SDRI's issuances of securities or assumptions of liability.

Notice is hereby given that the deadline for filing motions to intervene or protests, as set forth above, is September 23, 1996. Copies of the full text of the order are available from the Commission's Public Reference Branch, 888 First Street, N.E. Washington, D.C. 20426.

Lois D. Cashell,

Secretary.

[FR Doc. 96–22909 Filed 9–6–96; 8:45 am]

BILLING CODE 6717–01–M

[Docket No. TM97–1–80–000]

Tarpon Transmission Company; Notice of Change in Annual Charge Adjustment

September 3, 1996.

Take notice that on August 29, 1996, Tarpon Transmission Company (Tarpon) tendered for filing to be a part of its FERC Gas Tariff, Original Volume No. 1, the following tariff sheets, with a proposed effective date of October 1, 1996:

Fourteenth Revised Sheet No. 2A
Fourth Revised Sheet No. 2E
Seventh Revised Sheet No. 86A
Ninth Revised Sheet No. 96A

Tarpon states that the purpose of this filing is to revise its Annual Charge Adjustment surcharge in order to recover the Commission's annual charges for the 1996 fiscal year. Also note that Tarpon proposes to delete language related to certain surcharges which are no longer effective.

Tarpon states that copies of the filing have been mailed to its customers and interested parties.

Any person desiring to be heard or to protest said filing should file a motion to intervene or protest with the Federal Energy Regulatory Commission, 888 First Street, N.E., Washington, D.C. 20426, in accordance with Rules 211 and 214 of the Commission's Rules of Practice and Procedures (18 CFR 385.211 and 385.214). Such motions or protests must be filed as provided in Section 154.210 of the Commission's Regulations. Protests will be considered by the Commission in determining the appropriate action to be taken, but will not serve to make protestants parties to the proceedings. Any person desiring to become a party must file a motion to intervene. Copies of this filing are on file with the Commission and are available for public inspection.

Lois D. Cashell,

Secretary.

[FR Doc. 96–22873 Filed 9–6–96; 8:45 am]

BILLING CODE 6717–01–M

[Docket No. TM97–1–82–000]

Viking Gas Transportation Company; Notice of Proposed Changes in FERC Gas Tariff

September 3, 1996.

Take notice that on August 28, 1996, Viking Gas Transmission Company (Viking) tendered for filing as part of its FERC Gas Tariff, First Revised Volume No. 1, Sixth Revised Sheet No. 6, to be effective October 1, 1996.

Viking states that the purpose of this filing is to reduce Viking's Annual Charge Adjustment (ACA) surcharge from $0.0023 per dekatherm to $0.0020 per dekatherm, as permitted by Section 154.204 of the Commission's Regulations.

Viking states that copies of this filing have been mailed to all of its customers and to affected State regulatory commissions.

Any person desiring to be heard or to protest said filing should file a motion to intervene or protest with the Federal Energy Regulatory Commission, 888 First Street, N.E., Washington, D.C. 20426, in accordance with Sections 385.214 and 385.211 of the Commission's Rules of Practice and Procedure. All such motions must be filed as provided in Section 154.210 of the Commission's Regulations. Protests will be considered by the Commission in determining the appropriate action to be taken, but will not serve to make protestants parties to the proceeding. Any person wishing to become party must file a motion to intervene. Copies of this filing are on file with the Commission and are available for public inspection in the Public Reference Room.

Lois D. Cashell,

Secretary.

[FR Doc. 96–22872 Filed 9–6–96; 8:45 am]

BILLING CODE 6717–01–M

[Docket No. ER96–2798–000, et al.]

New England Power Pool, et al.; Electric Rate and Corporate Regulation Filings

September 3, 1996.

Take notice that the following filings have been made with the Commission:

1. New England Power Pool

[Docket No. ER96–2798–000]

Take notice that on August 23, 1996, the New England Power Pool Executive Committee filed a signature page to the NEPOOL Agreement dated September 1, 1971, as amended, signed by Natural Resources Group, Inc. (Natural Resources). The New England Power Pool Agreement, as amended, has been designated NEPOOL FPC No. 2.

The Executive Committee states that acceptance of the signature page would permit Natural Resources to join the over 100 Participants already in the Pool. NEPOOL further states that the filed signature page does not change the NEPOOL Agreement in any manner, other than to make Natural Resources a Participant in the Pool. NEPOOL requests an effective date of October 1, 1996, for commencement of participation in the Pool by Natural Resources.

Comment date: September 16, 1996, in accordance with Standard Paragraph E at the end of this notice.

2. Louisville Gas and Electric Company

[Docket No. ER96–2799–000]

Take notice that on August 26, 1996, Louisville Gas and Electric Company (LG&E), tendered for filing a copy of a Purchase and Sales Agreement between LG&E and Entergy Power Marketing Corp. under Rate Schedule GSS—Generation Sales Service.

Comment date: September 16, 1996, in accordance with Standard Paragraph E at the end of this notice.

3. Louisville Gas and Electric Company

[Docket No. ER96–2800–000]

Take notice that on August 26, 1996, Louisville Gas and Electric Company, tendered for filing copies of service agreements between Louisville Gas and Electric Company and Koch Power Services, Inc. under Rate GSS.

Comment date: September 16, 1996, in accordance with Standard Paragraph E at the end of this notice.

4. Louisville Gas and Electric Company

[Docket No. ER96–2801–000]

Take notice that on August 26, 1996, Louisville Gas and Electric Company, tendered for filing copies of a service agreement between Louisville Gas and Electric Company and Rainbow Energy Marketing Corp. under Rate GSS.

Comment date: September 16, 1996, in accordance with Standard Paragraph E at the end of this notice.

5. Louisville Gas and Electric Company

[Docket No. ER96–2802–000]

Take notice that on August 26, 1996, Louisville Gas and Electric Company, tendered for filing copies of service agreements between Louisville Gas and Electric Company and South Mississippi Electric Power Assoc. under Rate GSS.

Comment date: September 16, 1996, in accordance with Standard Paragraph E at the end of this notice.

6. Northern States Power Company (Minnesota Company)

[Docket No. ER96–2803–000]

Take notice that on August 26, 1996, Northern States Power Company (Minnesota) (NSP), tendered for filing a Supplement No. 1 (Supplement) to the Municipal Interconnection and Interchange Agreement (Agreement) dated February 6, 1996, between NSP and the City of Ada (City). NSP files this Supplement on behalf of City and itself.

The Supplement provides for a change in the language in Service Schedules A, B, and D of the Agreement to remove a reference to a specified billing date. NSP requests the Commission waive its Part 35 notice requirements and accept this Supplement for filing effective December 1, 1995.

Comment date: September 16, 1996, in accordance with Standard Paragraph E at the end of this notice.

7. Louisville Gas and Electric Company

[Docket No. ER96–2805–000]

Take notice that on August 26, 1996, Louisville Gas and Electric Company (LG&E), tendered for filing a copy of a Non-Firm Transmission Agreement

between Louisville Gas and Electric Company and Morgan Stanley Capital Group Services under Rate TS.

Comment date: September 16, 1996, in accordance with Standard Paragraph E at the end of this notice.

8. Wisconsin Public Service Corporation

[Docket No. ER96–2807–000]

Take notice that on August 26, 1996, Wisconsin Public Service Corporation (WPSC), tendered for filing an executed Transmission Service Agreement between WPSC and VTEC Energy Inc. The Agreement provides for transmission service under the Open Access Transmission Service Tariff, FERC Original Volume No. 11.

WPSC asks that the agreement becomes effective on the date of execution by WPSC.

Comment date: September 16, 1996, in accordance with Standard Paragraph E at the end of this notice.

9. New England Power Company

[Docket No. ER96–2808–000]

Take notice that on August 26, 1996, New England Power Company filed a Service Agreement and Certificate of Concurrence with Sonat Power Marketing Inc. for service under NEP's FERC Electric Tariffs, Original Volume Nos. 5 and 6.

Comment date: September 16, 1996, in accordance with Standard Paragraph E at the end of this notice.

10. New England Power Company

[Docket No. ER96–2809–000]

Take notice that on August 26, 1996, New England Power Company filed Service Agreements and Certificates of Concurrence with VTEC Energy Inc. for service under NEP's FERC Electric Tariffs, Original Volume Nos. 5 and 6.

Comment date: September 16, 1996, in accordance with Standard Paragraph E at the end of this notice.

11. Wisconsin Public Service Corporation

[Docket No. ER96–2810–000]

Take notice that on August 26, 1996, Wisconsin Public Service Corporation, tendered for filing an executed service agreement with Nebraska Public Power District under its CS–1 Coordination Sales Tariff.

Comment date: September 16, 1996, in accordance with Standard Paragraph E at the end of this notice.

12. Louisville Gas and Electric Company

[Docket No. ER96–2811–000]

Take notice that on August 26, 1996, Louisville Gas and Electric Company (LG&E), tendered for filing a copy of a Non-Firm Transmission Agreement between Louisville Gas and Electric Company and Entergy Power Marketing Corp. under Rate TS.

Comment date: September 16, 1996, in accordance with Standard Paragraph E at the end of this notice.

13. Louisville Gas and Electric Company

[Docket No. ER96–2812–000]

Take notice that on August 26, 1996, Louisville Gas and Electric Company (LG&E), tendered for filing a copy of a Non-Firm Transmission Agreement between Louisville Gas and Electric Company and Jacksonville Electric Company under Rate TS.

Comment date: September 16, 1996, in accordance with Standard Paragraph E at the end of this notice.

14. Baltimore Gas and Electric Company

[Docket No. ER96–2813–000]

Take notice that on August 26, 1996, Baltimore Gas and Electric Company (BGE), filed a Service Agreement dated July 2, 1996, with Duke/Louis Dreyfus L.L.C. under BGE's FERC Electric Tariff Original Volume No. 3 (Tariff). Under the tendered Service Agreement, BGE agrees to provide services to Duke/Louis Dreyfus L.L.C. under the provisions of the Tariff. BGE requests an effective date of July 2, 1996 for the Service Agreement. BGE states that a copy of the filing was served upon the Public Service Commission of Maryland.

Comment date: September 16, 1996, in accordance with Standard Paragraph E at the end of this notice.

15. Cinergy Services, Inc.

[Docket No. ER96–2814–000]

Take notice that on August 26, 1996, Cinergy Services, Inc. (Cinergy), tendered for filing on behalf of its operating companies, The Cincinnati Gas & Electric Company (CG&E) and PSI Energy, Inc. (PSI), an Interchange Agreement, dated August 1, 1996 between Cinergy, CG&E, PSI and Illinova Power Marketing, Inc. (Illinova).

The Interchange Agreement provides for the following service between Cinergy and Illinova:

1. Exhibit A—Power Sales by Illinova
2. Exhibit B—Power Sales by Cinergy

Cinergy and Illinova have requested an effective date of August 26, 1996.

Copies of the filing were served on Illinova Power Marketing, Inc., Public Service Commission of Utah, the Kentucky Public Service Commission, the Public Utilities Commission of Ohio and the Indiana Utility Regulatory Commission.

Comment date: September 16, 1996, in accordance with Standard Paragraph E at the end of this notice.

16. UtiliCorp United Inc.

[Docket No. ES96–40–000]

Take notice that on August 28, 1996, UtiliCorp United Inc., (UtiliCorp) filed an application, under § 204 of the Federal Power Act, seeking authorization to issue and sell up to and including 2 million shares of Common Stock pursuant to the UtiliCorp amended and restated 1986 Stock Incentive Plan.

Comment date: September 27, 1996, in accordance with Standard Paragraph E at the end of this notice.

17. Upper Peninsula Power Company

[Docket No. ES96–42–000]

Take notice that on August 29, 1996, Upper Peninsula Power Company filed an application, under § 204 of the Federal Power Act, seeking authorization to issue not more than $18 million of unsecured promissory notes on or before October 1, 1998, with final maturities not later than October 1, 1999.

Comment date: September 27, 1996, in accordance with Standard Paragraph E at the end of this notice.

Standard Paragraph

E. Any person desiring to be heard or to protest said filing should file a motion to intervene or protest with the Federal Energy Regulatory Commission, 888 First Street, N.E., Washington, D.C. 20426, in accordance with Rules 211 and 214 of the Commission's Rules of Practice and Procedure (18 CFR 385.211 and 18 CFR 385.214). All such motions or protests should be filed on or before the comment date. Protests will be considered by the Commission in determining the appropriate action to be taken, but will not serve to make protestants parties to the proceeding. Any person wishing to become a party must file a motion to intervene. Copies of this filing are on file with the Commission and are available for public inspection.

Lois D. Cashell,

Secretary.

[FR Doc. 96–22910 Filed 9–6–96; 8:45 am]

BILLING CODE 6717–01–P

[Docket No. EC96–30–000, et al.]

Western Resources, Inc., et al.; Electric Rate and Corporate Regulation Filings

August 30, 1996.

Take notice that the following filings have been made with the Commission:

1. Western Resources, Inc.

[Docket No. EC96–30–000]

Take notice that on August 22, 1996, Western Resources, Inc. filed an Application pursuant to Section 203 of the Federal Power Act and Part 33 of the Commission's Regulations requesting authorization and approval of a merger between Western Resources and Kansas City Power and Light Co. (KCPL). KCPL will be merged with and into Western Resources, with Western Resources being the surviving corporation.

Western Resources has submitted testimony and other evidence in support of the request that the merger be approved. Western Resources has requested that the Commission issue its approval of the merger expeditiously without conducting an evidentiary hearing.

Comment date: September 30, 1996, in accordance with Standard Paragraph E at the end of this notice.

2. Niagara Mohawk Power Corporation

[Docket No. EC96–31–000]

Take notice that on August 21, 1996, Niagara Mohawk Power Corporation filed an application under Section 203 of the Federal Power Act to transfer its interest in the jurisdictional interconnection facilities associated with the Medina power plant.

Copies of the application were served on the Medina Power Company and the New York Public Service Commission.

Comment date: September 23, 1996, in accordance with Standard Paragraph E at the end of this notice.

3. North American Energy Conservation, Inc.

Docket No. EC96–32–000

On August 22, 1996, North American Energy Conservation, Inc., an authorized power marketer, filed an application seeking expedited approval pursuant to Section 203 of the Federal Power Act for the transfer of an ownership interest to York Research Corporation, an affiliated company.

Comment date: September 23, 1996, in accordance with Standard Paragraph E at the end of this notice.

4. MidAmerican Energy Company

[Docket Nos. ER95–1542–001, ER95–188–002, and EL96–38–000]

Take notice that on July 9, 1996, MidAmerican Energy Company filed, pursuant to Rule 602 of the Commission's Regulations, an Offer of Settlement which would resolve all issues in Docket No. EL96–38–000. The Offer of Settlement, if accepted, would provide a lower point-to-point transmission rate cap during off-peak periods and reduce the need for further proceedings at the Commission.

Comment date: September 13, 1996, in accordance with Standard Paragraph E at the end of this notice.

5. Louisville Gas & Electric Company

[Docket No. ER96–2622–000]

Take notice that on August 5, 1996, Louisville Gas and Electric Company tendered for filing copies of a service agreement between Louisville Gas and Electric Company and Koch Power Services, Inc. under Rate GSS.

Comment date: September 13, 1996, in accordance with Standard Paragraph E at the end of this notice.

6. PECO Energy Company

[Docket No. ER96–2661–000]

Take notice that on July 29, 1996, PECO Energy Company filed a summary of transactions made during the first quarter of calendar year 1996 under PECO's market based rate tariff for power service accepted by the Commission in Docket No. ER96–640–000.

Comment date: September 13, 1996, in accordance with Standard Paragraph E at the end of this notice.

7. Illinois Power Company

[Docket No. ER96–2781–000]

Take notice that on August 22, 1996, Illinois Power Company (Illinois Power), 500 South 27th Street, Decatur, Illinois 62526, tendered for filing firm and non-firm transmission agreements under which AES Power, Inc. will take transmission service pursuant to its open access transmission tariff. The agreements are based on the Form of Service Agreement in Illinois Power's tariff.

Illinois Power has requested an effective date of August 15, 1996.

Comment date: September 13, 1996, in accordance with Standard Paragraph E at the end of this notice.

8. PacifiCorp

[Docket No. ER96–2782–000]

Take notice that on August 22, 1996, PacifiCorp, tendered for filing in accordance with 18 CFR Part 35 of the Commission's Rules and Regulations, a Letter Agreement dated April 26, 1996 between PacifiCorp and Black Hills Corporation (Black Hills).

Copies of this filing were supplied to Black Hills, the Public Utility Commission of Oregon and the Washington Utilities and Transportation Commission.

A copy of this filing may be obtained from PacifiCorp's Regulatory Administration Department's Bulletin Board System through a personal computer by calling (503) 464–6122 (9600 baud, 8 bits, no parity, 1 stop bit).

Comment date: September 13, 1996, in accordance with Standard Paragraph E at the end of this notice.

9. Illinois Power Company

[Docket No. ER96–2783–000]

Take notice that on August 22, 1996, Illinois Power Company (Illinois Power), 500 South 27th Street, Decatur, Illinois 62526, tendered for filing a Power Sales Tariff, Service Agreement under which Valero Power Services Company will take service under Illinois Power Company's Power Sales Tariff. The agreements are based on the Form of Service Agreement in Illinois Power's tariff.

Illinois Power has requested an effective date of August 6, 1996.

Comment date: September 13, 1996, in accordance with Standard Paragraph E at the end of this notice.

10. Illinois Power Company

[Docket No. ER96–2784–000]

Take notice that on August 22, 1996, Illinois Power Company (Illinois Power), 500 South 27th Street, Decatur, Illinois 62526, tendered for filing a Power Sales Tariff, Service Agreement under which The Cincinnati Gas & Electric Company (CG&E), an Ohio corporation, PSI Energy, Inc., (PSI), an Indiana corporation, (collectively Cinergy Operating Companies) and Cinergy Services, Inc. (Cinergy Services, a Delaware corporation, as agent for on behalf of the Cinergy Operating Companies) will take service under Illinois Power Company's Power Sales Tariff. The agreements are based on the Form of Service Agreement in Illinois Power's tariff.

Illinois Power has requested an effective date of August 5, 1996.

Comment date: September 13, 1996, in accordance with Standard Paragraph E at the end of this notice.

11. Illinois Power Company

[Docket No. ER96–2785–000]

Take notice that on August 22, 1996, Illinois Power Company (Illinois

Power), 500 South 27th Street, Decatur, Illinois 62526, tendered for filing a Power Sales Tariff, Service Agreement under which Missouri Public Service, a Division of UtiliCorp United, Inc. will take service under Illinois Power Company's Power Sales Tariff. The agreements are based on the Form of Service Agreement in Illinois Power's tariff.

Illinois Power has requested an effective date of August 6, 1996.

Comment date: September 13, 1996, in accordance with Standard Paragraph E at the end of this notice.

12. New England Power Pool

[Docket No. ER96–2786–000]

Take notice that on August 22, 1996, the New England Power Pool Executive Committee filed a signature page to the NEPOOL Agreement dated September 1, 1971, as amended, signed by Energy Choice, L.L.C. (Energy Choice). The New England Power Pool Agreement, as amended, has been designated NEPOOL FPC No. 2.

The Executive Committee states that acceptance of the signature page would permit Energy Choice to join the over 100 Participants that already participate in the Pool. NEPOOL further states that the filed signature page does not change the NEPOOL Agreement in any manner, other than to make Energy Choice a Participant in the Pool. NEPOOL requests an effective date on or before October 1, 1996, or as soon as possible thereafter for commencement of participation in the Pool by Energy Choice.

Comment date: September 13, 1996, in accordance with Standard Paragraph E at the end of this notice.

13. Idaho Power Company

[Docket No. ER96–2787–000]

Take notice that on August 22, 1996, Idaho Power Company (IPC), tendered for filing with the Federal Energy Regulatory Commission a Service Agreement under Idaho Power Company's FERC Electric Tariff No. 5, Open Access Transmission Tariff, between Montana Power Company and Idaho Power Company.

Comment date: September 13, 1996, in accordance with Standard Paragraph E at the end of this notice.

14. New England Power Pool

[Docket No. ER96–2788–000]

Take notice that on August 22, 1996, the New England Power Pool Executive Committee filed a signature page to the NEPOOL Agreement dated September 1, 1971, as amended, signed by AIG Trading Corporation (AIG). The New England Power Pool Agreement, as amended, has been designated NEPOOL FPC No. 2.

The Executive Committee states that acceptance of the signature page would permit AIG to join the over 100 Participants already in the Pool. NEPOOL further states that the filed signature page does not change the NEPOOL Agreement in any manner, other than to make AIG a Participant in the Pool. NEPOOL requests an effective date of October 1, 1996 for commencement of participation in the Pool by AIG.

Comment date: September 13, 1996, in accordance with Standard Paragraph E at the end of this notice.

15. Puget Sound Power & Light Company

[Docket No. ER96–2789–000]

Take notice that on August 22, 1996, Puget Sound Power & Light Company, tendered for filing the Northwest Power Pool Agreement dated December 22, 1995 (the Agreement).

Comment date: September 13, 1996, in accordance with Standard Paragraph E at the end of this notice.

16. Union Electric Company

[Docket No. ER96–2790–000]

Take notice that on August 23, 1996, Union Electric Company (UE), tendered for filing a First Amendment dated August 8, 1996, to the Wholesale Electric Service Agreement dated March 23, 1989, between the City of Perry, Missouri and UE. Said Amendment provides for extending terms of the agreement through December 31, 2005.

Also filed was a First Amendment dated August 8, 1996 to the Substitute Power Agreement dated September 5, 1989, which also extends the terms of the agreement through December 31, 2005.

UE requests that these filings be permitted to become effective November 1, 1996.

Comment date: September 13, 1996, in accordance with Standard Paragraph E at the end of this notice.

17. Louisville Gas and Electric Company

[Docket No. ER96–2791–000]

Take notice that on August 23, 1996, Louisville Gas and Electric Company (LG&E), tendered for filing a copy of a Non-Firm Transmission Agreement between Louisville Gas and Electric Company and Vitol Gas and Electric L.L.C. under Rate TS.

Comment date: September 13, 1996, in accordance with Standard Paragraph E at the end of this notice.

18. Louisville Gas and Electric Company

[Docket No. ER96–2792–000]

Take notice that on August 23, 1996, Louisville Gas and Electric Company (LG&E), tendered for filing a copy of a Non-Firm Transmission Agreement between Louisville Gas and Electric Company and Koch Power Services under Rate TS.

Comment date: September 13, 1996, in accordance with Standard Paragraph E at the end of this notice.

19. Louisville Gas and Electric Company

[Docket No. ER96–2793–000]

Take notice that on August 23, 1996, Louisville Gas and Electric Company, tendered for filing copies of a service agreement between Louisville Gas and Electric Company and Entergy Services, Inc., under Rate GSS.

Comment date: September 13, 1996, in accordance with Standard Paragraph E at the end of this notice.

20. Louisville Gas and Electric Company

[Docket No. ER96–2794–000]

Take notice that on August 23, 1996, Louisville Gas and Electric Company, tendered for filing copies of a service agreement between Louisville Gas and Electric Company and South Mississippi Electric Power Association under Rate GSS.

Comment date: September 13, 1996, in accordance with Standard Paragraph E at the end of this notice.

21. Superior Water, Light & Power Company

[Docket No. ER96–2796–000]

Take notice that on August 23, 1996, Superior Water, Light & Power Company, tendered for filing Amendment No. 1 to the Phase Angle Regulating Transformer Cost Sharing Agreement between Dairyland Power Cooperative, Minnesota Power & Light Company, Northern States Power Company (Minnesota), Northern States Power Company (Wisconsin), and Superior Water, Light & Power Company dated as of December 31, 1995.

Comment date: September 13, 1996, in accordance with Standard Paragraph E at the end of this notice.

22. Florida Power & Light Company

[Docket No. ER96–2797–000]

Take notice that on August 23, 1996, Florida Power & Light Company (FPL), tendered for filing proposed service agreements with PECO Energy Power Team for Non-Firm transmission service

under FPL's Open Access Transmission Tariff.

FPL requests that the proposed service agreements be permitted to become effective September 1, 1996.

FPL states that this filing is in accordance with Part 35 of the Commission's Regulations.

Comment date: September 13, 1996, in accordance with Standard Paragraph E at the end of this notice.

Standard Paragraph

E. Any person desiring to be heard or to protest said filing should file a motion to intervene or protest with the Federal Energy Regulatory Commission, 888 First Street, N.E., Washington, D.C. 20426, in accordance with Rules 211 and 214 of the Commission's Rules of Practice and Procedure (18 CFR 385.211 and 18 CFR 385.214). All such motions or protests should be filed on or before the comment date. Protests will be considered by the Commission in determining the appropriate action to be taken, but will not serve to make protestants parties to the proceeding. Any person wishing to become a party must file a motion to intervene. Copies of this filing are on file with the Commission and are available for public inspection.

Lois D. Cashell,

Secretary.

[FR Doc. 96–22912 Filed 9–6–96; 8:45 am]

BILLING CODE 6717–01–P

[Project Nos. 11585–000, et al.]

Hydroelectric Applications (Coon Rapids Energy Associates, et al.); Notice of Applications

Take notice that the following hydroelectric applications have been filed with the Commission and are available for public inspection:

1 a. *Type of Application:* Preliminary Permit.

b. *Project No.:* 11585–000.

c. *Date filed:* July 5, 1996.

d. *Applicant:* Coon Rapids Energy Associates.

e. *Name of Project:* Coon Rapids Dam Project.

f. *Location:* On the Mississippi River, near Brooklyn Park and Coon Rapids, Hennepin and Anoka Counties, Minnesota.

g. *Filed Pursuant to:* Federal Power Act 16 U.S.C. §§ 791 (a)—825(r).

h. *Applicant Contact:* Mr. George Waldow, Coon Rapids Energy Associates, 1390 Kingsview Lane, Plymouth, Minnesota 55447, (612) 476–4440.

i. *FERC Contact:* Mary Golato (202) 219–2804.

j. *Comment Date:* October 7, 1996.

k. *Description of Project:* The proposed project would consist of the following facilities: (1) An existing concrete gravity, 450-foot-long dam which is integral with the powerhouse and a main concrete spillway that is approximately 1,000 feet long; (2) an existing reservoir extending approximately 6.5 miles with a surface area of 600 acres at a normal pool elevation of 830.1 feet NGVD; (3) a new powerhouse containing two to four turbine-generator units having a total capacity of 8 megawatts; (4) a new 600-foot- long, 4.16-kilovolt transmission line; and (5) appurtenant facilities. The dam is owned by the Surburban Hennepin Regional Park District. The average annual generation is estimated to be 45 gigawatthours. The cost of the studies under the permit will be approximately $30,000.

l. *This notice also consists of the following standard paragraphs:* A5, A7, A9, A10, B, C, and D2.

m. *Available Locations of Application:* A copy of the application is available for inspection and reproduction at the Commission's Public Reference and Files Maintenance Branch, located at 888 North Capitol Street, N.E., Room 2–A, Washington, D.C. 20426, or by calling (202) 219–1371. A copy is also available for inspection and reproduction at Mr. George Waldow, 1390 Kingsview Lane, Plymouth, MN 55447 (612) 476–4440.

2 a. *Type of Application:* Preliminary Permit.

b. *Project No.:* P–11590–000.

c. *Date filed:* July 29, 1996.

d. *Applicant:* Joint Ventures.

e. *Name of Project:* Burnside Hydro Project.

f. *Location:* On the Hockanum River in Hartford County, Connecticut.

g. *Filed Pursuant to:* Federal Power Act 16 USC §§ 791(a)—825(r).

h. *Applicant Contact:* Mr. Joseph P. Keegan, Keegan Construction, 530 Fish Rock Road, Southbury, CT 06488, (203) 264–7386.

i. *FERC Contact:* Edward Lee at (202) 219–2809.

j. *Comment Date:* October 25, 1996.

k. *Description of Project:* The proposed project would consist of: (1) An existing 12-foot-high, 160-foot-long concrete gravity dam; (2) an existing 21 acre-foot reservoir with a surface area of 3 acres; (3) a concrete intake structure; (4) a 62-foot-long masonry intake flume; (5) an existing concrete and brick powerhouse containing a 150-kW generating unit; (6) a 251-foot-long concrete tailrace; (7) an existing 150-foot-long transmission line; and (8) appurtenant facilities. The applicant estimates that the average annual generation would be 570,000 kWh. No new access roads will be needed to conduct the studies. The applicant estimates that the cost of the studies to be conducted under the preliminary permit would be $10,000. All project structures are owned by the applicant.

l. *Purpose of Project:* Project power would be sold to a local ultility.

m. *This notice also consists of the following standard paragraphs:* A5, A7, A9, A10, B, C, and D2.

3 a. *Type of Application:* Minor License.

b. *Project No.:* P–11566–000.

c. *Date Filed:* December 12, 1995.

d. *Applicant:* Consolidated Hydro Maine, Inc.

e. *Name of Project:* Damariscotta Mills Hydro Project.

f. *Location:* On the Damariscotta River, in Lincoln County, near Newcastle, Nobleboro, and Jefferson, Maine.

g. *Filed Pursuant to:* Federal Power Act, 16 U.S.C. 791(a)–825(r).

h. *Applicant Contact:* Mr. Wayne E. Nelson, Consolidated Hydro Maine, Inc., Director of Environmental Affairs, Andover Business Park, 200 Bulfinch Drive, Andover, MA 01810, (508) 681–1900.

i. *FERC Contact:* Ed Lee (202) 219–2809.

j. *Comment Date:* October 25, 1996.

k. *Status of Environmental Analysis:* This application has been accepted for filing but is not ready for environmental analysis at this time—see attached standard paragraph E1.

l. *Description of Project:* The project consists of the following: (1) An existing reservoir with a surface area of 4,625 acres and usable storage volume of 6,875 acre-feet at the normal surface elevation of 54.35 feet (ft), National Geodetic Vertical Datum (NGVD); (2) an existing concrete mass dam, referred to as the ''Fishway Dam'', about 124 ft long, containing three stoplog bays; (3) an existing concrete dike, about 40 ft long; (4) an existing concrete mass dam, referred to as the ''Waste Gate Dam'', about 57 ft long, containing two waste gates and a stoplog bay; (5) an existing concrete mass intake structure, referred to as the ''intake Dam'', consisting of: (a) Two stone masonry wing walls, extending 125 ft along the east bank and 50 ft along the west bank of the impoundment, (b) steel trashracks, and (c) a wooden gatehouse containing a manually operated wooden headgate; (6) an existing 5.6 ft diameter steel penstock, about 350 ft long, extending from the intake dam to the powerhouse;

(7) an existing two ft diameter surge tank, extending vertically from the penstock about 20 ft upstream of the powerhouse; (8) an existing powerhouse, constructed of brick and concrete, about 30 feet by 35 feet, containing: (a) a double runner Francis turbine, with minimum and maximum hydraulic capacities of 65 cubic feet per second (cfs) and 175 cfs, respectively, and (b) a synchronous generator, rated at 460 kW; and (9) existing appurtenant facilities.

m. *Purpose of Project:* Project generation would be sold to a local utility.

n. *This notice also consists of the following standard paragraphs:* B1 and E1.

o. *Available Location of Application:* A copy of the application, as amended and supplemented, is available for inspection and reproduction at the Commission's Public Reference and Files Maintenance Branch, located at 888 First Street, N.E., Room 2A, Washington, D.C., 20426, or by calling (202) 208–1371. A copy is also available for inspection and reproduction at Consolidated Hydro Maine, Inc., Andover Business Park, 200 Bulfinch Drive, Andover, MA 01810, or by calling (508) 681–1900.

4 a. *Type of Application:* New License.

b. *Project No.:* 2612–005.

c. *Date Filed:* December 28, 1995.

d. *Applicant:* Central Maine Power Company.

e. *Name of Project:* Flagstaff Water Storage Project.

f. *Location:* On the Dead River in Somerset and Franklin Counties, near the towns of Eustis and Stratton, Maine.

g. *Filed Pursuant to:* Federal Power Act, 16 U.S.C. 791(a)–825(r).

h. *Applicant Contact:* F. Allen Wiley, Managing Director of Generation, Central Maine Power Company, 41 Anthony Avenue, Augusta, ME 04330.

i. *FERC Contact:* Thomas Dean (202) 219–2778.

j. *Deadline Date:* See standard paragraph D10.

k. *Status of Environmental Analysis:* This application has been accepted for filing and is ready for environmental analysis at this time.

l. *Description of Project:* The existing Flagstaff Project consists of: (1) The Long Falls dam about 1,339 feet long and 45 feet high, consisting of, from left to right (looking downstream), (a) a 450-foot-long concrete spillway section topped with 2-foot-high flashboards, (b) a 125-foot-long concrete section containing five, 20-foot-wide Taintor gates, (c) a 70-foot-long concrete section containing two Broome gates, a fishway, and a log sluice, and (d) a 694-foot-long earthen dike topped with a 2-foot-high wave barrier; (2) a reservoir having a length of about 23 miles, a width of about 6 miles at the widest point, a surface area of 17,950 acres, and a storage capacity of about 275,482 acre-feet at full pond elevation of 1,146.0 feet U.S. Geological Survey datum; and (3) appurtenant facilities.

m. *Purpose of Project:* The Flagstaff Project is a water storage facility and is operated to regulate and augment flows that are used by nine downstream mainstem Kennebec River hydropower projects and to control flooding.

n. *This notice also consists of the following standard paragraph(s):* A4 and D10.

o. *Available Location of Application:* A copy of the application, as amended and supplemented, is available for inspection and reproduction at the Commission's Public Reference and Files Maintenance Branch, located at 888 First Street, N.E., Room 2–A, Washington, D.C., 20426, or by calling (202) 208–1371. A copy is also available for inspection and reproduction at Central Maine Power Company, 41 Anthony Avenue, Augusta, ME, 04330 or by calling Frank Dunlap (207) 621–4469.

5 a. *Type of Application:* Amendment of license.

b. *Project No:* 2736–019.

c. *Date Filed:* August 1, 1996.

d. *Applicant:* Idaho Power Company.

e. *Name of Project:* American Falls Project.

f. *Location:* Power County, American Falls, Idaho.

g. *Filed Pursuant to:* Federal Power Act, 16 U.S.C. Section 791(a)–825(r).

h. *Applicant Contact:* Laurel Heacock, Idaho Power Company, P.O. Box 70, Boise, ID 83707, (208) 388–2918.

i. *FERC Contact:* Allyson Lichtenfels, (202) 219–3274.

j. *Comment Date:* October 11, 1996.

k. *Description of Project:* The licensee filed revised exhibit K, Sheets 1 and 2, drawings to indicate minor real estate and project boundary updates, an easement previously awarded to Power County, update the structural appearance of the dam, power plant, and spillway, and update the transmission line data shown.

l. *This notice also consists of the following standard paragraphs:* B, C1, and D2.

Standard Paragraphs

A4. Development Application—Public notice of the filing of the initial development application, which has already been given, established the due date for filing competing applications or notices of intent. Under the Commission's regulations, any competing development application must be filed in response to and in compliance with public notice of the initial development application. No competing applications or notices of intent may be filed in response to this notice.

A5. 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.

A7. Preliminary Permit—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.

A9. 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.

B. Comments, Protests, or Motions to Intervene—Anyone may submit comments, a protest, or a motion to intervene in accordance with the requirements of Rules of Practice and Procedure, 18 CFR 385.210, .211, .214. In determining the appropriate action to take, the Commission will consider all protests or other comments filed, but only those who file a motion to intervene in accordance with the Commission's Rules may become a

party to the proceeding. Any comments, protests, or motions to intervene must be received on or before the specified comment date for the particular application.

B1. Protests or Motions to Intervene—Anyone may submit a protest or a motion to intervene in accordance with the requirements of Rules of Practice and Procedure, 18 CFR 385.210, 385.211, and 385.214. In determining the appropriate action to take, the Commission will consider all protests 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 protests or motions to intervene must be received on or before the specified deadline date for the particular application.

C. 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'', ''MOTION TO INTERVENE'', as applicable, and the Project Number of the particular application to which the filing refers. Any of the above-named documents must be filed by providing the original and the number of copies provided by the Commission's regulations to: The Secretary, Federal Energy Regulatory Commission, 888 First Street, N.E., Washington, D.C. 20426. An additional copy must be sent to Director, Division of Project Review, 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.

C1. Filing and Service of Responsive Documents—Any filings must bear in all capital letters the title ''COMMENTS'', ''RECOMMENDATIONS FOR TERMS AND CONDITIONS'', ''PROTEST'', OR ''MOTION TO INTERVENE'', as applicable, and the Project Number of the particular application to which the filing refers. Any of the above-named documents must be filed by providing the original and the number of copies provided by the Commission's regulations to: The Secretary, Federal Energy Regulatory Commission, 888 First Street, N.E., Washington, D.C. 20426. A copy of any motion to intervene must also be served upon each representative of the Applicant specified in the particular application.

D2. Agency Comments—Federal, state, and local agencies are invited to file comments on the described application. A copy of the application may be obtained by agencies directly from the Applicant. If an agency does not file comments within the time specified for filing comments, it will be presumed to have no comments. One copy of an agency's comments must also be sent to the Applicant's representatives.

D10. Filing and Service of Responsive Documents—The application is ready for environmental analysis at this time, and the Commission is requesting comments, reply comments, recommendations, terms and conditions, and prescriptions.

The Commission directs, pursuant to section 4.34(b) of the regulations (see Order No. 533 issued May 8, 1991, 56 FR 23108, May 20, 1991) that all comments, recommendations, terms and conditions and prescriptions concerning the application be filed with the Commission within 60 days from the issuance date of this notice (October 21, 1996 for Project No. 2612–005). All reply comments must be filed with the Commission within 105 days from the date of this notice (December 4, 1996 for Project No. 2612–005).

Anyone may obtain an extension of time for these deadlines from the Commission only upon a showing of good cause or extraordinary circumstances in accordance with 18 CFR 385.2008.

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. Any of these documents must be filed by providing the original and the number of copies required by the Commission's regulations to: The Secretary, Federal Energy Regulatory Commission, 888 First Street, N.E., Washington, D.C. 20426. An additional copy must be sent to Director, Division of Project Review, Office of Hydropower Licensing, Federal Energy Regulatory Commission, at the above address. 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.

E1. Filing and Service of Responsive Documents—The application is not ready for environmental analysis at this time; therefore, the Commission is not now requesting comments, recommendations, terms and conditions, or prescriptions.

When the application is ready for environmental analysis, the Commission will issue a public notice requesting comments, recommendations, terms and conditions, or prescriptions.

All filings must (1) bear in all capital letters the title ''PROTEST'' or ''MOTION TO INTERVENE;'' (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 protesting or intervening; and (4) otherwise comply with the requirements of 18 CFR 385.2001 through 385.2005. Agencies may obtain copies of the application directly from the applicant. Any of these documents must be filed by providing the original and the number of copies required by the Commission's regulations to: The Secretary, Federal Energy Regulatory Commission, 888 First Street, N.E., Washington, D.C. 20426. An additional copy must be sent to Director, Division of Project Review, Office of Hydropower Licensing, Federal Energy Regulatory Commission, at the above address. A copy of any protest or motion to intervene must be served upon each representative of the applicant specified in the particular application.

Dated: August 26, 1996, Washington, D.C.

Lois D. Cashell,

Secretary.

[FR Doc. 96–22913 Filed 9–6–96; 8:45 am]

BILLING CODE 6717–01–P

[Docket No. CP96–686–000, et al.]

Transcontinental Gas Pipe Line Corporation, et al., Natural Gas Certificate Filings

September 3, 1996.

Take notice that the following filings have been made with the Commission:

1. Transcontinental Gas Pipe Line Corporation

[Docket No. CP96–686–000]

Take notice that on July 31, 1996, Transcontinental Gas Pipe Line Corporation (Transco), P.O. Box 1396, Houston, Texas 77251, filed an application, as supplemented on August

22, 1996, with the Commission in Docket No. CP96–686–000 pursuant to Sections 7(b) and 7(c) of the Natural Gas Act (NGA) requesting a blanket certificate of public convenience and necessity, authorizing Transco to install and operate mobile compressors on a temporary basis while existing compressors are undergoing maintenance, and permission and approval to abandon the mobile compressors when the maintenance work is completed, all as more fully set forth in the application which is open to the public for inspection.

Transco states that it requires the blanket certificate in order to maintain throughput in the event of scheduled or unscheduled maintenance. Transco also states that it would attempt to achieve comparable horsepower and deliverability with the temporary compressors as that which is available with the permanent compressors. Transco asserts that the blanket certificate would enable Transco to install temporary compressors without a prior filing and to avoid interruptions of service to customers. Transco states that it does not own a compressor unit which could be used on an as-needed, temporary basis and that it would use rental units at a cost estimated to be no greater than $95,000 per unit per month.

Comment date: September 24, 1996, in accordance with Standard Paragraph F at the end of this notice.

2. Texas Gas Transmission Corporation

[Docket No. CP96–726–000]

Take notice that on August 19, 1996, Texas Gas Transmission Corporation (Texas Gas), P.O. Box 20008, Owensboro, Kentucky 42304, filed in Docket No. CP96–726–000 a request pursuant to Section 157.205 and 157.212 of the Commission's Regulations under the Natural Gas Act (18 CFR 157.205 and 157.212) for authorization to reclassify an existing delivery point, in Gibson County, Indiana by converting it from a rural farm tap facility to a specifically designated delivery point for Southern Indiana Gas and Electric Company (SIGECO). Texas Gas makes such request, under its blanket certificate issued in Docket No. CP82–407–000 pursuant to Section 7 of the Natural Gas Act, all as more fully set forth in the request on file with the Commission and open to public inspection.

Texas Gas indicates that the reclassified delivery facility will be used to provide firm transportation service to SIGECO, which will allow SIGECO to continue serving the existing right-of-way grantors at this point and a new customer, Smith Greenhouse, which is not a right-of-way grantor. It is stated that the reclassified facility will be known as the Kirkville delivery point.

Texas Gas further states that the reclassification of this delivery point will not require any new facilities by Texas Gas; however, SIGECO will install, own, operate and maintain measurement, regulation, odorization and other related facilities necessary to provide service to its customers at this point. Texas Gas indicates that SIGECO will require 158 MMBtu per day, with an annual maximum quantity of 6,716 MMBtu at this point, for residential heating by the current customers and heating at Smith Greenhouse.

Comment date: October 18, 1996, in accordance with Standard Paragraph G at the end of this notice.

3. Eastern Shore Natural Gas Company

[Docket No. CP96–728–000]

Take notice that on August 20, 1996, Eastern Shore Natural Gas Company (Eastern Shore), Post Office Box 1769, Dover, Delaware 19903, filed in Docket No. CP96–728–000, an application pursuant to Section 7(b) and (c) of the Natural Gas Act (NGA), and Part 157 of the Federal Energy Regulatory Commission's (Commission) regulations, for a certificate of public convenience and necessity authorizing Eastern Shore to reduce, on a pro-rata basis, the firm storage service it provides to its customers under Rate Schedule GSS, all as more fully set forth in the application which is on file with the Commission and open to public inspection.

Eastern Shore states that as a direct result of the authorization granted Transcontinental Gas Pipe Line Corporation in Docket No. CP96–226–000 [1] it is necessary for Eastern Shore to reduce, on a pro-rata basis, the firm storage service it provides to its customers under Rate Schedule GSS.

Comment date: September 24, 1996, in accordance with Standard Paragraph F at the end of this notice.

4. Columbia Gulf Transmission Company

[Docket No. CP96–732–000]

Take notice that on August 21, 1996, Columbia Gulf Transmission Company (Columbia Gulf), 2603 Augusta STE 125, Houston, Texas 77057–5637, filed in Docket No. CP96–732–000 a request pursuant to Section 157.205 and 157.211 of the Commission's Regulations under the Natural Gas Act (18 CFR 157.205 and 157.211) for authorization to operate in interstate commerce certain facilities in Vermilion Parish, Louisiana that were previously operated to effectuate transportation service pursuant to Section 311 of the Natural Gas Policy Act (NGPA). Columbia Gulf makes such request, under its blanket certificate issued in Docket No. CP83–496–000 pursuant to Section 7 of the Natural Gas Act, all as more fully set forth in the request on file with the Commission and open to public inspection.

Columbia Gulf states that the delivery point to Torch Operating Company (Torch) was originally installed as a receipt point from an independent producer, and that minor revisions were made to the station in order that the receipt point could be used as a delivery point from Columbia Gulf under Section 311 of the NGPA, to Torch on behalf of Illini Carrier, L.P., an intrastate pipeline. It is indicated that the existing point of interconnection allows Columbia Gulf to deliver natural gas to Torch for use in its gas lift operation. Columbia Gulf is now requesting authorization to convert the Section 311 facilities to 7(c) certification, in order that the point may be used to provide both Subpart B and G transportation service to Torch, under Part 284, on an interruptible basis.

Comment date: October 18, 1996, in accordance with Standard Paragraph G at the end of this notice.

5. Florida Gas Transmission Company

[Docket No. CP96–743–000]

Take notice that on August 26, 1996, Florida Gas Transmission Company (FGT), 1400 Smith Street, Houston, Texas 77002, filed in the above docket, a request pursuant to Sections 157.205 and 157.212 of the Commission's Regulations under the Natural Gas Act for authorization to construct and operate a new delivery point for West Florida Natural Gas Company WFNG) to accommodate natural gas deliveries to the State of Florida Liberty Prison under FGT's blanket authority issued in Docket No. CP82–553–000 pursuant to Section 7(c) of the NGA, all as more fully set forth in the request that is on file with the Commission and open to public inspection.

Specifically, FGT proposes to construct, operate, and own a new delivery point at or near mile post 383 on its existing 30-inch mainline in Liberty County, Florida. FGT also proposes to add the subject delivery point to an existing firm gas transportation service agreement by and between FGT and the State of Florida, Department of Corrections dated October 1, 1993, and contracted under FGT's FERC Gas Tariff Rate Schedule FTS–1. FGT will transport gas to the new delivery point on a self-

[1] 75 FERC ¶ 61,285 (1996).

implementing basis under its blanket transportation certificate issued by the Commission in Docket No. CP89–555–000, pursuant to Subpart G of Part 284 of the Commission's Regulations.

FGT states that the subject delivery point will consist of a 4-inch tap, minor connecting pipe, electronic flow measurement equipment, and any related appurtenant facilities necessary for FGT to deliver gas up to 60 MMBtu per hour at line pressure. WFNG will reimburse FGT for the $57,000 estimated construction cost. FGT further states that WFNG will construct, own and operate the meter and regulation station.

Comment date: October 18, 1996, in accordance with Standard Paragraph G at the end of this notice.

6. Northwest Pipeline Corporation

[Docket No. CP96–752–000]

Take notice that on August 28, 1996, Northwest Pipeline Corporation (Northwest), 295 Chipeta Way, Salt Lake City, Utah 84108, filed in Docket No. CP96–752–000 a request pursuant to Sections 157.205, 157.216 and 157.211 of the Commission's Regulations under the Natural Gas Act (18 CFR 157.205, 157.216 and 157.211) for permission and approval to abandon certain facilities and operations at the Enumclaw Meter Station in King County, Washington. Northwest also request authorization to construct and operate upgraded replacement facilities at the Enumclaw Meter Station, in order to accommodate a request from the City of Enumclaw, Washington for an additional 3,000 Dth of firm natural gas per day. Northwest makes such request, under its blanket certificate issued in Docket No. CP82–433–000 pursuant to Section 7 of the Natural Gas Act, all as more fully set forth in the request on file with the Commission and open to public inspection.

Northwest proposes to upgrade the Enumclaw Meter Station by replacing approximately 60 feet of 2-inch heater piping and appurtenances with approximately 60 feet of 4-inch heater piping and appurtenances, and by replacing the 50 percent trim plates in the existing 2-inch regulators with new 100 percent trim plates. As a result of the proposed upgrades, Northwest states that the maximum design capacity of the meter station will increase from approximately 6,863 Dth per day at 250 psig to approximately 10,924 Dth per day at 250 psig.

Northwest indicates that the estimated $26,078 cost to upgrade the facilities will be reimbursed by the City of Enumclaw.

Comment date: October 18, 1996, in accordance with Standard Paragraph G at the end of this notice.

7. Northern Natural Gas Company

[Docket No. CP96–754–000]

Take notice that on August 29, 1996, Northern Natural Gas Company (Northern), 1111 South 103rd Street, Omaha, Nebraska 68124–1000, filed in Docket No. CP96–754–000 a request pursuant to Section 157.205 and 157.212 of the Commission's Regulations under the Natural Gas Act (18 CFR 157.205 and 157.212) for authorization to install and operate the NNG/Sid Richardson, a new delivery point to be located in Lea County, New Mexico, to accommodate incremental interruptible natural gas deliveries to Sid Richardson Gasoline, Ltd. (Sid Richardson). Northern makes such request, under its blanket certificate issued in Docket No. CP82–401–000 pursuant to Section 7 of the Natural Gas Act, all as more fully set forth in the request on file with the Commission and open to public inspection.

Northern states that service will be provided to Sid Richardson pursuant to Northern's currently effective interruptible throughput service agreement(s) with Sid Richardson. Northern asserts that Sid Richardson has requested the installation of the new delivery point to provide fuel for their processing plant.

It is asserted that the proposed volumes to be delivered to Sid Richardson at the NNG/Sid Richardson delivery point are 5 MMBtu on a peak day and 1,825 MMBtu on an annual basis. Northern estimates a cost of $10,000 to install the new delivery point, and states that Sid Richardson will reimburse Northern for the total cost of constructing the proposed delivery point.

Comment date: October 18, 1996, in accordance with Standard Paragraph G at the end of this notice.

Standard Paragraphs

F. Any person desiring to be heard or make any protest with reference to said filing should on or before the comment date file with the Federal Energy Regulatory Commission, 888 First Street, N.E., Washington, D.C. 20426, a motion to intervene or a protest in accordance with the requirements of the Commission's Rules of Practice and Procedure (18 CFR 385.211 and 385.214) and the Regulations under the Natural Gas Act (18 CFR 157.10). All protests filed with the Commission will be considered by it in determining the appropriate action to be taken but will not serve to make the protestants parties to the proceeding. Any person wishing to become a party to a proceeding or to participate as a party in any hearing therein must file a motion to intervene in accordance with the Commission's Rules.

Take further notice that, pursuant to the authority contained in and subject to jurisdiction conferred upon the Federal Energy Regulatory Commission by Sections 7 and 15 of the Natural Gas Act and the Commission's Rules of Practice and Procedure, a hearing will be held without further notice before the Commission or its designee on this filing if no motion to intervene is filed within the time required herein, if the Commission on its own review of the matter finds that a grant of the certificate is required by the public convenience and necessity. If a motion for leave to intervene is timely filed, or if the Commission on its own motion believes that a formal hearing is required, further notice of such hearing will be duly given.

Under the procedure herein provided for, unless otherwise advised, it will be unnecessary for the applicant to appear or be represented at the hearing.

G. Any person or the Commission's staff may, within 45 days after the issuance of the instant notice by the Commission, file pursuant to Rule 214 of the Commission's Procedural Rules (18 CFR 385.214) a motion to intervene or notice of intervention and pursuant to Section 157.205 of the Regulations under the Natural Gas Act (18 CFR 157.205) a protest to the request. If no protest is filed within the time allowed therefore, the proposed activity shall be deemed to be authorized effective the day after the time allowed for filing a protest. If a protest is filed and not withdrawn within 30 days after the time allowed for filing a protest, the instant request shall be treated as an application for authorization pursuant to Section 7 of the Natural Gas Act.

Lois D. Cashell,

Secretary.

[FR Doc. 96–22911 Filed 9–6–96; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Office of the Secretary

Statement of Organization, Functions and Delegations of Authority; Assistant Secretary for Management and Budget

Part A, Office of the Secretary, Statement of Organization, Functions and Delegations of Authority for the

Department of Health and Human Services, Office of Management and Budget, is amended. Chapter AMN, Office of Finance, as last amended at 57 FR 37820, 8/20/92 is deleted and replaced with a new Chapter AMS. The changes are as follows:

1. Delete in its entirety Chapter AMN and replace with the following:

Section AMS.00 Mission. The Office of Finance (AMS) provides financial management advice and leadership to the Secretary and the Assistant Secretary for Management and Budget/Chief Financial Officer (ASMB/CFO), and the Operating Division CFOs, on (1) budget execution policies and standards for financial systems and financial reporting including audited financial statements in conformance with governmentwide accounting concepts and standards; (2) cash and credit management, debt management, payment management including disbursement activities and functions, and travel management; (3) the design, development, operation, and enhancement of Department-wide and component financial systems; (4) the preparation of the HHS Financial Management Status Report and Five Year Plan and the HHS Annual Report including financial statement and discussion and analysis and performance measures; (5) the development of outcome-based performance measures and performance plans through facilitation and training forums and best practices; (6) in coordination with other ASMB components, participates in the clearance/approval process for program information systems that provide financial and/or program performance data which are used in financial statements; (7) approval of the job descriptions and skill requirements for OPDIV CFOs, on the selection of OPDIV CFOs, and provides advice to the ASMB/CFO who participates with the OPDIV Head in the annual performance plan/evaluation of the OPDIV CFO; and (9) on the qualifications recruitment, performance, training and retention of all financial management personnel.

Section AMS.10 Organization. The Office of Finance is headed by the Deputy Assistant Secretary, Finance, who is also the Deputy Chief Financial Officer and reports to the Assistant Secretary for Management and Budget/Chief Financial Officer. The organization is composed of the following:

Immediate Office (AMS)
Office of Financial Policy (AMS1)
Division of Financial Management Policy (AMS11)
Division of Accounting and Fiscal Policy (AMS12)
Office of Financial Systems (AMS2)
Office of Budget Execution (AMS3)

Section AMS.20 Functions. The Office of Finance (AMS):

a. Manages and directs HHS' implementation of major financial management legislation including the Chief Financial Officers Act of 1990 as amended by the Government Management Reform Act of 1994 (GMRA), the Prompt Payment Act, Debt Collection Improvement Act of 1996 and the Cash Management Improvement Act (CMIA) among others.

b. Develops and executes, in coordination with the Office of the Budget, spending policies and procedures for continuing resolutions and appropriations.

c. Makes specific studies and appraisals of the financial aspects of program operations systems designs and data requirements to ensure compliance with objectives of the CFO Act and related legislation as assigned Assistant Secretary for Management and Budget/Chief Financial Officer (ASMB/CFO).

d. Establishes a financial management planning process under the CFO Act for providing guidance and performance measurement indicators that enable the ASMB/CFO to evaluate the Operating Divisions.

e. Provides support and guidance to the Operating Divisions (OPDIVs) for strategic planning and for the development and implementation of performance measures under the Government Performance and Results Act (GPRA).

f. Develops and manages a Department-wide system for estimating and controlling outlays. Assists the Office of Budget in the presentation of budget outlay estimates to the Office of Management and Budget and the Congress.

g. Recommends and issues Department-wide policies and procedures relating to the expenditure and collection of funds administered by the Department.

h. Establishes uniform standards, policies, classifications, and terminologies to be used throughout the Department in budget execution, and financial and cost reporting.

i. Develops and maintains financial management data collection and reporting systems on programs, activities and operations of the Department.

j. Oversees, monitors, and evaluates the design, development, implementation, operation and enhancement of Department-wide and component accounting and financial management systems.

k. Provides Departmental policy guidance to the Payment Management System (PMS) operated by the Program Support Center to assure that a consistent Departmental policy is maintained.

l. Ensures that financial systems provide for timely and accurate reporting of grantee and/or contractor costs and performance data.

m. In coordination with other ASMB components, participates in the clearance/approval process for program information systems that provide financial and/or program performance data which are used in financial statements.

n. Develops and executes policies and procedures relating to the evaluation of accounting and related systems for conformance with Governmentwide principles and standards.

o. Develops and executes policies and procedure relating to cash management and financing of recipient organizations that receive funding from HHS.

p. Develops, coordinates and issues policy related to the development, implementation, and maintenance of Department-wide financial systems.

q. In its area of responsibility represents the Department in its relationship with the Office of Management and Budget, General Accounting Office, General Services Administration, Treasury, and other Federal Agencies. Oversees Departmental implementation of central agency directives on budget execution, fiscal and accounting policy, debt and credit management.

r. Provides advice to the ASMB/CFO on the approval of the job descriptions and skill requirements for OPDIV CFOs and on the approval of the selection of OPDIV CFOs. Provides advice to the ASMB/CFO who participates with the OPDIV Head in the annual performance plan/evaluation of the OPDIV CFO.

s. Provides advice to the ASMB/CFO on the qualifications, recruitment, performance, training, and retention of all financial management personnel.

t. Prepares the HHS Annual Report including financial statement and program performance information as guided by the ASMB/CFO.

u. Serves as the Departmental liaison with GAO, OMB, Treasury, and other Federal agencies on financial matters.

v. Provides administrative services for the Office of Finance, including personnel, budget, travel, procurement, supplies and other general administrative functions.

2. Office of Financial Policy (AMS1). The Office of Financial Policy, is

comprised of the Division of Financial Management Policy (DFMP) and the Division of Accounting and Fiscal Policy (DAFP).

1. Division of Financial Management Policy (AMS11).

The Division (a) Develops Department-wide policies, procedures, and standards for financial management areas including cash management, credit management, debt management, travel management, payment and disbursement activities and functions, and promulgates these and related government-wide financial management requirements through the Departmental Staff Manual System; (b) Establishes a financial management planning process for the development of strategic and tactical plans and prepares the Department's annual Financial Management Status Report and 5 Year Plan under the CFO Act; (c) Provides support and guidance to Operating Division program and financial mangers for strategic planning and for the development and implementation of performance measures under the Government Performance and Results Act (GPRA); (d) Provides support to the Operating Division Chief Financial Officers for financial planning and improvement initiatives; (e) Serves as principal staff advisors on fiscal and accounting policy matters to the Office of Finance; (f) Reviews and drafts Departmental reports on Congressional bills affecting financial management of the Department's programs; (g) Maintains liaison with the Office of Management and Budget (OMB), the Treasury Department, the General Accounting Office (GAO), the General Services Administration (GSA) and other agencies on all financial management matters; (h) Recommends policy and maintains a system for tracking and improving cash and credit management and debt collection performance throughout the Department; (i) Develops and maintains travel voucher examination policies, payment, and disbursing policies and procedures for Department-Wide applications and publishes them through the Departmental Staff Manual System; (j) Performs studies and analyses in any of these subject areas singularly or with outside organizations. Maintains continuous contact with GAO, OMB, Treasury, GSA, and other agencies; (k) Establishes a financial management planning process for providing guidance and financial management indicators that enable the ASMB/CFO to evaluate the financial management programs and activities of the Department; (1) Makes specific studies and appraisals of the financial aspects of program operations to ensure compliance with CFO objectives in area assigned by the Deputy CFO.

2. The Division of Accounting and Fiscal Policy (AMS12).

The Division (a) Develops policies, procedures, and standards for Department-wide accounting and fiscal areas and financial operations including legislative or special accounting initiatives such as the Standard General Ledger (SGL), and promulgates these policies, procedures, and standards as well as other government-wide accounting and fiscal procedures through the Departmental Staff Manual System and maintains appropriate reference material; (b) Develops and maintains financial statement presentation policies, procedures, and standards consistent with governmentwide accounting concepts and standards developed by the Federal Accounting Standards Advisory Board and issued by OMB and oversees the preparation of audited financial statements under the Chief Financial Officers Act as amended by the Government Management Reform Act; (b) Provides advice and assistance to OPDIVs and STAFFDIVs on accounting and related fiscal matters; (d) Serves as principal advisor to the Office of Finance on accounting and related fiscal matters and provides advice and assistance to Operating Divisions and Staff Divisions on these matters; (e) Reviews and drafts Departmental reports on Congressional bills affecting accounting and fiscal matters. (f) Maintains liaison with the Office of Management and Budget (OMB), the General Accounting Office (GAO), Treasury Department, and other agencies on matters involving accounting and related fiscal matters; (g) Performs studies and analyses of any of these or related subjects independently or in conjunction with outside organizations and maintains continuous contact with OMB, GAO, Treasury, GSA and other agencies; (h) Makes specific studies and appraisals of the financial aspects of program operations to ensure compliance with CFO objectives in areas assigned by the Deputy CFO; (i) Prepares the annual HHS report on CFO activities as guided by the DASF/Deputy CFO.

3. Office of Financial Systems (AMS2).

The Office of Financial Systems (a) Develops departmentwide policies and standards for financial and mixed financial systems; (b) Provides advice and serves as the focal point with Federal control agencies on financial systems matters; (c) Provides for the establishment of Department-wide financial definitions and data structures; (d) Provides for the administration of a data integrity and quality control program to ensure compliance with applicable Federal directives, Departmental financial systems policy and automated financial data exchange requirements; (e) Oversees, monitors, evaluates, and recommends approval for the design, implementation, operation, and enhancement of Department-wide and component financial management systems; (f) Evaluates and recommends approval for the design, implementation, operation and enhancement of Department-wide and component accounting and financial management systems; (g) Establishes and maintains a Department-wide quality assurance program that ensures the auditability of financial data and functions as a data; (h) Develops financial systems requirements and policy regarding data structure and interface techniques necessary to communicate between HHS financial systems and with Departmental systems; (i) Makes specific studies and appraisals of the financial aspects of program operations including systems designs and data requirements to ensure compliance with CFO objectives in areas assigned by the Deputy CFO; (j) Provides Departmental policy guidance to the Payment Management System (PMS) operated by the program Support Center to assure that a consistent Departmental policy is maintained; (k) Serves as principal staff adviser to the Office of Finance on all financial systems related matters; (1) Maintains liaison with the Office of Management and Budget, the Treasury Department, the General Accounting Office, and other agencies on matters involving financial systems; (M) Develops and issues policies and procedures relating to the evaluation of accounting and related systems for conformance with OMB Circular A 127; (m) Maintains the Departmental financial systems inventory.

4. Office of Budget Execution (AMS3).

The Office of Budget Execution: (a) Provides leadership and direction in the Department-wide review, analysis and appraisal of financial elements of program execution and the development and execution of policies related to efficient allocation, expenditure and control of funds; (b) Coordinates and tracks outlay projections: (1) to assist OMB in the continuing effort to monitor spending and to thereby improve the management of the Government's overall cash and debt operations; and (2) in support of formulation of the budget, including the maintenance of DHHS ceiling controls and the development of

outlay estimates shown in the President's Budget for controllable programs; (c) Promulgates Departmental spending policies, especially in the event of Continuing Resolutions and possible suspension of operations due to the failure of the Congress to enact appropriations on time and works with agency budget officers and the Office of Budget in formulating agency funding plans; (d) Maintains a system of Department-wide budget execution, including the management and control of the apportionment of funds in accordance with the requirements of the Anti-Deficiency Act and OMB regulations; and requests and monitors the receipt of Treasury warrants; (e) Serves as principal staff advisor to the Office of Finance on all matters involving budget execution; (f) Liaises with the Office of Management and Budget, the Treasury Department, the Congressional Budget Office, and other agencies on matters involving budget execution; (g) Maintains the Catalog of Federal Domestic Assistance and develops State tables of projected obligations for selected programs; (f) Responsible for the development and maintenance of a system of financial information which involves the collection, organization, and maintenance of financial data in electronic form as well as the development of reporting mechanisms for making the financial information useful and available for decision making.

Dated: August 2, 1996.

John J. Callahan,

Assistant Secretary for Management and Budget.

[FR Doc. 96–22933 Filed 9–6–96; 8:45 am]

BILLING CODE 4150–04–M

Administration for Children and Families

Submission for OMB Review; Comment Request

Title: Refugee State-of-Origin Report.

OMB No.: 0970–0043.

Description: The information collection of the ORR–11 (Refugee State-of-Origin Report) is designed to satisfy the statutory requirements of the Immigration and Nationality Act. Section 412(a)(3) of the Act requires ORR to compile and maintain data on the secondary migration of refugees within the United States after arrival.

In order to meet this legislative requirement, ORR requires each State to submit an annual count of the number of refugees who were initially resettled in another State. The State does this by counting the number of refugees with social security numbers indicating residence in another State at the time of arrival in the U.S. (The first three digits of the social security number indicate the State of residence of the applicant.)

Data submitted by the States are compiled and analyzed by the ORR statistician, who then prepares a summary report which is included in ORR's annual Report to Congress. The primary use of the data is to quantify and analyze refugee secondary migration among the 50 States. ORR uses these data to adjust its refugee arrival totals in order to calculate the ORR social services formula allocation.

Respondents: State governments.

ANNUAL BURDEN ESTIMATES

Instrument	Number of respondents	Number of responses per respondent	Average burden hours per response	Total burden hours
State-of-origin report	50	1	.434	217

Estimated Total Annual Burden Hours: 217.

Additional Information: Copies of the proposed collection may be obtained by writing to The Administration for Children and Families, Office of Information Services, Division of Information Resource Management Services, 370 L'Enfant Promenade, S.W., Washington, D.C. 20447, Attn: ACF Reports Clearance Officer.

OMB Comment: OMB is required to make a decision concerning the collection of information between 30 and 60 days after publication of this document in the Federal Register. Therefore, a comment is best assured of having its full effect if OMB receives it within 30 days of publication. Written comments and recommendation for the proposed information collection should be sent directly to the following: Office of Management and Budget, Paperwork Reduction Project, 725 17th Street, N.W., Washington, D.C. 20503, Attn: Ms. Wendy Taylor.

Dated: September 3, 1996.

Bob Sargis,

Acting Reports Clearance Officer.

[FR Doc. 96–22853 Filed 9–6–96; 8:45 am]

BILLING CODE 4184–01–M

DEPARTMENT OF HOUSING AND URBAN DEVELOPMENT

[Docket No. FR–4065–N–04]

Office of the Assistant Secretary for Community Planning and Development; Notice of Funding Availability (NOFA) and Program Guidelines for the Economic Development Initiative (EDI) Program; Amendment and Extension of Application Due Date

AGENCY: Office of the Assistant Secretary for Community Planning and Development, HUD.

ACTION: Amendment and Extension of Application Due Date for Notice of Funding Availability (NOFA) for the Economic Development Initiative Grant Program.

SUMMARY: On July 16, 1996, the Department published a Notice of Funding Availability (NOFA) in the Federal Register announcing the availability of approximately $50,000,000 in Fiscal Year (FY) 1996 funding for the Economic Development Initiative (EDI) program. This notice amends that NOFA to establish set-asides of up to $30 million in EDI grant funds to fund proposals for Homeownership Zones, and of up to $20 million for proposals for Community and Individual Investment Corporations (CIICs) and all other eligible economic development projects. In order to provide applicants due notice of this amendment, this notice also extends the application due date.

DATES: Applications are due in HUD Headquarters at the address stated below under **ADDRESSES** by October 9, 1996. HUD will not accept applications that are submitted to HUD via facsimile (FAX) transmission. Applications that are mailed prior to October 9, 1996, and received within ten (10) days after that date will be deemed to have been received by that date if postmarked by the United States Postal Service by no

later than October 8, 1996. Overnight delivery items received within ten (10) days after October 9, 1996 will be deemed to have been received by that date upon submission of documentary evidence that they were placed in transit with the overnight delivery service by no later than October 8, 1996.

ADDRESSES: On or prior to October 9, 1996, completed applications will be accepted at the following address: Processing and Control Unit, Room 7255, Office of Community Planning and Development, Department of Housing and Urban Development, 451 Seventh Street, SW, Washington, DC 20410, Attention: EDI Grant. At close of business on the deadline date, completed applications will also be received in the south lobby of the Department of Housing and Urban Development at the above address (inquire at the security guard desk). However, any application received by the Office of Community Planning and Development in Headquarters, Washington, DC, by October 9, 1996 will be accepted.

FOR FURTHER INFORMATION CONTACT: Paul Webster, Director, Financial Management Division, Office of Block Grant Assistance, Room 7178, Department of Housing and Urban Development, 451 Seventh Street, SW, Washington, DC 20410; telephone (202) 708–1871.

With respect to proposals for Homeownership Zones contact: Gordon McKay, Director, Office of Affordable Housing Programs, Office of Community Planning and Development, Room 7164, Department of Housing and Urban Development, 451 Seventh Street, SW, Washington, DC 20410; telephone (202) 708–2685. (These are not toll-free numbers.)

Persons with hearing or speech impairments may access these numbers via TTY by calling the Federal Information Relay Service at (800) 877–8339.

SUPPLEMENTARY INFORMATION: On July 16, 1996 (61 FR 37132), the Department published a Notice of Funding Availability (NOFA) in the Federal Register announcing the availability of approximately $50,000,000 in Fiscal Year (FY) 1996 funding for the Economic Development Initiative (EDI) program. The FY 1996 EDI NOFA solicited a wide range of proposals for eligible economic development projects and activities under the EDI grant program. The NOFA particularly emphasized those proposals that would undertake large-scale projects to create Homeownership Zones—proposals designed to reclaim hard-pressed neighborhoods by creating homeownership opportunities for hardworking low- and moderate-income families, and serving as a catalyst for private investment, business creation, and neighborhood revitalization.

The NOFA also solicited proposals for Community and Individual Investment Corporations (CIICs)—a particular type of community development bank that provides residents with opportunities for equity participation—and proposals for more traditional economic development projects, such as site specific economic development projects and grants for economic development revolving loan funds.

The July 16, 1996, NOFA was structured so that the Department would rate all applications based upon the quality of an applicant's response to seven selection criteria. Upon the rating of the applications, the Department would give all proposals for Homeownership Zones and CIICs 10 bonus points. The Department would then rank all proposals regardless of whether the proposal was for a Homeownership Zone, a CIIC, or other economic development project.

Thus, under the procedures outlined in the July 16, 1996 NOFA, it is possible that the rating and ranking of applications could result in only one type of proposal being funded, i.e., all funded projects could potentially be either Homeownership Zone projects, CIIC projects, or the traditional economic development projects. Such an outcome would not reflect the Department's intention to fund a range of different proposals.

Accordingly, the Department is amending the July 16, 1996 EDI NOFA to establish set-asides of up to $30 million to fund proposals for Homeownership Zones, and of up to $20 million to fund proposals for Community and Individual Investment Corporations and all other proposals for economic development projects.

Authority. Title I, Housing and Community Development Act of 1974, as amended, (42 U.S.C. 5301–5320); 24 CFR part 570.

Accordingly, FR Doc. 96–18012, the NOFA and Program Guidelines for the Economic Development Initiative (EDI), published in the Federal Register on July 16, 1996 (61 FR 37132), is amended as follows:

1. On page 37139, in column 3, section II.(D) under the heading ''Selection Process'' is amended to read as follows:

II. The Application Process

* * * * *

(D) *Selection Process*—Once all proposals are scored under the selection criteria above, applications for Homeownership Zones and CIICs will each have 10 additional points added to their total score. Applications will then be selected for funding in two groups as follows:

(1) All applications for Homeownership Zones will be separately ranked in order of points assigned, with the applications receiving more points ranking above those receiving fewer points. Homeownership Zone applications will be funded in rank order until the total aggregate amount of applications funded is equal to $30 million (subject to the Department's discretion described in section II.(D)(3), below);

(2) All applications for Community and Individual Investment Corporations and all other EDI grant applications for economic development projects and programs will be placed in a second group of applications and will be ranked in order of points assigned, with the applications receiving more points ranking above those receiving fewer points. These applications will be funded in rank order until the total aggregate amount of applications funded is equal to $20 million (subject to the Department's discretion described in section II.(D)(3), below);

(3) HUD, in its sole discretion, may choose to award EDI assistance to a lower rated approvable application over a higher rated application in the same group in order to increase the level of geographic diversity of grants approved under this NOFA. The parameters of any such diversity factors used in the selection process will be described in writing by the panel and/or selecting official, and consistently applied in the final selections. However, no application will be funded out of rank order for geographic diversity purposes that does not have a selection score of at least 80 points.

(4) As discussed in paragraph I.(F) above, HUD reserves the right to determine a minimum and a maximum amount of any EDI award or Section 108 commitment per applicant, application, or project, and to modify requests accordingly. In addition, if HUD determines that an application rated, ranked, and fundable could be funded at a lesser EDI grant amount than requested consistent with feasibility of the funded project or activities and the purposes of the Act, HUD reserves the right to reduce the amount of the EDI award and/or increase the Section 108 loan guarantee commitment, if necessary, in accordance with such determination.

HUD may decide not to award the full amount of EDI grant funds available

under this NOFA and may make any remaining amounts available under a future NOFA.

To review and rate applications, HUD may establish panels including persons not currently employed by HUD to obtain certain expertise and outside points of view, including views from other Federal agencies. HUD reserves the right to use two separate panels to review and rate applications in the two groups, and to announce the awards under the two groups at different times.

* * * * *

Dated: August 30, 1996.

Howard Glaser,

Deputy Assistant Secretary for Community Planning and Development.

[FR Doc. 96–22894 Filed 9–4–96; 4:03 pm]

BILLING CODE 4210–29–P

DEPARTMENT OF THE INTERIOR

Fish and Wildlife Service

Notice of Decision and Availability of Two Record of Decision Documents on the Issuance of Permits for Incidental Take of Threatened and Endangered Species

AGENCY: Fish and Wildlife Service, Interior.

ACTION: Notice of availability.

Record of Decision for the Proposed Issuance of a Section 10(a)(1)(B) Permit for the Incidental Take of Stephens' Kangaroo Rat, Riverside County, California; and Record of Decision for the Proposed Issuance of a Permit to Allow Incidental Take of Threatened and Endangered Species to Plum Creek Timber Company, L.P., for Lands in the I–90 Corridor of King and Kittitas Counties, Washington.

SUMMARY: This notice advises the public that a decision on the applications for permits by the Riverside County Habitat Conservation Agency and Plum Creek Timber Company, L.P. (Plum Creek), pursuant to section 10(a)(1)(B) of the Endangered Species Act of 1973, as amended, have been made and that the Records of Decision are available.

FOR FURTHER INFORMATION CONTACT: For the Riverside County Habitat Conservation Agency: Supervisor, U.S. Fish and Wildlife Service, Carlsbad Field Office, 2730 Loker Avenue West, Carlsbad, California 92008, telephone (619) 431–9440, between the hours of 8:00 a.m. and 5:00 p.m. weekdays, and for Plum Creek: Supervisor, U.S. Fish and Wildlife Service, Western Washington Office, 3704 Griffin Lane SE, Suite 102, Olympia, Washington 98501–2192, telephone (360–753–9440).

Individuals wishing copies of the Records of Decision should contact the respective U.S. Fish and Wildlife Service Office.

Riverside County Habitat Conservation Agency Decision

The U.S. Fish and Wildlife Service's decision is to adopt the Preferred Alternative and issue a permit authorizing incidental take of Stephens' kangaroo rats to the Riverside County Habitat Conservation Agency based on the Long-Term Habitat Conservation Plan in western Riverside County, as described in the final Environmental Impact Statement/Report. This decision is based on a thorough review of the alternatives and their environmental consequences. By adopting the preferred alternative with its assurances that the mitigation program and enforcement measures be implemented, all practicable means to avoid or minimize harm have been adopted.

Rationale for Decision

Implementation of the Long-Term Habitat Conservation Plan has been selected as the Preferred Alternative based on consideration of a number of environmental and social factors. These factors include: (1) proposed mitigation and minimization measures in the Long-Term Habitat Conservation Plan that would benefit Stephens' kangaroo rats on a regional scale in the core habitat area for the species by establishing seven Core Reserves; (2) the incidental take would occur within western Riverside County, where a viable population of Stephens' kangaroo rats cannot be maintained over the long-term; and (3) the proposed permit would allow incidental take of Stephens' kangaroo rats in areas outside the Core Reserves providing the opportunity for more orderly development and minimizing impacts to the social environment within western Riverside County.

Plum Creek Decision

The U.S. Fish and Wildlife Service's decision is to adopt the Preferred Habitat Conservation Plan Alternative, issue a permit authorizing incidental take of listed species and enter into an unlisted species agreement as described in the final Environmental Impact Statement. This decision is based on a thorough review of the alternatives and their environmental consequences. By adopting the preferred alternative with its assurances that the mitigation program and enforcement measures be implemented, all practicable means to avoid or minimize harm have been adopted.

Rationale for Decision

The Proposed Habitat Conservation Plan Alternative, as described in the applicant's Habitat Conservation Plan and analyzed in the final Environmental Impact Statement, provides the most comprehensive package of conservation prescriptions and activities of all of the Alternatives. None of the other alternatives provide as integrated and comprehensive a package of habitat conservation as the Proposed Habitat Conservation Plan Alternative. The Proposed Habitat Conservation Plan Alternative specifically addresses four listed species, two listed species for which incidental take coverage is not currently sought, riparian habitat management which captures the majority of species that might inhabit the plan area, including anadromous salmonids which are the subject of Federal Tribal Trust responsibility. Furthermore, the Proposed Habitat Conservation Plan Alternative provides management goals for 16 Lifeforms and associated species, as well as special habitat management such as caves, talus slopes, wetlands and snags. Only the Proposed Habitat Conservation Plan Alternative addresses talus, caves, wetlands, riparian management, Old Growth and spotted owl nesting, roosting, and foraging habitat, murrelets, owls, grizzly bears, gray wolves, snags, roads and accelerated watershed analysis. No other alternative addresses all of these resource concerns, together, in an integrated way.

Dated: August 28, 1996.

Thomas Dwyer,

Acting Regional Director, Region 1, Portland, Oregon.

[FR Doc. 96–22921 Filed 9–06–96; 8:45 am]

BILLING CODE 4310–55–P

Bureau of Indian Affairs

Indian Gaming; Bureau of Indian Affairs, Interior

ACTION: Notice of approved amendment to Tribal-State compact.

SUMMARY: Pursuant to 25 U.S.C. § 2710, of the Indian Gaming Regulatory Act of 1988 (Pub. L. 100–497), the Secretary of the Interior shall publish, in the Federal Register, notice of approved amendments to Tribal-State Compacts for the purpose of engaging in Class III (casino) gaming on Indian reservations. The Assistant Secretary—Indian Affairs, Department of the Interior, through her delegated authority, has approved Amendment III to the Gaming Compact Between the Confederated Tribes of the Umatilla Indian Reservation and the

State of Oregon, which was executed on June 21, 1996.

DATES: September 9, 1996.

FOR FURTHER INFORMATION CONTACT: George T. Skibine, Director, Indian Gaming Management Staff, Bureau of Indian Affairs, Washington, D.C. 20240, (202) 219–4068.

Dated: August 23, 1996.

Ada E. Deer,

Assistant Secretary—Indian Affairs.

[FR Doc. 96–22950 Filed 9–6–96; 8:45 am]

BILLING CODE 4310–02–P

National Park Service

Notice of Inventory Completion for Native American Human Remains and Associated Funerary Objects From Bay County, MI, in the Possession of the Michigan State University Museum, Michigan State University, East Lansing, MI

AGENCY: National Park Service

ACTION: Notice

Notice is hereby given in accordance with provisions of the Native American Graves Protection and Repatriation Act (NAGPRA), 25 U.S.C. 3003(d), of the completion of an inventory of human remains and associated funerary objects in the possession of the Michigan State University Museum, Michigan State University, East Lansing, MI.

A detailed assessment of the human remains was made by Michigan State University Museum professional staff in consultation with representatives of the Saginaw Chippewa Indian Tribe of Michigan.

During 1967–68 and 1970, human remains representing a minimum of 145 individuals were recovered during legally authorized excavations of the Fletcher site by the MSU Museum. Mr. Joseph Fletcher, the owner of the Fletcher site, donated these human remains and associated funerary objects to the MSU Museum during this time. No known individuals were identified. The 65,160 associated funerary objects include glass beads, wampum, silver jewelry, hair ornaments, armbands, animal bones, feathers, cooking utensils, muskets, knives, tomahawks, buttons, woven fabrics, scissors, awls, pipes, tools, tin cones, bells, wood/bark fragments, gorgets, keys, locks, lithics, bottles, leather, projectile points, and fishing spears.

The Fletcher site has been identified as a late 18th century occupation site based on the associated funerary objects and manner of the internments. Historic documents indicate Saginaw Chippewa settlements in close proximity to this cemetery area during the late 18th century. The location of this site compared to historically documented Saginaw Chippewa village locations, the presence of 18th century village debris in the area, and documented use of this area in the 19th century by the Saginaw Chippewa all indicate cultural affiliation of this cemetery to the Saginaw Chippewa Tribe of Michigan. Oral tradition presented by representatives of the Saginaw Chippewa Indian Tribe indicates this area was a cemetery area used by the band into the historic period.

Based on the above mentioned information, officials of the Michigan State University Museum have determined that, pursuant to 43 CFR 10.2 (d)(1), the human remains listed above represent the physical remains of a minimum of 145 individuals of Native American ancestry. Officials of the Michigan State University Museum have also determined that, pursuant to 25 U.S.C. 3001 (3)(A), the 65,160 objects listed above are reasonably believed to have been placed with or near individual human remains at the time of death or later as part of the death rite or ceremony. Lastly, officials of the Michigan State University Museum have determined that, pursuant to 25 U.S.C. 3001 (2), there is a relationship of shared group identity which can be reasonably traced between these Native American human remains and associated funerary objects and the Saginaw Chippewa Indian Tribe of Michigan.

This notice has been sent to officials of the Saginaw Chippewa Indian Tribe of Michigan. Representatives of any other Indian tribe that believes itself to be culturally affiliated with these human remains and associated funerary objects should contact Dr. William A. Lovis, Curator and Professor of Anthropology, MSU Museum, Michigan State University, East Lansing, MI; telephone: (517) 355–2370, before October 9, 1996. Repatriation of the human remains and associated funerary objects to the Saginaw Chippewa Indian Tribe of Michigan may begin after that date if no additional claimants come forward.

Dated: August 29, 1996

Francis P. McManamon,

Departmental Consulting Archeologist,

Manager, Archeology and Ethnography Program.

[FR Doc. 96–22852 Filed 9–6–96 8:45 am]

BILLING CODE 4310–70–F

DEPARTMENT OF JUSTICE

Federal Prison Industries, Inc.

Planning, Research and Activation Branch; Agency Information Collection Activities: Proposed Collection; Comment Request

ACTION: Notice of information collection under review; public involvement procedures regarding proposals to produce new products or expand the production of existing products.

Office of Management and Budget (OMB) approval is being sought for the information collection listed above. This proposed information collection was previously published in the Federal Register and allowed 60 days for public comment.

The purpose of this notice is to allow an additional 30 days for public comments from the date listed at the top of this page in the Federal Register. This process is conducted in accordance with 5 Code of Federal Regulations, Part 1320.10.

Written comments and/or suggestions regarding the item(s) contained in this notice, especially regarding the estimated public burden and associated response time, should be directed to the Office of Management and Budget, Office of Regulatory Affairs, Attention: Department of Justice Desk Officer, Washington, DC, 20530. Additionally, comments may be submitted to OMB via facsimile to 202–395–7285. Comments may also be submitted to the United States Department of Justice, Justice Management Division, Information Management and Security Staff, Attention: Department Clearance Officer, Suite 850, Washington Center, 1001 G Street, NW, Washington, D.C. 20530. Additionally, comments can be submitted to DOJ via facsimile to 202–514–1534.

Written comments and suggestions from the public and affected agencies should address one or more of the following points:

(1) 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;

(2) Evaluate the accuracy of the agency's estimate of the burden of the proposed collection of information,

(3) Enhance the quality, utility and clarity of the information to be collected; and

(4) 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.

Overview of this information collection:

(1) Type of Information Collection: Existing collection in use without an OMB control number.

(2) Title of the Form/Collection: Public Involvement Procedures Information Collection.

(3) Agency form number, if any, and the applicable component of the Department of Justice sponsoring the collection: Form=None. Planning, Research and Activation, Federal Prison Industries, Federal Bureau of Prisons, United States Department of Justice.

(4) Affected public who will be asked to respond, as well as a brief abstract: Primary: Business or other for profit. Other: Federal Government. The information is collected in order to provide private industry the opportunity to comment on new product and expansion proposals. All comments received become part of the public record submitted to the Federal Prison Industries, Board of Directors. This record is the basis from which the Board of Directors makes its decision on the proposal.

(5) An estimate of the total number of respondents and the amount of time estimated for an average respondent to respond: 125 responses at 3 hours per response.

(6) An estimate of the total public burden (in hours) associated with the collection: 375 total annual burden hours.

Public comment on this proposed information collection is strongly encouraged. If additional information is required contact: Mr. Robert B. Briggs, Clearance Officer, United States Department of Justice, Information Management and Security Staff, Justice Management Division, Suite 850, Washington Center, 1001 G Street, NW, Washington, DC 20530.

Dated: September 3, 1996.

Robert B. Briggs,

Department Clearance Officer, United States Department of Justice.

[FR Doc. 96–22932 Filed 9–6–96; 8:45 am]

BILLING CODE 4410–06–M

Immigration and Naturalization Service

Agency Information Collection Activities: Proposed Collection; Comment Request

ACTION: Notice of information collection under review: Driver application (North American Trade Automation Prototype).

The proposed information collection is published to obtain comments from the public affected agencies. Comments are encouraged and will be accepted for ''sixty days'' from the date listed at the top of this page in the Federal Register.

Request written comments and suggestions from the public and affected agencies concerning the proposed collection of information. Your comments should address one or more of the following four points:

(1) 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;

(2) Evaluate the accuracy of the agencies estimate of the burden of the proposed collection of information, 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 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.

If you have additional comments, suggestions, or need a copy of the proposed information collection instrument with instructions, or additional information, please contact Richard A. Sloan at 202–616–7600, Director, Policy Directives and Instructions Branch, Immigration and Naturalization Service, U.S. Department of Justice, Room 5307, 425 I Street, NW, Washington, DC 20536. Additionally, comments and/or suggestions regarding the items(s) contained in this notice especially, regarding public burden and associated response time may also be directed to Mr. Richard A. Sloan.

Overview of this information collection:

(1) Title of the Form/Collection: Driver Application (North American Trade Automation Prototype).

(3) Agency form number, if any, and the applicable component of the Department of Justice sponsoring the collection: Form I-859. Inspections Division, Immigration and Naturalization Service.

(4) Affected public who will be asked or required to respond, as well as a brief abstract: Primary: Individuals or Households, Business or other for profit. This prototype program will allow drivers of commercial trucks who meet certain requirements to immediately apply for participation in a prototype program that will facilitate access to the United States from Canada and Mexico, while still safeguarding U.S. borders.

(5) An estimate of the total number of respondents and the amount or time estimated for an average respondent to respond: 500 respondents at 70 minutes (1.166) per response.

(6) An estimate of the total public burden (in hours) associated with the collection: 583 annual burden hours.

If additional information is required contact: Mr. Robert B. Briggs, Clearance Officer, United States Department of Justice, Information Management and Security Staff, Justice Management Division, Suite 850, Washington Center, 1001 G Street, NW, Washington, DC 20530.

Dated: September 3, 1996.

Robert B. Briggs,

Department Clearance Officer, United States Department of Justice.

[FR Doc. 96–22931 Filed 9–6–96; 8:45 am]

BILLING CODE 4410–18–M

Office of Justice Programs

Office of Juvenile Justice Delinquency and Prevention; Agency Information Collection Activities: Proposed Collection; Comment Request

ACTION: Notice of information collection under review; a survey of law enforcement, prosecutors, social service providers, and non-profit agencies to determine which communities have a multi-agency response to missing and exploited children.

The Office of Juvenile Justice Delinquency and Prevention, Office of Justice Programs, United States Department of Justice has submitted the following information collection request utilizing the emergency review procedures, to the Office of Management and Budget for review and clearance in accordance with the Paperwork Reduction Act of 1995. OMB approval has been requested by September 9, 1996. This proposed information collection was previously published in the Federal Register and allowed 60 days for public comments.

Written comments and/or suggestions regarding the item(s) contained in this notice, especially regarding the estimated public burden and associated response time, should be directed to the Office of Management and Budget, Office of Regulatory Affairs, Attention: Department of Justice Desk Officer, Washington, DC, 20530. Additionally, comments may be submitted to OMB via facsimile to 202–395–7285. Comments may also be submitted to the Department of Justice (DOJ), Justice Management Division, Information Management and Security Staff, Attention: Department Clearance Officer, Suite 850, 1001 G Street, NW, Washington, DC, 20530. Additionally, comments may be submitted to DOJ via facsimile to 202–514–1534.

Written comments and suggestions from the public and affected agencies should address one or more of the following points:

(1) Evaluate whether the proposed collection of information is necessary for the proper performance of the functions of the agency/component, including whether the information will have practical utility;

(2) Evaluate the accuracy of the agencies/components estimate of the burden of the proposed collection of information, 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 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.

The proposed collection is listed below:

(1) Type of information collection. New data collection.

(2) The title of the form/collection. A Survey of Law Enforcement, Prosecutors, Social Service Providers, and Non-Profit Agencies to Determine Which Communities have a Multi-Agency Response to Missing and Exploited Children.

(3) The agency form number, if any, and the applicable component of the Department sponsoring the collection. Form: None. Office of Juvenile Justice and Delinquency Prevention, Office of Justice Programs, United States Department of Justice.

(4) Affected public who will be asked or required to respond, as well as a brief abstract. Primary: State or Local. Other: Not-for-profit institutions and Federal Government.

(5) An estimate of the total number of respondents and the amount of time estimated for an average respondent to respond: 750 respondents to complete a one-time 15 minute mail survey.

(6) An estimate of the total public burden (in hours) associated with the collection: 188 annual burden hours.

Public comment on this proposed information collection is strongly encouraged.

Dated: September 3, 1996.

Robert B. Briggs,

Department Clearance Officer, United States Department of Justice.

[FR Doc. 96–22929 Filed 9–6–96; 8:45 am]

BILLING CODE 4410–18–M

Office of Juvenile Justice Delinquency and Prevention Agency Information Collection Activities: Proposed Collection; Comment Request

ACTION: Notice of information collection under review; a survey of law enforcement, prosecutors, social service providers, and non-profit agencies to determine which communities have a multi-agency response to missing and exploited children.

Office of Management and Budget (OMB) approval is being sought for the information collection listed below. This proposed information collection was previously published in the Federal Register and allowed 60 days for public comment.

The purpose of this notice is to allow an additional 30 days for public comments from the date listed at the top of this page in the Federal Register. This process is conducted in accordance with 5 Code of Federal Regulation, § 1320.10.

Written comments and/or suggestions regarding the item(s) contained in this notice, especially regarding the estimate public burden and associated response time, should be directed to the Office of Management and Budget, Office of Regulatory Affairs, Attention: Department of Justice Desk Officer, Washington, DC, 20530. Additionally, comments may be submitted to OMB via facsimile to 202–395–7285. Comments may also be submitted to the Department of Justice (DOJ), Justice Management Division, Information Management and Security Staff, Attention: Department Clearance Office, Suite 850, 1001 G Street, NW, Washington, DC, 20530. Additionally, comments may be submitted to DOJ via facsimile to 202–514–1534.

Written comments and suggestions from the public and affected:

(1) Evaluate whether the proposed collection of information is necessary for the proper performance of the functions of the agency/component, including whether the information will have practical utility;

(2) Evaluate the accuracy of the agencies/components estimate of the burden of the proposed collection of information, 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 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.

The proposed collection is listed below:

(1) Type of information collection. New data collection.

(2) The title of the form/collection. A Survey of Law Enforcement, Prosecutors, Social Service Providers, and Non-Profit Agencies to Determine Which Communities have a Multi-Agency Response to Missing and Exploited Children.

(3) The agency form number, if any, and the applicable component of the Department sponsoring the collection. Form: None. Office of Juvenile Justice and Delinquency Prevention, Office of Justice Programs, United States Department of Justice.

(4) Affected public who will be asked or required to respond, as well as a brief abstract. Primary: State or Local. Other: Not-for-profit institutions and Federal Government.

(5) An estimate of the total number of respondents and the amount of time estimated for an average respondent to respond: 750 respondent to complete a one-time 15minute mail survey.

(6) An estimate of the total public burden (in hours) associated with the collection: 188 annual burden hours.

Public comment on this proposed information collection is strongly encouraged.

Dated: September 3, 1996.

Robert B. Briggs,

Department Clearance Officer, United States Department of Justice.

[FR Doc. 96–22930 Filed 9–6–96; 8:45 am]

BILLING CODE 4410–18–M

NUCLEAR REGULATORY COMMISSION

[Docket No. 50–387]

Susquehanna Steam Electric Station, Unit 1; Notice of Consideration of Issuance of Amendment to Facility Operating License, Proposed No Significant Hazards Consideration Determination, and Opportunity for a Hearing

The U.S. Nuclear Regulatory Commission (the Commission) is considering issuance of an amendment to Facility Operating License No. NPF–14 issued to Pennsylvania Power and Light Company (the licensee) for operation of the Susquehanna Steam Electric Station, Unit 1, located in Luzerne County, Pennsylvania.

The proposed amendment would revise the Minimum Critical Power Ratio safety limit values, adding two references to reflect the use of the ANF–B Critical Power Ratio Correlation and to reflect the use of the ABB Combustion Engineering licensing methodology, with a modification to the associated Bases.

Before issuance of the proposed license amendment, the Commission will have made findings required by the Atomic Energy Act of 1954, as amended (the Act) and the Commission's regulations.

The Commission has made a proposed determination that the amendment request involves no significant hazards consideration. Under the Commission's regulations in 10 CFR 50.92, this means that operation of the facility in accordance with the proposed amendment would not (1) involve a significant increase in the probability or consequences of an accident previously evaluated; or (2) create the possibility of a new or different kind of accident from any accident previously evaluated; or (3) involve a significant reduction in a margin of safety. As required by 10 CFR 50.91(a), the licensee has provided its analysis of the issue of no significant hazards consideration, which is presented below:

1. The proposed change does not involve a significant increase in the probability or consequences of an accident previously evaluated.

The change to the ANFB correlation and corresponding MCPR Safety Limits does not physically change the plant systems, structures, or components. Thus, the probability of occurrence of an event evaluated in the SAR [Safety Analysis Report] is not increased. The acceptance criterion for the MCPR Safety Limit (i.e., 99.9% of the fuel rods expected to avoid boiling transition) is not changed. Only the methodology used to demonstrate compliance is changed. Therefore, the consequences of anticipated operational occurrence (which must show the Safety Limit is not violated) are not changed.

Adding the reference of CENPD–300–P, ''Reference Safety Report for Boiling Water Reactor Reload Fuel,'' to the list of references in Unit 1 Technical Specifications will allow the use of the ABB methodology to calculate the operating limits for the four Lead Use Assemblies which are of different mechanical design from the Siemens 9x9–2 fuel. The use of this ABB methodology will ensure that the applicable safety limits of the safety analysis are met for the four LUAs [Lead Use Assemblies]. Results of incorporating this change will not significantly increase the probability or the consequences of an accident previously evaluated.

2. The proposed change does not create the possibility of a new or different kind of accident from any accident previously evaluated.

As stated above, this methodology change does not impact the acceptance criterion for the MCPR Safety Limits and does not physically change the plant safety, structures, or components. Since no changes to the physical plant are being made, this change does not create the possibility of a new event not previously evaluated in the SAR.

The incorporation of this change will allow the use of the ABB methodology to be referenced as the methodology to show that all applicable limits of the safety analysis are met by the four ABB LUAs. Therefore, the incorporation of this change will not create the possibility of a new or different kind of accident from any accident previously evaluated.

3. The proposed change does not involve a significant reduction in a margin of safety.

A cycle specific MCPR Safety Limit analysis was performed by SPC [Siemens Power Corporation]. The analysis used NRC approved methods described in the SPC report: ANF–524(P)(A), Revision 2 and Supplement 1, Revision 2. The MCPR Safety Limit value is calculated such that at least 99.9% of the fuel rods are expect to avoid boiling transition during normal operation or anticipated operational occurrences. Both the existing analysis using XN–3 and the new analysis using ANFB utilize NRC approved methods to accomplish this same objective. Therefore, the change to ANFB based Safety Limit does not involve a significant reduction in a margin of safety.

The use of the ABB methodology will not result in a change in safety margin, but will ensure that the safety margin is maintained with the insertion of the four ABB LUAs in the Unit 1 Cycle 10 core. Therefore, the incorporation of these changes will have no impact on current safety margins, nor will they involve a significant reduction in the margin of safety.

The NRC staff has reviewed the licensee's analysis and, based on this review, it appears that the three standards of 10 CFR 50.92(c) are satisfied. Therefore, the NRC staff proposes to determine that the amendment request involves no significant hazards consideration.

The Commission is seeking public comments on this proposed determination. Any comments received within 30 days after the date of publication of this notice will be considered in making any final determination.

Normally, the Commission will not issue the amendment until the expiration of the 30-day notice period. However, should circumstances change during the notice period such that failure to act in a timely way would result, for example, in derating or shutdown of the facility, the Commission may issue the license amendment before the expiration of the 30-day notice period, provided that its final determination is that the amendment involves no significant hazards consideration. The final determination will consider all public and State comments received. Should the Commission take this action, it will publish in the Federal Register a notice of issuance and provide for opportunity for a hearing after issuance. The Commission expects that the need to take this action will occur very infrequently.

Written comments may be submitted by mail to the Chief, Rules Review and Directives Branch, Division of Freedom of Information and Publications Services, Office of Administration, U.S. Nuclear Regulatory Commission, Washington, DC 20555–0001, and should cite the publication date and page number of this Federal Register notice. Written comments may also be delivered to Room 6D22, Two White Flint North, 11545 Rockville Pike, Rockville, Maryland, from 7:30 a.m. to 4:15 p.m. Federal workdays. Copies of written comments received may be examined at the NRC Public Document Room, the Gelman Building, 2120 L Street, NW., Washington, DC.

The filing of requests for hearing and petitions for leave to intervene is discussed below.

By October 9, 1996, the licensee may file a request for a hearing with respect to issuance of the amendment to the subject facility operating license and any person whose interest may be affected by this proceeding and who wishes to participate as a party in the proceeding must file a written request for a hearing and a petition for leave to intervene. Requests for a hearing and a petition for leave to intervene shall be filed in accordance with the Commission's ''Rules of Practice for Domestic Licensing Proceedings'' in 10 CFR Part 2. Interested persons should consult a current copy of 10 CFR 2.714 which is available at the Commission's Public Document Room, the Gelman

Building, 2120 L Street, NW., Washington, DC, and at the local public document room located at the Osterhout Free Library, Reference Department, 71 South Franklin Street, Wilkes-Barre, PA 18701. If a request for a hearing or petition for leave to intervene is filed by the above date, the Commission or an Atomic Safety and Licensing Board, designated by the Commission or by the Chairman of the Atomic Safety and Licensing Board Panel, will rule on the request and/or petition; and the Secretary or the designated Atomic Safety and Licensing Board will issue a notice of hearing or an appropriate order.

As required by 10 CFR 2.714, a petition for leave to intervene shall set forth with particularity the interest of the petitioner in the proceeding, and how that interest may be affected by the results of the proceeding. The petition should specifically explain the reasons why intervention should be permitted with particular reference to the following factors: (1) the nature of the petitioner's right under the Act to be made party to the proceeding; (2) the nature and extent of the petitioner's property, financial, or other interest in the proceeding; and (3) the possible effect of any order which may be entered in the proceeding on the petitioner's interest. The petition should also identify the specific aspect(s) of the subject matter of the proceeding as to which petitioner wishes to intervene. Any person who has filed a petition for leave to intervene or who has been admitted as a party may amend the petition without requesting leave of the Board up to 15 days prior to the first prehearing conference scheduled in the proceeding, but such an amended petition must satisfy the specificity requirements described above.

Not later than 15 days prior to the first prehearing conference scheduled in the proceeding, a petitioner shall file a supplement to the petition to intervene which must include a list of the contentions which are sought to be litigated in the matter. Each contention must consist of a specific statement of the issue of law or fact to be raised or controverted. In addition, the petitioner shall provide a brief explanation of the bases of the contention and a concise statement of the alleged facts or expert opinion which support the contention and on which the petitioner intends to rely in proving the contention at the hearing. The petitioner must also provide references to those specific sources and documents of which the petitioner is aware and on which the petitioner intends to rely to establish those facts or expert opinion. Petitioner must provide sufficient information to show that a genuine dispute exists with the applicant on a material issue of law or fact. Contentions shall be limited to matters within the scope of the amendment under consideration. The contention must be one which, if proven, would entitle the petitioner to relief. A petitioner who fails to file such a supplement which satisfies these requirements with respect to at least one contention will not be permitted to participate as a party.

Those permitted to intervene become parties to the proceeding, subject to any limitations in the order granting leave to intervene, and have the opportunity to participate fully in the conduct of the hearing, including the opportunity to present evidence and cross-examine witnesses.

If a hearing is requested, the Commission will make a final determination on the issue of no significant hazards consideration. The final determination will serve to decide when the hearing is held.

If the final determination is that the amendment request involves no significant hazards consideration, the Commission may issue the amendment and make it immediately effective, notwithstanding the request for a hearing. Any hearing held would take place after issuance of the amendment.

If the final determination is that the amendment request involves a significant hazards consideration, any hearing held would take place before the issuance of any amendment.

A request for a hearing or a petition for leave to intervene must be filed with the Secretary of the Commission, U.S. Nuclear Regulatory Commission, Washington, DC 20555–0001, Attention: Docketing and Services Branch, or may be delivered to the Commission's Public Document Room, the Gelman Building, 2120 L Street NW., Washington, DC, by the above date. Where petitions are filed during the last 10 days of the notice period, it is requested that the petitioner promptly so inform the Commission by a toll-free telephone call to Western Union at 1–(800) 248–5100 (in Missouri 1–(800) 342–6700). The Western Union operator should be given Datagram Identification Number N1023 and the following message addressed to John F. Stolz: petitioner's name and telephone number, date petition was mailed, plant name, and publication date and page number of this Federal Register notice. A copy of the petition should also be sent to the Office of the General Counsel, U.S. Nuclear Regulatory Commission, Washington, DC 20555–0001, and to Jay Silberg, Esquire, Shaw, Pittman, Potts and Trowbridge, 2300 N Street NW., Washington, DC 20037, attorney for the licensee.

Nontimely filings of petitions for leave to intervene, amended petitions, supplemental petitions and/or requests for hearing will not be entertained absent a determination by the Commission, the presiding officer or the presiding Atomic Safety and Licensing Board that the petition and/or request should be granted based upon a balancing of the factors specified in 10 CFR 2.714(a)(1) (i)–(v) and 2.714(d).

For further details with respect to this action, see the application for amendment dated May 28, 1996, as supplemented by letter dated July 25, 1996, which is available for public inspection at the Commission's Public Document Room, the Gelman Building, 2120 L Street NW., Washington, DC, and at the local public document room located at the Osterhout Free Library, Reference Department, 71 South Franklin Street, Wilkes-Barre, PA 18701.

Dated at Rockville, Maryland, this 3rd day of September 1996.

For the Nuclear Regulatory Commission.

Chester Poslusny,

Senior Project Manager, Project Directorate I–2, Division of Reactor Projects—I/II, Office of Nuclear Reactor Regulation.

[FR Doc. 96–22924 Filed 9–6–96; 8:45 am]

BILLING CODE 7590–01–P

OFFICE OF PERSONNEL MANAGEMENT

Federal Employees Health Benefits Program; Medically Underserved Areas for 1997

AGENCY: Office of Personnel Management.

ACTION: Notice of medically underserved areas for 1997.

SUMMARY: The Office of Personnel Management (OPM) has completed its annual calculation of the States that qualify as Medically Underserved Areas under the Federal Employees Health Benefits (FEHB) Program for the calendar year 1997. This is necessary to comply with a provision of FEHB law that mandates special consideration for enrollees of certain FEHB plans who receive covered health services in states with critical shortages of primary care physicians. Accordingly, for calendar year 1997, OPM's calculations show that the following States are Medically Underserved Areas under the FEHB Program: Alabama, Louisiana, Mississippi, New Mexico, North Dakota, South Carolina, South Dakota, West Virginia, and Wyoming. Arkansas and

Idaho have been removed from the list, with no new additions for 1997.

EFFECTIVE DATE: January 1, 1997.

FOR FURTHER INFORMATION CONTACT: Kenneth A. Lease, 202–606–0004.

SUPPLEMENTARY INFORMATION: FEHB law [5 U.S.C. 8902(m)(2)] mandates special consideration for enrollees of certain FEHB plans who receive covered health services in States with critical shortages of primary care physicians. Such States are designated as Medically Underserved Areas for purposes of the FEHB Program, and the law requires payment to all qualified providers in the States.

FEHB regulations (5 CFR 890.701) require OPM to make an annual calculation of the States that qualify as Medically Underserved Areas for the next calendar year by comparing the latest Department of Health and Human Services State-by-State population counts on primary medical care manpower shortage areas with U.S. Census figures on State resident population.

U.S. Office of Personnel Management.

James B. King,

Director.

BILLING CODE 6325–01–M

C:MEDUND97

FEHB MEDICALLY UNDERSERVED AREAS FOR CALENDAR YEAR 1997

STATE	HHS TOTAL POPULATION 1)	COMMERCE RESIDENT POPULATION 2)	FEHB PERCENTAGE 3)	NOTE
Alabama	1,377,168	4,253,000	32.381%	MUA
Alaska	94,707	604,000	15.680%	
Arizona	340,504	4,218,000	8.073%	
Arkansas	558,379	2,484,000	22.479%	
California	4,043,173	31,589,000	12.799%	
Colorado	405,815	3,747,000	10.830%	
Connecticut	346,839	3,275,000	10.591%	
Delaware	55,579	717,000	7.752%	
Florida	1,664,615	14,166,000	11.751%	
Georgia	1,649,301	7,201,000	22.904%	
Hawaii	43,435	1,187,000	3.659%	
Idaho	285,341	1,163,000	24.535%	
Illinois	1,690,746	11,830,000	14.292%	
Indiana	883,097	5,803,000	15.218%	
Iowa	362,073	2,842,000	12.740%	
Kansas	365,751	2,565,000	14.259%	
Kentucky	946,323	3,860,000	24.516%	
Louisiana	1,650,505	4,342,000	38.013%	MUA
Maine	165,835	1,241,000	13.363%	
Maryland	236,335	5,042,000	4.687%	
Massachusetts	777,007	6,074,000	12.792%	
Michigan	1,859,326	9,549,000	19.471%	
Minnesota	327,743	4,610,000	7.109%	
Mississippi	1,402,441	2,697,000	52.000%	MUA
Missouri	1,042,748	5,324,000	19.586%	
Montana	133,212	870,000	15.312%	
Nebraska	270,683	1,637,000	16.535%	
Nevada	293,865	1,530,000	19.207%	
New Hampshire	117,178	1,148,000	10.207%	
New Jersey	809,649	7,945,000	10.191%	
New Mexico	490,555	1,685,000	29.113%	MUA
New York	3,838,377	18,136,000	21.164%	
North Carolina	1,604,720	7,195,000	22.303%	
North Dakota	175,210	641,000	27.334%	MUA
Ohio	1,475,522	11,151,000	13.232%	
Oklahoma	651,771	3,278,000	19.883%	
Oregon	403,493	3,141,000	12.846%	
Pennsylvania	1,113,888	12,072,000	9.227%	
Rhode Island	171,220	990,000	17.295%	
South Carolina	1,268,513	3,673,000	34.536%	MUA
South Dakota	184,379	729,000	25.292%	MUA
Tennessee	1,060,501	5,256,000	20.177%	
Texas	3,492,491	18,724,000	18.652%	
Utah	291,827	1,951,000	14.958%	
Vermont	75,405	585,000	12.890%	
Virginia	795,155	6,618,000	12.015%	

Washington	940,677	5,431,000	17.321%	
West Virginia	574,864	1,828,000	31.448%	MUA
Wisconsin	1,048,788	5,123,000	20.472%	
Wyoming	120,295	480,000	25.061%	MUA

1) From the "Total Population" column of the Department of Health and Human Services report entitled "Table 3. Health Professional Shortage Areas, Designated HPSA Summary Listing, Primary Medical Care HPSAs, As of March 31,1996."

HHS contact for copy of report: Lisa Steinbruckner, 301–594–0816

2) From the most recent year column of the Department of Commerce Report entitled "Table 3. Rankings of State Population Estimates and Components of Change: July 1, 1994 to July 1, 1995."

Commerce contact for report Karen Jones, 301–457–2435

3) Computation Formula for this column = the HHS number divided by the Commerce number.

Note: FEHB percentage equal to greater than 25% =MUA= medically underserved area.

[FR Doc. 96–22905 Filed 9–6–96; 8:45 am]
BILLING CODE 6325–01–C

SECURITIES AND EXCHANGE COMMISSION

Submission for OMB Review; Comment Request

Upon written request, copies available from: Securities and Exchange Commission, Office of Filings and Information Services, Washington, DC 20549.

Extension:

Rule 17f–2(c) SEC File No. 270–35; OMB Control No. 3235–0029

Rule 17f–2(d) SEC File No. 270–36; OMB Control No. 3235–0028

Rule 17f–2(e) SEC File No. 270–37; OMB Control No. 3235–0031

Notice is hereby given that pursuant to the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 et seq.), the Securities and Exchange Commission (''Commission'') has submitted to the Office of Management and Budget requests for approval of extension on the following rules:

Rule 17f–2(c) allows persons required to be fingerprinted, pursuant to Section 17(f)(2) of the Securities Exchange Act of 1934 (Exchange Act), to submit their fingerprints through a national securities exchange or a national securities association in accordance with a plan submitted to and approved by the Commission. Plans have been approved for the American, Boston, Chicago, New York, Pacific, and Philadelphia stock exchanges and for the National Association of Securities Dealers and the Chicago Board Options Exchange.

It is estimated that 8,500 registered broker-dealers submit approximately 275,000 fingerprint cards to exchanges or a registered security association on an annual basis. It is approximated that it should take 15 minutes to comply with Rule 17f–2(c). The total reporting burden is estimated to be 68,750 hours.

Rule 17f–2(d), requires that records produced, pursuant to the fingerprinting requirements of Section 17(f)(2) of the Exchange Act, be maintained; permits the designated examining authorities of broker-dealers or members of exchanges, under certain circumstances, to store and to maintain records required to be kept by this rule; and permits the required records to be maintained on microfilm.

Approximately 10,025 respondents are subject to the recordkeeping requirements of the rule. Each respondent keeps approximately 32 new records per year, which take approximately 2 minutes per record for the respondent to maintain, for an annual burden of 64 minutes per respondent. All records subject to the rule must be retained for the term of employment plus 3 years.

Rule 17f–2(e) requires entities claiming an exemption from the fingerprinting requirements to prepare and maintain a notice supporting their claim for exemption and exempts certain small transfer agents from the requirement.

While the Commission no longer receives notices pursuant to Rule 17f–2(e), the covered entities are still required to prepare and retain such notice. Based on the indications of several covered entities, most notices require one-half hour to prepare. Approximately 75 respondents will prepare notices each year. The total average annual burden to covered entities is approximately 37.5 hours of preparation and maintenance time.

General comments regarding the estimated burden hours should be directed to the Desk Officer for the securities and exchange Commission at the address below. Any comments concerning the accuracy of the estimated average burden hours for compliance with Commission rules and forms should be directed to Michael E. Bartell, Associate Executive Director, Office of Information Technology, Securities and Exchange Commission, 450 Fifth Street, N.W., Washington, D.C. 20549 and Desk Officer for the Securities and Exchange Commission, Office of Information and Regulatory Affairs, Office of Management and Budget, Room 3208, New Executive

Office Building, Washington, D.C. 20503.

Dated: August 29, 1996.

Margaret H. McFarland,

Deputy Secretary.

[FR Doc. 96–22934 Filed 9–6–96; 8:45 am]

BILLING CODE 8010–01–M

Submission for OMB Review; Comment Request

Upon written request, copies available from: Securities and Exchange Commission, Office of Filings and Information Services, Washington, DC 20549.

Extension:

Schedule 13E–4; SEC File No. 270–190; OMB Control No. 3235–0203

Notice is hereby given that pursuant to the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 et seq.), the Securities and Exchange Commission (''Commission'') has submitted to the Office of Management and Budget a request for approval of extension on the following:

Schedue 13E–4 is filed pursuant to Section 13(e)(1) of the Securities Exchange Act of 1934 by issuers conducting a tender offer. this information is needed to provide full and fair disclosure to the investing public. Schedule 13E–4 takes approximately 232 hours to prepare and is filed by an estimate 121 respondents annually for a total of 28,072 burden hours.

General comments regarding the estimated burden hours should be directed to the Desk Officer for the Securities and Exchange Commission at the address below. Any comments concerning the accuracy of the estimated average burden hours for compliance with Commission rules and forms should be directed to Michael E. Bartell, Associate Executive Director, Office of Information Technology, Securities and Exchange Commission, 450 Fifth Street, N.W., Washington, D.C. 20549 and Desk Officer for the Securities and Exchange Commission, Office of Information and Regulatory Affairs, Office of Management and Budget, Room 3208, New Executive Office Building, Washington, D.C. 20503.

Dated: August 30, 1996.

Margaret H. McFarland,

Deputy Secretary.

[FR Doc. 96–22935 Filed 9–6–96; 8:45 am]

BILLING CODE 8010–01–M

[Release No. 34–37631; File No. SR–NSCC–96–08]

Self-Regulatory Organizations; National Securities Clearing Corporation; Order Approving a Proposed Rule Change Modifying Rules and Procedures Relating to the New York Window System

September 3, 1996.

On April 3, 1996, the National Securities Clearing Corporation (''NSCC'') filed with the Securities and Exchange Commission (''Commission'') a proposed rule change (File No. SR–NSCC–96–08) pursuant to Section 19(b)(1) of the Securities Exchange Act of 1934 (''Act'')[1] to modify its rules and procedures relating to the New York Window (''NYW'') service. Notice of the proposal was published on June 27, 1996, in the Federal Register to solicit comments on the proposed rule change.[2] No comment letters were received. On August 30, 1996, NSCC amended the proposal.[3] For the reasons discussed below, the Commission is approving the proposed rule change.

I. Description

NSCC's proposed rule change modifies NSCC's rules and procedures regarding the NYW service (i) to allow members to use the NYW through their individual systems, (ii) to modify the terms and conditions under which NYW services are provided with respect to the use of the NYW through NSCC's proprietary system, and (iii) to clarify that members may elect to use all or some of the services offered under the NYW service.[4]

NSCC's NYW service provides for the processing of receives and deliveries of physical securities and for related services. The NYW service also provides custodial services and custodial related services. When NSCC sought permanent approval of the NYW service, it anticipated that members accessing the NYW through their own systems eventually would migrate to using NSCC's proprietary system. However, because of the number of industry initiatives currently underway and the resulting demand on members' technological resources, a number of participants continue to access the NYW through their own systems. This proposed rule change clarifies NSCC's NYW rules to explicitly allow members to take advantage of the NYW through the use of their individual systems.[5]

Presently, reimbursement for losses related to the use of the NYW service is within the sole discretion of NSCC. In order to encourage members to use NSCC's proprietary system for the NYW service, NSCC will accept responsibility for certain categories of losses with respect to members who access the NYW service through NSCC's proprietary system. Under the proposed rule change, NSCC will be responsible for: (1) the replacement cost of certificates lost while in the care, custody, or control of NSCC employees or agents, (2) with respect to a lost security, the cost to carry the lost security from the date of the scheduled delivery or the redemption date until the date when replacement securities are delivered or presented,[6] and (3) the cost to carry the lost security for the number of days that NSCC is unable to complete a scheduled delivery if such failure is due to circumstances other than those set forth in clause (1) above. However, with respect to the NSCC's obligations under clauses (2) and (3) above, NSCC will have no obligations unless (a) instructions regarding delivery and the subject securities are delivered to NSCC within time parameters established by NSCC from time to time, (b) the final delivery destination is within the New York City downtown financial district, and (c) other NYW services operational criteria, as established by NSCC from time to time, are met. Notwithstanding clauses (1), (2), and (3) above, NSCC will not be liable for (a) special, incidental, or consequential damages or any direct or indirect damages other than the cost to carry or (b) the cost to carry resulitng from any failure or delay arising out of conditions beyond NSCC's reasonable control including, but not limited to, work stoppages, fire, civil disobedience, riots, rebellions, storms, electrical failures, acts of God, and similar occurrences. These revised terms will be offered to current users of NSCC's NYW services as well as prospective NYW service users that access the NYW service through NSCC's proprietary system.

NSCC is adding a section to Addendum K, Interpretation of the Board of Directors, Application of

[1] 15 U.S.C. 78s(b)(1) (1988).

[2] Securities Exchange Act Release No. 37347 (June 21, 1996), 61 FR 33565.

[3] Letter from Julie Beyers, Associate Counsel, NSCC, to Jerry Carpenter, Commission (August 30, 1996). The Commission is not noticing the amendment because the change is technical in nature.

[4] For a complete description of NYW services, refer to Securities Exchange Act Release No. 34629 (September 1, 1994), 59 FR 46680 [File No. SR–NSCC–94–12] (order granting permanent approval of the NYW service).

[5] NSCC Rule 31, Section 1.

[6] The cost to carry a security represents the interest costs associated with a participant's failure to receive timely payment.

Clearing Fund to Excess Losses and Losses Outside of a System, which will provide that if NSCC were to have an unsatisfied loss due to a member's use of the NYW service, the loss may be satisfied from the entire clearing fund.[7]

An additional purpose of the filing is to clarify that members may choose to use only some of the NYW services (*e.g.*, custodial and custodial related services). Members may enter into agreement(s) with NSCC limiting their access to specified NYW services which they desire to access.

II. Discussion

The Commission finds that the proposed rule change is consistent with the requirements of the Act and the rules and regulations thereunder and particularly with the requirements of Sections 17A(b)(3) (A) and (F).[8] Sections 17A(b)(3) (A) and (F) require that the rules of a clearing agency be designed to promote the prompt and accurate clearance and settlement of securities transactions and to safeguard securities and funds in its custody or control or for which it is responsible.

NSCC's rule change will provide participants with greater access to the NYW service by allowing participants to continue to access the service through their own systems which should facilitate the prompt and accurate clearance and settlement of securities transactions. Furthermore, when participants elect to access the NYW service via NSCC's proprietary system, NSCC will assume greater responsibility for certain losses resulting therefrom. In connection with assuming greater responsibility for certain losses, NSCC will apply its usual procedures to ensure the safeguarding of securities and funds processed through NSCC.

III. Conclusion

On the basis of the foregoing, the Commission finds that the proposal is consistent with the requirements of the Act and in particular with Sections 17A(b)(3) (A) and (F) of the Act and the rules and regulations thereunder.

It is therefore ordered, pursuant to Section 19(b)(2) of the Act, that the proposed rule change (File No. SR–NSCC–96–08) be and hereby is approved.

For the Commission, by the Division of Market Regulation, pursuant to delegated authority.[9]

Margaret H. McFarland,

Deputy Secretary.

[FR Doc. 96–22938 Filed 9–6–96; 8:45 am]

BILLING CODE 8010–01–M

[7] Interpretation of the Board of Directors, Application of Clearing Fund, Addendum K, II, 2.

[8] 15 U.S.C. 78q–1(b)(3) (A) and (F) (1988).

[9] 17 CFR 200.30–3(a)(12) (1996).

[Release No. 34–37630; File No. SR–OCC–96–03]

Self-Regulatory Organizations; the Options Clearing Corporation; Order Approving a Proposed Rule Change Relating to the Clearance and Settlement of Flexibly Structured Equity Options

September 3, 1996.

On April 30, 1996, The Options Clearing Corporation (''OCC'') filed with the Securities and Exchange Commission (''Commission'') a proposed rule change (File No. SR–OCC–96–03) under Section 19(b)(1) of the Securities Exchange Act of 1934 (''Act'')[1] to enable OCC to clear and settle flexibly structured equity options. Notice of the proposal was published in the Federal Register on June 25, 1996.[2] No comment letters were received. For the reasons discussed below, the Commission is approving the proposed rule change.

I. Description

OCC is modifying its existing by-laws and rules to allow for the clearance and settlement of flexibly structured options on individual equity securities as proposed for trading by the American Stock Exchange, Inc. (''AMEX''), the Chicago Board Options Exchange, Incorporated (''CBOE''), the Philadelphia Stock Exchange, Inc. (''PHLX''), and the Pacific Stock Exchange, Inc. (''PSE''— (collectively, ''Exchange'' or ''Exchanges'').[3] Flexibly structured equity options will allow the parties to each flexibly structured equity option trade to customize certain terms of the option within specified limits established by the Exchange. Specifically, for each flexibly structured equity option trade the parties may establish the exercise price, the exercise style (*i.e.*, American,[4] European[5] or capped)[6] the cap interval in the case of a capped-style option, the expiration date, and the option type (*i.e.*, put or call).[7] In addition to customization, flexibly structured equity option trades will require a minimum transaction size of 250 contracts in opening trades in currently unopened series and 100 contracts in the case of opening and most closing trades in currently open series. Flexibly structured equity options thus will differ from existing Exchanged-traded equity options both in terms of customization and size.

From a clearance and settlement prospective, flexibility structured equity options will be treated and processed in virtually all respects like any other equity option. While Exchange rules permit a Request for Quotes[8] to specify a quote either as a dollar amount or as a percentage of the underlying stock price, the option premium always will be expressed as a dollar amount when a trade is reported to OCC. Therefore, when a flexibly structured equity option trade is reported to OCC by one of the Exchanges, all of the terms of that option will have been established in the Exchange's report, and the terms will correspond to existing equity options term categories. As a result, on receipt of a matched trade report from an Exchange, OCC will establish long and short flexibility structured equity option positions in clearing member accounts in precisely the same way it does for existing equity options. Furthermore, flexibly structured equity option positions should exhibit virtually the

[1] 15 U.S.C. 78(b)(1) (1988).

[2] Securities Exchange Act Release No. 37318 (June 18, 1996), 61 FR 32873.

[3] For a complete description of flexibly structured equity options, refer to Securities Exchange Act Release Nos. 36841 (February 14, 1996), 61 FR 6666 [File Nos. SR–CBOE–95–43 and SR–PSE–95–24] (order approving the trading of flexibly structured equity options by the CBOE and PSE) and 37366 (June 19, 1996), 61 FR 33558 [File No. SR–AMEX–95–57] (order approving the trading of flexibly structured equity options by the AMEX). The PHLX filed and subsequently withdrew a proposed rule change regarding the trading of flexibly structured equity options. The Commission anticipates that the PHLX will refile in the near future.

[4] An American-style equity option may be exercised at any time prior to its expiration date.

[5] A European-style equity option may be exercised only during a specified period before the option expires.

[6] A capped-style equity option will be exercised automatically prior to expiration if the options market on which the option is trading determines that the value of the underlying interest at a specified time on a trading day ''hits the cap price'' for the option (*i.e.*, when the cap price is less than or equal to the closing price of the underlying security for calls or when the cap price is greater than or equal to the closing price of the underlying security for puts).

[7] Although the rules of the Exchanges provide for capped-style flexibly structured equity options, the Exchanges advised OCC that they do not intend to provide a market in capped-style equity options at the outset. Accordingly, this proposed rule change does not include the rules that would be required for the clearance and settlement of such options. The commencement of trading in capped-style flexibly structured equity options will require that OCC file and that the Commission approve another proposed rule change filed by OCC under Section 19(b)(1) of the Act.

[8] A Request for Quotes is the initial request by an exchange member to initiate flexibly structured option bidding and offering.

same characteristics as existing equity options.

Because of the similarities between existing equity options and flexibly structured equity options, only a few of OCC's by-laws and rules need adjustment to accommodate flexibly structured equity options.[9] OCC is amending Section 1 of Article I to add an all-purpose definition of ''flexibly structured option.'' Thus, the definition of flexibly structured option set forth in Articles XV, XVII, and XXIII will be deleted. The definition of ''expiration date'' is being amended to make clear that flexibly structured equity options may expire on dates other than the Saturday following the third Friday of the expiration month. The expiration date of any such option will be the date reported to OCC by the Exchange, subject to such constraints on the range of possible expiration dates as set forth in the rules of the Exchanges.

Section 11 of Article VI regarding adjustments to equity and index options also will apply to the adjustment of flexibly structured equity and index options.[10] However, paragraph (j) has been amended to reserve to the Securities Committee [11] the power to make special exceptions for flexibly structured options whenever it determines that such exceptions are appropriate. This is intended to give the Securities Committee the flexibility to deal with situations where a different adjustment for flexibly structured options is warranted.

OCC also is adding Interpretation and Policy .08 to Section 11. The interpretation provides that when a flexibly structured option with a European style exercise is adjusted to require the delivery upon exercise of a fixed amount of cash, such as would ordinarily occur in a merger where the underlying security is converted into a right to receive a fixed amount of cash, the expiration date of the option will ordinarily be accelerated so that the option will expire on or shortly after the date when the underlying stock is converted into the right to receive cash. Without this adjustment, the option position would have to be maintained until it could be exercised at its regular expiration even though the amount to be received on exercise had already been fixed. This special adjustment is being made to accommodate flexibly structured equity options because, unlike existing equity options, flexibly structured equity options may have European-style exercise features.

The only change being made to OCC's rules is the addition of Interpretation and Policy .03 to Rule 805 which clarifies that OCC's exercise procedures as set forth in Rule 805 shall apply to the exercise of flexibly structured equity options. The new interpretation also gives OCC the flexibility, if necessary, to depart from regular expiration date procedures and deadlines in the case of flexibly structured options. Such departures are not currently anticipated and adequate notice will be given to all clearing members prior to such departures being made.

II. Discussion

Sections 17A(b)(3) (A) and (F) [12] of the Act require that a clearing agency be structured and its rules designed to facilitate the prompt and accurate clearance and settlement of securities transactions and to safeguard securities and funds in its custody or control or for which it is responsible. Because from a clearance and settlement perspective, OCC will process flexibly structured equity options like any other equity option, the Commission believes that OCC's proposed change is consistent with Sections 17A(b)(3) (A) and (F) of the Act because the proposed rule change establishes a framework in which existing, reliable OCC systems, rules, and procedures are extended to the processing of flexibly structured equity options. As a result, the proposed rule change should promote the prompt and accurate clearance and settlement of such options and should provide for the safeguarding of related securities and funds.

III. Conclusion

The Commission finds that OCC's proposal is consistent with the requirements of the Act and particularly with Section 17A and the rules and regulations thereunder.

It is therefore ordered, pursuant to Section 19(b)(2) of the Act, that the proposed rule change (File No. SR–OCC–96–03) be, and hereby is, approved.

For the Commission, by the Division of Market Regulation, pursuant to delegated authority.[13]

Margaret H. McFarland,

Deputy Secretary.

[FR Doc. 96–22937 Filed 9–6–96; 8:45 am]

BILLING CODE 8010–01–M

[9] The specific changes to OCC's by-laws and rules are set forth in OCC's proposed rule change, which is available for review at the principal office of OCC and at the Commission's Public Reference Room.

[10] Adjustments may be made to the number of option contracts, the unit of trading, the exercise price, and the underlying security with respect to all outstanding option contracts open for trading on an underlying security which is the subject of a dividend, stock dividend, stock distribution, stock split, reverse stock split, rights offering, distribution, reorganization, recapitalization, reclassification or similar event, or the merger, consolidation, dissolution, or liquidation of the issuer of the underlying security.

[11] The Securities Committee consists of one designated representative of each exchange and the Chairman of OCC.

[12] 15 U.S.C. 78q–1(b)(3) (A) and (F) (1988).

[13] 17 CFR 200.30–3(a)(12) (1996).

[Release No. 34–37627; File No. SR–PSE–96–27]

Self-Regulatory Organizations; Notice of Filing and Immediate Effectiveness of Proposed Rule Change by the Pacific Stock Exchange Incorporated

September 3, 1996.

Pursuant to Section 19(b)(1) of the Securities Exchange Act of 1934 (''Act''),[1] notice is hereby given that on August 11, 1996, the Pacific Stock Exchange Incorporated (''PSE'' or ''Exchange'') filed with the Securities and Exchange Commission (''Commission'') the proposed rule change as described in Items I, II, and III below, which Items have been prepared by the self-regulatory organization. The Commission is publishing this notice to solicit comments on the proposed rule change from interested persons.

I. Self-Regulatory Organization's Statement of the Terms of Substance of the Proposed Rule Change

The Exchange hereby amends its Schedule of Rates for Exchange Services by reducing the current cap on transaction charges for equity block trades and by adopting a transaction fee cap per 100 shares for equity securities. The text of the proposed rule change is set forth below [new text is italicized; deleted text is bracketed]:

[1] 15 U.S.C. 78s(b)(1).

SCHEDULE OF FEES AND CHARGES FOR EXCHANGE SERVICES

	Cumulative billable trade value per month	Charge per $1,000 of trade value *
* * * * * * *		
PSE EQUITIES: TRADE-RELATED CHARGES		
EXCHANGE TRANSACTIONS	No change.	No change
DISCOUNTS *AND CAPS* [ON AUTOMATED TRANSACTIONS]:		
AUTOMATED TRADE DISCOUNTS	No change.	
BLOCK TRADES (5,000 SHARES OR MORE)	Transaction charges for block trades of 5,000 shares or more are subject to a minimum charge of $15 per trade side and a maximum charge of *$75* [$100] per trade side.	
CAP ON TRANSACTION CHARGES	*Aggregate monthly transaction charges are subject to a cap of $.45 per 100 shares.*	

II. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

In its filing with the Commission, the self-regulatory organization included statements concerning the purpose of and basis for the proposed rule change and discussed any comments it received on the proposed rule change. The text of these statements may be examined at the places specified in Item IV below. The self-regulatory organization has prepared summaries, set forth in Sections A, B, and C below, of the most significant aspects of such statements.

A. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

1. Purpose

The Exchange is proposing to amend its charges for equity transactions in two respects: First, the Exchange is proposing to reduce from $100 to $75 the current cap on transaction charges for block trades (i.e., trades involving 5,000 shares or more). Second, the Exchange proposes to establish a cap on aggregate monthly transaction charges equal to $.45 per 100 shares. These changes are intended to make the Exchange's equity transaction charges more competitive.

2. Statutory Basis

The proposed rule change is consistent with Section 6(b) of the Act [2] in general and furthers the objectives of Section 6(b)(4) [3] in particular in that it provides for the equitable allocation of reasonable dues, fees, and other charges among the Exchange's members and other persons using its facilities.

B. Self-Regulatory Organization's Statement on Burden on Competition

The proposed rule change does not impose any burden on competition that is not necessary or appropriate in furtherance of the purposes of the Act.

C. Self-Regulatory Organization's Statement on Comments on the Proposed Rule Change Received from Members, Participants, or Others

The Exchange has neither solicited nor received written comments on the proposed rule change.

III. Date of Effectiveness of the Proposed Rule Change and Timing for Commission Action

The foregoing rule change constitutes or changes a due, fee, or other charge imposed by the Exchange and, therefore, has become effective pursuant to Section 19(b)(3)(A) of the Act [4] and subparagraph (e) of Rule 19b–4 thereunder.[5]

At any time within 60 days of the filing of the proposed rule change, the Commission may summarily abrogate such rule change if it appears to the Commission that such action is necessary or appropriate in the public interest, for the protection of investors, or otherwise in furtherance of the purposes of the Act.

IV. Solicitation of Comments

Interested persons are invited to submit written data, views, and arguments concerning the foregoing. Persons making written submissions should file six copies thereof with the Secretary, Securities and Exchange Commission, 450 Fifth Street, N.W., Washington, D.C. 20549. Copies of the submission, all subsequent amendments, all written statements with respect to the proposed rule change that are filed with the Commission, and all written communications relating to the proposed rule change between the Commission and any person, other than those that may be withheld from the public in accordance with the provisions of 5 U.S.C. § 552, will be available for inspection and copying at the Commission's Public Reference Section, 450 Fifth Street, N.W., Washington, D.C. 20549. Copies of such filing also will be available for inspection and copying at the principal office of the Pacific Stock Exchange. All submissions should refer to File No. SR–PSE–96–27 and should be submitted by September 30, 1996.

For the Commission, by the Division of Market Regulation, pursuant to delegated authority.[6]

Margaret H. McFarland,

Deputy Secretary.

[FR Doc. 96–22880 Filed 9–6–96; 8:45 am]

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[2] 15 U.S.C. 78f(b).

[3] 15 U.S.C. 78f(b)(4).

[4] 15 U.S.C. 78s(b)(3)(A).

[5] 17 CFR 240.19b–4.

[6] 17 CFR 200.30–3(a)(12).

[Release No. 34–37628; File No. SR–Phlx–96–37]

Self-Regulatory Organizations; Notice of Filing of Proposed Rule Change by the Philadelphia Stock Exchange, Inc. Relating to Rule 452, Limitations on Members' Trading Because of Customers' Orders

September 3, 1996.

Pursuant to Section 19(b)(1) of the Securities Exchange Act of 1934 (''Act''), 15 U.S.C. § 78s(b)(1), notice is hereby given that on August 22, 1996, the Philadelphia Stock Exchange, Inc. (''Phlx'' or ''Exchange'') filed with the Securities and Exchange Commission (''Commission'') filed with the Securities and Exchange Commission

(''Commission'') the proposed rule change as described in Items I, II, and III below, which Items have been prepared by the self-regulatory organization. The Commission is publishing this notice to solicit comments on the proposed rule change from interested persons.

I. Self-Regulatory Organization's Statement of the Terms of Substance of the Proposed Rule Change

The Phlx, pursuant to Rule 19b–4 of the Act, proposes to amend Rule 452, Limitations on Members' Trading Because of Customers' Orders, which prohibits members from trading along with their customers on the same side of the market. Specifically, Rule 452 is proposed to be amended and reorganized as follows: paragraph (a) restates the prohibitions and extends such to member organizations; paragraph (b) exempts certain consensual arrangements between firms and customers; and paragraph (c) exempts odd-lot orders, trades specifying delivery other than regular way, and certain market making activity.

Proposed paragraph (a) will continue to prohibit a member's proprietary trades while the member is holding a customer order executable at the same price, except that the prohibition will be extended to member organizations. Paragraph (b) provides that a member or member organization may enter a proprietary order if the customer has given express permission, agreeing and understanding the method of allocating executions, including the prices and sizes, with respect to three categories of trading activities. The first exempted activity relates to a member or member organization liquidating a position held in a proprietary facilitation account where the customer's order is for 10,000 shares or more. The term ''proprietary facilitation account'' is an account used to record transactions whereby the member organization acquires positions in the course of facilitating customer orders. Thus, only those positions which are recorded in a proprietary facilitation account may be liquidated in accordance with this provision.

The second exempted activity relates to a member or member organization effecting one or more transactions for the purpose of facilitating or hedging the grant of a stop for 10,000 shares or more to the customer, or facilitating or hedging one or more principal transactions of 10,000 shares or more in the aggregate with the customer. The third exempted activity relates to a member or member organization trading for its own proprietary account and for the account(s) of one or more customers in an agreed-upon strategy or course of trading, such as bona fide arbitrage or risk arbitrage. A member organization that seeks to rely on the exclusion in paragraph (b)(3) may do so only if the member organization reasonably believes that the customer, alone or together with an investment representative, understands the nature of the transaction with respect to which he or she is giving consent. In addition, the reference to bona fide arbitrage and risk arbitrage in paragraph (b)(3) is intended to be illustrative and not exclusive.

Paragraph (c) provides an unqualified exemption for transactions by a member or member organization acting in the capacity of: (A) a market maker pursuant to Rule 19c–3 of the Commission in a security traded on the Exchange; or (B) a specialist or market maker on a national securities exchange. The Exchange notes that Phlx specialists and alternate specialists would be exempt from the prohibitions of the Rule pursuant to this provision.

Supplementary Material sections .01 and .02 are proposed to be adopted. Supplementary Material .01 states that a member or employee of a member organization responsible for entering proprietary orders shall be presumed to have knowledge of a particular customer order unless the member organization has implemented a reasonable system of internal policies and procedures to prevent the misuse of information about customer orders by those responsible for entering such proprietary orders.

Supplementary Material .02 provides that the Rule applies to a member on the Floor who may not execute a proprietary order at the same price, or at a better price, as an unexecuted customer order that he or she is representing, except to the extent that the member organization itself could do so under this Rule.

The Exchange notes that Supplementary Material .03 contains the current version of Supplementary Material .01, relating to a commitment to trade through the Intermarket Trading System (''ITS''), which is deemed to be initiating a purchase or sale of a security on the Exchange as referred to in this Rule.

The proposal will take effect upon notice to the membership. The text of the proposed rule change is as follows [new text is italicized; deleted text is bracketed]:

Rule 452. (a) *Except as provided in this Rule, n*[N]o member *or member organization* shall *cause the entry of an order to buy (sell)* [(1) personally buy or initiate the purchase of] any security on the Exchange for *any account in which such member or member organization or approved person thereof is directly or indirectly interested (a ''proprietary order''), if the person responsible for the entry of such order has knowledge of any particular unexecuted customer's order to buy (sell) such security which could be executed at the same price.*

[His account or for any account in which he, or the firm of which he is partner or any partner of such firm, is directly or indirectly interested, while such member personally holds or has knowledge that his firm or any partner thereof holds an unexecuted market order to buy such security in the unit of trading for a customer, or (2) personally sell or initiate the sale of any security on the Exchange for any such account, while he personally holds or has knowledge that his firm or any partner thereof holds an unexecuted market order to sell such security in the unit of trading for a customer.]

(b) *A member or member organization may enter a proprietary order if the customer has given express permission, agreeing and understanding the method of allocating executions, including the prices and sizes, with respect to the following trading strategies:*

(1) The member or member organization is liquidating a position held in a proprietary facilitation account, and the customer's order is for 10,000 shares or more.

The term ''proprietary facilitation account'' shall mean an account in which a member organization has a direct interest and which is used to record transactions whereby the member organization acquires positions in the course of facilitating customer orders. Only those positions which are recorded in a proprietary facilitation account may be liquidated as provided herein;

(2) The member or member organization is effecting one or more transactions for the purpose of facilitating or hedging the grant of a stop for 10,000 shares or more to the customer or facilitating or hedging one or more principal transactions of 10,000 shares or more in the aggregate with the customer; or

(3) The member or member organization is trading for its own proprietary account and for the account(s) of one or more customers in an agreed-upon strategy or course of trading, such as bona fide arbitrage or risk arbitrage. A member organization that seeks to rely on this exemption may do so only if the member organization reasonably believes that the customer, alone or together with an investment representative, understands the nature of the transaction with respect to which he or she is giving consent. The reference to bona fide arbitrage and risk arbitrage is intended to be illustrative and not exclusive.

[No member shall (1) personally buy or initiate the purchase of any security on the Exchange for any such account, at or below the price at which he personally holds or has knowledge that his firm or any partner thereof holds an unexecuted limited price order to buy such security in the unit of trading for a customer, or (2) personally sell or initiate the sale of any security on the Exchange for any such account at or above the price at which he personally holds or has

knowledge that his firm or any partner thereof holds an unexecuted limited price order to sell such security in the unit of trading for a customer.]

[Exceptions]

(c) The provisions of this Rule shall not apply *to:*

(1) [To] any purchase or sale of any security in an amount of less than the unit of trading made by an odd-lot dealer to offset odd-lot orders of customers [, or]*;*

(2) [To] any purchase or sale of any security, delivery which is to be upon a day other than the day of delivery provided in such unexecuted market or limited price order [.]*; or*

(3) transactions by a member or member organization acting in the capacity of:

(A) A market maker pursuant to Regulation 240.19c–3 of the Securities and Exchange Commission in a security traded on the Exchange; or

(B) A specialist or market maker on a national securities exchange.

Supplementary Material

.01 *A member or employee of a member organization responsible for entering proprietary orders shall be presumed to have knowledge or a particular customer order unless the member organization has implemented a reasonable system of internal policies and procedures to prevent the misuse of information about customer orders by those responsible for entering such proprietary orders.*

.02 This Rule shall also apply to a member organization's member on the Floor who may not execute a proprietary order at the same price, or at a better price, as an unexecuted customer order that he or she is representing, except to the extent that the member organization itself could do so under this Rule.

.03 A member who issues a commitment to trade from the Exchange through ITS or any other Application of the System shall, as a consequence thereof, be deemed to be initiating a purchase or sale of a security on the Exchange as referred to in this Rule.

II. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

In its filing with the Commission, the self-regulatory organization included statements concerning the purpose of and basis for the proposed rule change and discussed any comments it received on the proposed rule change. The text of these statements may be examined at the places specified in Item IV below. The self-regulatory organization has prepared summaries, set forth in Sections A, B, and C below, of the most significant aspects of such statements.

A. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

1. Purpose

In 1994, the NYSE filed a proposed rule change with the Commission to amend NYSE Rule 92 to: (1) extend the prohibition against trading along with customers to member organizations and NYSE member trading on other market centers; and (2) exempt the liquidation of block facilitation positions in NYSE securities, subject to specified conditions. Following publication of the proposal for notice and comment,[1] the Phlx, as well as other commenters, sought clarification of the reach of the proposal.[2] The Exchange commented that a significant burden on competition would result due to the impact on regional trading operations.[3]

Thereafter, the NYSE filed Amendment No. 2 to their proposal on July 13, 1995, specifically excluding: (1) securities not listed on the NYSE; (2) transactions by Rule 19c–3 market makers, and regional specialists if the principal trade is liquidated immediately at the same price to a customer on that exchange; and (3) certain bona fide or risk arbitrage transactions.[4] In response, the Exchange commented that the exemption for regional specialists should be unqualified, similar to the exemption for Rule 19c–3 market makers.[5] The Exchange further explained how the restrictions on specialist trades would be unduly disruptive to regional exchange market operations, and questioned the application of a NYSE rule to Phlx members affiliated with NYSE member organizations where there is no connection to NYSE floor trading.[6]

Recently, the NYSE filed Amendment No. 3 to the proposal, exempting without qualification regional exchange specialists and market makers from the provisions of the rule when acting as such on that exchange, deleting the limitation that the principal trade must be liquidated immediately at the same price to a customer on that exchange.[7] To date, the proposed amendments to NYSE Rule 92 continue to extend the rule to transactions on other market centers. The Phlx has commented adversely on this aspect of the amendments.[8]

At this time, the Exchange is adopting its own rule amendments governing the restricted activities and exempting certain transactions, which would otherwise have been governed by the NYSE rule, noting that the Rule 92 exemptions are limited to NYSE transactions. The Phlx's proposal at hand is conditioned upon the NYSE amending its proposal to delete application to other market centers. In this regard, the Phlx does not intend to take any disciplinary action against Phlx members or member organizations for violation of the Phlx rule for engaging in trading on another market center that is consistent with the rules of such market center. Moreover, although many Phlx member organizations also trade on other exchanges, the Exchange does not profess that its Rule 452 should extend to those transactions in view of Commission policy against the application of exchange rules to trading on another market center.[9]

In light of the conduct restricted and exemptions contained in the NYSE's proposal, the Exchange reviewed its own comparable rule, noting that currently, Phlx Rule 452 is divided into three paragraphs, with paragraph (a) prohibiting trading for a member's own account if the member's firm has an unexecuted market order on the same side of the market in that security; paragraph (b) containing the same prohibition for limit orders at that price or better; and paragraph (c) exempting odd-lot orders and transactions other than regular way.

In conjunction with the expected amendment to the NYSE's proposal limiting its application to NYSE members' and member organizations' transactions on the NYSE floor, the Phlx is proposing to amend its own rule to adopt similar exceptions to permit certain types of proprietary trading activity that the Phlx believes is consistent with the purposes of Phlx Rule 452 and the analogous NYSE Rule 92. Phlx Rule 452, as well as the

[1] Securities Exchange Act Release No. 35139 (Dec. 22, 1994), 60 FR 156 (SR–NYSE–94–34).

[2] *See* letter from William W. Uchimoto, General Counsel, Phlx, to Margaret H. McFarland, Deputy Secretary, Commission, dated February 15, 1995.

[3] *See* letter from William W. Uchimoto, General Counsel, Phlx, to Margaret H. McFarland, Deputy Secretary, Commission, dated April 4, 1995.

[4] Securities Exchange Act Release No. 36015 (July 21, 1995), 60 FR 38875 (Notice of Filing of Amendment No. 2 to SR–NYSE–94–34).

[5] *See* letter from William W. Uchimoto, General Counsel, Phlx, to Margaret H. McFarland, Deputy Secretary, Commission, dated August 11, 1995.

[6] *See* letter from William W. Uchimoto, General Counsel, Phlx, to Margaret H. McFarland, Deputy Secretary, Commission, dated October 27, 1995.

[7] Securities Exchange Act Release No. 37428 (July 11, 1996) (notice of Filing of Amendment No. 3 to SR–NYSE–94–34).

[8] *See* letter from Michele R. Weisbaum, Associate General Counsel, Phlx, to Margaret H. McFarland, Deputy Secretary, Commission, dated August 8, 1996.

[9] Securities Exchange Act Release No. 12249 (Mar. 23, 1976).

comparable rules of other exchanges, was intended to prevent members from taking advantage of their customers. Although customer protection is of paramount importance in furthering the purposes of the Act, fulfilling the self-regulatory mission and promoting an auction marketplace, the Exchange recognizes that it should not impair the business of trading by drafting away a customer's ability to enter into voluntary and consensual agreements with a member or member organization.

At this time, the Exchange proposes to adopt three exemptions in paragraph (b) requiring customer disclosure and consent: (1) liquidating block facilitation positions, (2) facilitating or hedging the grant of a stop in connection with executing a customer block order, and (3) any other consensual transactions agreed upon with the customer, including bona fide and risk arbitrage. All three exemptions are predicated upon the customer giving express permission for the firm to trade along with that customer. The express permission must also include the method of allocating executions, such as the prices and sizes of execution reports. The Exchange believes that these three transactions reflect the reality of today's trading environment, balanced against the need to preserve agency principles and promote customer protection by requiring the consent of the customer. Moreover, the Exchange believes that its proposal recognizes that informed consent, which reflects the true objectives of the customer, should prevail over arbitrary prohibitions. The Exchange believes that the enumerated exemptions are crafted to be consistent with a member's fiduciary relationship with its customer. For the purposes of Rule 452, the Exchange does not believe that informed consent can only be given by certain types of customers, nor should the exemption be premised on sophistication or wealth. In fact, the exemptions involving block orders by virtue of their size create a wealth standard. The Exchange believes that consensual arrangements should be available for all informed investors.

The first two consent-based exemptions codify current block trade practices, which the Exchange has included, because they are a universally accepted and common type of trading activity involving trading along with a customer. Block facilitation business, where positioning firms facilitate their institutional customers, by definition, involve customer disclosure and consent. The exemption in paragraph (b)(2) is designed to apply where a member organization may need to effect certain proprietary transactions in advance of trading with or stopping a customer block-sized order, in anticipation of accepting such market risk. Thus, this exemption goes beyond mere liquidation, as contemplated by the paragraph (b)(1) exemption, by permitting proprietary transactions to, for example, hedge or facilitate the execution of the block order.

The third exemption covers other transactions agreed upon by the customer, predicated upon consent. Recognizing the importance of informed consent, this provision specifically requires that the member organization reasonably believe that the customer, alone or together with an investment representative, understands the nature of the transactions with respect to which consent is given. For example, a customer may consent to a transaction subject to Rule 452 to adjust the risk allocation with a member organization, thus achieving certain economic objectives without resorting to off-exchange or other venues.

Bona fide and risk arbitrage are examples of strategies covered by the third exemption, where customers desire to trade along with the member in a potentially lucrative trading strategy. These specific strategies, however, are listed as nonexclusive examples. Because arbitrage strategies are listed as an example, Rule 452 does not purport to define these strategies nor list all other strategies covered by this exemption. The Exchange anticipates that other strategies will fall under this exemption. The Exchange believes that it is inefficient and ineffective to list every possible type of trading strategy that could be exempt, because trading strategies are constantly evolving in response to market conditions, constantly honed to specific economic circumstances. Because the premise behind exempting any such strategy that may evolve is that customer consent to trade with the customer is given, the Exchange believes that its third exemption is appropriate and would facilitate other shared trading arrangements that customers may require in the future.

The strategies proposed to be exempted involve the allocation of risk between firms and their customers. Because of the shared risk and the informed consent involved, these types of transactions have historically been viewed as integrally related to the customers' own trading objectives, which need not be disclosed generally to the market. Nevertheless, in relying upon the exemptive provisions of Rule 452, members and member organizations must be mindful of potential front-running situations; if they take advantage of their knowledge of customer trading objectives outside of efforts to facilitate customer trading objectives outside of efforts to facilitate customer trades, such member or member organization trading may violate Phlx Rule 707, Just and Equitable Principles of Trade. Of course, in crafting the proposed exemptions to Rule 452, the Exchange does not endeavor to exempt certain activity from existing front-running proscriptions.

The Exchange also proposes to exempt two types of market making activity: specialists and market makers on a national securities exchange as well as upstairs market makers acting as such pursuant to SEC Rule 19c–3. These market makers are proposed to be exempted because they foster depth and liquidity in the marketplace, and, at least with respect to specialists and market makers on a national securities exchange, are extensively monitored and subject to affirmative and negative obligations imposed by the various exchanges. Thus, such market makers are integral to the auction market.

The burden of proof to demonstrate that customer consent was obtained and the conditions of each exemption were met falls upon the member or member organization relying on the respective exemptive provision. The Exchange expects that internal procedures be adopted to assure compliance with the exemptive provisions.

With respect to the prohibitions of Rule 452, the Exchange proposes to extend such to member organizations in order to capture trading within a Phlx member organization, without limitation to the floor members involved.[10] Thus, whenever a member organization is representing an agency order, its own proprietary trading could be restricted. In this regard, new Supplementary Material .01 acknowledges that the agency order could be held in a different organizational component than the proprietary order such that a reasonable system of internal policies and procedures to prevent the misuse of customer information operates to dispel the presumption of knowledge by all employees of the member organization. Where such a system is in place, if an employee did not in fact know of the customer's order, then no violation occurred. The Exchange notes that a member organization would implement

[10] The Exchange notes that adding ''member organization'' to Rule 452 does not suggest that other Phlx rules do not apply to Phlx member organizations, but that the Exchange is intending to parallel the language of NYSE Rule 92 to prevent confusion.

information barriers appropriate to its business activity in accordance with this provision, taking into account that organization's supervisory/staffing structure and business operations, as well as the scope and nature of its business. The Exchange also notes that the prohibitions of Rule 452 apply once customer ''orders'' exist, such that proprietary trading is not impacted until customer interest takes the form of an order.

2. Statutory Basis

The proposed rule change is consistent with Section 6 of the Act in general, and in particular, with Section 6(b)(5), in that it is designed to promote just and equitable principles of trade, remove impediments to and perfect the mechanism of a free and open market and a national market system, as well as to protect investors and the public interest by preserving the customer protection principle that members and member organizations should place a customer's interests ahead of the firm's, yet facilitating consensual arrangements with customers demanded by the evolving marketplace. Permitting certain proprietary trading coincident with customer trading, with a customer's consent, should contribute to the depth and liquidity of the marketplace, which should also be fostered by exempting specialist and market making activity.

B. Self-Regulatory Organization's Statement on Burden on Competition

The Exchange does not believe that the proposed rule change will impose any inappropriate burden on competition.

C. Self-Regulatory Organization's Statement on Comments on the Proposed Rule Change Received from Members, Participants, or Others

No written comments were either solicited or received.

III. Date of Effectiveness of the Proposed Rule Change and Timing for Commission Action

Within 35 days of the publication of this notice in the Federal Register or within such other period (i) as the Commission may designate up to 90 days of such date if it finds such longer period to be appropriate and publishes its reasons for so finding or (ii) as to which the self-regulatory organization consents, the Commission will:

(A) By order approve the proposed rule change, or

(B) Institute proceedings to determine whether the proposed rule change should be disapproved.

IV. Solicitation of Comments

Interested persons are invited to submit written data, views, and arguments concerning the foregoing. Persons making written submissions should file six copies thereof with the Secretary, Securities and Exchange Commission, 450 Fifth Street, N.W., Washington, D.C. 20549. Copies of the submission, all subsequent amendments, all written statements with respect to the proposed rule change that are filed with the Commission, and all written communications relating to the proposed rule change between the Commission and any person, other than those that may be withheld from the public in accordance with the provisions of 5 U.S.C. 552, will be available for inspection and copying at the Commission's Public Reference Section, 450 Fifth Street, N.W., Washington, D.C. 20549. Copies of such filing will also be available for inspection and copying at the principal office of the Exchange. All submissions should refer to File No. SR–Phlx–96–37 and should be submitted by September 30, 1996.

For the Commission, by the Division of Market Regulation, pursuant to delegated authority.

Margaret H. McFarland,

Deputy Secretary.

[FR Doc. 96–22936 Filed 9–6–96; 8:45 am]

BILLING CODE 8010–01–M

SMALL BUSINESS ADMINISTRATION

[Declaration of Disaster Loan Area #2893]

New York; Declaration of Disaster Loan Area

Queens County and the contiguous counties of Bronx, Kings, Nassau, and New York in the State of New York constitute a disaster area as a result of damages caused by flooding which occurred on July 31, 1996. Applications for loans for physical damages may be filed until the close of business on October 28, 1996 and for economic injury until the close of business on May 29, 1997 at the address listed below: U.S. Small Business Administration, Disaster Area 1 Office, 360 Rainbow Boulevard South, 3rd Floor, Niagara Falls, New York 14303, or other locally announced locations.

The interest rates are:

	Percent
For physical damage:	
Homeowners with credit available elsewhere	8.000
Homeowners without credit available elsewhere	4.000
Businesses with credit available elsewhere	8.000
Businesses and non-profit organizations without credit available elsewhere	4.000
Others (including non-profit organizations) with credit available elsewhere	7.125
For economic injury:	
Businesses and small agricultural cooperatives without credit available elsewhere	4.000

The number assigned to this disaster for physical damage is 289306 and for economic injury the number is 917000.

(Catalog of Federal Domestic Assistance Program Nos. 59002 and 59008)

Date: August 29, 1996.

John T. Spotila,

Acting Administrator.

[FR Doc. 96–22898 Filed 9–6–96; 8:45 am]

BILLING CODE 8025–01–P

[Declaration of Disaster Loan Area #2891]

Tennessee; (and Contiguous Counties in Georgia); Declaration of Disaster Loan Area

Hamilton County and the contiguous counties of Bledsoe, Bradley, Marion, Rhea, and Sequatchie in the State of Tennessee, and Catoosa, Dade, Walker, and Whitfield Counties in the State of Georgia constitute a disaster area as a result of damages caused by severe storms and flooding which occurred on August 11, 1996. Applications for loans for physical damage as a result of this disaster may be filed until the close of business on October 28, 1996 and for economic injury until the close of business on May 29, 1997 at the address listed below: U.S. Small Business Administration, Disaster Area 2 Office, One Baltimore Place, Suite 300, Atlanta, GA 30308, or other locally announced locations.

The interest rates are:

	Percent
For physical damage:	
Homeowners with credit available elsewhere	8.000
Homeowners without credit available elsewhere	4.000
Businesses with credit available elsewhere	8.000
Businesses and non-profit organizations without credit available elsewhere	4.000
Others (including non-profit organizations) with credit available elsewhere	7.125

	Percent
For economic injury:	
Businesses and small agricultural cooperatives without credit available elsewhere	4.000

The numbers assigned to this disaster for physical damage are 289106 for Tennessee and 289206 for Georgia.

For economic injury the numbers are 916800 for Tennessee and 916900 for Georgia.

(Catalog of Federal Domestic Assistance Program Nos. 59002 and 59008)

Date: August 29, 1996.

John T. Spotila,

Acting Administrator.

[FR Doc. 96–22897 Filed 9–6–96; 8:45 am]

BILLING CODE 8025–01–P

SOCIAL SECURITY ADMINISTRATION

Research Plan For the Development of a Redesigned Method of Evaluating Disability in Social Security Claims

AGENCY: Social Security Administration (SSA).

ACTION: Notice and solicitation of comments.

SUMMARY: SSA has formulated a research plan for developing a new method of determining whether an individual is ''disabled,'' as defined in the Social Security Act (the Act), for purposes of entitlement or eligibility to disability benefits under titles II and XVI of the Act. The goal of this research will be to devise a more efficient and more accurate method for making timely determinations of disability for Social Security claimants. This notice describes SSA's research plan for developing the new methodology.

DATES: To be considered, all comments must be received in writing on or before October 24, 1996.

ADDRESSES: Please submit comments on the research plan in one of the following manners:

- By E-mail, to David.Barnes@ssa.gov
- By telefax, to 410–966–0148
- By mail, to Disability Process Redesign Staff, Office of Disability, Social Security Administration, 6401 Security Boulevard, Room 560 Altmeyer, Baltimore MD 21235.

FOR FURTHER INFORMATION, CONTACT: David Barnes, 410–965–9121.

SUPPLEMENTARY INFORMATION:

Background

In late 1993, the Social Security Administration (SSA) began an initiative to improve its disability process through business reengineering, which involves redesigning the business process to improve efficiency and service to the customers. In September 1994, the Commissioner of Social Security issued a report on SSA's disability process redesign entitled *Plan for a New Disability Claim Process.* That report discussed the need for a structured approach to disability decisionmaking that takes into consideration the large number of claims (2.7 million initial disability decisions in fiscal year 1994) and still provides a basis for consistent, equitable decisionmaking by adjudicators at each level of review.

The Commissioner described a proposal for a new method for determining whether individuals are ''disabled'' under the Social Security Act (the Act) with a goal of focusing decisionmaking on the functional consequences of an individual's medically determined impairments. However, she also acknowledged that certain aspects of the proposed new disability methodology would require much study and deliberation.

A November 1994 follow-up report, *Disability Process Redesign: Next Steps in Implementation,* discussed effectuation of the new disability claim process. The report noted that long-term research, consultation, development, and refinement will be needed in order to decide on and implement a new disability decision methodology.

Integration of Disability Evaluation Study and Disability Redesign Research

In response to concerns about growth in the disability rolls, SSA began research in early 1993 to identify factors contributing to this growth. One major research question remains unanswered:

How many adults in the U.S. are ''disabled,'' based on SSA criteria? (Existing estimates of the number of disabled vary widely because they are based on small sub-groups within the population, varying definitions of ''disability,'' and less reliable self-reports.)

To provide reliable estimates of the number of disabled adults, SSA has developed plans for a national survey, the Disability Evaluation Study (DES), which would include not only survey questions, but also physical and/or mental examination(s) and current medical records.

The DES will be in the field as SSA develops a new disability decision methodology. By integrating the DES with these plans to develop a new disability decision methodology, SSA will be able to use DES data to estimate the number of adults with disabilities in the United States, and also to collect the data needed to test the new proposed disability decision methodology.

More comprehensively, the DES will attempt to answer four fundamental questions:

(1) Would the types of people found disabled be affected by any change in disability decision methodology?

(2) Why can some persons with disabling impairments work, while others cannot?

(3) How many adults who meet SSA's definition of disability (irrespective of work status) are in the population?

(4) How can SSA cost-effectively monitor, for program planning purposes, future changes in the U.S. population of people who meet SSA's definition of disability?

The DES will attempt to answer these questions by screening a nationally representative sample of adults aged 18 to 69 in order to identify those with either self-identified diagnoses or other positive indicators of physical or mental impairment(s). For those screened in, the DES will collect sufficient data for accurate predictions of whether they would be found disabled under both current SSA criteria and the proposed new disability decision methodology.

The disability methodology research and DES will feed into each other in a variety of ways. In general terms, the DES design will reflect input from the disability methodology research and, to the extent that it can be specified, the new disability methodology itself. During a planned Stage 1, the DES will gather a wide range of information on functioning of individuals with physical and mental impairments and will include functional assessment measures that appear to have potential for eventual use in a functionally-based decision process. In Stage 2, the DES can field-test proposed functional assessment measures and decision processes on a nationally representative sample, perhaps concurrently with planned methodology laboratory testing.

In effect, the results and findings from DES Stage 1 and several other research projects will assist in the development of a proposed decision methodology that can be tested in Stage 2 of the DES. Further, the initial work to develop and implement Stage 1, conducted by SSA in conjunction with the expert staff of the eventual DES contractor, will provide additional relevant information to complement the output of the methodology research. It is also likely that, even before the full DES sample has been evaluated, certain findings that emerge from the field work will provide useful input for decisions on the new methodology.

Critical elements of the integrated research process will be:

- The combined product of two research projects on (1) functional assessment tools and (2) occupational classification systems. This will provide a comprehensive review and analysis of existing tools and systems, and also provide a basis for further research, which will allow SSA to make informed judgments about an appropriate way(s) of assessing functional capacity and how an individual's functional capacities relate to capacity for work.

- Two additional comprehensive research programs addressing disability methodology issues other than functional capacity measurement. Information derived from these programs will be used to develop the new proposed disability decision methodology. These programs are:

1. A survey of existing systems and methods of identifying disabled individuals (such as foreign and other domestic disability programs using functionally based methodologies, existing methods of screening in or screening out clear-cut cases, comparable to the proposed steps for use in the SSA disability determinations). The survey will provide an overview of how other disability programs address similar methodology problems; and

2. An analysis of the relationship between vocational factors (age, education, and work experience) and an individual's ability to work, which will be considered in making policy decisions on how to incorporate the statutorily-required consideration of such vocational factors into the new methodology.

- A project management approach [see Organization, below] that provides senior executive oversight, multi-level involvement of outside consultants, and both internal and external stakeholder consultation.

- Methodology laboratories, which will allow testing, in a controlled setting, of proposed components of a new methodology (e.g., specific functional assessment tools, proposed screening mechanisms). The laboratory setting and testing procedures will vary depending on the issue under investigation. Data from this testing will help to narrow choices among possible policy options by developing empirical data on which to base policy decisions.

- DES Stage 1 and Stage 2 data, which can provide a focused analysis of a new disability methodology in a nationally representative sample.

Organization

The organizational structure supporting the disability decision methodology research will have seven components:

A. Steering Committee

A three-person Steering Committee consisting of executives from SSA's Office of Disability (OD), Office of Research, Evaluation and Statistics (ORES), and Disability Process Redesign Team (DPRT) will be charged with overall supervision of the project. The Steering Committee will be advised by an Expert Panel and will delegate day-to-day management and operation of the project to a Research Workgroup.

B. Independent Review and Oversight

SSA intends to enter a contractual relationship with the National Academy of Sciences (NAS). NAS will review the overall research design, as well as specific research plans and products, and will advise the Steering Committee on all aspects of the project.

C. Research Workgroup

The Research Workgroup will be composed of OD, ORES, and DPRT staff, possibly supplemented by one or more consultants from outside SSA (see section D below). The Workgroup will direct day-to-day operation of all aspects of the project. Subject to Steering Committee oversight and direction, the Research Workgroup will review research products, develop laboratory testing scenarios, oversee laboratory testing, review test results, and identify and address policy options.

The Research Workgroup will rely on four sources for advice and comment: Consultants, Internal Stakeholders, External Stakeholders, and the General Public. Any recommendations of the Research Workgroup are subject to review and approval of the Steering Committee.

D. Consultants

We will contract with experts in relevant fields including medicine, disability, rehabilitation, health research, and research methodology, to review and evaluate research plans and products, recommend additional research activities, consult on the design of testing laboratories, etc. They will be selected for their expertise in one of the preceding subject areas, and they will provide advice to the research workgroup on an individual basis.

E. Internal Stakeholders

Internal Stakeholders will be individual representatives from other interested or affected SSA components (e.g., State Disability Determination Services, Field Offices, Office of Program and Integrity Reviews, Office of Systems, Office of Hearings and Appeals). They will review and comment on specific aspects of the project. Internal Stakeholders will be identified by their respective components.

F. External Stakeholders

External Stakeholders will be individuals and organizations, many of whom already interact with SSA, with a special interest in SSA disability programs. They will not meet or operate as a single entity, but will individually review and comment on major activities and products mailed to them. Individuals or organizations interested in being considered External Stakeholders should submit their request to the contact point listed above.

G. General Public

The Research Workgroup will seek, receive, and consider comments from the general public through a series of notices published in the Federal Register. The notices will describe the Agency's research goals and plans, discuss major developments in the research process (e.g., results of research activities, Research Workgroup and Steering Committee decisions, laboratory test procedures and results), and invite public comment. If necessary, the Research Workgroup will consider organizing public hearings or asking contractors to convene groups or to hold public forums.

Process

SSA is committed to conducting this research in an inclusive environment. To that end, SSA is simultaneously publishing this notice in the Federal Register and sending the same notice to a comprehensive list of Internal and External Stakeholders.

At major milestones in the research and development process when consultant and/or stakeholder input is appropriate (e.g., receipt of a research product or laboratory test result, change in research plans, preliminary policy decision), SSA will publish a Federal Register notice, including a request for comments, and transmit the same notice to External Stakeholders.

SSA also will present the same issue(s) to the Consultants for advice and, as needed, to some or all of the Internal Stakeholders for comment.

Upon completion of all research actions, a report will be made to the Commissioner making final recommendations for the new disability methodology.

Time Line

Action	Date
Development of Research Plan	Completed.
Publication of Research Plan in **Federal Register**; Request for Internal and External Stakeholder Comments	8/96.
Completion of Initial Research on Functional Assessment Instruments	11/96.
Federal Register Notice Describing Initial Research Products; Request for Internal and External Stakeholder Comments	1/97.
Award of DES Contract	7/97.
Further Research (Other Disability Programs, Vocational Factors); Laboratory Testing; DES Stage 1 Field Work Begins	7/97–9/97.
Federal Register Notice Describing Further Research and Testing; Request for Internal and External Stakeholder Comments	9/97.
Supplemental Research (as needed) and Testing; DES Stage 1 Field Work	1/98–9/98.
Federal Register Notice Describing Supplemental Research and Testing Based on Results to Date; Request for Internal and External Stakeholder Comments.	9/98.
Review of All Research, Comments, and Testing in Conjunction with DES Stage 1 Data; DES Stage 2 Field Work	10/98–10/99
FEDERAL REGISTER Notice Describing DES Research Including Interim Results; Request for Internal and External Stakeholder Comments.	11/99
Final Review of All Research, Testing, Comments, and DES Data; Recommendation of Final Disability Decision Methodology	11/99–12/99

Dated: August 30, 1996.

John Dyer,

Acting, Principal Deputy Commissioner of Social Security.

[FR Doc. 96–22925 Filed 9–6–96; 8:45 am]

BILLING CODE 4190–29–P

DEPARTMENT OF TRANSPORTATION

Coast Guard

[CGD08–96–040]

Houston/Galveston Navigation Safety Advisory Committee Meeting

AGENCY: Coast Guard, DOT.

ACTION: Notice of full committee meeting.

SUMMARY: The Houston/Galveston Navigation Safety Advisory Committee (HOGANSAC) will meet to discuss waterway improvements, aids to navigation, current meters, and various other navigation safety matters affecting the Houston/Galveston area. All meetings will be open to the public.

DATES: The meeting of HOGANSAC will be held on Thursday, October 3, 1996 from 9:30 a.m. to approximately 1 p.m. Members of the public may present written or oral statements at the meetings.

ADDRESSES: The HOGANSAC meeting will be held in the conference room of the Houston Pilots Office, 8150 South Loop East, Houston, Texas.

FOR FURTHER INFORMATION CONTACT: Captain K. Eldridge, Executive Director of HOGANSAC, telephone (713) 671–5101, or Commander P. Carroll, Executive Secretary of HOGANSAC, telephone (713) 671–5164.

SUPPLEMENTARY INFORMATION: Notice of this meeting is given pursuant to the Federal Advisory Committee Act, 5 U.S.C. App. 2.

Agenda of the Meeting

Houston/Galveston Navigation Safety Advisory Committee (HOGANSAC). The tentative agenda includes the following:

(1) Introductory remarks by the new sponsor (Rear Admiral T. W. Josiah) and Executive Director (Captain K. Eldridge).

(2) Approval of the May 23, 1996 minutes.

(3) Report from the Navigation Subcommittee.

(4) Report from the Waterways Subcommittee.

Procedural

All meetings are open to the public. Members of the public may make oral presentations during the meetings.

Information on Services for the Handicapped

For information on facilities or services for the handicapped or to request special assistance at the meetings, contact the Executive Director as soon as possible.

Dated: August 23, 1996.

T.W. Josiah,

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

[FR Doc. 96–22948 Filed 9–6–96; 8:45 am]

BILLING CODE 4910–14–M

National Highway Traffic Safety Administration

Research and Development Programs Meeting Agenda

AGENCY: National Highway Traffic Safety Administration, DOT.

ACTION: Notice.

SUMMARY: This notice provides the agenda for a public meeting at which the National Highway Traffic Safety Administration (NHTSA) will describe and discuss specific research and development projects.

DATES AND TIMES: As previously announced, NHTSA will hold a public meeting devoted primarily to presentations of specific research and development projects on September 11, 1996, beginning at 1:30 p.m. and ending at approximately 5:00 p.m.

ADDRESS: The meeting will be held at the Tysons Westpark Hotel, 8401 Westpark Drive, McLean, Virginia 22102.

SUPPLEMENTARY INFORMATION: This notice provides the agenda for the fourteenth in a series of public meetings to provide detailed information about NHTSA's research and development programs. This meeting will be held on September 11, 1996. The meeting was announced on August 13, 1996 (61 FR 42083). For additional information about the meeting consult that announcement.

Starting at 1:30 p.m. and concluding by 5:00 p.m., NHTSA's Office of Research and Development will discuss the following topics:

Air bag assessment research,
Status of ejection mitigation research,
Improved frontal crash protection—update on oblique moving barrier testing,
Preliminary estimates of safety benefits for ITS collision avoidance systems,
National Center for Statistics and Analysis information services,
National Accident Sampling System (NASS) status report,
Pedestrian special NASS study,
On-line tracking system for NHTSA's research projects.

NHTSA has based its decisions about the agenda, in part, on the suggestions it received by August 22, 1996, in response to the announcement published August 13, 1996.

As announced on August 13, 1996, in the time remaining at the conclusion of

the presentations, NHTSA will provide answers to questions on its research and development programs, where those questions have been submitted in writing by 4:15 p.m. on August 29, 1996, to William A. Boehly, Associate Administrator for Research and Development, NRD–01, National Highway Traffic Safety Administration, Washington, DC 20590. Fax number: 202–366–5930.

FOR FURTHER INFORMATION CONTACT: Rita I. Gibbons, Staff Assistant, Office of Research and Development, 400 Seventh Street, SW, Washington, DC 20590. Telephone: 202–366–4862. Fax number: 202–366–5930.

Issued: September 4, 1996.

William A. Boehly,

Associate Administrator for Research and Development.

[FR Doc. 96–22943 Filed 9–6–96; 8:45 am]

BILLING CODE 4910–59–P

[Docket Nos. 96–045; Notice 2, 96–058; Notice 2, 96–059; Notice 2, 96–060; Notice 2, 96–061; Notice 2, 96–062; Notice 2, 96–063; Notice 2, 96–064; Notice 2]

Decision That Nonconforming 1992 Jeep Cherokee Multi-Purpose Passenger Vehicles Manufactured for the Venezuelan Market, et al., are Eligible for Importation

AGENCY: National Highway Traffic Safety Administration (NHTSA), DOT.

ACTION: Notice of decision by NHTSA that nonconforming 1992 Jeep Cherokee multi-purpose passenger vehicles manufactured for the Venezuelan market, 1983 Yamaha RD 350 motorcycles, 1993 Mercedes-Benz 420E passenger cars, 1994–1996 Mercedes-Benz E420 passenger cars, 1993 Mercedes-Benz 280E passenger cars, 1994–1996 Mercedes-Benz E280 passenger cars, 1992 Mercedes-Benz 250D passenger cars, 1993–1996 Mercedes-Benz 220TE station wagons, 1993 Mercedes-Benz 220E passenger cars, 1994–1996 Mercedes-Benz E220 passenger cars, and 1993, 1995, and 1996 Porsche Carrera 2-door passenger cars are eligible for importation.

SUMMARY: This notice announces the decision by NHTSA that 1992 Jeep Cherokee multi-purpose passenger vehicles manufactured for the Venezuelan market, 1983 Yamaha RD 350 motorcycles, 1993 Mercedes-Benz 420E passenger cars, 1994–1996 Mercedes-Benz E420 passenger cars, 1993 Mercedes-Benz 280E passenger cars, 1994–1996 Mercedes-Benz E280 passenger cars, 1992 Mercedes-Benz 250D passenger cars, 1993–1996 Mercedes-Benz 220TE station wagons, 1993 Mercedes-Benz 220E passenger cars, 1994–1996 Mercedes-Benz E220 passenger cars, and 1993, 1995, and 1996 Porsche Carrera 2-door passenger cars not originally manufactured to comply with all applicable Federal motor vehicle safety standards are eligible for importation into the United States because they are substantially similar to vehicles originally manufactured for importation into and sale in the United States and certified by their manufacturers as complying with the safety standards, and they are capable of being readily altered to conform to the standards.

DATE: This decision is effective as of September 9, 1996.

FOR FURTHER INFORMATION CONTACT: George Entwistle, Office of Vehicle Safety Compliance, NHTSA (202–366–5306).

SUPPLEMENTARY INFORMATION:

Background

Under 49 U.S.C. § 30141(a)(1)(A) (formerly section 108(c)(3)(A)(i) of the National Traffic and Motor Vehicle Safety Act (the Act)), a motor vehicle that was not originally manufactured to conform to all applicable Federal motor vehicle safety standards shall be refused admission into the United States unless NHTSA has decided that the motor vehicle is substantially similar to a motor vehicle originally manufactured for importation into and sale in the United States, certified under 49 U.S.C. § 30115 (formerly section 114 of the Act), and of the same model year as the model of the motor vehicle to be compared, and is capable of being readily altered to conform to all applicable Federal motor vehicle safety standards.

Petitions for eligibility decisions may be submitted by either manufacturers or importers who have registered with NHTSA pursuant to 49 CFR Part 592. As specified in 49 CFR 593.7, NHTSA publishes notice in the Federal Register of each petition that it receives, and affords interested persons an opportunity to comment on the petition. At the close of the comment period, NHTSA decides, on the basis of the petition and any comments that it has received, whether the vehicle is eligible for importation. The agency then publishes this decision in the Federal Register.

NHTSA received petitions from registered importers to decide whether 1992 Jeep Cherokee multi-purpose passenger vehicles manufactured for the Venezuelan market, 1983 Yamaha RD 350 motorcycles, 1993 Mercedes-Benz 420E passenger cars, 1994–1996 Mercedes-Benz E420 passenger cars, 1993 Mercedes-Benz 280E passenger cars, 1994–1996 Mercedes-Benz E280 passenger cars, 1992 Mercedes-Benz 250D passenger cars, 1993–1996 Mercedes-Benz 220TE station wagons, 1993 Mercedes-Benz 220E passenger cars, 1994–1996 Mercedes-Benz E220 passenger cars, and 1993, 1995, and 1996 Porsche Carrera 2-Door passenger cars are eligible for importation into the United States. To afford an opportunity for public comment, NHTSA published notice of these petitions as follows:

Vehicle	Notice date and cite
1992 Jeep Cherokee	May 10, 1996 (61 FR 21530).
1983 Yamaha RD 350.	June 25, 1996 (61 FR 32891).
1993 Mercedes-Benz 420E.	June 19, 1996 (61 FR 31220).
1994–1996 Mercedes-Benz E420.	June 19, 1996 (61 FR 31220).
1993 Mercedes-Benz 280E.	June 12, 1996 (61 FR 29788).
1994–1996 Mercedes-Benz E280.	June 12, 1996 (61 FR 29788).
1992 Mercedes-Benz 250D.	June 25, 1996 (61 FR 32892).
1993–1996 Mercedes-Benz 220TE.	June 12, 1996 (61 FR 29793).
1993 Mercedes-Benz 220E.	June 12, 1996 (61 FR 29791).
1994–1996 Mercedes-Benz E220.	June 12, 1996 (61 FR 29791).
1993, 1995 and 1996 Porsche Carrera 2-door.	June 19, 1996 (61 FR 31216).

The reader is referred to those notices for a thorough description of the petitions. No comments were received in response to these notices. Based on its review of the information submitted by the petitioners, NHTSA has decided to grant the petitions.

Vehicle Eligibility Number for Subject Vehicles

The importer of a vehicle admissible under any final decision must indicate on the form HS–7 accompanying entry the appropriate vehicle eligibility number indicating that the vehicle is eligible for entry. Vehicle eligibility numbers assigned to vehicles admissible under this decision are as follows:

Vehicle	Vehicle eligibility number
1992 Jeep Cherokee (Venezuelan).	VSP–164.
1983 Yamaha RD 350	VSP–171.
1993 Mercedes-Benz 420E	VSP–169.
1994–96 Mercedes-Benz E420	VSP–169.
1993 Mercedes-Benz 280E	VSP–166.
1994–96 Mercedes-Benz E280	VSP–166.
1992 Mercedes-Benz 250D	VSP–172.

Vehicle	Vehicle eligibility number
1993–96 Mercedes-Benz 220TE	VSP–167.
1993 Mercedes-Benz 220E	VSP–168.
1994–96 Mercedes-Benz E220	VSP–168.
1993, 1995 and 1996 Porsche Carrera 2-door.	VSP–165.

Final Decision

Accordingly, on the basis of the foregoing, NHTSA hereby decides that:

1. A 1992 Jeep Cherokee multi-purpose passenger vehicle manufactured for the Venezuelan market that was not originally manufactured to comply with all applicable Federal motor vehicle safety standards is substantially similar to a 1992 Jeep Cherokee multi-purpose passenger vehicle originally manufactured for sale in the United States and certified under 49 U.S.C. § 30115, and is capable of being readily altered to conform to all applicable Federal motor vehicle safety standards;

2. A 1983 Yamaha RD 350 motorcycle not originally manufactured to comply with all applicable Federal motor vehicle safety standards is substantially similar to a 1983 Yamaha RZ 350 motorcycle originally manufactured for importation into and sale in the United States and certified under 49 U.S.C. § 30115, and is capable of being readily altered to conform to all applicable Federal motor vehicle safety standards;

3. A 1993 Mercedes-Benz 420E passenger car not originally manufactured to comply with all applicable Federal motor vehicle safety standards is substantially similar to a 1993 Mercedes-Benz 400E passenger car originally manufactured for importation into and sale in the United States and certified under 49 U.S.C. § 30115, and is capable of being readily altered to conform to all applicable Federal motor vehicle safety standards;

4. 1994–1996 Mercedes-Benz E420 passenger cars not originally manufactured to comply with all applicable Federal motor vehicle safety standards are substantially similar to 1994–1996 Mercedes-Benz E420 passenger cars originally manufactured for importation into and sale in the United States and certified under 49 U.S.C. § 30115, and are capable of being readily altered to conform to all applicable Federal motor vehicle safety standards;

5. A 1993 Mercedes-Benz 280E passenger car not originally manufactured to comply with all applicable Federal motor vehicle safety standards is substantially similar to a 1993 Mercedes-Benz 300E passenger car originally manufactured for importation into and sale in the United States and certified under 49 U.S.C. § 30115, and is capable of being readily altered to conform to all applicable Federal motor vehicle safety standards;

6. 1994–1996 Mercedes-Benz E280 passenger cars not originally manufactured to comply with all applicable Federal motor vehicle safety standards are substantially similar to 1994–1996 Mercedes-Benz E320 passenger cars originally manufactured for importation into and sale in the United States and certified under 49 U.S.C. § 30115, and are capable of being readily altered to conform to all applicable Federal motor vehicle safety standards;

7. A 1992 Mercedes-Benz 250D passenger car not originally manufactured to comply with all applicable Federal motor vehicle safety standards is substantially similar to a 1992 Mercedes-Benz 300E passenger car originally manufactured for importation into and sale in the United States and certified under 49 U.S.C. § 30115, and is capable of being readily altered to conform to all applicable Federal motor vehicle safety standards;

8. 1993–1996 Mercedes-Benz 220TE station wagons not originally manufactured to comply with all applicable Federal motor vehicle safety standards are substantially similar to the 1993 Mercedes-Benz 300TE and 1994–1996 Mercedes-Benz E320 station wagons originally manufactured for importation into and sale in the United States and certified under 49 U.S.C. § 30115, and are capable of being readily altered to conform to all applicable Federal motor vehicle safety standards;

9. A 1993 Mercedes-Benz 220E passenger car not originally manufactured to comply with all applicable Federal motor vehicle safety standards is substantially similar to a 1993 Mercedes-Benz 300E passenger car originally manufactured for importation into and sale in the United States and certified under 49 U.S.C. § 30115, and is capable of being readily altered to conform to all applicable Federal motor vehicle safety standards;

10. 1994–1996 Mercedes-Benz E220 passenger cars not originally manufactured to comply with all applicable Federal motor vehicle safety standards are substantially similar to 1994–1996 Mercedes-Benz E320 passenger cars originally manufactured for importation into and sale in the United States and certified under 49 U.S.C. § 30115, and are capable of being readily altered to conform to all applicable Federal motor vehicle safety standards; and

11. 1993, 1995, and 1996 Porsche Carrera 2–Door passenger cars not originally manufactured to comply with all applicable Federal motor vehicle safety standards are substantially similar to 1993, 1995, and 1996 Porsche Carrera 2–Door passenger cars originally manufactured for importation into and sale in the United States and certified under 49 U.S.C. § 30115, and are capable of being readily altered to conform to all applicable Federal motor vehicle safety standards.

Authority: 49 U.S.C. 30141 (a)(1)(A) and (b)(1); 49 CFR 593.8; delegations of authority at 49 CFR 1.50 and 501.8.

Issued on: September 3, 1996.

Marilynne Jacobs,

Director, Office of Vehicle Safety Compliance.

[FR Doc. 96–22879 Filed 9–6–96; 8:45 am]

BILLING CODE 4910–59–P

Surface Transportation Board

[STB Finance Docket No. 33021]

Atlantic & Western Railway, L.P.—Acquisition Exemption—Lines of Norfolk Southern Railway Company

Atlantic & Western Railway, L.P. (ATW),[1] a Class III rail carrier, has filed a notice of exemption under 49 CFR 1150.41 to acquire from Norfolk Southern Railway Company approximately 6.4 route miles of rail line between milepost CF–123.65, at Cumnock, NC, and milepost CF–130.04, at Sanford, NC. ATW will operate the property.

The exemption was effective on August 28, 1996. The parties indicate that consummation of the transaction will occur approximately 90 days after the effective date of the exemption.

If the notice contains false or misleading information, the exemption is void *ab initio.* Petitions to revoke the exemption under 49 U.S.C. 10502(d) may be filed at any time. The filing of a petition to revoke does not automatically stay the transaction.

An original and 10 copies of all pleadings, referring to STB Finance Docket No. 33021, must be filed with the Surface Transportation Board, Office of the Secretary, Case Control Branch, 1201 Constitution Avenue, NW., Washington, DC 20423. In addition, a copy of each pleading must be served on: Donald G. Avery, Esq., Slover &

[1] The ICC Termination Act of 1995, Pub. L. No. 104–88, 109 Stat. 803, which was enacted on December 29, 1995, and took effect on January 1, 1996, abolished the Interstate Commerce Commission and transferred certain functions to the Surface Transportation Board (Board). This notice relates to functions that are subject to Board jurisdiction pursuant to 49 U.S.C. 10902.

Loftus, 1224 Seventeenth Street, NW., Washington, DC 20036. Telephone: (202) 347–7170.

Decided: August 30, 1996.

By the Board, David M. Konschnik, Director, Office of Proceedings.

Vernon A. Williams,

Secretary.

[FR Doc. 96–22914 Filed 9–6–96; 8:45 am]

BILLING CODE 4915–00–P

[Docket No. AB–33 (Sub-No. 91X)]

Union Pacific Railroad Company—Abandonment Exemption—in Caribou County, ID

AGENCY: Surface Transportation Board.[1]

ACTION: Notice of exemption.

SUMMARY: The Board, under 49 U.S.C. 10505, exempts from the prior approval requirements of 49 U.S.C. 10903–04 the abandonment by Union Pacific Railroad Company of a 5.7-mile line of railroad, known as the Grace Industrial Lead, from milepost 0.1 near Alexander to the end of the line at milepost 5.8 near Grace, in Caribou County, ID, subject to standard labor protective conditions and an environmental condition.

DATES: Provided no formal expression of intent to file an offer of financial assistance (OFA) has been received, this exemption will be effective on October 9, 1996. Formal expressions of intent to file an OFA under 49 CFR 1152.27(c)(2)[2] must be filed by September 19, 1996; petitions to stay must be filed by September 24, 1996; requests for a public use condition in conformity with 49 CFR 1152.28(a)(2) must be filed by September 30, 1996; and petitions to reopen must be filed by October 4, 1996.

ADDRESSES: Send pleadings referring to Docket No. AB–33 (Sub-No. 91X) to: (1) Surface Transportation Board, Office of the Secretary, Case Control Branch, 1201 Constitution Avenue, N.W., Washington, D.C. 20423; and (2) Petitioner's representative, Jeanna L. Regier, 1416 Dodge Street, Room 830, Omaha, NE 68179–0830.

FOR FURTHER INFORMATION CONTACT: Beryl Gordon, (202) 927–5660. [TDD for the hearing impaired: (202) 927–5721.]

SUPPLEMENTARY INFORMATION: Additional information is contained in the Board's decision. To purchase a copy of the full decision, write to, call, or pick up in person from DC News and Data, Inc., Room 2229, 1201 Constitution Avenue, N.W., Washington, D.C. 20423. Telephone: (202) 289–4357/4359. [Assistance for the hearing impaired is available through TDD services (202) 927–5721.]

Decided: August 27, 1996.

By the Board, Chairman Morgan, Vice Chairman Simmons, and Commissioner Owen.

Vernon A. Williams,

Secretary.

[FR Doc. 96–22915 Filed 9–6–96; 8:45 am]

BILLING CODE 4915–00–P

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[1] The ICC Termination Act of 1995, Pub. L. No. 104–88, 109 Stat. 803 (the ICCTA), which was enacted on December 29, 1995, and took effect on January 1, 1996, abolished the Interstate Commerce Commission (ICC) and transferred certain functions and proceedings to the Surface Transportation Board (Board). Section 204(b)(1) of the ICCTA provides, in general, that proceedings pending before the ICC on the effective date of that legislation shall be decided under the law in effect prior to January 1, 1996, insofar as they involve functions retained by the ICCTA. This notice relates to a proceeding that was pending with the ICC prior to January 1, 1996, and to functions that are subject to Board jurisdiction pursuant to 49 U.S.C. 10903. Therefore, this notice applies the law in effect prior to the ICCTA, and citations are to the former sections of the statute, unless otherwise indicated.

[2] *See Exempt. of Rail Abandonment—Offers of Finan. Assist.,* 4 I.C.C.2d 164 (1987).

DEPARTMENT OF THE TREASURY

Internal Revenue Service

Privacy Act of 1974; System of Records

AGENCY: Internal Revenue Service, Treasury.

ACTION: Notice of Proposed New Privacy Act System of Records.

SUMMARY: The Treasury Department, Internal Revenue Service, gives notice of a proposed new system of records entitled Automated Information Analysis System—Treasury/IRS 46.050, which is subject to the Privacy Act of 1974, 5 U.S.C. 552a. This proposed system has been developed to assist the Internal Revenue Service in accomplishing its mission of encouraging and achieving the highest possible degree of voluntary compliance with the Internal Revenue laws. It is further proposed to have the system exempt from meeting certain requirements of the Privacy Act of 1974.

DATES: Comments must be received no later than October 9, 1996. This new system of records will be effective October 21, 1996, unless comments are received which result in a contrary determination.

ADDRESSES: Comments should be sent to the Office of Disclosure, Internal Revenue Service, 1111 Constitution Avenue, NW, Washington, DC 20224. Comments will be made available for inspection and copying in the Freedom of Information Reading Room upon request.

FOR FURTHER INFORMATION CONTACT: Wayne Loving, Director, Office of Policy and Information Division, Criminal Investigation, (202) 622–5676.

SUPPLEMENTARY INFORMATION:

The Internal Revenue Service's Criminal Investigation Division (CID) seeks to establish and maintain the proposed new system of records as a more efficient means of performing its responsibilities. Among Criminal Investigation's principal responsibilities are probing and referring for prosecution criminal cases centering largely on violations of tax laws, including income tax evasion, refund fraud, and other crimes contributing to the Federal tax gap. Criminal Investigation also investigates violations of certain money laundering laws. The Automated Information Analysis System will automatically identify potential leads to money laundering and income tax violations which might not otherwise surface through traditional information gathering efforts. The Automated Information Analysis System only relies upon internal data included in other Privacy Act systems of records. This action should encourage individuals and businesses to fully comply with the tax laws and other reporting requirements and aid Internal Revenue's Criminal Investigation Division in identifying potential violations.

The Automated Information Analysis System is designed to provide the Internal Revenue Service with high quality investigative leads to tax noncompliance at a substantial savings.

The Automated Information Analysis System produces an output record that identifies leads appropriate for further evaluation by field special agents. Once the output record is sent to the District Criminal Investigation office that will investigate the leads, it will be covered by system of records Treasury/IRS 46.009, Centralized Evaluation and Processing of Information Items (CEPIIs).

In a separate publication, the Internal Revenue Service is also giving public notice of a proposed rule to exempt this system of records from certain provisions of 5 U.S.C. 552a pursuant to subsections (j)(2), and (k)(2) of the same section.

Treasury/IRS 46.050

SYSTEM NAME:

Automated Information Analysis System - Treasury/IRS.

SYSTEM LOCATION:

Detroit Computing Center, 1300 John C. Lodge Drive, Detroit, Michigan 48226 and Automated Criminal Investigation Office, 7940 Kentucky Drive, Boone County, Kentucky 41042.

CATEGORIES OF INDIVIDUALS COVERED BY THE SYSTEM:

Taxpayers and other individuals involved in financial transactions which require the filing of information reflected in the Categories of records below.

CATEGORIES OF RECORDS IN THE SYSTEM:

The information included in the Automated Information Analysis System is from reported income and tax information on the Individual Master File (IMF)—Treasury/IRS 24.030; Individual Returns Files, Adjustments and Miscellaneous Documents File—Treasury/IRS 22.034. The Automated Information Analysis System also includes information from such sources as: Currency Transaction Reports (CTRs), Currency and Monetary Instrument Reports (CMIR's), Bank Secrecy Reports File, Foreign Bank Account Reports (FBARs), Forms 8300 (Currency Received in Trade or Business),—Treasury/CS .067; the Taxpayer Delinquent Account Files (TDA)—Treasury/IRS 26.019, which includes adjustments and payment tracer files and collateral files; Taxpayer Delinquency Investigation Files (TDI)—Treasury/IRS 26.020, which includes taxpayer information on delinquent returns; the Examination Administrative File—Treasury/IRS 42.001, and Casino Transaction Reports from the Detroit Computing Center.

AUTHORITY FOR MAINTENANCE OF THE SYSTEM:

5 U.S.C. 301; 26 U.S.C. 7602, 7801, and 7802.

PURPOSE(S):

The purpose is to maintain records which identify transaction patterns that are indicative of criminal and/or civil noncompliance with Federal income tax and money laundering laws and to simultaneously evaluate diverse data sources.

ROUTINE USES OF RECORDS MAINTAINED IN THE SYSTEM, INCLUDING CATEGORIES OF USERS AND THE PURPOSES OF SUCH USES:

Disclosure of returns and return information may be made only as provided by 26 U.S.C. 6103.

POLICIES AND PRACTICES FOR STORING, RETRIEVING, ACCESSING, RETAINING, AND DISPOSING OF RECORDS IN THE SYSTEM:

STORAGE:

Electronic and Magnetic Media.

RETRIEVABILITY:

Records are retrievable by name, address, and social security number.

SAFEGUARDS:

All Criminal Investigation personnel accessing the system will have successfully passed a background investigation. Criminal Investigation will furnish information from the system of records to approved personnel only on a ''need to know'' basis using passwords and access controls. Access control will not be less than those provided by the Manager's Security Handbook, IRM 1(16)12. Procedural and physical safeguards to be utilized include the logging of all queries and periodic review of the query logs; compartmentalization of information to restrict access to authorized personnel; encryption of electronic communications; intruder alarms; and 24–hour building guards.

RETENTION AND DISPOSAL:

All records are disposed of after 4 years. Records will be disposed of by erasure of magnetic media.

SYSTEM MANAGER(S) AND ADDRESS:

Official prescribing policies and practices—Assistant Commissioner (Criminal Investigation), National Office. Officials maintaining the system—Detroit Computing Center, CI Representative, and the Automated Criminal Investigation Office Manager, 7940 Kentucky Drive, Boone County, Kentucky 41042.

NOTIFICATION PROCEDURE:

This system of records may not be accessed for purposes of determining if the system contains a record pertaining to a particular individual.

RECORD ACCESS PROCEDURES:

This system of records may not be accessed for purposes of inspection or for contest of content of records.

CONTESTING RECORDS PROCEDURES:

26 U.S.C. 7852(e) prohibits Privacy Act amendment of tax records.

RECORD SOURCE CATEGORIES:

This system of records may not be accessed for purposes of determining the source of the records. Records to be included all come from existing Treasury and Internal Revenue Service databases. The databases are comprised of records submitted by taxpayers, financial institutions, casinos and businesses pursuant to federal law.

EXEMPTIONS CLAIMED FOR THE SYSTEM:

This system is exempt from 5 U.S.C. 552a(c)(3), (c)(4), (d)(1), (d)(2), (d)(3), (d)(4),(e)(1), (e)(2), (e)(3), (e)(4)(G), (H), and (I), (e)(5), (e)(8), (f), and (g) of the Privacy Act pursuant to 5 U.S.C. 552a(j)(2), and (k)(2).

Dated: August 21, 1996.

Alex Rodriguez,

Deputy Assistant Secretary (Administration)

[FR Doc.22895 Filed 9–6–96: 8:45am]

Billing Code: 4830–01–F

DEPARTMENT OF VETERANS AFFAIRS

Medical Research Service Merit Review Committee; Notice of Meetings

The Department of Veterans Affairs gives notice under the Federal Advisory Committee Act, 5 U.S.C. App., of the following meetings to be held from 8 a.m. to 5 p.m. as indicated below:

Subcommittee for	Date	Location
Nephrology	September 19–20, 1996	Crowne Plaza Hotel.
Gastroenterology	September 26–27, 1996	Crowne Plaza Hotel.
Alcoholism and Drug Dependence	September 30–October 1, 1996	Crowne Plaza Hotel.
Hematology	October 3–4, 1996	Holiday Inn Central.
Infectious Diseases	October 3–4, 1996	Holiday Inn Central.
Neurobiology	October 7–9, 1996	Crowne Plaza Hotel.
Cardiovascular Studies	October 7–8, 1996	Holiday Inn Central.
Aging and Clinical Geriatrics	October 10, 1996	Holiday Inn Central.
Immunology	October 14–15, 1996	Washington Vista.
General Medical Science	October 17–18, 1996	Holiday Inn Central.
Mental Health and Behavioral Sciences	October 17–18, 1996	Double Tree Hotel.
Surgery	October 19, 1996	Crowne Plaza Hotel.
Endocrinology	October 21–22, 1996	Crowne Plaza Hotel.

Subcommittee for	Date	Location
Respiration	October 21, 1996	Holiday Inn Central.
Oncology	October 24–25, 1996	Holiday Inn Central.
Medical Research Service Merit Review Committee	December 3, 1996	Holiday Inn Central.

Crowne Plaza Hotel, 14th & K Streets, NW, Washington, DC 20005.
Double Tree Hotel, 1515 Rhode Island Avenue, NW, Washington, DC 20005.
Holiday Inn Central, 1501 Rhode Island Avenue, NW, Washington, DC 20005.
Washington Vista, 1400 M Street, NW, Washington, DC 20005.

These meetings will be for the purpose of evaluating the scientific merit of research conducted in each specialty by Department of Veterans Affairs (VA) investigators working in VA Medical Centers and Clinics.

These meetings will be open to the public up to the seating capacity of the rooms at the start of each meeting to discuss the general status of the program. All of the Merit Review Subcommittee meetings will be closed to the public after approximately one hour from the start for the review, discussion, and evaluation of initial and renewal projects.

The closed portion of the meeting involves discussion, examination, reference to, and oral review of site visits, staff and consultant critiques of research protocols and similar documents. During this portion of the meeting, discussion and recommendations will deal with qualifications of personnel conducting the studies, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy, as well as research information, the premature disclosure of which would be likely to significantly frustrate implementation of proposed agency action regarding such research projects. As provided by subsection 10(d) of Public Law 92–463, as amended by Public Law 94–409, closing portions of these meetings is in accordance with 5 U.S.C., 552b (c)(6) and (9)(B). Because of the limited seating capacity of the rooms, those who plan to attend should contact Dr. LeRoy Frey, Chief, Program Review Division, Medical Research Service, Department of Veterans Affairs, Washington, DC, (202) 565–5942, at least five days prior to each meeting. Minutes of the meetings and rosters of the members of the Subcommittee may be obtained from this source.

Dated: August 29, 1996.

By Direction of the Secretary.

Eugene A. Brickhouse,

Committed Management Officer.

[FR Doc. 96–22882 Filed 9–6–96; 8:45 am]

BILLING CODE 8320–01–M

Corrections

Federal Register
Vol. 61, No. 175
Monday, September 9, 1996

This section of the FEDERAL REGISTER contains editorial corrections of previously published Presidential, Rule, Proposed Rule, and Notice documents. These corrections are prepared by the Office of the Federal Register. Agency prepared corrections are issued as signed documents and appear in the appropriate document categories elsewhere in the issue.

DEPARTMENT OF EDUCATION

34 CFR Parts 75, 76, 77, 270, 271, 272, 607, 642, 648, 662, 663, and 664

48 CFR Chapter 34

Regulatory Reinvention

Correction

In proposed rule document 96–21568 beginning on page 43640 in the issue of Friday, August 23, 1996, make the following correction:

On page 43641, in the first column, in the second paragraph, under *Contact:*, in the sixth and seventh lines, ''kathy—thomas@ed.gov'' should read ''kathy__thomas@ed.gov''.

BILLING CODE 1505–01–D

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Parts 801, 803, 804, 807, 820, and 897

[Docket No. 95N–0253]

RIN 0910–AA48

Regulations Restricting the Sale and Distribution of Cigarettes and Smokeless Tobacco to Protect Children and Adolescents

Correction

In rule document 96–21900 beginning on page 44396 in the issue of Wednesday, August 28, 1996, make the following corrections:

1. On page 44396, in the second column, under ''DATES: *Effective date.*'', in the last line ''February 28, 1998'' should read ''August 28, 1998''.

2. On the same page, in the same column, under ''DATES: *Compliance dates.*, in the last line ''February 28, 1998'' should read ''August 28, 1998''.

BILLING CODE 1505–01–D

DEPARTMENT OF JUSTICE

Immigration and Naturalization Service

8 CFR Parts 3, 103, and 242

[EOIR No. 114I; A.G. Order No. 2051-96]

RIN 1125-AA15

Fees for Motions to Reopen or Reconsider

Correction

In rule document 96–22335 beginning on page 46373 in the issue of Tuesday, September 3, 1996, make the following corrections:

PART 3 [CORRECTED]

1. On page 46374, in the first column, in the authority citation, in the third line, after ''509,'' add ''510,''.

§103.7 [Corrected]

2. On the same page, in the second column, in §103.7(b)(1), in the second paragraph, in the 12th line, ''on or'' should read ''or on''.

PART 242 [CORRECTED]

3. On the same page, in the third column, in the authority citation, in the second line, ''1524'' should read ''1254''.

BILLING CODE 1505–01–D

federal register

Monday
September 9, 1996

Part II

Environmental Protection Agency

Proposed Guidelines for Ecological Risk Assessment; Notice

ENVIRONMENTAL PROTECTION AGENCY

[FRL–5605–9]

Proposed Guidelines for Ecological Risk Assessment

AGENCY: U.S. Environmental Protection Agency.

ACTION: Notice of Availability and Opportunity to Comment on Proposed Guidelines for Ecological Risk Assessment.

SUMMARY: The U.S. Environmental Protection Agency (EPA) is today publishing a document entitled Proposed Guidelines for Ecological Risk Assessment (hereafter ''Proposed Guidelines''). These Proposed Guidelines were developed as part of an interoffice Guidelines development program by a Technical Panel of the Risk Assessment Forum. The Proposed Guidelines expand upon the previously published EPA report Framework for Ecological Risk Assessment (EPA/630/R–92/001, February 1992), while retaining the report's broad scope. When final, these Proposed Guidelines will help improve the quality of ecological risk assessments at EPA while increasing the consistency of assessments among the Agency's program offices and regions.

DATES: The Proposed Guidelines are being made available for a 90-day public review and comment period. Comments must be in writing and must be postmarked by December 9, 1996. See Addresses section for guidance on submitting comments.

FOR FURTHER INFORMATION CONTACT: Bill van der Schalie, National Center for Environmental Assessment-Washington Office, telephone: 202–260–4191.

ADDRESSES: The Proposed Guidelines will be made available in the following ways:

(1) The electronic version will be accessible on EPA's Office of Research and Development home page on the Internet at http://www.epa.gov/ORD/WebPubs/fedreg.

(2) 3½″ high-density computer diskettes in Wordperfect 5.1 format will be available from ORD Publications, Technology Transfer and Support Division, National Risk Management Research Laboratory, Cincinnati, OH; telephone: 513–569–7562; fax: 513–569–7566. Please provide the EPA No. (EPA/630/R–95/002B) when ordering.

(3) This notice contains the full proposed guideline. In addition, copies will be available for inspection at EPA headquarters and regional libraries, through the U.S. Government Depository Library program, and for purchase from the National Technical Information Service (NTIS), Springfield, VA; telephone: 703–487–4650, fax: 703–321–8547. Please provide the NTIS No. PB96–193198; Price Code A13: ($47.00) when ordering.

Submitting Comments

Comments on the Proposed Guidelines should be submitted to: U.S. Environmental Protection Agency, Air and Radiation Docket and Information Center (6102), Attn: File ORD–ERA–96–01, Waterside Mall, 401 M St. SW, Washington, DC 20460. Please submit one unbound original with pages numbered consecutively, and three copies. For attachments, provide an index, number pages consecutively, provide comment on how the attachments relate to the main comment(s), and submit an unbound original and three copies. Please identify all comments and attachments with the file number ORD–ERA–96–01. Mailed comments must be postmarked by the date indicated. Comments may also be submitted electronically by sending electronic mail (e-mail) to: A-and-R-Docket@epamail.epa.gov. Electronic comments must be submitted as an ASCII file avoiding the use of special characters and any form of encryption. Comments and data will also be accepted on disks in WordPerfect 5.1 file format or ASCII file format. All comments in electronic form also must be identified by the file number ORD–ERA–96–01.

The Air and Radiation Docket and Information Center is open for public inspection and copying between 8:00 a.m. and 5:30 p.m., weekdays, in Room M–1500, Waterside Mall, 401 M St. SW, Washington, DC 20460. The Center is located on the ground floor in the commercial area of Waterside Mall. The file index, materials, and comments are available for review in the information center or copies may be mailed on request from the Air and Radiation Docket and Information Center by calling (202) 260–7548 or –7549. The FAX number for the Center is (202) 260–4400. A reasonable fee may be charged for copying materials.

Please note that all technical comments received in response to this notice will be placed in the public record. For that reason, commentors should not submit personal information such as medical data or home addresses, confidential business information, or information protected by copyright. Due to limited resources, acknowledgments will not be sent.

SUPPLEMENTARY INFORMATION: These Proposed Guidelines are EPA's first Agency-wide ecological risk assessment guidelines. They are broad in scope, describing general principles and providing numerous examples to show how ecological risk assessment can be applied to a wide range of systems, stressors, and biological/spatial/temporal scales. This general approach provides sufficient flexibility to permit EPA's offices and regions to develop specific guidance suited to their particular needs. Because of their broad scope, the Proposed Guidelines do not provide detailed guidance in specific areas nor are they highly prescriptive. Frequently, rather than requiring that certain procedures always be followed, the Proposed Guidelines describe the strengths and limitations of alternate approaches. Agency preferences are expressed where possible, but because ecological risk assessment is a relatively new, rapidly evolving discipline, requirements for specific approaches could soon become outdated. EPA is working to expand the references in the Proposed Guidelines to include additional review articles or key publications that will help provide a ''window to the literature'' as recommended by peer reviewers. In the future, EPA intends to develop a series of shorter, more detailed guidance documents on specific ecological risk assessment topics after these Proposed Guidelines have been finalized.

These Proposed Guidelines were prepared during a time of increasing interest in the field of ecological risk assessment and reflect input from many sources outside as well as inside the Agency. Over the last few years, the National Research Council proposed an ecological risk paradigm (NRC, 1993), there has been a marked increase in discussion of ecological risk assessment issues at meetings of professional organizations, and numerous articles and books on the subject have been published. Agency work on the Proposed Guidelines has proceeded in a step-wise fashion during this time. Preliminary work began in 1989 and included a series of colloquia sponsored by EPA's Risk Assessment Forum to identify and discuss significant issues in ecological risk assessment (U.S. EPA, 1991). Based on this early work and on a consultation with EPA's Science Advisory Board (SAB), the Agency decided to produce ecological risk assessment guidance sequentially, beginning with basic terms and concepts and continuing with the development of source materials for these Proposed Guidelines. The first product of this effort was the Risk Assessment Forum report, Framework

for Ecological Risk Assessment (Framework Report; U.S. EPA, 1992a,b), which proposes principles and terminology for the ecological risk assessment process. Since then, the Agency has solicited suggestions for ecological risk assessment guidelines structuring (U.S. EPA, 1992c) and has sponsored the development of other peer-reviewed materials, including ecological assessment case studies (U.S. EPA, 1993a, 1994a), and a set of issue papers that highlight important principles and approaches that EPA scientists should consider in preparing these Proposed Guidelines (U.S. EPA, 1994b,c).

The nature and content of these Proposed Guidelines have been shaped by these documents as well as numerous meetings and discussions with individuals both within and outside of EPA. In late 1994 and early 1995, the Agency solicited responses to the planned nature and structure of these Proposed Guidelines at three colloquia with Agency program offices and regions, other Federal agencies, and the public. Draft Proposed Guidelines were discussed at an external peer review workshop in December, 1995 (U.S. EPA, In Press). Subsequent reviews have included the Agency's Risk Assessment Forum and the Regulatory and Policy Development Committee, and interagency comment by members of subcommittees of the Committee on the Environment and Natural Resources of the Office of Science and Technology Policy. The EPA appreciates the efforts of all participants in the process and has tried to address their recommendations in these Proposed Guidelines.

The EPA's Science Advisory Board will review these Proposed Guidelines at a future meeting. Following public and SAB reviews, Agency staff will prepare comment summaries. Appropriate comments will be incorporated, and the revised Guidelines will be submitted to EPA's Risk Assessment Forum for review. The Agency will consider comments from the public, the SAB, and the Risk Assessment Forum when finalizing these Proposed Guidelines.

The public is invited to provide comments to be considered in EPA decisions about the content of the final Guidelines. EPA asks those who respond to this notice to include their views on the following:

(1) Consistent with a recent National Research Council report (NRC, 1996), these Proposed Guidelines emphasize the importance of interactions between risk assessors and risk managers as well as the critical role of problem formulation to ensuring that the results of the risk assessment can be used for decision-making. Overall, how compatible are these Proposed Guidelines with the National Research Council concept of the risk assessment process and the interactions between risk assessors, risk managers, and other interested parties?

(2) The Proposed Guidelines are intended to provide a starting point for Agency program and regional offices that wish to prepare ecological risk assessment guidance suited to their needs. In addition, the Agency intends to sponsor development of more detailed guidance on certain ecological risk assessment topics. Examples might include identification and selection of assessment endpoints, selection of surrogate or indicator species, or the development and application of uncertainty factors. Considering the state of the science of ecological risk assessment and Agency needs and priorities, what topics most require additional guidance?

(3) Some reviewers have suggested that the Proposed Guidelines should provide more discussion of topics related to the use of field observational data in ecological risk assessments, such as selection of reference sites, interpretation of positive and negative field data, establishing causal linkages, identifying measures of ecological condition, the role and uses of monitoring, and resolving conflicting lines of evidence between field and laboratory data. Given the general scope of these Proposed Guidelines, what, if any, additional material should be added on these topics and, if so, what principles should be highlighted?

(4) The scope of the Proposed Guidelines is intentionally broad. However, while the intent is to cover the full range of stressors, ecosystem types, levels of biological organization, and spatial/temporal scales, the contents of the Proposed Guidelines are limited by the present state of the science and the relative lack of experience in applying risk assessment principles to some areas. In particular, given the Agency's present interest in evaluating risks at larger spatial scales, how could the principles of landscape ecology be more fully incorporated into the Proposed Guidelines?

(5) Assessing risks when multiple stressors are present is a challenging task. The problem may be how to aggregate risks attributable to individual stressors or to identify the principal stressors responsible for an observed effect. Although some approaches for evaluating risks associated with chemical mixtures are available, our ability to conduct risk assessments involving multiple chemical, physical, and biological stressors, especially at larger spatial scales, is limited. Consequently, the Proposed Guidelines primarily discuss predicting the effects of chemical mixtures and on general approaches for evaluating causality of an observed effect. What additional principles can be added?

(6) Ecological risk assessments are frequently conducted in tiers that proceed from simple evaluations of exposure and effects to more complex assessments. While the Proposed Guidelines acknowledge the importance of tiered assessments, the wide range of applications of tiered assessments make further generalizations difficult. Given the broad scope of the Proposed Guidelines, what additional principles for conducting tiered assessments can be discussed?

(7) Assessment endpoints are ''explicit expression of the environmental value that is to be protected''. As used in the Proposed Guidelines, assessment endpoints include both an ecological entity and a specific attributes of the entity (e.g., eagle reproduction or extent of wetlands). Some reviewers have recommended that assessment endpoints also include a decision criterion that is defined early in the risk assessment process (e.g., no more than a 20% reduction in reproduction, no more than a 10% loss of wetlands). While not precluding this possibility, the Proposed Guidelines suggest that such decisions are more appropriately made during discussions between risk assessors and managers in risk characterization at the end of the process. What are the relative merits of each approach?

Dated: August 21, 1996.

Carol M. Browner,

Administrator.

Proposed Guidelines for Ecological Risk Assessment

Contents

Lists of Figures, Tables, and Text Notes
Executive Summary
1. Introduction
1.1. Ecological Risk Assessment in a Management Context
1.1.1. Contributions of Ecological Risk Assessment to Environmental Decisionmaking
1.1.2. Risk Management Considerations
1.2. Scope and Intended Audience
1.3. Guidelines Organization
2. Planning the Risk Assessment: Dialogue Between Risk Managers and Risk Assessors
2.1. Establishing Management Goals
2.2. Management Decisions

2.3. Scope and Complexity of the Risk Assessment
2.4. Planning Outcome
3. Problem Formulation Phase
3.1. Products of Problem Formulation
3.2. Integration of Available Information
3.3. Selecting Assessment Endpoints
3.3.1. Selecting What to Protect
3.3.1.1. Ecological Relevance
3.3.1.2. Susceptibility to Known or Potential Stressors
3.3.1.3. Representation of Management Goals
3.3.2. Defining Assessment Endpoints
3.4. Conceptual Models
3.4.1. Risk Hypotheses
3.4.2. Conceptual Model Diagrams
3.4.3. Uncertainty in Conceptual Models
3.5. Analysis Plan
3.5.1. Selecting Measures
3.5.2. Relating Analysis Plans to Decisions
4. Analysis Phase
4.1. Evaluating Data and Models for Analysis
4.1.1. Strengths and Limitations of Different Types of Data
4.1.2. Evaluating Measurement or Modeling Studies
4.1.2.1. Evaluating the Purpose and Scope of the Study
4.1.2.2. Evaluating the Design and Implementation of the Study
4.1.3. Evaluating Uncertainty
4.2. Characterization of Exposure
4.2.1. Exposure Analyses
4.2.1.1. Describe the Source
4.2.1.2. Describe the Distribution of the Stressor or Disturbed Environment
4.2.1.3. Describe Contact or Co-occurrence
4.2.2. Exposure Profile
4.3. Characterization of Ecological Effects
4.3.1. Ecological Response Analysis
4.3.1.1. Stressor-Response Analysis
4.3.1.2. Establishing Cause and Effect Relationships (Causality)
4.3.1.3. Linking Measures of Effect to Assessment Endpoints
4.3.2. Stressor-Response Profile
5. Risk Characterization
5.1. Risk Estimation
5.1.1. Risk Estimates Expressed as Qualitative Categories
5.1.2. Single-Point Estimates
5.1.3. Estimates Incorporating the Entire Stressor-Response Relationship
5.1.4. Estimates Incorporating Variability in Exposure or Effects
5.1.5. Estimates Based on Process Models
5.1.6. Field Observational Studies
5.2. Risk Description
5.2.1. Lines of Evidence
5.2.2. Determining Ecological Adversity
5.3. Reporting Risks
6. Relating Ecological Information to Risk Management Decisions
7. Text Notes
Appendix A: Changes from EPA's Ecological Risk Assessment Framework
Appendix B: Key Terms
Appendix C: Conceptual Model Examples
Appendix D: Analysis Phase Examples
Appendix E: Criteria for Determining Ecological Adversity: a Hypothetical Example
References

List of Figures

Figure 1–1. The framework for ecological risk assessment.
Figure 1–2. The ecological risk assessment framework, with an expanded view of each phase.
Figure 3–1. Problem formulation phase.
Figure 3–2. Elements of a conceptual model diagram.
Figure 4–1. Analysis phase.
Figure 4–2. A simple example of a stressor-response relationship.
Figure 5–1. Risk characterization.
Figure 5–2. Risk estimation techniques. a. Comparison of exposure and stressor-response point estimates. b. Comparison of point estimates from the stressor-response relationship with uncertainty associated with an exposure point estimate.
Figure 5–3. Risk estimation techniques: comparison of point estimates with associated uncertainties.
Figure 5–4. Risk estimation techniques: stressor-response curve versus a cumulative distribution of exposures.
Figure 5–5. Risk estimation techniques: comparison of exposure distribution of an herbicide in surface waters with freshwater single species toxicity data.

List of Tables

Table 4–1. Uncertainty Evaluation in the Analysis Phase.

List of Text Notes

Text Note 1–1. Related Terminology.
Text Note 1–2. Flexibility of the Framework Diagram.
Text Note 1–3. The Iterative Nature of Ecological Risk Assessment.
Text Note 2–1. Who Are Risk Managers?
Text Note 2–2. Who Are Risk Assessors?
Text Note 2–3. Questions Addressed by Risk Managers and Risk Assessors.
Text Note 2–4. The Role of Interested Parties.
Text Note 2–5. Sustainability as a Management Goal.
Text Note 2–6. Management Goals for Waquoit Bay.
Text Note 2–7. Questions to Ask About Scope and Complexity.
Text Note 3–1. Avoiding Potential Shortcomings Through Problem Formulation.
Text Note 3–2. Uncertainty in Problem Formulation.
Text Note 3–3. Initiating a Risk Assessment: What's Different When Stressors, Effects, or Values Drive the Process?
Text Note 3–4. Assessing Available Information: Questions to Ask Concerning Source, Stressor, and Exposure Characteristics, Ecosystem Characteristics, and Effects.
Text Note 3–5. Salmon and Hydropower: Why Salmon Would Provide the Basis for an Assessment Endpoint.
Text Note 3–6. Cascading Adverse Effects: Primary (Direct) and Secondary (Indirect).
Text Note 3–7. Sensitivity and Secondary Effects: The Mussel-Fish Connection.
Text Note 3–8. Examples of Management Goals and Assessment Endpoints.
Text Note 3–9. Common Problems in Selecting Assessment Endpoints.
Text Note 3–10. What Are Risk Hypotheses and Why Are They Important?
Text Note 3–11. Examples of Risk Hypotheses.
Text Note 3–12. What Are the Benefits of Developing Conceptual Models?
Text Note 3–13. Uncertainty in Problem Formulation.
Text Note 3–14. Examples of Assessment Endpoints and Measures.
Text Note 3–15. Selecting What to Measure.
Text Note 3–16. How Do Water Quality Criteria Relate to Assessment Endpoints?
Text Note 3–17. Data Quality Objectives (DQO) Process.
Text Note 4–1. Data Collection and the Analysis Phase.
Text Note 4–2. The American National Standard for Quality Assurance
Text Note 4–3. Questions for Evaluating a Study's Utility for Risk Assessment.
Text Note 4–4. Considering the Degree of Aggregation in Models.
Text Note 4–5. Questions for Source Description.
Text Note 4–6. Questions to Ask in Evaluating Stressor Distribution.
Text Note 4–7. General Mechanisms of Transport and Dispersal.
Text Note 4–8. Questions to Ask in Describing Contact or Co-occurrence.
Text Note 4–9. Example of an Exposure Equation: Calculating a Potential Dose via Ingestion.
Text Note 4–10. Measuring Internal Dose Using Biomarkers and Tissue Residues.
Text Note 4–11. Questions Addressed by the Exposure Profile.
Text Note 4–12. Questions for Stressor-Response Analysis.
Text Note 4–13. Qualitative Stressor-Response Relationships.
Text Note 4–14. Median Effect Levels.
Text Note 4–15. No-Effect Levels Derived From Statistical Hypothesis Testing.
Text Note 4–16. General Criteria for Causality.
Text Note 4–17. Koch's Postulates.
Text Note 4–18. Examples of Extrapolations to Link Measures of Effect to Assessment Endpoints.
Text Note 4–19. Questions Related to Selecting Extrapolation Approaches.
Text Note 4–20. Questions to Consider When Extrapolating From Effects Observed in the Laboratory to Field Effects of Chemicals.
Text Note 4–21. Questions Addressed by the Stressor-Response Profile.
Text Note 5–1. Using Qualitative Categories to Estimate Risks of an Introduced Species.
Text Note 5–2. Applying the Quotient Method.
Text Note 5–3. Comparing an Exposure Distribution With a Point Estimate of Effects.
Text Note 5–4. Comparing Cumulative Exposure and Effects Distributions for Chemical Stressors.
Text Note 5–5. Estimating Risk With Process Models.
Text Note 5–6. An Example of Field Methods Used for Risk Estimation.

Text Note 5–7. What Are Statistically Significant Effects?
Text Note 5–8. Possible Risk Assessment Report Elements.
Text Note 5–9. Clear, Transparent, Reasonable, and Consistent Risk Characterizations.
Text Note 6–1. Questions Regarding Risk Assessment Results.
Text Note 6–2. Risk Communication Considerations for Risk Managers.

Executive Summary

The ecological problems facing environmental scientists and decisionmakers are numerous and varied. Growing concern over potential global climate change, loss of biodiversity, acid precipitation, habitat destruction, and the effects of multiple chemicals on ecological systems has highlighted the need for flexible problem-solving approaches that can link ecological measurements and data with the decisionmaking needs of environmental managers. Increasingly, ecological risk assessment is being suggested as a way to address this wide array of ecological problems.

Ecological risk assessment ''evaluates the likelihood that adverse ecological effects may occur or are occurring as a result of exposure to one or more stressors'' (U.S. EPA, 1992a). It is a process for organizing and analyzing data, information, assumptions, and uncertainties to evaluate the likelihood of adverse ecological effects. Ecological risk assessment provides a critical element for environmental decisionmaking by giving risk managers an approach for considering available scientific information along with the other factors they need to consider (e.g., social, legal, political, or economic) in selecting a course of action.

To help improve the quality and consistency of EPA's ecological risk assessments, EPA's Risk Assessment Forum initiated development of these guidelines. The primary audience for this document is risk assessors and risk managers at EPA, although these guidelines may be useful to others outside the Agency (e.g., Agency contractors, state agencies, and other interested parties). These guidelines are based on and replace the 1992 report, Framework for Ecological Risk Assessment (referred to as the Framework Report). They were written by a Forum work group and have been extensively revised based on comments from outside peer reviewers as well as Agency staff. The guidelines retain the Framework Report's broad scope, while expanding on some framework concepts and modifying others to reflect Agency experiences. EPA intends to follow these guidelines with a series of shorter, more detailed documents that address specific ecological risk assessment topics. This ''bookshelf'' approach provides the flexibility necessary to keep pace with developments in the rapidly evolving field of ecological risk assessment while allowing time to form consensus, where appropriate, on science policy inferences (default assumptions) to bridge gaps in knowledge.

Ecological risk assessment includes three primary phases (problem formulation, analysis, and risk characterization). Within problem formulation, important areas include identifying goals and assessment endpoints, preparing the conceptual model, and developing an analysis plan. The analysis phase involves evaluating exposure to stressors and the relationship between stressor levels and ecological effects. In risk characterization, key elements are estimating risk through integration of exposure and stressor-response profiles, describing risk by discussing lines of evidence and determining ecological adversity, and preparing a report. The interface between risk assessors and risk managers at the beginning and end of the risk assessment is critical for ensuring that the results of the assessment can be used to support a management decision.

Both risk assessors and risk managers bring valuable perspectives to the initial planning activities for an ecological risk assessment. Risk managers charged with protecting environmental values can ensure that the risk assessment will provide information relevant to a decision. Ecological risk assessors ensure that science is effectively used to address ecological concerns. Both evaluate the potential value of conducting a risk assessment to address identified problems. Further objectives of the initial planning process are to establish management goals that are agreed upon, clearly articulated, and contain a way to measure success; determine the purpose for the risk assessment by defining the decisions to be made within the context of the management goals; and agree upon the scope, complexity, and focus of the risk assessment, including the expected output and available resources.

Problem formulation, which follows these planning discussions, provides a foundation upon which the entire risk assessment depends. Successful completion of problem formulation depends on the quality of three products: assessment endpoints, conceptual models, and an analysis plan. Since problem formulation is inherently interactive and iterative, not linear, substantial reevaluation is expected to occur within and among all products of problem formulation.

Assessment endpoints are ''explicit expressions of the actual environmental value that is to be protected'' (U.S. EPA, 1992a) that link the risk assessment to management concerns. Assessment endpoints include both a valued ecological entity and an attribute of that entity that is important to protect and potentially at risk (e.g., nesting and feeding success of piping plovers or areal extent and patch size of eelgrass). For a risk assessment to have scientific validity, assessment endpoints must be ecologically relevant to the ecosystem they represent and susceptible to the stressors of concern. Assessment endpoints that represent societal values and management goals are more effective in that they increase the likelihood that the risk assessment will be used in management decisions. Assessment endpoints that fulfill all three criteria provide the best foundation for an effective risk assessment.

Potential interactions between assessment endpoints and stressors are explored by developing a conceptual model. Conceptual models link anthropogenic activities with stressors and evaluate interrelationships between exposure pathways, ecological effects, and ecological receptors. Conceptual models include two principal components: risk hypotheses and a conceptual model diagram.

Risk hypotheses describe predicted relationships between stressor, exposure, and assessment endpoint response. Risk hypotheses are hypotheses in the broad scientific sense; they do not necessarily involve statistical testing of null and alternative hypotheses or any particular analytical approach. Risk hypotheses may predict the effects of a stressor (e.g., a chemical release) or they may postulate what stressors may have caused observed ecological effects. Key risk hypotheses are identified for subsequent evaluation in the risk assessment.

A useful way to express the relationships described by the risk hypotheses is through a diagram of a conceptual model. Conceptual model diagrams are useful tools for communicating important pathways in a clear and concise way and for identifying major sources of uncertainty. Risk assessors can use these diagrams and risk hypotheses to identify the most important pathways and relationships that will be evaluated in the analysis phase. Risk assessors justify what will be done as well as what will not be done in the assessment in an analysis plan.

The analysis plan also describes the data and measures to be used in the risk assessment and how risks will be characterized.

The analysis phase, which follows problem formulation, includes two principal activities: characterization of exposure and characterization of ecological effects. The process is flexible, and interaction between the ecological effects and exposure evaluations is recommended. Both activities include an evaluation of available data for scientific credibility and relevance to assessment endpoints and the conceptual model. In exposure characterization, data analyses describe the source(s) of stressors, the distribution of stressors in the environment, and the contact or co-occurrence of stressors with ecological receptors. In ecological effects characterization, data analyses may evaluate stressor-response relationships or evidence that exposure to a stressor causes an observed response.

The products of analysis are summary profiles that describe exposure and the stressor-response relationships. Exposure and stressor-response profiles may be written documents or modules of a larger process model. Alternatively, documentation may be deferred until risk characterization. In any case, the objective is to ensure that the information needed for risk characterization has been collected and evaluated.

The exposure profile identifies receptors and exposure pathways and describes the intensity and spatial and temporal extent of exposure. The exposure profile also describes the impact of variability and uncertainty on exposure estimates and reaches a conclusion about the likelihood that exposure will occur.

The stressor-response profile may evaluate single species, populations, general trophic levels, communities, ecosystems, or landscapes—whatever is appropriate for the assessment endpoints. For example, if a single species is affected, effects should represent appropriate parameters such as effects on mortality, growth, and reproduction, while at the community level, effects may be summarized in terms of structure or function depending on the assessment endpoint. The stressor-response profile summarizes the nature and intensity of effect(s), the time scale for recovery (where appropriate), causal information linking the stressor with observed effects, and uncertainties associated with the analysis.

Risk characterization is the final phase of an ecological risk assessment. During risk characterization, risks are estimated and interpreted and the strengths, limitations, assumptions, and major uncertainties are summarized. Risks are estimated by integrating exposure and stressor-response profiles using a wide range of techniques such as comparisons of point estimates or distributions of exposure and effects data, process models, or empirical approaches such as field observational data.

Risk assessors describe risks by evaluating the evidence supporting or refuting the risk estimate(s) and interpreting the adverse effects on the assessment endpoint. Criteria for evaluating adversity include the nature and intensity of effects, spatial and temporal scales, and the potential for recovery. Agreement among different lines of evidence of risk increases confidence in the conclusions of a risk assessment.

When risk characterization is complete, a report describing the risk assessment can be prepared. The report may be relatively brief or extensive depending on the nature and the resources available for the assessment and the information required to support a risk management decision. Report elements may include:

- A description of risk assessor/risk manager planning results.
- A review of the conceptual model and the assessment endpoints.
- A discussion of the major data sources and analytical procedures used.
- A review of the stressor-response and exposure profiles.
- A description of risks to the assessment endpoints, including risk estimates and adversity evaluations.
- A summary of major areas of uncertainty and the approaches used to address them.
- A discussion of science policy judgments or default assumptions used to bridge information gaps, and the basis for these assumptions.

To facilitate understanding, risk assessors should characterize risks ''in a manner that is clear, transparent, reasonable, and consistent with other risk characterizations of similar scope prepared across programs in the Agency'' (U.S. EPA, 1995c).

After the risk assessment is completed, risk managers may consider whether additional follow-up activities are required. Depending on the importance of the assessment, confidence level in the assessment results, and available resources, it may be advisable to conduct another iteration of the risk assessment in order to facilitate a final management decision. Ecological risk assessments are frequently designed in sequential tiers that proceed from simple, relatively inexpensive evaluations to more costly and complex assessments. Initial tiers are based on conservative assumptions, such as maximum exposure and ecological sensitivity. When an early tier cannot sufficiently define risk to support a management decision, a higher assessment tier that may require either additional data or applying more refined analysis techniques to available data may be needed. Higher tiers provide more ecologically realistic assessments while making less conservative assumptions about exposure and effects.

Another option is to proceed with a management decision based on the risk assessment and develop a monitoring plan to evaluate the results of the decision. For example, if the decision was to mitigate risks through exposure reduction, monitoring could help determine whether the desired reduction in exposure (and effects) was achieved. Monitoring is also critical for determining the extent and nature of any ecological recovery that may be occurring. Experience obtained by using focused monitoring results to evaluate risk assessment predictions can help improve the risk assessment process and is encouraged.

Communicating ecological risks to the public is usually the responsibility of risk managers. Although the final risk assessment document (including its risk characterization sections) can be made available to the public, the risk communication process is best served by tailoring information to a particular audience. It is important to clearly describe the ecological resources at risk, their value, and the costs of protecting (and failing to protect) the resources (U.S. EPA, 1995c). The degree of confidence in the risk assessment and the rationale for risk management decisions and options for reducing risk are also important (U.S. EPA, 1995c).

1. Introduction

Ecological risk assessment is a process for organizing and analyzing data, information, assumptions, and uncertainties to evaluate the likelihood of adverse ecological effects. Ecological risk assessment provides a critical element for environmental decisionmaking. This document, which is structured by the stages of the ecological risk assessment process, provides Agency personnel with broad guidelines that can be adapted to their specific requirements.

The full definition of ecological risk assessment is:

''The process that evaluates the likelihood that adverse ecological effects may occur or are occurring as a result of exposure to one or more stressors.'' (U.S. EPA, 1992a)

Several terms within this definition require further explanation:

• ''* * * likelihood * * *'' Descriptions of risk may range from qualitative judgments to quantitative probabilities. While risk assessments may include quantitative risk estimates, the present state of the science often may not support such quantitation. It is preferable to convey qualitatively the relative magnitude of uncertainties to a decision maker than to ignore them because they may not be easily understood or estimated.

• ''* * * adverse ecological effects * * *'' Ecological risk assessments deal with anthropogenic changes that are considered undesirable because they alter valued structural or functional characteristics of ecological systems. An evaluation of adversity may consider the type, intensity, and scale of the effect as well as the potential for recovery.

• ''* * * may occur or are occurring * * *'' Ecological risk assessments may be prospective or retrospective. Retrospective ecological risk assessments evaluate the likelihood that observed ecological effects are associated with previous or current exposures to stressors. Many of the same methods and approaches are used for both prospective and retrospective assessments, and in the best case, even retrospective assessments contain predictive elements linking sources, stressors and effects.

• ''* * * one or more stressors * * *'' Ecological risk assessments may address single or multiple chemical, physical, or biological stressors. (See Appendix A for definitions of stressor types.) Because risk assessments are conducted to provide input to management decisions, this document focuses on stressors generated or influenced by anthropogenic activity.

The overall ecological risk assessment process is shown in figure 1–1.[1] Problem formulation is the first phase of the process where the assessment purpose is stated, the problem defined, and the plan for analyzing and characterizing risk determined. In the analysis phase, data on potential effects of and exposures to stressor(s) identified during problem formulation are technically evaluated and summarized as exposure and stressor-response profiles. These profiles are integrated in risk characterization to estimate the likelihood of adverse ecological effects. Major uncertainties, assumptions, and strengths and limitations of the assessment are summarized during this phase. While discussions between risk assessors and risk managers are emphasized both at risk assessment initiation (planning) and completion (communicating results), these guidelines maintain a distinction between risk assessment and risk management. Risk assessment focuses on evaluating the likelihood of adverse effects, and risk management involves the selection of a course of action in response to an identified risk that is based on many factors (e.g., social, legal, political, or economic) in addition to the risk assessment results. Section 1.1 briefly discusses how risk assessments fit into a decisionmaking context.

[1] Changes in process and terminology from EPA's previous ecological risk assessment framework (U.S. EPA, 1992a) are summarized in Appendix A.

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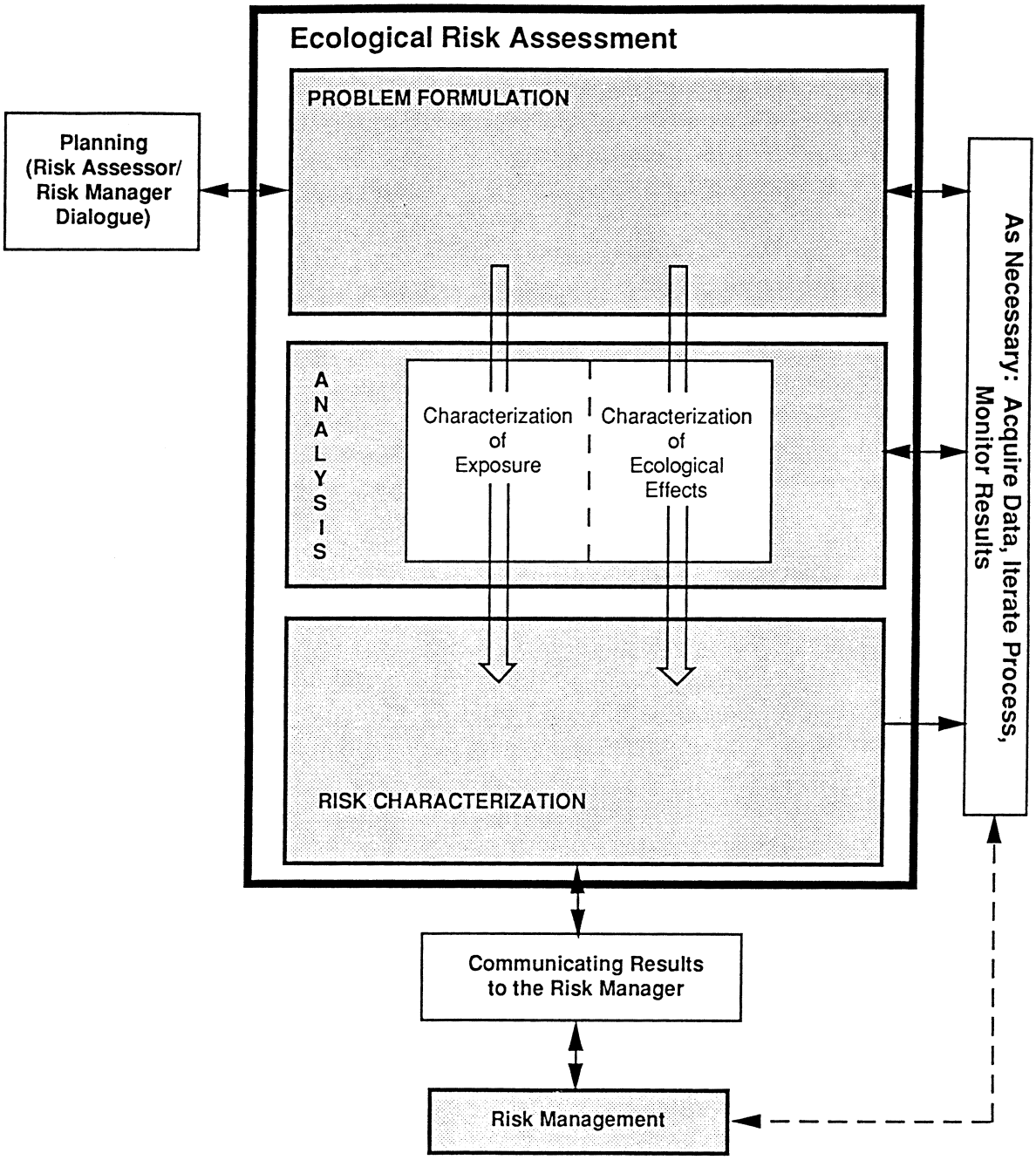

Figure 1-1. The framework for ecological risk assessment (U.S. EPA, 1992a). Ecological risk assessment is shown as a three-phase process including problem formulation, analysis, and risk characterization. Important activities associated with ecological risk assessment include discussions between risk assessors and risk managers and data acquisition and monitoring. Ecological risk assessments frequently follow an iterative or tiered approach.

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The bar along the right side of figure 1–1 shows several activities that are associated with risk assessments: data acquisition, iteration, and monitoring. While the risk assessment may focus on data analysis and interpretation, acquiring the appropriate quantity and quality of data for use in the process is critical. If such data are lacking, the risk assessment may stop until the necessary data are acquired. As discussed in text note 1–3, the process is more frequently iterative than linear, since the evaluation of new data or information may require revisiting a part of the process or conducting a new assessment.

Monitoring data can provide important input to all phases of the risk assessment process. For example, monitoring can provide the impetus for initiating a risk assessment by identifying changes in ecological condition. In addition, monitoring data can be used to evaluate the results predicted by the risk assessment. For example, follow-up studies could be used to determine whether techniques used to mitigate pesticide exposures in field situations in fact reduce exposure and effects as predicted by the risk assessment. Or, for a hazardous waste site, monitoring might help verify whether source reduction resulted in anticipated ecological changes. Monitoring is also critical for determining the extent and nature of any ecological recovery that may occur. The experience gained by comparing monitoring results to evaluate risk assessment predictions can help improve the risk assessment process and is encouraged.

1.1. Ecological Risk Assessment in a Management Context

Ecological risk assessment is important for environmental decisionmaking because of the high cost of eliminating environmental risks associated with human activities and the necessity of making regulatory decisions in the face of uncertainty (Ruckelshaus, 1983; Suter, 1993a). Even so, ecological risk assessment provides only a portion of the information required to make risk management decisions. This section describes how ecological risk assessments fit into a larger management framework.

1.1.1. Contributions of Ecological Risk Assessment to Environmental Decisionmaking

At EPA, ecological risk assessments provide input to a diverse set of environmental decisionmaking processes, such as the regulation of hazardous waste sites, industrial chemicals, and pesticides, or the management of watersheds affected by multiple nonchemical and chemical stressors. The ecological risk assessment process has several features that contribute to managing ecological risks:

- In a risk assessment, changes in ecological effects can be expressed as a function of changes in exposure to a stressor. This inherently predictive aspect of risk assessment may be particularly useful to the decision maker who must evaluate tradeoffs and examine different alternatives.
- Risk assessments include an explicit evaluation of uncertainties. Uncertainty analysis lends credibility and a degree of confidence to the assessment that can strengthen its use in decisionmaking and can help the risk manager focus research on those areas that will lead to the greatest reductions in uncertainty.
- Risk assessments can provide a basis for comparing, ranking, and prioritizing risks. The risk manager can use such information to help decide among several management alternatives.
- Risk assessments emphasize consistent use of well-defined and relevant endpoints. This is especially important for ensuring that the results of the risk assessment will be expressed in a way that the risk manager can use.

1.1.2. Risk Management Considerations

Although risk assessors and risk managers interact both at the initiation and completion of an ecological risk assessment (sections 2, 3, 5 and 6), risk managers decide how to use the results of an assessment and whether a risk assessment should be conducted. While a detailed review of management issues is beyond the scope of these guidelines, key areas are highlighted below.

- A risk assessment is not always required for management action. When faced with compelling ecological risks and an immediate need to make a decision, a risk manager might proceed without an assessment, depending on professional judgment and statutory requirements (U.S. EPA, 1992a).
- Because initial management decisions or statutory requirements significantly affect the scope of an assessment, it is important, where possible, for risk managers to consider a broader scope or alternative actions for a risk assessment. Sometimes a particular statute may require the risk assessment to focus on one type of stressor (e.g., chemicals) when there are other, perhaps more important, stressors in the system (e.g., habitat alteration). In other situations, however, it may be possible to evaluate a range of options. For example, before requesting an ecological risk assessment of alternative sites for the construction and operation of a dam for hydroelectric power, risk managers may consider larger issues such as the need for the additional power and the feasibility of using other power-generating options.
- Risk managers consider many factors in making regulatory decisions. Legal mandates may require the risk manager to take certain courses of action. Political and social considerations may lead the risk manager to make decisions that are either more or less ecologically protective. Economic factors may also be critical. For example, a course of action that has the least ecological risk may be too expensive or technologically infeasible. If cost-benefit analysis is applied, ecological risks may be translated into monetary terms to be compared against other monetary considerations. Thus, while ecological risk assessment provides critical information to risk managers, it is only part of the whole environmental decisionmaking process.

1.2. Scope and Intended Audience

These guidelines replace the EPA report, Framework for Ecological Risk Assessment (referred to as the Framework Report, U.S. EPA, 1992a). As a next step in developing Agency-wide guidance, the guidelines expand on and modify framework concepts to reflect Agency experience in the several years since the Framework Report was published (see Appendix A). Like the Framework Report, these guidelines are broad in scope, describing general principles and providing numerous examples to show how ecological risk assessment can be applied to a wide range of systems, stressors, and biological, spatial, and temporal scales. This approach provides flexibility to permit EPA's offices and regions to develop specific guidance suited to their particular needs.

The proposed policies set out in this document are intended as internal guidance for EPA. Risk assessors and risk managers at EPA are the primary audience for this document, although these guidelines may be useful to others outside the Agency (e.g., Agency contractors, state agencies, and other interested parties). These Proposed Guidelines are not intended, nor can they be relied upon, to create any rights enforceable by any party in litigation with the United States. This document is not a regulation and is not intended for EPA regulations. These Proposed Guidelines set forth current scientific thinking and approaches for conducting and evaluating ecological risk

assessments. As with other EPA guidelines (developmental toxicity, 56 FR 63798–63826; exposure assessment, 57 FR 22888–22938; and carcinogenicity, 61 FR 17960–18011), EPA will revisit these guidelines as experience and scientific consensus evolves.

These guidelines do not provide detailed guidance in specific areas nor are they intended to be highly prescriptive. These guidelines describe the strengths and limitations of alternate approaches and may not apply to a particular situation based upon the circumstances. Agency preferences are expressed where possible, but because ecological risk assessment is a rapidly evolving discipline, requirements for specific approaches could soon become outdated. EPA intends to develop a series of shorter, more detailed guidance documents on specific ecological risk assessment topics after these guidelines have been finalized.

These guidelines emphasize processes and approaches for analyzing data rather than specific data collection techniques, methods, or models. Also, while these guidelines discuss the interface between the risk assessor and risk manager, a detailed discussion of the use of ecological risk assessment information in the risk management process (e.g., the economic, legal, political, or social implications of the risk assessment results) is beyond the scope of these guidelines. Other EPA publications discuss how ecological concerns have been addressed in decisionmaking at EPA (U.S. EPA, 1994g) and provide an introduction to ecological risk assessment for risk managers (U.S. EPA, 1995b).

1.3. Guidelines Organization

These guidelines are structured according to the ecological risk assessment process as shown in figure 1–2. Within problem formulation (section 3), important areas addressed include identifying goals and assessment endpoints, preparing the conceptual model, and developing an analysis plan. The analysis phase (section 4) involves evaluating exposure to stressors and the relationship between stressor levels and ecological effects. In risk characterization (section 5), key elements are estimating risk through integration of exposure and stressor-response profiles and describing risk by discussing lines of evidence, interpreting adversity, and summarizing uncertainty. In addition, discussions between the risk assessor and risk manager at the beginning (section 2) and end of the risk assessment (section 6) are highlighted.

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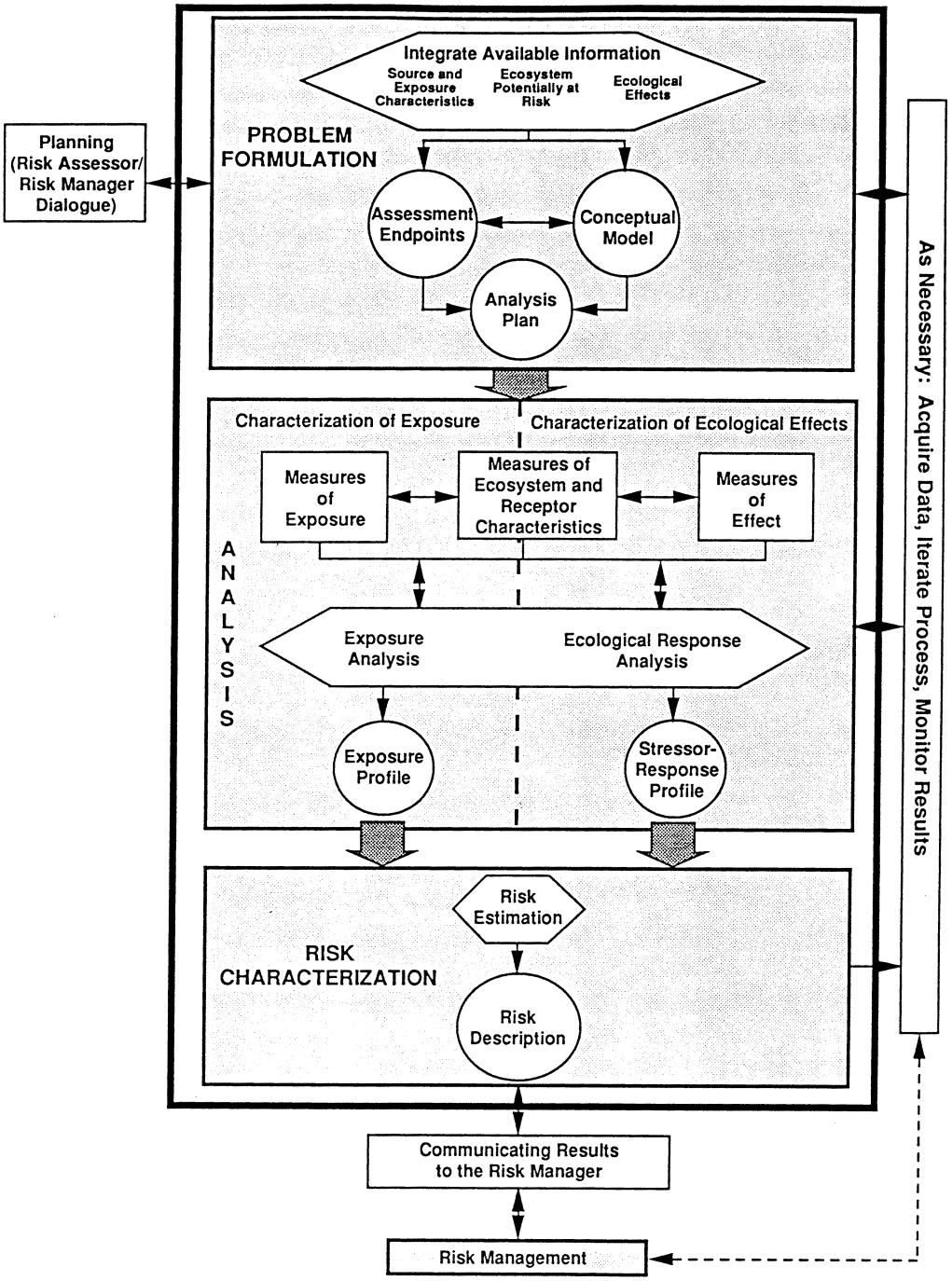

Figure 1-2. The ecological risk assessment framework, with an expanded view of each phase. Within each phase, rectangular boxes designate inputs, hexagon-shaped boxes indicate actions, and circular boxes represent outputs. Problem formulation, analysis, and risk characterization are discussed in sections 3, 4, and 5, respectively. Sections 2 and 6 describe interactions between risk assessors and risk managers.

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The reader may notice that cross-cutting topics are covered in several sections. These include uncertainty, models, evaluating data, causality, linking measures of effect to assessment endpoints, and identifying ecological effects. Considerations appropriate to the different phases of ecological risk assessment are discussed.

2. Planning The Risk Assessment: Dialogue Between Risk Managers and Risk Assessors

The purpose for an ecological risk assessment is to produce a scientific evaluation of ecological risk that enables managers to make informed environmental decisions. To ensure that ecological risk assessments meet risk managers' needs, a planning dialogue between risk managers and risk assessors (see text notes 2–1 and 2–2) is a critical first step toward initiating problem formulation and plays a continuing role during the conduct of the risk assessment. Planning is the beginning of a necessary interface between risk managers and risk assessors and is represented by a side box in the ecological risk assessment diagram (see figure 1–2). It is due to the importance of planning and the significant role it plays in ecological risk assessments that this section on planning is incorporated into guidelines on ecological risk assessment. However, it is imperative to remember that the planning process is distinct from the scientific conduct of an ecological risk assessment. This distinction helps ensure that political and social issues, while helping to define the objectives for the risk assessment, do not bias the scientific evaluation of risk.

During the planning dialogue, risk managers and risk assessors each bring important perspectives to the table. In general, risk managers are charged with protecting societal values (e.g., human health and the environment) and must ensure that the risk assessment will provide information relevant to a decision. To meet this charge, risk managers describe why the risk assessment is needed, what decisions it will support, and what they want to receive from the risk assessor. It is also helpful for managers to consider what problems they have encountered in the past when trying to use risk assessments for decisionmaking. In turn, it is the ecological risk assessors' role to ensure that science is effectively used to address ecological concerns. Risk assessors describe what they can provide to the risk manager, where problems are likely to occur, and where uncertainty may be problematic. Both evaluate the potential value of conducting a risk assessment to address identified problems.

Both risk managers and risk assessors are responsible for coming to agreement on the goals, scope, and timing of a risk assessment and the resources that are available and necessary to achieve the goals. Together they use information on the area's ecosystems, regulatory endpoints, and publicly perceived environmental values to interpret the goals for use in the ecological risk assessment. Examples of questions risk managers and risk assessors may address during planning are provided in text note 2–3.

The first step in planning may be to determine if a risk assessment is the best option for making the decision required. Questions concerning what is known about the degree of risk, what management options are available to mitigate or prevent it, and the value of conducting a risk assessment compared with other ways of learning about and addressing environmental concerns are asked during these discussions. In some cases, a risk assessment may add little value to the decision process. It is important for the risk manager and risk assessor to explore alternative options for addressing possible risk before continuing to the next planning stage (see section 1.1.2).

Once the decision is made to conduct a risk assessment, planning focuses on (1) establishing management goals that are agreed on, clearly articulated, and contain a way to measure success; (2) defining the decisions to be made within the context of the management goals; and (3) agreeing on the scope, complexity, and focus of the risk assessment, including the expected output and the technical and financial support available to complete it. To achieve these objectives, risk managers and risk assessors must each play an active role in planning the risk assessment.

2.1. Establishing Management Goals

Management goals for a risk assessment are established by risk managers but are derived in a variety of ways. Many Agency risk assessments are conducted based on legally established management goals (e.g., national regulatory programs generally have management goals written into the law governing the program). In this case, goal setting was previously completed through public debate in establishing the law. In most cases, legally established management goals do not provide sufficient guidance to the risk assessor. For example, the objectives under the Clean Water Act to ''protect and maintain the chemical, physical and biological integrity of the nation's waters'' are open to considerable interpretation. Agency managers and staff often interpret the law in regulations and guidance. Significant interaction between the risk assessor and risk manager may be needed to translate the law into management goals for a particular location or circumstance.

As the Agency increasingly emphasizes ''place-based'' or ''community-based'' management of ecological resources as recommended in the Edgewater Consensus (U.S. EPA, 1994e), management goals take on new significance for the ecological risk assessor. Management goals for ''places'' such as watersheds are formed as a consensus based on diverse values reflected in Federal, state, and local regulations; constituency group agendas; and public concerns. Significant interactions among a variety of interested parties are required to generate agreed-on management goals for the resource (see text note 2–4). Public meetings, constituency group meetings, evaluation of resource management organization charters, and other means of looking for management goals shared by these diverse groups may be necessary. Diverse risk management teams may elect to use social scientists trained in consensus-building methods to help establish management goals. While management goals derived in this way may require further definition (see text note 2–5), there is increased confidence that these goals are supported by the audience for the risk assessment.

Regardless of how management goals are established, goals that explicitly define which ecological values are to be protected are more easily used to design a risk assessment for decisionmaking than general management goals. Whenever goals are general, risk assessors must interpret those goals into ecological values that can be measured or estimated and ensure that the managers agree with their interpretation (see text note 2–6). Legally mandated goals generally are interpreted by Agency managers and staff. This interpretation may be performed once and then applied to the multiple similar assessments (e.g. evaluation of new chemicals). For other risk assessments, the interpretation is unique to the ecosystem being assessed and must be done on a case-by-case basis as part of the planning process.

2.2. Management Decisions

A risk assessment is shaped by the kind of decision it will support. When a management decision is explicitly

stated and closely aligned to management actions, the scope, focus, and conduct of the risk assessment are well defined by the specificity of the decision to be made. Some of these risk assessments are used to help establish national policy that will be applied consistently across the country (e.g., premanufacture notices for new chemicals, protection of endangered species). Other risk assessments are designed for a specific site (e.g., hazardous waste site clean-up level). When decision options (e.g., decision criteria in the data quality objectives process, U.S. EPA, 1994d; see section 3.5.2 for more details) are known prior to the risk assessment, a number of assumptions are inherent in those options that need to be explicitly stated during planning. This ensures that the decision criteria are not altering the scientific validity of the risk assessment by inappropriately applying assumptions or unnecessarily limiting the variables. For many risk assessments, there may be a range of possible management options for managing risk. When different management options have been identified (e.g., leave alone, clean up, or pave a contaminated site), risk assessment can be used to predict potential risk across the range of these management options.

Risk assessments may be designed to provide guidance for management initiatives for a region or watershed where multiple stressors, ecological values, and political factors influence decisionmaking. These risk assessments require great flexibility and breadth and may use national risk-based information and site-specific risk information in conjunction with regional evaluations of risk. As risk assessment is more frequently used to support landscape-scale management decisions, the diversity, breadth, and complexity of the risk assessments increase significantly and may include evaluations that focus on understanding ecological processes influenced by a diversity of human actions and management options. Risk assessments used in this application are often based on a general goal statement and require significant planning to establish the purpose, scope, and complexity of the assessment.

2.3. Scope and Complexity of the Risk Assessment

Although the purpose for the risk assessment determines whether it is national, regional, or local, the resources available for conducting the risk assessment determines how extensive and complex it can be within this framework and the level of uncertainty that can be expected. Each risk assessment is constrained by the availability of data, scientific understanding, expertise, and financial resources. Within these constraints there is much to consider when designing a risk assessment. Risk managers and risk assessors must discuss in detail the nature of the decision (e.g., national policy, local economic impact), available resources, opportunities for increasing the resource base (e.g., partnering, new data collection, alternative analytical tools), and the output that will provide the best information for decisions required (see text note 2–7).

Part of the agreement on scope and complexity is based on the maximum uncertainty that is acceptable in whatever decision the risk assessment supports. The lower the tolerance for uncertainty, the greater the scope and complexity needed in the risk assessment. Risk assessments completed in response to legal mandates and likely to be challenged in court often require rigorous attention to acceptable levels of uncertainty to ensure that the assessment will be used in a decision. A frank discussion is needed between the risk manager and risk assessor on sources of uncertainty in the risk assessment and ways uncertainty can be reduced (if necessary) through selective investment of resources. Where appropriate, planning could account for the iterative nature of risk assessment and include explicitly defined steps. These steps may take the form of ''tiers'' that represent increasing levels of complexity and investment, with each tier designed to reduce uncertainty. The plan may include an explicit definition of iterative steps with a description of levels of investment and decision criteria for each tier. Guidance on addressing the interplay of management decisions, study boundaries, data needs, uncertainty, and specifying limits on decision errors may be found in EPA's guidance on data quality objectives (U.S. EPA, 1994d).

2.4. Planning Outcome

The planning phase is complete when agreements are reached on the management goals, assessment objectives, the focus and scope of the risk assessment, resource availability, and the type of decisions the risk assessment is to support. Agreements may encompass the technical approach to be taken in a risk assessment as determined by the regulatory or management context and reason for initiating the risk assessment (see section 3.2), the spatial scale (e.g., local, regional, or national), and temporal scale (e.g., the time frame over which stressors or effects will be evaluated).

In mandated risk assessments, planning agreements are often codified in regulations, and little documentation of agreements is warranted. In risk assessments where planning decisions can be highly variable, a summary of planning agreements may be important for ensuring that the risk assessment remains consistent with early agreements. A summary can provide a point of reference for determining if early decisions may need to be changed in response to new information. There is no defined format, length, or complexity for a planning summary. It is a useful reference only and should be tailored to the complexity of the risk assessment it represents. However, a summary is recommended to help ensure quality communication between and among risk managers and risk assessors and to document the decisions that have been agreed upon.

Once planning is complete, the formal process of risk assessment begins through the initiation of problem formulation. During problem formulation, risk assessors should continue the dialogue with risk managers following assessment endpoint selection and once the analysis plan is completed. At these points, potential problems can be identified before the risk assessment proceeds.

3. Problem Formulation Phase

Problem formulation is a formal process for generating and evaluating preliminary hypotheses about why ecological effects have occurred, or may occur, from human activities. As the first stage of an ecological risk assessment, it provides the foundation on which the entire assessment depends. During problem formulation, management goals developed during planning are evaluated to establish objectives for the risk assessment, the problem is defined, and the plan for analyzing data and characterizing risk is determined. Any deficiencies in problem formulation will compromise all subsequent work on the risk assessment (see text note 3–1).

3.1. Products of Problem Formulation

Successful completion of problem formulation depends on the quality of three products: (1) assessment endpoints that adequately reflect management goals and the ecosystem they represent, (2) conceptual models that describe key relationships between a stressor and assessment endpoint or among several stressors and assessment

endpoints, and (3) an analysis plan. Essential to the development of these products are the effective integration and evaluation of available information.

The following discussion focuses on the products of problem formulation and the information that determines the nature of those products. The products are featured in the problem formulation diagram as circles (see figure 3–1). The types of information that must be evaluated to generate those products are shown in the hexagon.

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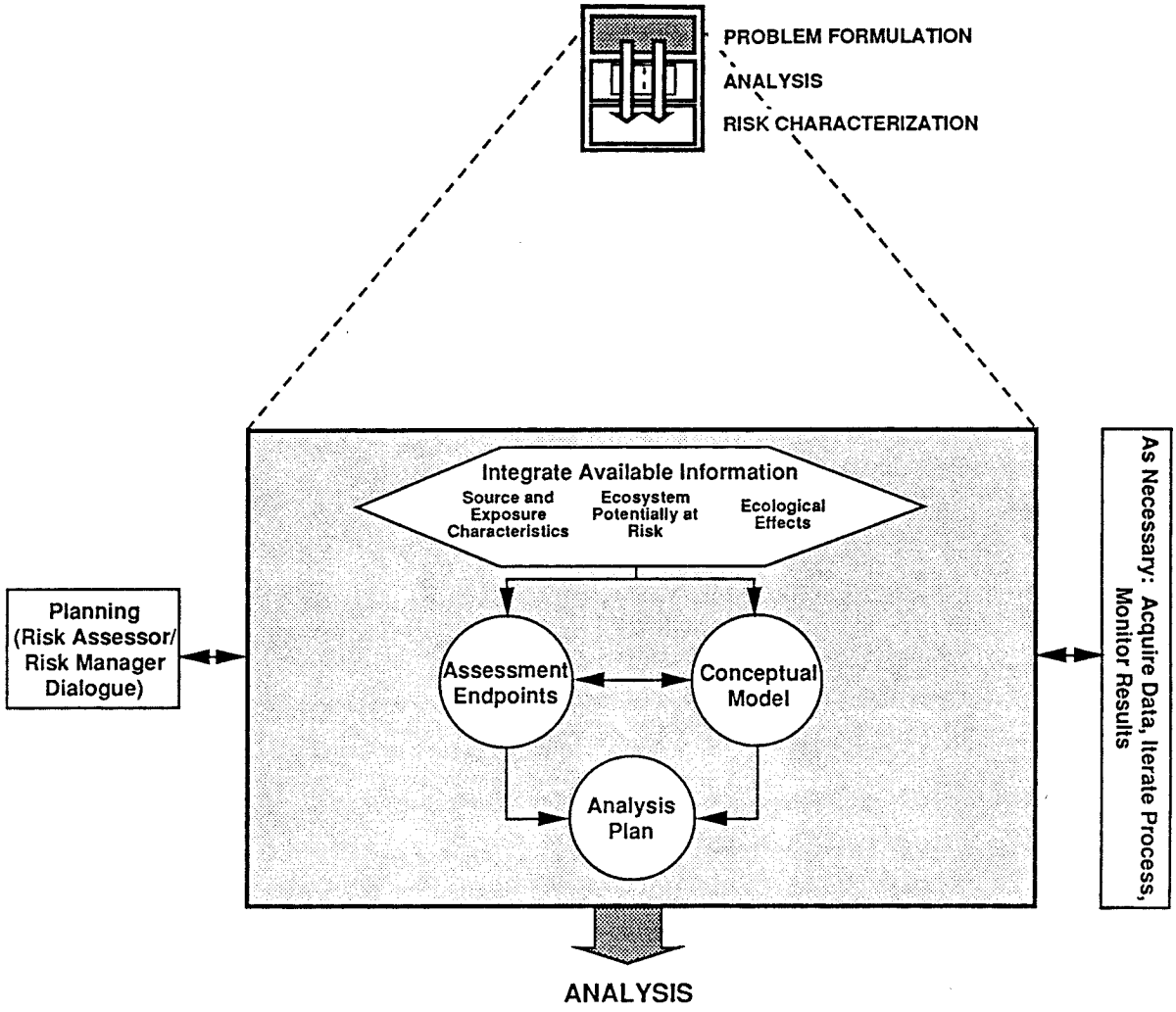

Figure 3-1. Problem formulation phase.

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To enhance clarity, the organization of the following discussion follows the above topics. However, problem formulation is not necessarily completed in the order presented here. First, the order in which products are produced is directly related to why the ecological risk assessment is initiated, as addressed in section 3.2. Second, problem formulation is inherently interactive and iterative, not linear. Substantial reevaluation is expected to occur within and among all products of problem formulation.

3.2. Integration of Available Information

The foundation for problem formulation is the integration of available information on the sources of stressors and stressor characteristics, exposure, the ecosystem(s) potentially at risk, and ecological effects (see figure 3–1). When key information is of the appropriate type and sufficient quality and quantity, problem formulation can proceed effectively. When key information is unavailable in one or more areas, the risk assessment may be temporarily suspended while new data are collected. If new data cannot be collected, then the risk assessment will depend on what is known and what can be extrapolated from that information. Complete information is not available at the beginning of many risk assessments. When this is the case, the process of problem formulation assists in identifying where key data are missing and provides the framework for further research where more data are needed. Where data are few, a clear articulation of the limitations of conclusions, or uncertainty, from the risk assessment becomes increasingly critical in risk characterization (see text note 3–2).

The reason why an ecological risk assessment is initiated directly influences what information is available at the outset, and what information must be found. A risk assessment can be initiated because a known or potential stressor may be released into the environment, an adverse effect or change in condition is observed, or better management of an important ecological value (e.g., valued ecological entities such as species, communities, ecosystems or places) is desired. Risk assessments are sometimes initiated for two or all three of these reasons.

Risk assessors beginning with information about the source or stressor will seek available information on the effects the stressor might be associated with and the ecosystems that it will likely be found in. Risk assessors beginning with information about an observed effect or change in condition will need to seek information about potential stressors and sources. Risk assessors starting with concern over a particular ecological value may need additional information on the specific condition or effect of interest, the ecosystems potentially at risk, and potential stressors and sources.

The initial use of available information is a scoping process similar to that used to develop environmental impact statements. During this process, data and information (i.e., actual, inferred, or estimated) are considered to ensure that nothing important is overlooked. A comprehensive evaluation of all information provides the framework for generating a large array of risk hypotheses to consider (see section 3.4.1). After the initial scoping process, information quality and applicability to the particular problem of concern are increasingly scrutinized as the risk assessor proceeds through problem formulation. When analysis plans are formed, data validity becomes a significant factor to consider. Issues relating to evaluating data quality are discussed in the analysis phase (see section 4.1).

As the complexity and spatial scale of a risk assessment increase, information needs escalate. Ecosystems characteristics directly influence when, how, and why particular ecological entities may become exposed and exhibit adverse effects due to particular stressors. Predicting risks from multiple chemical, physical, and biological stressors requires an understanding of their interactions. Risk assessments for a region or watershed, where multiple stressors are the rule, require consideration of ecological processes operating at larger spatial scales.

Despite limitations on what is known about ecosystems and the stressors influencing them, the process of problem formulation offers a valuable systematic approach for organizing and evaluating available information on all stressors and possible effects in a way that can be useful to risk assessors and decisionmakers. Text note 3–3 provides a series of questions that risk assessors should attempt to answer using available information, many of which were drawn from Barnthouse and Brown (1994). This exercise will help risk assessors identify known and unknown relationships, both of which are important in problem formulation.

Problem formulation proceeds with the identification of assessment endpoints, and the development of conceptual models and the analysis plan (discussed below). However, the order in which these task are done is influenced by the reason for initiating the assessment (text note 3–4). Early recognition that initiation effects the order of product generation will help facilitate the development of problem formulation.

3.3. Selecting Assessment Endpoints

Assessment endpoints are ''explicit expressions of the actual environmental value that is to be protected'' (U.S. EPA, 1992a). Assessment endpoints are critical to problem formulation because they link the risk assessment to management concerns and they are central to conceptual model development. Their relevance to ecological risk assessment is determined by how well they target susceptible ecological entities. Their ability to support risk management decisions depends on how well they represent measurable characteristics of the ecosystem that adequately represent management goals. The selection of ecological concerns and assessment endpoints in EPA has traditionally been done internally by individual Agency program offices (U.S. EPA, 1994g). More recently, Agency activities such as the watershed protection approach and community-based environmental protection have used contributions by interested parties in the selection of ecological concerns and assessment endpoints. This section describes criteria for selecting and defining assessment endpoints.

3.3.1. Selecting What To Protect

The ecological resources selected to represent management goals for environmental protection are reflected in the assessment endpoints that drive ecological risk assessments. Assessment endpoints often reflect environmental values that are protected by law, provide critical resources, or provide an ecological function that would be significantly impaired (or that society would perceive as having been impaired) if the resource were altered.

Although many potential assessment endpoints may be identified, considering the practicality of using particular assessment endpoints will help refine selections. For example, when the attributes of an assessment endpoint can be measured directly, extrapolation is unnecessary; therefore this uncertainty is not introduced into the results. Assessment endpoints that cannot be measured directly but can be represented by measures that are easily monitored and modeled still provide a good foundation for the risk assessment. Assessment endpoints that cannot be linked with measurable attributes are not appropriate for a risk assessment.

Three principal criteria are used when selecting assessment endpoints: (1) their

ecological relevance, (2) their susceptibility to the known or potential stressors, and (3) whether they represent management goals. Of these three criteria, ecological relevance and susceptibility are essential for selecting assessment endpoints that are scientifically valid. Rigorous selection based on these criteria must be maintained. However, to increase the likelihood that the risk assessment will be used in management decisions, assessment endpoints that represent societal values and management goals are more effective. Given the complex functioning of ecosystems and the interdependence of ecological entities, it is likely that assessment endpoints can be selected that are responsive to management goals while meeting scientific criteria. This provides a way to address changes that may occur over time in the public's perception of ecological value (e.g., wetlands viewed as infested swamps 30 years ago are considered prime wildlife habitat today; Suter, 1993a). Assessment endpoints that meet all three criteria provide the best foundation for an effective risk assessment (e.g., see text note 3–5).

3.3.1.1. Ecological Relevance

Ecologically relevant endpoints reflect important characteristics of the system and are functionally related to other endpoints (U.S. EPA, 1992a). These are endpoints that help sustain the natural structure, function, and biodiversity of an ecosystem. For example, ecologically relevant endpoints may contribute to the food base (e.g., primary production), provide habitat, promote regeneration of critical resources (e.g., decomposition or nutrient cycling), or reflect the structure of the community, ecosystem, or landscape (e.g., species diversity or habitat mosaic). Changes in ecologically relevant endpoints can result in unpredictable and widespread effects.

Ecological relevance becomes most important when risk assessors are identifying the potential cascade of adverse effects that could result from the loss or reduction of one or more species or a change in ecosystem function (see text note 3–6). Careful selection of assessment endpoints that address both specific organisms of concern and landscape-level ecosystem processes becomes increasingly important in landscape-level risk assessments. In some cases, it may be possible to select one or more species and an ecosystem process to represent larger functional community or ecosystem processes.

Determining ecological relevance in specific cases requires expert judgment based on site-specific information, preliminary site surveys, or other available information. The less information available, the more critical it is to have informed expert judgment to ensure appropriate selections. If assessment endpoints in a risk assessment are not ecologically relevant, the results of the risk assessment may predict risk to the assessment endpoints selected but seriously misrepresent risk to the ecosystem of concern, which could lead to misguided management.

3.3.1.2. Susceptibility to Known or Potential Stressors

Ecological resources are considered susceptible when they are sensitive to a human-induced stressor to which they are exposed. Sensitivity refers to how readily an ecological entity is affected by a particular stressor. Sensitivity is directly related to the mode of action of the stressors. For example, chemical sensitivity is influenced by individual physiology and metabolic pathways. Sensitivity also is influenced by individual and community life-history characteristics. For example, species with long life cycles and low reproductive rates will be more vulnerable to extinction from increases in mortality than those with short life cycles and high reproductive rates. Species with large home ranges may be more sensitive to habitat fragmentation when the fragment is smaller than their required home range compared to those with smaller home ranges within a fragment. However, habitat fragmentation may also affect species with small home ranges where migration is a necessary part of their life history and fragmentation prevents exchange among subpopulations.

Sensitivity may be related to the life stage of an organism when exposed to a stressor. Frequently, young animals are more sensitive to stressors than adults. For example, Pacific salmon eggs and fry are very sensitive to sedimentation from forest logging practices and road building because they can be smothered. Age-dependent sensitivity, however, is not only in the young. In many species, special events like migration (e.g., in birds) and molting (e.g., in harbor seals) represent significant energy investments that make these organisms more vulnerable to an array of possible stressors. Finally, sensitivity may be increased by the presence of other stressors or natural disturbances. For example, the presence of insect pests and disease may make plants more sensitive to damage from ozone (Heck, 1993).

Measures of sensitivity may include mortality or adverse reproductive effects from exposure to toxics, behavioral abnormalities, avoidance of significant food sources or nesting sites, or loss of offspring to predation because of the proximity of stressors such as noise, habitat alteration or loss, community structural changes, or other factors.

Exposure is the other key determinant in susceptibility. Exposure can mean co-occurrence, contact, or the absence of contact, depending on the stressor and assessment endpoint (see section 4 for more discussion). The amount and conditions of exposure directly influence how an ecological entity will respond to a stressor. Thus, to determine what entities are susceptible, it is important to consider information on the proximity of an ecological resource to the stressor, the timing of exposure (both in terms of frequency and duration), and the intensity of exposure occurring during sensitive life stages of the organisms.

Adverse effects of a particular stressor may be important during one part of an organism's life cycle, such as early development or reproduction. Adverse effects may result from exposure to a stressor or to the absence of a necessary resource during a critical life stage. For example, if fish are unable to find suitable nesting sites during their reproductive phase, risk is significant even when water quality is high and food sources abundant. The interplay between life stage and stressors can be very complex (e.g., see text note 3–7).

Exposure may occur in one place or time, and effects may not occur until another place or time. Both life history characteristics, as described under sensitivity, and the circumstances of exposure, influence susceptibility in this case. For example, the temperature of the incubation medium of marine turtle eggs affects the sex ratio of the offspring. But the population impacts of a change in incubation temperature may not be observable until years later when the cohort of affected turtles begins to reproduce. Delayed effects and multiple stressor exposures add complexity to evaluations of susceptibility. For example, although toxicity tests may determine receptor sensitivity to one stressor, the degree of susceptibility may depend on the co-occurrence of another stressor that significantly alters receptor response. Conceptual models (see section 3.4) need to reflect these factors. If a species is unlikely to be exposed to the stressor of concern, it is inappropriate as an assessment endpoint.

3.3.1.3. Representation of Management Goals

Ultimately, the value of a risk assessment depends on whether it can

support quality management decisions. Risk managers are more willing to use a risk assessment for making decisions when the assessment is based on values and organisms that people care about. These values, interpreted from management goals (see section 2) into assessment endpoints, provide a defined and measurable entity for the risk assessment. Candidates for assessment endpoints might include entities such as endangered species, commercially or recreationally important species, functional attributes that support food sources or flood control (wetland water sequestration, for example), or aesthetic values, such as clean air in national parks or the existence of charismatic species like eagles or whales.

Selection of assessment endpoints based on public perceptions alone could lead to management decisions that do not consider important ecological information. While being responsive to the public is important, it does not obviate the requirement for scientific validity as represented by the sections on ecological relevance and susceptibility. Many ecological entities and attributes meet the necessary scientific rigor as assessment endpoints; some will be recognized as valuable by risk managers and the public, and others will not. Midges, for example, can represent the base of a complex food web that supports a popular sports fishery. They may also be considered pests. While both midges and fish are important ecological entities in this ecosystem and represent key components of the aquatic community, selecting the fishery as the assessment endpoint and using midges as a critical ecological entity to measure allow both entities to be used in the risk assessment. This choice maintains the scientific validity of the risk assessment and is responsive to management concerns. In those cases where the risk assessor identifies a critical assessment endpoint that is unpopular with the public, the risk assessor may find it necessary to present a persuasive case in its favor based on scientific arguments.

3.3.2. Defining Assessment Endpoints

Assessment endpoints provide a transition between broad management goals and the specific measures used in an assessment. They help assessors identify measurable attributes to quantify and predict change. Assessment endpoints also help the risk assessor determine whether management goals have been or can be achieved (see text note 3–8).

Two elements are required to define an assessment endpoint. The first is the valued ecological entity. This can be a species (e.g., eelgrass, piping plover), a functional group of species (e.g., raptors), an ecosystem function or characteristic (e.g., nutrient cycling), a specific valued habitat (e.g., wet meadows) or a unique place (e.g., a remnant of native prairie). The second is the characteristic about the entity of concern that is important to protect and potentially at risk. For example, it is necessary to define what is important for piping plovers (e.g., nesting and feeding success), eelgrass (e.g., areal extent and patch size), and wetlands (e.g., endemic wet meadow community structure and function). For an assessment endpoint to provide a clear interpretation of the management goals and the basis for measurement in the risk assessment, both an entity and an attribute are required.

Assessment endpoints are distinct from management goals. They do not represent what the managers or risk assessors want to achieve. As such they do not contain words like ''protect,'' ''maintain,'' or ''restore,'' or indicate a direction for change such as ''loss'' or ''increase.''

Defining assessment endpoints can be difficult. They may be too broad, vague, or narrow, or they may be inappropriate for the ecosystem requiring protection. ''Ecological integrity'' is a frequently cited, but vague, goal and an even more vague assessment endpoint. ''Integrity'' can only be used effectively when its meaning is explicitly characterized for a particular ecosystem, habitat, or entity. This may be done by selecting key entities and processes of an ecosystem and describing characteristics that best represent integrity for that system. For example, general goals for Waquoit Bay were translated into several assessment endpoints, including ''estuarine eelgrass abundance and distribution'' (see text note 2–6).

Expert judgment and an understanding of the characteristics and function of an ecosystem are important for translating general goals into usable assessment endpoints. Endpoints that are too narrowly defined, however, may not support effective risk management. For example, if an assessment is focused on protecting the habitat of an endangered species, the risk assessment may overlook important characteristics of the ecosystem and fail to include critical variables (see text note 3–7).

Assessment endpoints must be appropriate for the ecosystem of concern. Selecting a game fish that grows well in reservoirs may meet a ''feasible'' management goal, but would be inappropriate for evaluating risk from a new hydroelectric dam if the ecosystem of concern is a stream in which salmon spawn (see text note 3–5). Although the game fish will satisfy the fishable goal and may be highly desired by local fishermen, a reservoir species does not represent the ecosystem at risk. A vague ''viable fish populations'' assessment endpoint substituted by ''reproducing populations of indigenous salmonids'' could therefore prevent the development of an inappropriate risk assessment.

Clearly defined assessment endpoints provide direction and boundaries for the risk assessment and can minimize miscommunication and reduce uncertainty. Assessment endpoints directly influence the type, characteristics, and interpretation of data and information used for analyses and the scale and character of the assessment. For example, an assessment endpoint such as ''egg production of pond invertebrates'' defines local population characteristics and requires very different types of data and ecosystem characterization compared with ''watershed aquatic community structure and function.'' If concerns are local, the assessment endpoints should not focus on landscape concerns. Where ecosystem processes and landscape mosaics are of concern, survival of a particular species would provide inadequate representation. Assessment endpoints that are poorly defined, inappropriate, or at the incorrect scale can be very problematic. Common problems encountered in selecting assessment endpoints are summarized in text note 3–9.

The presence of multiple stressors should influence the selection of assessment endpoints. When it is possible to select one assessment endpoint that is sensitive to many of the identified stressors, yet responds in different ways to different stressors, it is possible to consider the combined effects of multiple stressors while still discriminating among effects. For example, if recruitment of a fish population is the assessment endpoint, it is important to recognize that recruitment may be adversely affected at several life stages, in different habitats, through different ways, by different stressors. The measures of effect, exposure, and ecosystem and receptor characteristics chosen to evaluate recruitment provide a basis for discriminating among different stressors, individual effects, and their combined effect.

The assessment endpoint can provide a basis for comparing a range of stressors if carefully selected. For example, the National Crop Loss Assessment Network (Heck, 1993)

selected crop yields as the assessment endpoint to evaluate the cumulative effects of multiple stressors. Although the primary stressor was ozone, the crop-yield endpoint allowed them to consider the effects of sulfur dioxide and soil moisture. As Barnthouse et al. (1990) pointed out, an endpoint should be selected so that all the effects can be expressed in the same units (e.g., the abundance of 1-year-old fish to assess the effects from toxicity, fishing pressure, and habitat loss). These considerations are important when selecting assessment endpoints for addressing the combined effect of multiple stressors. However, in situations where multiple stressors act on the structure and function of aquatic and terrestrial communities in a watershed ecosystem, an array of assessment endpoints that represent the ecosystem community and processes is more effective than a single endpoint. When based on differing susceptibility to an array of stressors, the careful selection of assessment endpoints can help risk assessors distinguish among effects from diverse stressors. Exposure to multiple stressors may lead to effects at different levels of biological organization, for a cascade of adverse responses that should be considered.

Although assessment endpoints must be defined in terms of measurable attributes, selection does not depend on the ability to measure those attributes directly or on whether methods, models, and data are currently available. If the response of an assessment endpoint cannot be directly measured, it may be predicted from responses of surrogate or similar entities. Although for practical reasons it is helpful to use assessment endpoints that have well-developed test methods, field measurement techniques, and predictive models (see Suter, 1993a), it is not necessary for these methods to be established protocols. Measures that will be used to evaluate assessment endpoint response to exposures for the risk assessment are often identified during conceptual model development and specified in the analysis plan. See section 3.5 for issues surrounding the selection of measures.

It is important for risk assessors and risk managers to agree that selected assessment endpoints represent the management goals for the particular ecological value. The rationale for their selection should be clear. Assessment endpoint selection is an important risk manager-risk assessor checkpoint during problem formulation.

3.4. Conceptual Models

A conceptual model in problem formulation is a written description and visual representation of predicted responses by ecological entities to stressors to which they are exposed, and the model includes ecosystem processes that influence these responses. Conceptual models represent many relationships (e.g., exposure scenarios may qualitatively link land-use activities to sources and their stressors, may describe primary, secondary, and tertiary exposure pathways, and may describe co-occurrence between exposure pathways, ecological effects, and ecological receptors).

Conceptual models for ecological risk assessments are developed from information about stressors, potential exposure, and predicted effects on an ecological entity (the assessment endpoint). Depending on why a risk assessment is initiated, one or more of these categories of information is known at the outset. The process of creating conceptual models helps identify the unknown elements.

The complexity of the conceptual model depends on the complexity of the problem, number of stressors, number of assessment endpoints, nature of effects, and characteristics of the ecosystem. For single stressors and single assessment endpoints, conceptual models can be relatively simple relationships. In situations where conceptual models describe both the pathways of individual stressors and assessment endpoints and the interaction of multiple and diverse stressors and assessment endpoints (e.g., assessments initiated because of important values), several submodels normally will be required to describe individual pathways. Other models may then be used to explore how these individual pathways interact.

Conceptual models consist of two principal products:

- A set of risk hypotheses that describe predicted relationships between stressor, exposure, and assessment endpoint response, along with the rationale for their selection.
- A diagram that illustrates the relationships presented in the risk hypotheses.

3.4.1. Risk Hypotheses

Hypotheses are assumptions made in order to evaluate logical or empirical consequences (Merriam-Webster, 1972). Risk hypotheses are statements of assumptions about risk based on available information (see text note 3–10). They are formulated using a combination of expert judgment and information on the ecosystem at risk, potential sources of stressors, stressor characteristics, and observed or predicted ecological effects on selected or potential assessment endpoints. These hypotheses may predict the effects of a stressor event before it happens, or they may postulate why observed ecological effects occurred and ultimately what sources and stressors caused the effect. Depending on the scope of the risk assessment, the set of risk hypotheses may be very simple, predicting the potential effect of one stressor on one receptor, or extremely complex, as is typical in value-initiated risk assessments that often include prospective and retrospective hypotheses about the effects of multiple complexes of stressors on diverse ecological receptors.

Although risk hypotheses should be developed even when information is incomplete, the amount and quality of data will affect the specificity and level of uncertainty associated with risk hypotheses and the conceptual models they form. When preliminary information is conflicting, risk hypotheses can be constructed specifically to differentiate among competing predictions. The predictions can then be evaluated systematically either by using available data during the analysis phase or by collecting new data before proceeding with the risk assessment. Hypotheses and predictions set a framework for using data to evaluate functional relationships (e.g., stressor-response curves).

Early conceptual models are intended to be broad in scope, identifying as many potential relationships as possible. As more information is incorporated, the plausibility of specific risk hypotheses helps risk assessors sort through potentially large numbers of stressor-effect relationships and the ecosystem processes that influence them to identify those risk hypotheses most appropriate for the analysis phase. It is then that justifications for selecting and omitting selecting hypotheses are documented. Examples of risk hypotheses are provided in text note 3–11.

3.4.2. Conceptual Model Diagrams

Conceptual model diagrams may be based on theory and logic, empirical data, mathematical models, or probability models. They are useful tools for communicating important pathways in a clear and concise way and can be used to ask new questions about relationships that help generate plausible risk hypotheses. Some of the benefits gained by developing conceptual models are featured in text note 3–12.

Conceptual model diagrams frequently contain boxes and arrows to illustrate relationships (see figure 3–2

and Appendix C). When constructing these kinds of flow diagrams, it is helpful to use distinct and consistent shapes to distinguish stressors, assessment endpoints, responses, exposure routes, and ecosystem processes. Although flow diagrams are often used to illustrate conceptual models, there is no set configuration for conceptual model diagrams. Pictorial representations can be more effective (e.g., Bradley and Smith, 1989). Regardless of the configuration, a significant part of the usefulness of a diagram is linked to the detailed written descriptions and justifications for the pathways and relationships shown. Without this, diagrams can misrepresent the processes illustrated.

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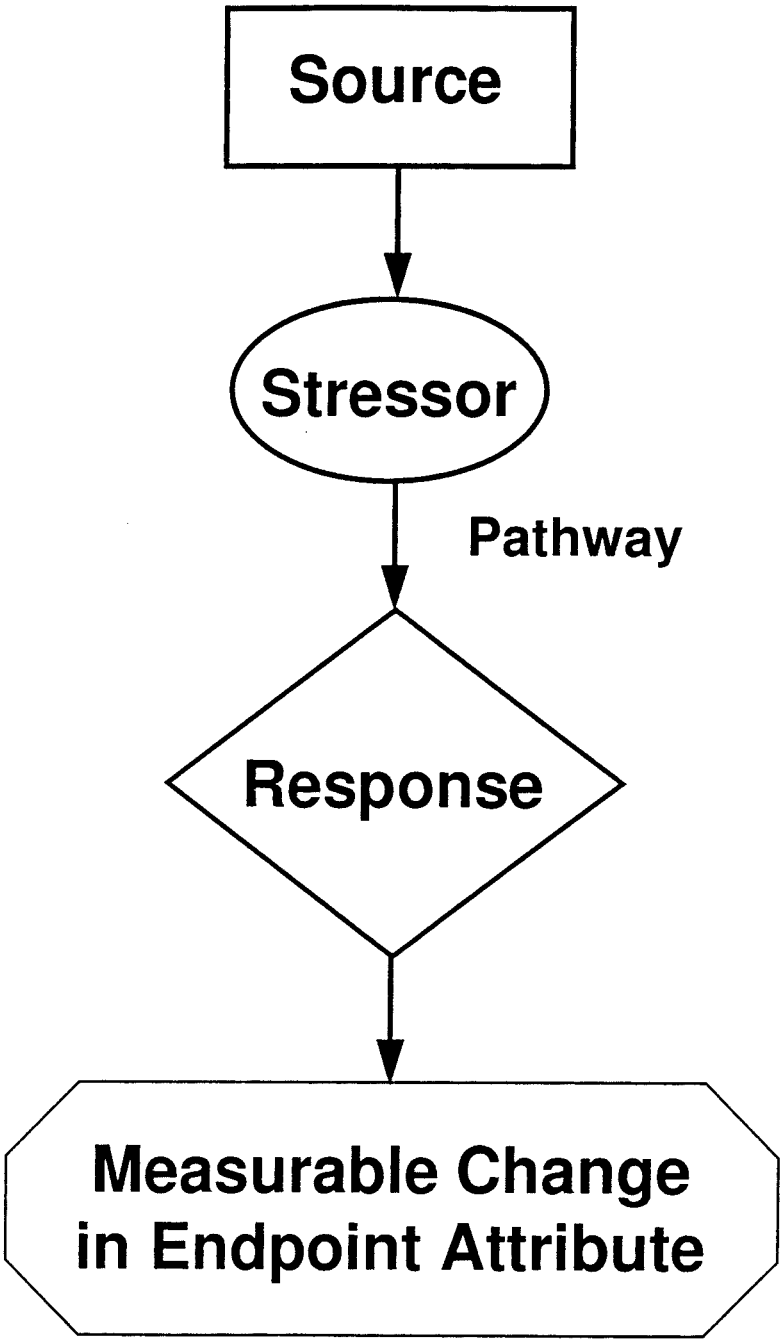

Figure 3-2. Elements of a conceptual model diagram. Illustrating the linkages between sources, stressors, and responses is an important function of the conceptual model diagram. However, the arrows in the diagram do not necessarily reflect the order in which this information is developed. See Appendix C for specific examples.

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When developing diagrams to represent a conceptual model, factors to consider include the number of relationships depicted, the comprehensiveness of the information, the certainty surrounding a pathway, and the potential for measurement. The number of relationships that can be depicted in one flow diagram depends on how comprehensive each relationship is. The more comprehensive, the fewer relationships that can be shown with clarity. Flow diagrams that highlight where data are abundant or scarce can provide insights on how the analyses should be approached and can be used to show the degree of confidence the risk assessor has in the relationship. Such flow diagrams can also help communicate why certain pathways were pursued and others were not.

Diagrams provide a working and dynamic representation of relationships. They should be used to explore different ways of looking at a problem before selecting one or several to guide analysis. Once the risk hypotheses are selected and flow diagrams drawn, they set the framework for final planning for the analysis phase.

3.4.3. Uncertainty in Conceptual Models

Conceptual model development may account for one of the most important sources of uncertainty in a risk assessment. If important relationships are missed or specified incorrectly, risks could be seriously under- or overestimated in the risk characterization phase. Uncertainty can arise from lack of knowledge on how the ecosystem functions, failing to identify and interrelate temporal and spatial parameters, not describing a stressor or suite of stressors, or not recognizing secondary effects. In some cases, little may be known about how a stressor moves through the environment or causes adverse effects. In most cases, multiple stressors are the norm and a source of confounding variables, particularly for conceptual models that focus on a single stressor. Opinions of experts on the appropriate conceptual model configuration may differ. While simplification and lack of knowledge may be unavoidable, risk assessors should document what is known, justify the model, and rank model components in terms of uncertainty (see Smith and Shugart, 1994).

Uncertainty associated with conceptual models can be reduced by developing alternative conceptual models for a particular assessment to explore possible relationships. In cases where more than one conceptual model is plausible, the risk assessor must decide whether it is feasible to follow separate models through the analysis phase or whether the models can be combined into a better conceptual model. It is important to revisit, and if necessary revise, conceptual models during risk assessments to incorporate new information and recheck the rationale. It is valuable to present conceptual models to risk managers to ensure the models communicate well and address key concerns the managers have. This check for completeness and clarity provides an opportunity to assess the need for changes before analysis begins.

Throughout the process of problem formulation, ambiguities, errors, and disagreements will occur, all of which contribute to uncertainty. Wherever possible, these sources of uncertainty should be eliminated through better planning. Because all uncertainty cannot be eliminated, a clear description of the nature of the uncertainties should be clearly summarized at the close of the problem formulation. Text note 3–13 provides recommendations for describing uncertainty in problem formulation.

The hypotheses considered most likely to contribute to risk are pursued in the analysis phase. As discussed previously, it is important to provide the rationale for selecting and omitting risk hypotheses and to acknowledge data gaps and uncertainties.

3.5. Analysis Plan

An analysis plan can be a usual final stage of problem formulation, particularly in the case of complex assessments. Here, risk hypotheses are evaluated to determine how they will be assessed using available and new data. The analysis plan can also delineate the assessment design, data needs, measures, and methods for conducting the analysis phase of the risk assessment. The analysis plan may be relatively brief or extensive depending on the nature of the assessment.

The analysis plan includes the most important pathways and relationships identified during problem formulation that will be pursued in the analysis phase. It is important for the risk assessor to describe what will be done and, in particular, what will not be done. It is important to address issues concerning the level of confidence needed for the management decision relative to the confidence that can be expected from an analysis in order to determine data needs and evaluate whether one analytical approach may be better than another. When new data are needed to conduct analyses, the feasibility of obtaining the data should be taken into account.

The selection of critical relationships in the conceptual model to pursue in analysis is based on several criteria, including:

- Availability of information.
- Strength of information about relationships between stressors and effects.
- The assessment endpoints and their relationship to ecosystem function.
- Relative importance or influence and mode of action of stressors.
- Completeness of known exposure pathways.

In situations where data are few and new data cannot be collected, it is possible to combine existing data with extrapolation models so that alternative data sources may be used. This allows the use of data from other locations or on other organisms where similar problems exist and data are available. For example, the relationship between nutrient availability and algal growth is well established. Although there will be differences in how the relationship is manifested based on the dynamics of a particular ecosystem, the relationship itself will tend to be consistent. When using data that require extrapolation, it is important to identify the source of the data, justify the extrapolation method and discuss major uncertainties apparent at this point.

Where data are not available, recommendations for new data collection should be part of problem formulation. An iterative, phased, or tiered approach (see text note 1–3) to the risk assessment may be selected to provide an opportunity for early management decisions on issues that can be addressed using available data. A decision to conduct a new iteration is based on the results of any previous iteration and proceeds using new data collected as specified in the analysis plan. When new data collection cannot be obtained, pathways that cannot be assessed are a source of uncertainty and should be described in the analysis plan.

3.5.1. Selecting Measures

It is in the analysis planning stage that measures are identified to evaluate the risk hypotheses. There are three categories of measures. Measures of effect are measures used to evaluate the response of the assessment endpoint when exposed to a stressor (formerly measurement endpoints). Measures of exposure are measures of how exposure may be occurring, including how a stressor moves through the environment and how it may co-occur with the assessment endpoint. Measures of

ecosystem and receptor characteristics include ecosystem characteristics that influence the behavior and location of assessment endpoints, the distribution of a stressor, and life history characteristics of the assessment endpoint that may affect exposure or response to the stressor. These diverse measures increase in importance as the complexity of the assessment increases and are particularly important for risk assessments initiated to protect ecological values (see text notes 3–14 and 3–15 for more information).

Text note 3–16, which describes water quality criteria, provides one example of how goals, endpoints, and measures are related. Although water quality criteria are often considered risk-based, they do not measure exposure. Instead, the water quality criteria provide an effects benchmark for decisionmaking. Within that benchmark there are a number of assumptions about significance (e.g., aquatic communities will be protected by achieving a benchmark derived from individual species' toxicological responses to a single chemical) and exposure (e.g., 1-hour and 4-day exposure averages). Assumptions embedded in decision rules should be articulated (see section 3.5.2).

The analysis plan provides a synopsis of measures that will be used to evaluate risk hypotheses. Potential extrapolations, model characteristics, types of data (including quality), and planned analyses (with specific tests for different types of data) are described. The plan should discuss how the results will be presented upon completion. The analysis plan provides the basis for making selections of data sets that will be used for the risk assessment.

The plan includes explanations of how data analyses will distinguish among hypotheses, an explicit expression of the approach to be used, and justifications for the elimination of some hypotheses and selection of others. It includes the measures selected, analytical methods planned, and the nature of the risk characterization options and considerations that will be generated (e.g., quotients, narrative discussion, stressor-response curve with probabilities). An analysis plan is enhanced if it contains explicit statements for how measures were selected, what they are intended to evaluate, and which analyses they support. During analysis planning, uncertainties associated with selected measures and analyses are articulated and, where possible, plans for addressing them are made.

3.5.2. Relating Analysis Plans to Decisions

The analysis plan is a risk manager-risk assessor checkpoint and an appropriate time for technical review. Discussions between the risk assessors and risk managers can help ensure that the analyses will provide the type and extent of information that the manager can use for decisionmaking. These discussions may also identify what can and cannot be done based on the preliminary evaluation of problem formulation, including which relationships to portray for the risk management decision. A reiteration of the planning discussion is important to ensure that the appropriate balance among the requirements for the decision, data availability, and resource constraints is established for the risk assessment.

The elements of an analysis plan share significant similarities with the data quality objectives (DQO) process (see text note 3–17), which emphasizes identifying the problem by establishing study boundaries and determining necessary data quality, quantity, and applicability to the problem being evaluated. The DQO guidance is a valuable reference for risk assessors (U.S. EPA, 1994d).

The most important difference between problem formulation and DQO is the presence of a decision rule that defines a benchmark for a management decision before the risk assessment is completed. The decision rule step specifies the statistical parameter that characterizes the population, specifies the action level for the study, and combines outputs from the previous DQO steps into an ''if * * * then'' decision rule that defines conditions under which the decision maker will choose alternative options. This approach provides the basis for establishing null and alternative hypotheses appropriate for statistical testing for significance. While this approach is appropriate for some risk assessments, many risk assessments are not based on benchmark decisions. Presentation of stressor-response curves with uncertainty bounds will be more appropriate than statistical testing of decision criteria where risk managers must evaluate the range of stressor effects to which they compare a range of possible management options.

The analysis plan is the final synthesis before the risk assessment proceeds. It summarizes what has been done during problem formulation, shows how the plan relates to management decisions that must be made, and indicates how data and analyses will be used to estimate risks. When it is determined that the problem is clearly defined and there are enough data to proceed, analysis begins.

4. Analysis Phase

The analysis phase consists of the technical evaluation of data to reach conclusions about ecological exposure and the relationships between the stressor and ecological effects. During analysis, risk assessors use measures of exposure, effects, and ecosystem and receptor attributes to evaluate questions and issues that were identified in problem formulation. The products of analysis are summary profiles that describe exposure and the stressor-response relationship. When combined, these profiles provide the basis for reaching conclusions about risk during the risk characterization phase.

The conceptual model and analysis plan developed during problem formulation provide the basis for the analysis phase. By the start of analysis, the assessor should know which stressors and ecological effects are the focus of investigation and whether secondary exposures or effects will be considered. In the analysis plan, the assessor identified the information needed to perform the analysis phase. By the start of analysis, these data should be available (text note 4–1).

The analysis phase is composed of two principal activities, the characterization of exposure and characterization of ecological effects (figure 4–1). Both activities begin by evaluating data (i.e., the measures of exposure, ecosystem and receptor characteristics, and effects) in terms of their scientific credibility and relevance to the assessment endpoint and conceptual model (discussed in section 4.1). In exposure characterization (section 4.2), these data are then analyzed to describe the source, the distribution of the stressor in the environment, and the contact or co-occurrence of the stressor with ecological receptors. In ecological effects characterization (section 4.3), data are analyzed to describe the relationship between the stressor and response and to evaluate the evidence that exposure to the stressor causes the response (i.e., stressor-response analyses). In many cases, extrapolation will be necessary to link the measures of effect with the assessment endpoint.

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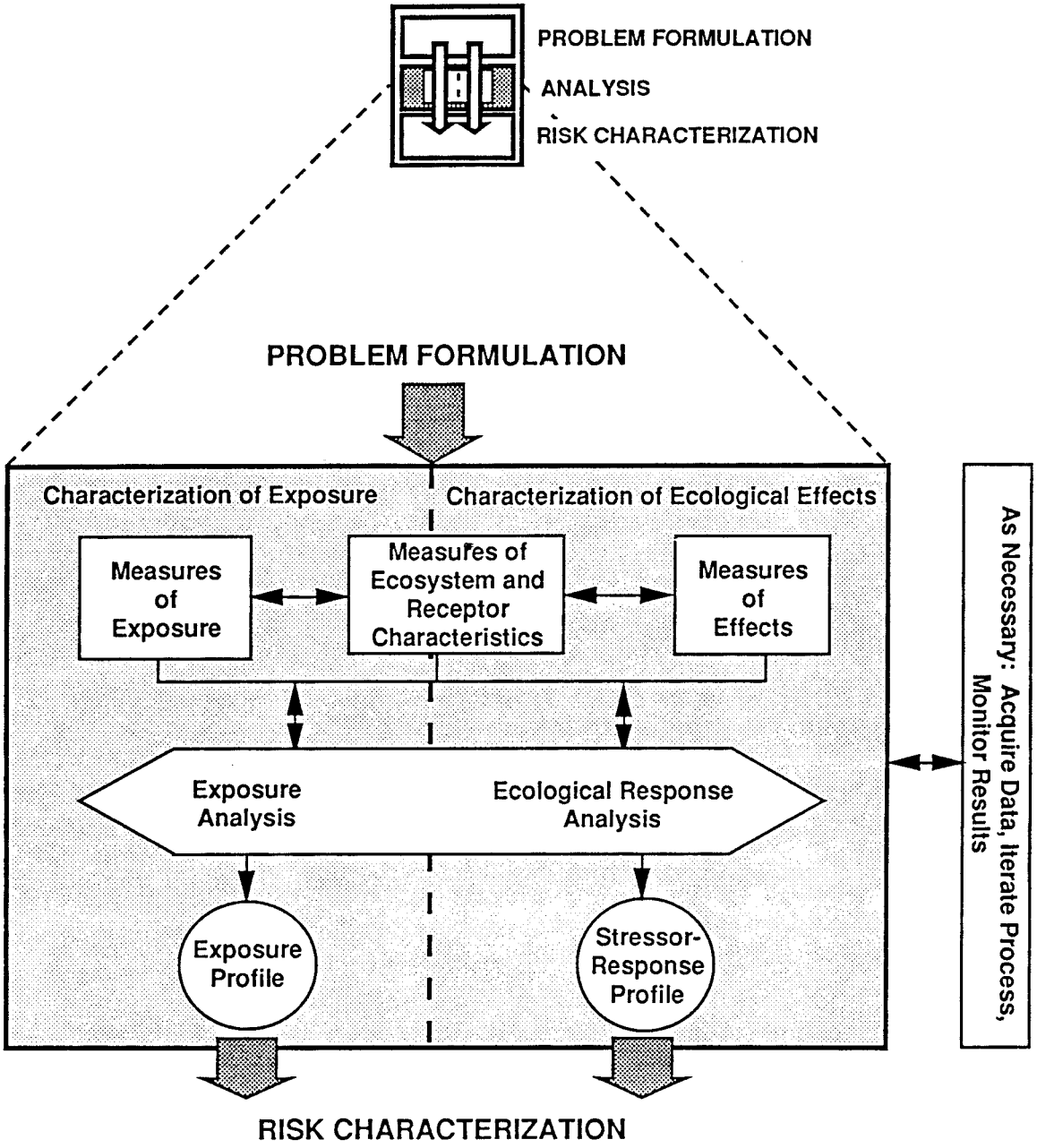

Figure 4-1. Analysis phase.

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Conclusions about exposure and the relationship between the stressor and response are summarized in profiles. The exposure and stressor-response profiles (sections 4.2.2 and 4.3.2, respectively) provide the opportunity to review what has been learned during the analysis phase and summarize this information in the most useful format for risk characterization. Depending on the risk assessment, these profiles may take the form of a written document or modules of a larger process model. Alternatively, documentation may be deferred until risk characterization. In any case, the purpose of these profiles is to ensure that the information needed for risk characterization has been collected and evaluated.

This process is intended to be flexible, and interaction between the ecological effects characterization and exposure characterization is recommended. When secondary stressors and effects are of concern, exposure and effects analyses are conducted iteratively for different ecological entities, and the analyses can become so intertwined that they are difficult to differentiate. The bottomland hardwoods example (Appendix D) illustrates this type of assessment. This assessment examined potential changes in the plant and animal communities under different flooding scenarios. The stressor-response and exposure analyses were combined within the FORFLO model for primary effects on the plant community and within the Habitat Suitability Index for secondary effects on the animal community.

In addition, the distinction between the analysis phase and risk estimation can become blurred. For example, the model results developed for the bottomland hardwoods example were used directly in risk characterization.

The nature of the stressor (that is, whether it is chemical, physical, or biological) will influence the types of analyses conducted and the details of implementation. Thus, the results of the analysis phase may range from highly quantitative to qualitative, depending on the stressor and the scope of the assessment. The estimation of exposure to chemicals emphasizes contact and uptake into the organism, and the estimation of effects often entails extrapolation from test organisms to the organism of interest. For physical stressors, the initial disturbance may be most closely related to the assessment endpoint (e.g., change of wetland to upland). In many cases, however, secondary effects (e.g., effects on wildlife that use the wetland) are the principal concern. The point of view taken during the analysis phase will depend on the assessment endpoints identified during problem formulation. Because adverse effects can occur even if receptors do not physically contact disturbed habitat, exposure analyses may emphasize co-occurrence with physical stressors rather than contact. For biological stressors, exposure analysis evaluates entry, dispersal, survival, and reproduction (Orr et al., 1993). Because biological stressors can reproduce, interact with other organisms, and evolve over time, exposure and effects cannot be quantified with confidence. Accordingly, exposure and effects are often assessed qualitatively by eliciting expert opinion (Simberloff and Alexander, 1994).

4.1. Evaluating Data and Models for Analysis

In problem formulation, the assessor identifies the information needed to perform the analysis phase and plans for collecting new data. The first step of the analysis phase is the critical evaluation of data and models to ensure that they can support the risk assessment. The sources and evaluation of data and models are discussed in sections 4.1.1 and 4.1.2, respectively. The evaluation of uncertainty, an important consideration when evaluating data and also throughout the analysis phase, is discussed in section 4.1.3.

4.1.1. Strengths and Limitations of Different Types of Data

The analysis phase relies on the measures identified in the analysis plan; these may come from laboratory or field studies or may be produced as output from a model. Data may have been developed for a specific risk assessment or for another purpose. A strategy that builds on the strengths of each type of data can improve confidence in the conclusions of a risk assessment.

Both laboratory and field studies (including field experiments and observational studies) can provide useful data for risk assessment. Because conditions can be controlled in laboratory studies, responses can be less variable and smaller differences easier to detect. However, the controls may limit the range of responses (for example, animals cannot seek alternate food sources), so they may not reflect responses in the environment. Field surveys are usually more representative of both exposures and effects (including secondary effects) found in natural systems than are estimates generated from laboratory studies or theoretical models. However, because conditions are not controlled, variability may be higher and it may be difficult to detect differences. Field studies are most useful for linking stressors with effects when stressor and effect levels are measured concurrently. In addition, the presence of confounding stressors can make it difficult to attribute observed effects to specific stressors. Preferred field studies use designs that minimize effects of potentially confounding factors. Intermediate between laboratory and field are studies that use environmental media collected from the field to conduct studies of response in the laboratory. Such studies may improve the power to detect differences and may be designed to provide evidence of causality.

Most data will be reported as measurements for single variables such as a chemical concentration or the number of dead organisms. In some cases, however, variables are combined into indices, and the index values are reported. Several indices are used to evaluate effects, for example, the rapid bioassessment protocols (U.S. EPA, 1989a) and the Index of Biotic Integrity, or IBI (Karr, 1981; Karr et al., 1986). These have several advantages (Barbour et al., 1995), including the ability to:

- Provide an overall indication of biological condition by incorporating many attributes of system structure and function, from individual to ecosystem levels.
- Evaluate responses from a broad range of anthropogenic stressors.
- Minimize the limitations of individual metrics for detecting specific types of responses.

Although indices are very useful, they have several drawbacks, many of which are associated with combining heterogeneous variables. For example, the final value may depend strongly on the function used to combine variables. Some indices (e.g., the IBI) combine only measures of effects. Differential sensitivity or other factors may make it difficult to attribute causality when many response variables are combined. Such indices may need to be separated into their components to investigate causality (Suter, 1993b; Ott, 1978). Interpretation becomes even more difficult when an index combines measures of exposure and effects because double-counting may occur or changes in one variable can mask changes in another. Exposure and effects measures may need to be separated in order to make appropriate conclusions. For these reasons, professional judgment plays a critical role in developing and applying indices.

Experience from similar situations is also an important data source that is particularly useful when predicting effects of stressors that have not yet

been released. For example, lessons learned from past experiences with related organisms are often critical in trying to predict whether an organism will survive, reproduce, and disperse in a new environment. Another example is the evaluation of toxicity of new chemicals through the use of structure-activity relationships, or SARs (Auer et al., 1994; Clements and Nabholz, 1994). The simplest application of SARs is to identify a suitable analog for which data are available to estimate the toxicity of the compound for which data are lacking. More advanced applications involve the use of quantitative structure-activity relationships (QSARs). QSARs describe the relationships between chemical structures and specific biological effects and are derived using information on sets of related chemicals (Lipnick, 1995; Cronin and Dearden, 1995). The use of analogous data without knowledge of the underlying processes may substantially increase the uncertainty in the risk assessment (e.g., Bradbury, 1994); however, these data may be the only option available.

While models are often developed and used as part of the risk assessment, sometimes the risk assessor relies on output of a previously developed model as input to the risk assessment. Models are particularly useful when measurements cannot be taken, for example when the assessment is predicting the effects of a chemical yet to be manufactured. Models can also provide estimates for times or locations that are impractical to measure and provide a basis for extrapolating beyond the range of observation. Starfield and Bleloch (1991) caution that ''the quality of the model does not depend on how realistic it is, but on how well it performs in relation to the purpose for which it was built.'' Thus, the assessor must review the questions that need to be answered and then ensure that a model can answer those questions. Because models are simplifications of reality, they may not include important processes for a particular system and may not reflect every condition in the real world. In addition, a model's output is only as good as the quality of its input variables, so critical evaluation of input data is important, as is comparing model outputs with measurements in the system of interest whenever possible.

Data and models for risk assessment are often developed in a tiered fashion (also see text note 1–3). For example, simple models that err on the side of conservatism may be used first, followed by more elaborate models that provide more realistic estimates. Effects data may also be collected by using a tiered approach. Short-term tests designed to evaluate effects such as lethality and immobility may be conducted first. If the chemical exhibits high toxicity or a preliminary characterization indicates a risk, then more expensive, longer-term tests that measure sublethal effects such as changes to growth and reproduction can be conducted. Later tiers may employ multispecies tests or field experiments. It is important to evaluate tiered data in light of the decision they are intended to support; data collected for early tiers may not be able to support more sophisticated needs.

4.1.2. Evaluating Measurement or Modeling Studies

Much of the information used in the analysis phase is available through published or unpublished studies that describe the purpose of the study, the methods used to collect data, and the results. Evaluating the utility of these studies relies on careful comparison of the objectives of the studies with the objectives of the risk assessment. In addition, study methods are examined to ensure that the intended objectives were met and that the data are of sufficient quality to support the risk assessment. Confidence in the information and the implications of using different studies should be described during risk characterization, when the overall confidence in the assessment is discussed. In addition, the risk assessor should identify areas where existing data do not meet risk assessment needs. In these cases, we recommend collecting new data.

EPA is in the process of adopting the American Society for Quality Control's E–4 guidelines for assuring environmental data quality throughout the Agency (ASQC, 1994) (text note 4–2). These guidelines describe procedures for collecting new data and provide a valuable resource for evaluating existing studies. (Readers are also referred to Smith and Shugart, 1994; U.S. EPA, 1994f; and U.S. EPA, 1990, for more information on evaluating data and models.)

A study's documentation directly influences the ability to evaluate its utility for risk assessment. Studies should contain sufficient information so that results can be reproduced, or at least so the details of the author's work can be accessed and evaluated. An additional advantage is the ability to access findings in their entirety; this provides the opportunity to conduct additional analyses of the data, if needed. For models, a number of factors increase the accessibility of methods and results. These begin with model code and documentation availability. Reports describing model results should include all important equations, tables of all parameter values, a description of any parameter estimation techniques, and tables or graphs of results.

Papers or reports describing studies may not provide all of the information needed to evaluate a study's utility for risk assessment. Assessors are encouraged to communicate with the principal investigator or other study participants to gain information on study plans and their implementation. Questions useful for evaluating studies are shown in text note 4–3.

4.1.2.1. Evaluating the Purpose and Scope of the Study

The assessor must often evaluate the utility of a study that was designed for a purpose other than risk assessment. In these cases, it is important that the objectives and scope of the original study be examined to evaluate their compatibility with the objectives and needs of the current risk assessment.

An examination of objectives can identify important uncertainties and ensure that the information is used appropriately in the assessment. An example is the evaluation of studies that measure condition (e.g., stream surveys, population surveys). While the measurements used to evaluate condition may be the same as the effects measures identified in problem formulation, to support a causal argument, effects measures must be linked with stressors. In the best case, this means that the stressor should be measured at the same time and place as the effect.

Similarly, a model may have been developed for purposes other than risk assessment. The model description should include the intended application, theoretical framework, underlying assumptions, and limiting conditions. This information can help assessors identify important limitations in its application for risk assessment. For example, a model developed to evaluate chemical transport in the water column alone may have limited utility for a risk assessment of a chemical that partitions readily into sediments.

The variables and conditions examined by studies should also be compared with those variables and conditions identified during problem formulation. In addition, the range of variability explored in the study should be compared with the range of variability of interest for the risk assessment. For example, a study that examines habitat needs of an animal during the winter may miss important breeding-season requirements. In

general, studies that minimize the amount of extrapolation needed are preferred. These are the studies that are designed to represent:

- The measures identified in the analysis plan (i.e., measures of exposure, effects, and ecosystem and receptor characteristics).
- The time frame of interest, considering seasonality and intermittent events.
- The ecosystem and location of interest.
- The environmental conditions of interest.
- The exposure route of interest.

4.1.2.2. Evaluating the Design and Implementation of the Study

The design and implementation of the study are evaluated to ensure that the study objectives were met and that the information is of sufficient quality to support the purposes of the risk assessment. The study design provides insight into the sources and magnitude of uncertainty associated with the results (see section 4.1.3 for further discussion of uncertainty). Among the most important design issues for studies of effects is whether a study had sufficient power to detect important differences or changes. Because this information is rarely reported (Peterman, 1990), the assessor may need to calculate the magnitude of an effect that could be detected under the study conditions (Rotenberry and Wiens, 1985).

Risk assessors should evaluate evidence that the study was conducted properly. For laboratory studies, this may mean determining whether test conditions were properly controlled and control responses were within acceptable bounds. For field studies, issues include the identification and control of potentially confounding variables and the careful selection of reference sites. For models, issues include the program's structure and logic and the correct specification of algorithms in the model code (U.S. EPA, 1994f).

Study evaluation is easier if a standard method or standard quality assurance/quality control (QA/QC) protocols are available and followed by the study. However, the assessor still needs to consider whether the precision and accuracy goals identified in the standard method were achieved and whether these goals are appropriate for the purposes of the risk assessment. For example, detection limits identified for one environmental matrix may not be achievable for another and may be higher than concentrations of interest for the risk assessment. Study results can still be useful even if a standard method was not used. However, it does place an additional burden on both the authors and the assessors to provide and evaluate evidence that the study was conducted properly.

4.1.3. Evaluating Uncertainty

Uncertainty evaluation is an ongoing theme throughout the analysis phase. The objective is to describe, and, where possible, quantify what is known and not known about exposure and effects in the system of interest. Uncertainty analyses increase credibility by explicitly describing the magnitude and direction of uncertainties, and they provide the basis for efficient data collection of or application of refined methods.

U.S. EPA (1992d) discusses sources of uncertainty that arise during the evaluation of information and conceptual model development (combined under the subject of scenario uncertainty), when evaluating the value of a parameter (e.g., an environmental measurement or the results of a toxicity test), and during the development and application of models. Uncertainty in conceptual model development is discussed in section 3.4.3. Many of the sources of uncertainty discussed by EPA (U.S. EPA, 1992d) are relevant to characterizing both exposure and ecological effects; these sources and example strategies for the analysis phase are shown in table 4–1.

TABLE 4–1.—UNCERTAINTY EVALUATION IN THE ANALYSIS PHASE

Source of uncertainty	Example analysis phase strategies	Specific example
Unclear communication	Contact principal investigator or other study participants if objectives and methods of literature studies are unclear.	Clarify whether the study was designed to characterize local populations or regional populations.
	Document decisions made during the course of the assessment.	Discuss rationale for selecting the critical toxicity study.
Descriptive errors	Verify that data sources followed appropriate QA/QC procedures.	Double-check calculations and data entry.
Variability	Describe heterogeneity using point estimates (e.g., central tendency and high end) or by constructing probability or frequency distributions.	Display differences in species sensitivity using a cumulative distribution function.
	Differentiate from uncertainty due to lack of knowledge.	
Data gaps	Describe approaches used for bridging gaps and their rationales.	Discuss rationale for using a factor of 10 to extrapolate between a LOAEL and a NOAEL.
	Differentiate science-based judgments from policy-based judgments.	
Uncertainty about a quantity's true value	Use standard statistical methods to construct probability distributions or point estimates (e.g., confidence limits).	Present the upper confidence limit on the arithmetic mean soil concentration, in addition to the best estimate of the arithmetic mean.
	Evaluate power of designed experiments to detect differences.	Ground-truth remote sensing data.
	Consider taking additional data if sampling error is too large.	
	Verify location of samples or other spatial features	
Model structure uncertainty (process models)	Discuss key aggregations and model simplifications.	Discuss combining different species into a group based on similar feeding habits.
	Compare model predictions with data collected in the system of interest.	

TABLE 4–1.—UNCERTAINTY EVALUATION IN THE ANALYSIS PHASE—Continued

Source of uncertainty	Example analysis phase strategies	Specific example
Uncertainty about a model's form (empirical models).	Evaluate whether alternative models should be combined formally or treated separately. Compare model predictions with data collected in the system of interest.	Present results obtained using alternative models. Compare results of a plant uptake model with data collected in the field.

Sources of uncertainty that are factors primarily when evaluating information include unclear communication of the information to the assessor, unclear communication about how the assessor handled the information, and errors in the information itself (descriptive errors). These sources are usually characterized by critically examining sources of information and documenting the rationales for the decisions made when handling it. The discussion should allow the reader to make an independent judgment about the validity of the decisions reached by the assessor.

Sources of uncertainty that arise primarily when estimating the value of a parameter include variability, uncertainty about a quantity's true value, and data gaps. The term variability is used here to describe the true heterogeneity in a characteristic influencing exposure or effects. Examples include the variability in soil organic carbon, seasonal differences in animal diets, or differences in chemical sensitivity among different species. This heterogeneity is usually described during uncertainty analysis, although heterogeneity may not reflect a lack of knowledge and cannot usually be reduced by further measurement. Variability can be described by presenting a distribution or specific percentiles from it (e.g., mean and 95th percentile).

Uncertainty about a quantity's true value may include uncertainty about its magnitude, location, or time of occurrence. This uncertainty can usually be reduced by taking additional measurements. Uncertainty about a quantity's true magnitude is usually described by sampling error (or variance in experiments) or measurement error. When the quantity of interest is biological response, sampling error can greatly influence the ability of the study to detect effects. Properly designed studies will specify sample sizes that are sufficiently large to detect important signals. Unfortunately, many studies have sample sizes that are too small to detect anything but gross changes (Smith and Shugart, 1994; Peterman, 1990). The discussion should highlight situations where the power to detect difference is low. Meta-analysis has been suggested as a way to combine results from different studies to improve the ability to detect effects (Laird and Mosteller, 1990; Petitti, 1994). However, these approaches have been applied primarily in the arena of human epidemiology and are still controversial (Mann, 1990).

Interest in quantifying spatial uncertainty has increased with the increasing use of geographic information systems. Strategies include verifying the locations of remotely sensed features, ensuring that the spatial resolution of data or a method is commensurate with the needs of the assessment, and using methods to describe and use the spatial structure of data (e.g., Cressie, 1993).

Nearly every assessment encounters situations where data are unavailable or where information is available on parameters that are different from those of interest for the assessment. Examples include using laboratory animal data to estimate a wild animal's response or using a bioaccumulation measurement from an ecosystem other than the one interest. These data gaps are usually bridged based on a combination of scientific data or analyses, scientific judgement, and policy judgement. For example, in deriving an ambient water quality criterion (text note 3–16), data and analyses are used to construct distributions of species sensitivity for a particular chemical. Scientific judgment is used to infer that species selected for testing will adequately represent the range of sensitivity of species in the environment. Policy judgment is used to define the extent to which individual species should be protected (e.g., 90 vs 95 percent of the species). It is important to differentiate among these elements when key assumptions and the approach used are documented.

In some circumstances scientists may disagree on the best way to bridge data gaps. This lack of consensus can increase uncertainty. Confidence can be increased through consensus building techniques such as peer reviews, workshops, and other methods to elicit expert opinion. Data gaps can often be filled by completing additional studies on the unknown parameter. Opportunities for reducing this source of uncertainty should be noted and carried through to risk characterization. Data gaps that preclude the analysis of exposure or ecological effects should also be noted and discussed in risk characterization.

An important objective of characterizing uncertainty in the analysis phase is to distinguish variability from uncertainties arising from lack of knowledge (e.g., uncertainty about a quantity's true value) (U.S. EPA, 1995c). This distinction facilitates the interpretation and communication of results. For example, in their food web models of herons and mink, MacIntosh et al. (1994) separated variability expected among feeding habits of individual animals from the uncertainty in the mean concentration of chemical in prey species. In this way, the assessors could place error bounds on the distribution of exposure among the animals using the site and estimate the proportion of the animal population that might exceed a toxicity threshold.

Sources of uncertainty that arise primarily during the development and application of models include the structure of process models and the description of the relationship between two or more variables in empirical models. Process model description should include key assumptions, simplifications, and aggregations of variables (see text note 4–4). Empirical model descriptions should include the rationale for selection, and statistics on model performance (e.g., goodness of fit). Uncertainty in process or empirical models can be quantitively evaluated by comparing model results to measurements taken in the system of interest or by comparing the results obtained using different model alternatives.

Methods for analyzing and describing uncertainty can range from simple to complex. The calculation of one or more point estimates is one of the most common approaches to presenting analysis results; point estimates that reflect different aspects of uncertainty can have great value if appropriately developed and communicated. Classical statistical methods (e.g., confidence limits, percentiles) can be readily applied to describing uncertainty in parameters. When a modeling approach

is used, sensitivity analysis can be used to evaluate how model output changes with changes in input variables, and uncertainty propagation can be analyzed to examine how uncertainty in individual parameters can affect the overall uncertainty of the assessment. The availability of software for Monte-Carlo analysis has greatly increased the use of probabilistic methods; readers are encouraged to follow best practices that have been suggested (e.g., Burmaster and Anderson, 1994; Haimes et al. 1994). Other methods (e.g., fuzzy mathematics, Bayesian methodologies) are available, but have not yet been extensively applied to ecological risk assessment (Smith and Shugart, 1994). These guidelines do not endorse the use of any one method over others and note that the poor execution of any method can obscure rather than clarify the impact of uncertainty on an assessment's results. No matter what technique is used, the sources of uncertainty discussed above should be addressed.

4.2. Characterization of Exposure

Exposure characterization describes the contact or co-occurrence of stressors with ecological receptors. The characterization is based on measures of exposure and of ecosystem and receptor characteristics (the evaluation of this information is discussed in section 4.1). These measures are used to analyze stressor sources, their distribution in the environment, and the extent and pattern of contact or co-occurrence (discussed in section 4.2.1). The objective is to produce a summary exposure profile (section 4.2.2) that identifies the receptor (i.e., the exposed ecological entity), describes the course a stressor takes from the source to the receptor (i.e., the exposure pathway), and describes the intensity and spatial and temporal extent of co-occurrence or contact. The profile also describes the impact of variability and uncertainty on exposure estimates and reaches a conclusion about the likelihood that exposure will occur.

The exposure profile is combined with an effects profile (discussed in section 4.3.2) to estimate risks. For the results to be useful, they must be compatible with the stressor-response relationship generated in the effects characterization.

4.2.1. Exposure Analyses

Exposure is analyzed by describing the source and releases, the distribution of the stressor in the environment, and the extent and pattern of contact or co-occurrence. The order of discussion of these topics is not necessarily the order in which they are evaluated in a particular assessment. For example, the assessor may start with information about tissue residues, and attempt to link these residues with a source.

4.2.1.1. Describe the Source

A source description identifies where the stressor originates, describes what stressors are generated, and considers other sources of the stressor. Exposure analyses may start with the source when it is known, but some analyses may begin with known exposures and attempt to link them to sources, while other analyses may start with known stressors and attempt to identify sources and quantify contact. The source is the first component of the exposure pathway and significantly influences where and when stressors eventually will be found. In addition, many management alternatives focus on modifying the source. Text note 4–5 provides some useful questions.

A source can be defined in several ways—as the place where the stressor is released (e.g., a smoke stack, historically contaminated sediments) or the management practice or action (e.g., dredging) that produces stressors. In some assessments, the original source no longer exists and the source is defined as the current origin of the stressors. For example, the source may be defined as contaminated sediments because the industrial plant that produced the contaminants no longer operates.

In addition to identifying the source, the assessor describes the generation of stressors in terms of intensity, timing, and location. The location of the source and the environmental medium that first receives stressors are two attributes that deserve particular attention. In addition, the source characterization should consider whether other constituents emitted by the source influence transport, transformation, or bioavailability of the stressor of interest. For example, the presence of chloride in the feedstock of a coal-fired power plant influences whether mercury is emitted in divalent (e.g., as mercuric chloride) or elemental form (Meij, 1991). In the best case, stressor generation is measured or modeled quantitatively; however, sometimes it can only be qualitatively described.

Many stressors have natural counterparts or multiple sources, and the characterization of these other sources can be an important component of the analysis phase. For example, many chemicals occur naturally (e.g., most metals), are generally widespread due to other sources (e.g., polycyclic aromatic hydrocarbons in urban ecosystems), or may have significant sources outside the boundaries of the current assessment (e.g., atmospheric nitrogen deposited in Chesapeake Bay). Many physical stressors also have natural counterparts. For example, construction activities may add fine sediments to a stream in addition to those from a naturally undercut bank. In addition, human activities may change the magnitude or frequency of natural disturbance cycles. For example, development may decrease the frequency but increase the severity of fires or may increase the frequency and severity of flooding in a watershed.

The way multiple sources are evaluated during the analysis phase depends on the objectives of the assessment articulated during problem formulation. Options include (in order of increasing complexity):

- Focus only on the source under evaluation and calculate incremental risks attributable to that source (common for assessments initiated with an identified source or stressor).
- Consider all sources of a stressor and calculate total risks attributable to that stressor. Relative source attribution can be accomplished as a separate step (common for assessments initiated with an observed effect or an identified stressor).
- Consider all stressors influencing an assessment endpoint and calculate cumulative risks to that endpoint (common for assessments initiated because of concern for an ecological value).

Source characterization can be particularly important for new biological stressors, since many of the strategies for reducing risks focus on preventing entry in the first place. Once the source is identified, the likelihood of entry may be characterized qualitatively. For example, in their analysis of risks from importation of Chilean logs, the assessment team concluded that the beetle *Hylurgus ligniperda* had a high potential for entry into the United States. They based this conclusion on the fact that they are attracted to freshly cut logs and tend to burrow under the bark and thus would be protected during transport (USDA, 1993).

The description of the source can set the stage for the second objective of exposure analysis, which is describing the distribution of the stressor in the environment.

4.2.1.2. Describe the Distribution of the Stressor or Disturbed Environment

The second objective of exposure analyses is to describe the spatial and temporal distribution of the stressor in

the environment. For physical stressors that directly alter or eliminate portions of the environment, the assessor describes the temporal and spatial distribution of the disturbed environment. Because exposure occurs where receptors co-occur with or contact stressors in the environment, characterizing the spatial and temporal distribution of a stressor is a necessary precursor to estimating exposure. The stressor's distribution in the environment is described by evaluating the pathways that stressors take from the source as well as the formation and subsequent distribution of secondary stressors.

Evaluating Transport Pathways. There are many pathways by which stressors can be transported in the environment (see text note 4–7). An evaluation of transport pathways can help ensure that measurements are taken in the appropriate media and locations and that models include the most important processes.

For chemical stressors, the evaluation of pathways usually begins by determining into which media a chemical will partition. Key considerations include physicochemical properties such as solubility and vapor pressure. For example, lipophilic chemicals tend to be found in environmental compartments with higher proportions of organic carbon, such as soils, sediments, and biota. From there, the evaluation may examine the transport of the contaminated medium. Because constituents of chemical mixtures may have different properties, it is important to consider how the composition of a mixture may change over time or as it moves through the environment. Guidance on evaluating the fate and transport of chemicals is beyond the scope of these guidelines; readers are referred to the exposure assessment guidelines (U.S. EPA, 1992d) for additional information.

The attributes of physical stressors may also influence where the stressors will go. For example, the size of silt particles determines where they will eventually deposit in a stream. Physical stressors that eliminate ecosystems or portions of them (e.g., logging activity or the construction of dams or parking lots) may require no modeling of pathways—the wetland is filled, the fish are harvested, or the valley is flooded. For these direct disturbances, the challenge is usually to evaluate the formation of secondary stressors and the effects associated with the disturbance.

The dispersion of biological stressors has been described in two ways, as diffusion and jump-dispersal (Simberloff and Alexander, 1994). Diffusion involves a gradual spread from the establishment site and is a function primarily of reproductive rates and motility. The other movement pattern, jump-dispersal, involves erratic spreads over periods of time, usually by means of a vector. The gypsy moth and zebra mussel have spread this way; the gypsy moth via egg masses on vehicles and the zebra mussel via boat ballast water. Biological stressors can use both diffusion and jump-dispersal strategies, and often one or more mechanisms are important. This makes dispersal rates very difficult to predict. Key considerations include the availability of vectors, whether the organism has natural attributes that enhance dispersal (e.g., ability to fly, adhere to objects, disperse reproductive units), and the habitat or host needs of the organism.

For biological stressors, assessors must consider the additional factors of survival and reproduction. There is a wide range of strategies organisms use to survive in adverse conditions, for example, fungi form resting stages such as sclerotia and chlamydospores and some amphibians became dormant during drought. The survival of some organisms can be measured to some extent under laboratory conditions. However, it may be impossible to determine how long some resting stages (e.g., spores) can survive under adverse conditions; many can remain viable for years. Similarly, reproductive rates may vary substantially, depending on specific environmental conditions. Therefore, while life-history data such as temperature and substrate preferences, important predators, competitors or diseases, habitat needs, and reproductive rates are of great value, they must be interpreted with caution.

Ecosystem characteristics influence the transport of all types of stressors. The challenge is to determine the particular aspects of the ecosystem that are most important. In some cases, ecosystem characteristics that influence distribution are known. For example, fine sediments tend to accumulate in areas of low energy in streams such as pools and backwaters. In other cases, much more professional judgment is needed. For example, when evaluating the likelihood that an introduced organism will become established, it is useful to know whether the ecosystem is generally similar to or different from the one where the biological stressor originated. In this case, professional judgment is needed to determine which characteristics of the current and original ecosystems should be compared.

Evaluating Secondary Stressors. The creation of secondary stressors can greatly alter conclusions about risk. Secondary stressors can be formed through biotic or abiotic transformation processes and may be of greater or lesser concern than the primary stressor. Evaluating the formation of secondary stressors is usually done as part of exposure characterization; however, coordination with the ecological effects characterization is important to ensure that all potentially important secondary stressors are evaluated.

For chemicals, the evaluation of secondary stressors usually focuses on metabolites or degradation products or chemicals formed through abiotic processes. For example, microbial action increases the bioaccumulation of mercury by transforming it from inorganic form to organic forms. Many azo dyes are not toxic because of their large molecular size but, in an anaerobic environment, the polymer is hydrolyzed into more toxic water-soluble units. In addition, secondary stressors can be formed through ecosystem processes. For example, nutrient inputs into an estuary can decrease dissolved oxygen concentrations because they increase primary production and subsequent decomposition. While the possibility and rates of transformation can be investigated in the laboratory, rates in the field may differ substantially, and some processes may be difficult or impossible to replicate in a laboratory. When evaluating field information, though, it may be difficult to distinguish between transformation processes (e.g., degradation of oil constituents by microorganisms) and transport processes (e.g., loss of oil constituents through volatilization).

Disturbances can also generate secondary stressors, and identifying the specific consequences that will affect the assessment endpoint can be a difficult task. For example, the removal of riparian vegetation can generate many secondary stressors, including increased nutrients, stream temperature, sedimentation, and altered stream flow. However, it may be the resulting increase in stream temperature that is the primary cause of adult salmon mortality in a particular stream.

The distribution of stressors in the environment can be described using measurements, models, or a combination of the two. If stressors have already been released, direct measurements of environmental media or a combination of modeling and measurement is preferred. However, a modeling approach may be necessary if the assessment is intended to predict future scenarios or if measurements are

not possible or practicable. Considerations for evaluating data collection and modeling studies are discussed in section 4.1. For chemical stressors, we also refer readers to the exposure assessment guidelines (U.S. EPA, 1992d). For biological stressors, the distribution in the environment is difficult to predict quantitatively. If measurements in the environment cannot be taken, distribution can be evaluated qualitatively by considering the potential for transport, survival, and reproduction (see above).

By the end of this step, the environmental distribution of the stressor or the disturbed environment should be described. This description can be an important precursor to the next objective of exposure analysis—estimating the contact or co-occurrence of the stressor with ecological entities. In cases where the extent of contact is known, describing the environmental distribution of the stressor can help identify potential sources, and ensure that all important exposures have been addressed. In addition, by identifying the pathways a stressor takes from a source, the second component of an exposure pathway is described.

4.2.1.3. Describe Contact or Co-occurrence

The third objective of the exposure analysis is to describe the extent and pattern of co-occurrence or contact between a stressor and a receptor (i.e., exposure). The objective of this step is to describe the intensity and temporal and spatial extent of exposure in a form that can be compared with the stressor-response profile generated in the effects assessment. The description of exposure is a critical element of estimating risk—if there is no exposure, there can be no risk. Questions for describing contact or co-occurrence are shown in text note 4–8.

Exposure can be described in terms of co-occurrence of the stressor with receptors, of the actual contact of a stressor with receptors, or of the uptake of a stressor into a receptor. The terms by which exposure is described depend on how the stressor causes adverse effects. Co-occurrence is particularly useful for evaluating stressors that can cause effects without actually contacting ecological receptors. For example, whooping cranes use sandbars in rivers for their nesting areas, and they prefer sandbars with unobstructed views. Manmade obstructions, such as bridges, can interfere with nesting behavior without ever actually contacting the birds. Most stressors, however, must contact receptors to cause an effect. For example, flood waters must contact tree roots before their growth is impaired. Finally, some stressors must not only be contacted, but also must be internally absorbed. For example, a toxicant that causes liver tumors in fish must be absorbed through the gills and reach the target organ to cause the effect.

Co-occurrence is evaluated by comparing the distribution of the stressor with the distribution of the ecological receptor. For example, maps of the stressor may be overlaid with maps of ecological receptors (e.g., the placement of bridges overlaid on maps showing habitat historically used for crane nests). The increased availability of geographic information systems (GIS) has provided new tools for evaluating co-occurrence.

Contact is a function of the amount of a stressor in an environmental medium and activities or behavior that brings receptors into contact with the stressor. For biological stressors, this step relies extensively on professional judgment; contact is often assumed to occur in areas where the two overlap. For chemicals, contact is quantified as the amount of a chemical ingested, inhaled, or in material applied to the skin (i.e., the potential dose). In its simplest form, it is quantified as an environmental concentration, with the assumptions that the chemical is well mixed and that the organism contacts a representative concentration. This approach is commonly used for respired media (e.g., water for aquatic organisms, air for terrestrial organisms). For ingested media (e.g., food, soil), another common approach combines modeled or measured concentrations of the contaminant with assumptions or parameters describing the contact rate (U.S. EPA, 1993c) (see text note 4–9).

Uptake is evaluated by considering the amount of stressor that is internally absorbed into an organism. Uptake is a function of the stressor (e.g., a chemical's form or valence state), the medium (e.g., sorptive properties or presence of solvents), the biological membrane (e.g., integrity, permeability), and the organism (e.g., sickness, active uptake) (Suter et al., 1994). Because of interactions among these four factors, uptake will vary on a situation-specific basis. Uptake is usually assessed by modifying an estimate of contact with a factor indicating the proportion of the stressor that is available for uptake (i.e., the bioavailable fraction) or actually absorbed. Absorption factors and bioavailability measured for the chemical, ecosystem, and organism of interest are preferred. Internal dose can also be evaluated by using a pharmacokinetic model or by measuring biomarkers or residues in receptors (see text note 4–10). Most stressor-response relationships express the amount of stressor in terms of media concentration or potential dose rather than internal dose; this limits the utility of using estimates of uptake for risk estimation. However, biomarkers and tissue residues can provide valuable confirmatory evidence that exposure has occurred, and tissue residues in prey organisms can be used for estimating risks to their predators.

The characteristics of the ecosystem and receptors must be considered to reach appropriate conclusions about exposure. Abiotic attributes may increase or decrease the amount of a stressor contacted by receptors. For example, the presence of naturally anoxic areas above contaminated sediments in an estuary may reduce the amount of time that bottom-feeding fish spend in contact with the contaminated sediments and thereby reduce exposure to the contamination. Biotic interactions can also influence exposure. For example, competition for high-quality resources may force some organisms to utilize disturbed areas. The interaction between exposure and receptor behavior can influence both the initial and subsequent exposures. For example, some chemicals reduce the prey's ability to escape predators and thereby may increase predator exposure to the chemical as well as the prey's risk of predation. Alternatively, organisms may avoid areas, food, or water with contamination they can detect. While avoidance can reduce exposure to chemicals, it may increase other risks by altering habitat usage or other behavior.

Three dimensions must be considered when estimating exposure: intensity, time, and space. Intensity is the most familiar dimension for chemical and biological stressors and may be expressed as the amount of chemical contacted per day or the number of pathogenic organisms per unit area.

The temporal dimension of exposure has aspects of duration, frequency, and timing. Duration can be expressed as the time over which exposure occurs, exceeds some threshold intensity, or over which intensity is integrated. If exposure occurs as repeated, discrete events of about the same duration (e.g., floods), frequency is the important temporal dimension of exposure. If the repeated events have significant and variable durations, both duration and frequency must be considered. In addition, the timing of exposure, including the order or sequence of events, can be an important factor to describe. For example, in the Northeast, lakes receive high concentrations of hydrogen ions and aluminum during

snow melt; this period also corresponds to the sensitive life stages of some aquatic organisms.

In chemical assessments, the dimensions of intensity and time are often combined by averaging intensity over time. The duration over which intensity is averaged is determined by considering both the ecological effects of concern and the likely pattern of exposure. For example, an assessment of bird kills associated with granular carbofuran focused on short-term exposures because the effect of concern was acute lethality (Houseknecht, 1993). Because toxicological tests are usually conducted using constant exposures, the most realistic comparisons between exposure and effects are made when exposure in the real world does not vary substantially. In these cases, the arithmetic average exposure over the time period of toxicological significance is the appropriate statistic to use (U.S. EPA, 1992d). However, as concentrations or contact rates become more episodic or variable, the arithmetic average may not reflect the toxicologically significant aspect of the exposure pattern. In extreme cases, averaging may not be appropriate at all, and assessors may need to use a toxic dynamic model to assess chronic effects.

Spatial extent is another dimension of exposure. It is most commonly expressed in terms of area (e.g., hectares of filled wetland, square meters that exceed a particular chemical threshold). At larger spatial scales, however, the shape or arrangement of exposure may be an important issue, and area alone may not be the appropriate descriptor of spatial extent for risk assessment. A general solution to the problem of incorporating pattern into ecological assessments has yet to be developed; however, the emerging field of landscape ecology and the increased availability of geographic information systems have greatly expanded the options for analyzing and presenting the spatial dimension of exposure.

This step completes exposure analysis. Exposure should be described in terms of intensity, space, and time, in units that can be combined with the effects assessment. In addition, the assessor should be able to trace the paths of stressors from the source to the receptors, completing the exposure pathway. The results of exposure analysis are summarized in the exposure profile, which is discussed in the next section.

4.2.2. Exposure Profile

The final product of exposure analysis is a summary profile of what has been learned. Depending on the risk assessment, the profile may be a written document, or a module of a larger process model. Alternatively, documentation may be deferred until risk characterization. In any case, the objective is to ensure that the information needed for risk characterization has been collected and evaluated. In addition, compiling the exposure profile provides an opportunity to verify that the important exposure pathways identified in the conceptual model were evaluated.

The exposure profile identifies the receptor and describes the exposure pathways and intensity and spatial and temporal extent of co-occurrence or contact. It also describes the impact of variability and uncertainty on exposure estimates and reaches a conclusion about the likelihood that exposure will occur (text note 4–11).

The profile should describe the relevant exposure pathways. If exposure can occur through many pathways, it may be useful to rank them, perhaps by contribution to total exposure. For example, consider an assessment of risks to grebes feeding on a mercury-contaminated lake. The grebes may be exposed to methyl mercury in fish that originated from historically contaminated sediments. They may also be exposed by drinking lake water, but comparing the two exposure pathways may show that the fish pathway contributes the vast majority of exposure to mercury.

The profile should describe the ecological entity that is exposed and represented by the exposure estimates described below. For example, the exposure profile may focus on the local population of grebes feeding on a specific lake during the summer months.

The assessor should state how each of the three general dimensions of exposure (intensity, time, and space) was treated and why that treatment is necessary or appropriate. Continuing with the grebe example, exposure might be expressed as the daily potential dose averaged over the summer months and over the extent of the lake.

The profile should also describe how variability in receptor attributes or stressor levels can change exposure. For example, variability in receptor attributes of the grebes may be addressed by using data on how the proportion of fish in the diet varies among individuals. If several lakes were the subject of the assessment and individual grebes tended to feed on the same lake throughout the season, variability in stressor levels could be addressed by comparing exposures among the lakes.

Variability can be described by using a distribution or by describing where a point estimate is expected to fall on a distribution. Cumulative-distribution functions (CDFs) and probability-density functions (PDFs) are two common presentation formats; (see Appendix B, figures B1 and B2). Figures 5–4 to 5–6 show examples of cumulative frequency plots of exposure data. The point estimate/descriptor approach is used when there is not enough information to describe a distribution. We recommend using the descriptors discussed in U.S. EPA, 1992d, including central tendency to refer to the mean or median of the distribution, high end to refer to exposure estimates that are expected to fall between the 90th and 99.9th percentile of the exposure distribution, and bounding estimates to refer to those higher than any actual exposure.

The exposure profile should summarize important uncertainties (i.e., lack of knowledge) (see section 4.1.3 for a discussion of the different sources of uncertainty). In particular, the assessor should:

- Identify key assumptions and describe how they were handled.
- Discuss (and quantify if possible) the magnitude of sampling and/or measurement error.
- Identify the most sensitive variables influencing exposure.
- Identify which uncertainties can be reduced through the collection of more data.

Uncertainty about a quantity's true value can be shown by calculating error bounds on a point estimate, as shown in figure 5–2.

All of the above information is synthesized to reach a conclusion about the likelihood that exposure will occur. The exposure profile is one of the products of the analysis phase. It is combined with the stressor-response profile (the product of the ecological effects characterization discussed in the next section) during risk characterization.

4.3. Characterization of Ecological Effects

Characterization of ecological effects describes the effects that are elicited by a stressor, links these effects with the assessment endpoints, and evaluates how the effects change with varying stressor levels. Ecological effects characterization begins by evaluating effects data (discussed generally in section 4.1) to further specify the effects that are elicited, confirm that the effects are consistent with the assessment endpoints, and confirm that the conditions under which they occur are

consistent with the conceptual model. Once the effects of interest are identified, then an ecological response analysis (section 4.3.1) is conducted to evaluate how the magnitude of the effects change with varying stressor levels, evaluate the evidence that the stressor causes the effect, and link the effects with the assessment endpoint. The conclusions of the ecological effects characterization are summarized in a stressor-response profile (section 4.3.2).

4.3.1. Ecological Response Analysis

Ecological response analysis has three primary elements: determining the relationship between stressor levels and ecological effects (section 4.3.1.1), evaluating the plausibility that effects may occur or are occurring as a result of exposure to stressors (section 4.3.1.2), and linking measurable ecological effects with the assessment endpoints when assessment endpoints cannot be directly measured (section 4.3.1.3).

4.3.1.1. Stressor-Response Analysis

Evaluating ecological risks requires an understanding of the relationships between stressor levels and resulting ecological responses. The stressor-response relationships used in a particular assessment depend on the scope and nature of the ecological risk assessment as defined in problem formulation and reflected in the analysis plan. For example, an assessor may need a point estimate of an effect (such as an LC_{50}) to compare with point estimates from other stressors. The shape of the stressor-response curve may be critical for determining the presence or absence of an effects threshold or for evaluating incremental risks, or stressor-response curves may be used as input for ecological effects models. If sufficient data are available, the risk assessor may construct cumulative distribution functions using multiple point estimates of effects. Or the assessor may use process models that already incorporate empirically derived stressor-response relationships (section 4.3.1.3). Some questions for stressor-response analysis are provided in text note 4–12.

This section describes a range of stressor-response approaches available to risk assessors following a theme of variations on the classical stressor-response relationship (e.g., figure 4–2). While quantifying this relationship is encouraged, qualitative stressor-response evaluations are also possible (text note 4–13). In addition, many stressor-response relationships are more complex than the simple curve shown in this figure. Ecological systems frequently show responses to stressors that may involve abrupt shifts to new community or system types (Holling, 1978).

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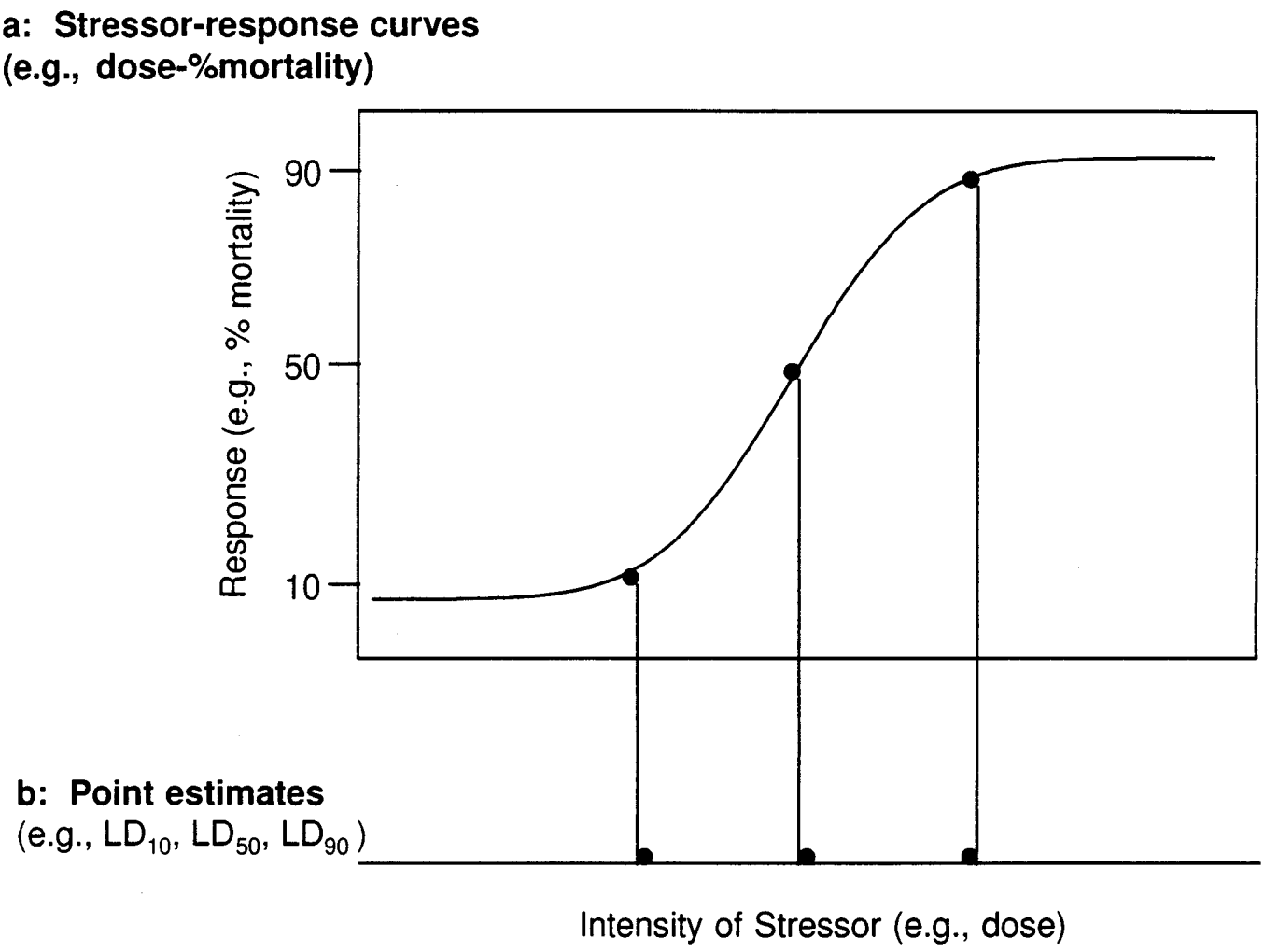

Figure 4-2. A simple example of a stressor-response relationship.

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In simple cases, the response will be one variable (e.g., mortality, incidence of abnormalities), and most quantitative techniques have been developed for univariate analysis. If the response of interest is composed of many individual variables (e.g., species abundances in an aquatic community), multivariate statistical techniques may be useful. These techniques have a long history of use in ecology (see texts by Gauch, 1982; Pielou, 1984; Ludwig and Reynolds, 1988) but have not yet been extensively applied in risk assessment.

Stressor-response relationships can be described using any of the dimensions of exposure (i.e., intensity, time, or space). Intensity is probably the most familiar dimension and is often used for chemicals (e.g., dose, concentration). The duration of exposure is also commonly used for chemical stressor-response relationships; for example, median acute effects levels are always associated with a time parameter (e.g., 24 hr, 48 hr, 96 hr). As noted in text note 4–13, the timing of exposure was the critical dimension in evaluating the relationship between seed germination and flooding (Pearlstine et al., 1985). The spatial dimension is often of concern for physical stressors. For example, the spatial extent of suitable habitat was related to the probability of sighting a spotted owl (Thomas et al., 1990), and water-table depth was related to the growth of tree species by Phipps (1979).

Single-point estimates and stressor-response curves can be generated for some biological stressors. For pathogens such as bacteria and fungi, inoculum levels (e.g., spores per ml; propagules per unit of substrate) may be related to the level of symptoms in a host (e.g., lesions per area of leaf surface, total number of plants infected) or actual signs of the pathogen (asexual or sexual fruiting bodies, sclerotia, etc.). For other biological stressors such as introduced species, developing simple stressor-response relationships may be inappropriate.

Data from individual experiments can be used to develop curves and point estimates both with and without associated uncertainty estimates (see figures 5–2 and 5–3). The advantages of curve-fitting approaches include using all of the available experimental data and the ability to interpolate to values other than the data points measured. If extrapolation outside the range of experimental data is required, risk assessors should justify that the observed experimental relationships remain valid. A disadvantage of curve fitting is that the number of data points required to complete an analysis may not always be available. For example, while standard toxicity tests with aquatic organisms frequently contain sufficient experimental treatments to permit regression analysis, frequently this is not the case for toxicity tests with wildlife species.

Risk assessors sometimes use curve-fitting analyses to determine particular levels of effect for evaluation. These point estimates are interpolated from the fitted line. Point estimates may be adequate for simple assessments or comparative studies of risk and are also useful if a decision rule for the assessment was identified during the planning phase (see section 2). Median effect levels (text note 4–14) are frequently selected because the level of uncertainty is minimized at the midpoint of the regression curve. While a 50% effect for an endpoint such as survival may not be appropriately protective for the assessment endpoint, median effect levels can be used for preliminary assessments or comparative purposes, especially when used in combination with uncertainty modifying factors (see text note 5–2). Selection of a different effect level (10%, 20%, etc.) can be arbitrary unless there is some clearly defined benchmark for the assessment endpoint. Thus, it is preferable to carry several levels of effect or the entire stressor-response curve forward to risk estimation.

When risk assessors are particularly interested in effects at lower stressor levels, they may seek to establish ''no-effect'' levels of a stressor based on comparisons between experimental treatments and controls. Statistical hypothesis testing is frequently used for this purpose. (Note that statistical hypotheses are different from the risk hypotheses discussed in problem formulation; see text note 3–10). An example of this approach for deriving chemical no-effect levels is provided in text note 4–15. An advantage of statistical hypothesis testing is that the risk assessor is not required to pick a particular effect level of concern. The no-effect level is determined instead by experimental conditions such as the number of replicates as well as the variability inherent in the data. Thus it is important to consider the level of effect detectable in the experiment (i.e., its power) in addition to reporting the no-effect level. Another drawback of this approach is that it is difficult to evaluate effects associated with stressor levels other than the actual treatments tested. Several investigators (Stephan and Rogers, 1985; Suter, 1993a) have proposed using regression analysis as an alternative to statistical hypothesis testing.

In observational field studies, statistical hypothesis testing is often used to compare site conditions with a reference site(s). The difficulties of drawing proper conclusions from these types of studies (which frequently cannot employ replication) have been discussed by many investigators, including Hurlbert (1984), Stewart-Oaten et al. (1986), Wiens and Parker (1995), and Eberhardt and Thomas (1991). Risk assessors should examine whether sites were carefully matched to minimize differences other than the stressor and consider whether potential covariates should be included in any analysis. An advantage of experimental field studies is that treatments can be replicated, increasing the confidence that observed differences are due to the treatment.

Data available from multiple experiments can be used to generate multiple point estimates that can be displayed as cumulative distribution functions. Figure 5–6 shows an example of a cumulative distribution function for species sensitivity derived from multiple point estimates (EC5s) for freshwater algae exposed to a herbicide. These distributions facilitate identification of stressor levels that affect a minority or majority of species. A limiting factor in the use of cumulative frequency distributions is the amount of data needed as input. Cumulative effects distribution functions can also be derived from models that use Monte Carlo or other methods to generate distributions based on measured or estimated variation in input parameters for the models.

When multiple stressors are present, stressor-response analysis is particularly challenging. Stressor-response relationships can be constructed for each stressor separately and then combined. Alternatively, the relationship between response and the suite of stressors can be combined in one analysis. It is preferable to directly evaluate complex chemical mixtures present in environmental media (e.g., wastewater effluents, contaminated soils; U.S. EPA, 1986b), but it is important to consider the relationship between the samples tested and the potential spatial and temporal variability in the mixture. The approach taken for multiple stressors depends on the feasibility of measuring the suite of stressors and whether an objective of the assessment is to project different stressor combinations.

In some cases, multiple regression analysis can be used to empirically relate multiple stressors and a response. Detenbeck (1994) used this approach to evaluate change in the water quality of

wetlands resulting from multiple physical stressors. Multiple regression analysis can be difficult to interpret if the explanatory variables (i.e., the stressors) are not independent. Principal components analysis can be used to extract independent explanatory variables formed from linear combinations of the original variables (Pielou, 1984).

4.3.1.2. Establishing Cause and Effect Relationships (Causality)

Causality is the relationship between cause (one or more stressors) and effect (assessment endpoint response to one or more stressors). Without a sound basis for linking cause and effect, uncertainty in the conclusions of an ecological risk assessment is likely to be high. Developing causal relationships is especially important for risk assessments driven by observed adverse ecological effects such as bird or fish kills or a shift in the species composition of an area. This section proposes considerations for evaluating causality based on criteria primarily for observational data developed by Fox (1991) and additional criteria for experimental evaluation of causality modified from Koch's postulates (e.g. see Woodman and Cowling, 1987).

Evidence of causality may be derived from observational evidence (e.g., bird kills are associated with field application of a pesticide) or experimental data (e.g., laboratory tests with the pesticides in question show bird kills at levels similar to those found in the field), and causal associations can be strengthened when both types of information are available. But since not all situations lend themselves to formal experimentation, scientists have looked for other criteria, based largely on observation rather than experiment, to support a plausible argument for cause and effect. Text note 4–16 provides criteria based on Fox (1991) that are very similar to others reviewed by Fox (U.S. Department of Health, Education, and Welfare, 1964; Hill, 1965; Susser, 1986a,b). While data to support some criteria may be incomplete or missing for any given assessment, these criteria offer a useful way of evaluating available information.

The strength of association between stressor and response is often the main reason that adverse effects (such as bird kills) are first noticed. A stronger response to a hypothesized cause is more likely to indicate true causation. Additional strong evidence of causation is when a response follows after a change in the hypothesized cause (predictive performance).

The presence of a biological gradient or stressor-response relationship is another important criterion for causality. The stressor-response relationship need not be linear. It can be a threshold, sigmoidal, or parabolic phenomenon, but in any case it is important that it can be demonstrated. Biological gradients, such as decreasing effects downstream of a toxic discharge, are frequently used as evidence of causality. To be credible, such relationships should be consistent with current biological or ecological knowledge (biological plausibility).

A cause-effect relationship that is demonstrated repeatedly (consistency of association) provides strong evidence of causality. Consistency may be shown by a greater number of instances of association between stressor and response, occurrences in diverse ecological systems, or associations demonstrated by diverse methods (Hill, 1965). Fox (1991) adds that in ecoepidemiology the occurrence of an association in more than one species and species population is very strong evidence for causation. An example would be the numerous species of birds that were killed as a result of carbofuran application (Houseknecht, 1993). Fox (1991) also believes that causality is supported if the same incident is observed by different persons under different circumstances and at different times.

Conversely, inconsistency in association between stressor and response is strong evidence against causality (e.g., the stressor is present without the expected effect, or the effect occurs but the stressor is not found). Temporal incompatibility (i.e., the presumed cause does not precede the effect) and incompatibility with experimental or observational evidence (factual implausibility) are also indications against a causal relationship.

Two other criteria may be of some help in defining causal relationships: specificity of an association and probability. The more specific the effect, the more likely it is to have a consistent cause. However, Fox (1991) argues that effect specificity does little to strengthen a causal claim. Disease can have multiple causes, a substance can behave differently in different environments or cause several different effects, and biochemical events may result in a diverse array of biological responses. But in general, the more specific or localized the effects, the easier it is to identify the cause. Sometimes, a stressor may have a distinctive mode of action that suggests its role. Yoder and Rankin (1995) found that patterns of change observed in fish and benthic invertebrate communities could serve as indicators for different types of anthropogenic impact (e.g., nutrient enrichment vs. toxicity).

For some pathogenic biological stressors, the causal evaluations proposed by Koch (text note 4–17) may be useful. For chemicals, ecotoxicologists have slightly modified Koch's postulates to provide evidence of causality (Adams, 1963; Woodman and Cowling, 1987). The modifications are:

- The injury, dysfunction, or other putative effect of the toxicant must be regularly associated with exposure to the toxicant and any contributory causal factors.
- Indicators of exposure to the toxicant must be found in the affected organisms.
- The toxic effects must be seen when normal organisms or communities are exposed to the toxicant under controlled conditions, and any contributory factors should be manifested in the same way during controlled exposures.
- The same indicators of exposure and effects must be identified in the controlled exposures as in the field.

These modifications are conceptually identical to Koch's postulates. While useful, this approach may not be practical if resources for experimentation are not available or if an adverse effect may be occurring over such a wide spatial extent that experimentation and correlation may prove difficult or yield equivocal results.

Experimental techniques are frequently used for evaluating causality in complex chemical mixtures. Options include evaluating separated components of the mixture, developing and testing a synthetic mixture, or determining how the toxicity of a mixture relates to the toxicity of individual components. The choice of method depends on the goal of the assessment and the resources and test data that are available.

Laboratory toxicity identification evaluations (TIEs) can be used to help determine which components of a chemical mixture are causing toxic effects. By using fractionation and other methods, the TIE approach can help identify chemicals responsible for toxicity and show the relative contributions to toxicity of different chemicals in aqueous effluents (U.S. EPA, 1988a, 1989b, c) and sediments (e.g., Ankley et al., 1990).

Risk assessors may utilize data from synthetic chemical mixtures if the individual chemical components are well characterized. This approach

allows for manipulation of the mixture and investigation of how varying the components that are present or their ratios may affect mixture toxicity but also requires additional assumptions about the relationship between effects of the synthetic mixture and those of the environmental mixture.

When the modes of action of chemicals in a mixture are known to be similar, an additive model has been successful in predicting combined effects (Könemann, 1981; Hermens et al., 1984a; McCarty and Mackay, 1993; Sawyer and Safe, 1985; Broderius et al., 1995). In this situation, the contribution of each chemical to the overall toxicity of the mixture can be evaluated. However, the situation is more complicated when the modes of action of the chemical constituents are unknown or partially known (see additional discussion in section 5.1.2).

4.3.1.3. Linking Measures of Effect to Assessment Endpoints

Assessment endpoints express the environmental values of concern for a risk assessment, but they cannot always be measured directly. When measures of effect differ from assessment endpoints, sound and explicit linkages between the two are needed. Risk assessors may make these linkages in the analysis phase or, especially when linkages rely on expert judgment, risk assessors may work with measures of effect through risk estimation (in risk characterization) and then make the connection with the assessment endpoints. Common extrapolations used to link measures of effect with assessment endpoints are shown in text note 4–18.

General Considerations. During the preparation of the analysis plan in problem formulation, risk assessors identify the extrapolations required between assessment endpoints and measures of effect. During the analysis phase, risk assessors should revisit the questions listed in text note 4–19 before proceeding with specific extrapolation approaches to use.

The scope and nature of the risk assessment and the environmental decision to be made help determine the degree of uncertainty (and type of extrapolation) that is acceptable. At an early stage of a tiered risk assessment, extrapolations from minimal data that involve large uncertainties are acceptable when the primary purpose is to determine whether a risk exists given worst-case exposure and effects scenarios. To define risk further at later stages of the assessment, additional data and more sophisticated extrapolation approaches are usually required.

The scope of the risk assessment also influences extrapolation through the nature of the assessment endpoint. Preliminary assessments that evaluate risks to general trophic levels, such as fish and birds, may extrapolate among different genera or families to obtain a range of sensitivity to the stressor. On the other hand, assessments concerned with management strategies for a particular species may employ population models.

Analysis phase activities may suggest additional extrapolation needs. Evaluation of exposure may indicate different spatial or temporal scales than originally anticipated. If spatial scales are broadened, additional receptors may need to be included in extrapolation models. If a stressor persists for an extended time in the environment, it may be necessary to extrapolate short-term responses over a longer period of exposure, and population level effects may become more important.

Whatever methods are employed to link assessment endpoints with measures of effect, it is important to apply the methods in a manner consistent with sound ecological principles and the availability of an appropriate database. For example, it is inappropriate to use structure-activity relationships to predict toxicity from chemical structure unless the chemical under consideration has a similar mode of toxic action to the reference chemicals (Bradbury, 1994). Similarly, extrapolations from upland avian species to waterfowl may be more credible if factors such as differences in food preferences, body mass, physiology, and seasonal behavior (e.g., mating and migration habits) are considered. Extrapolations made in a rote manner or that are biologically implausible will erode the overall credibility of the assessment.

Finally, many extrapolation methods are limited by the availability of suitable databases. Although these databases are generally largest for chemical stressors and aquatic species, data do not exist for all taxa or effects. Chemical effects databases for mammals, amphibians, or reptiles are extremely limited, and there is even less information on most biological and physical stressors. Risk assessors should be aware that extrapolations and models are only as useful as the data on which they are based and should recognize the great uncertainties associated with extrapolations that lack an adequate empirical or process-based rationale.

The rest of this section addresses the approaches used by risk assessors to link measures of effect to assessment endpoints, as noted below.

- Linkages based on expert judgment. This approach is not as desirable as empirical or process-based approaches, but is the only option when data are lacking.
- Linkages based on empirical or process models. Empirical extrapolations use experimental or observational data that may or may not be organized into a database. Process-based approaches are based on some level of understanding of the underlying operations of the system under consideration.

Judgment Approaches for Linking Measures of Effect to Assessment Endpoints. Expert judgment approaches rely on the professional expertise of risk assessors, expert panels, or others to relate changes in measures of effect to changes in the assessment endpoint. They are essential when databases are inadequate to support empirical models and process models are unavailable or inappropriate. Expert judgment linkages between measures of effect and assessment endpoints can be just as credible as empirical or process-based expressions, provided they have a sound scientific basis. This section highlights expert judgment extrapolations between species, from laboratory data to field effects, and between geographic areas.

Because of the uncertainties in predicting the effects of biological stressors such as introduced species, expert judgment approaches are commonly used. For example, there may be measures of effect data on a foreign pathogen that attacks a certain tree species not found in the United States, but the assessment endpoint concerns the survival of a commercially important tree found only in the United States. In this case, a careful evaluation and comparison of the life history and environmental requirements of both the pathogen and the two tree species may contribute toward a useful determination of potential effects, even though the uncertainty may be high. Expert panels are typically used for this kind of evaluation (USDA, 1993).

Risks to organisms in field situations are best estimated from studies at the site of interest. However, such data are not always available. Frequently, risk assessors must extrapolate from laboratory toxicity test data to field effects. Text note 4–20 summarizes some of the considerations for risk assessors when extrapolating from laboratory toxicity test results to field situations for chemical stressors. Factors altering exposure in the field are among the most important factors limiting extrapolations from laboratory test results, but indirect effects on exposed

organisms due to predation, competition, or other biotic or abiotic factors not evaluated in the laboratory may also be significant. Variations in direct chemical effects between laboratory tests and field situations may not contribute as much to the overall uncertainty of the extrapolation.

In addition to single-species tests, laboratory multiple species tests are sometimes used to predict field effects. While these tests have the advantage of evaluating some aspects of a real ecological system, they also have inherent scale limitations (e.g., lack of top trophic levels) and may not adequately represent features of the field system important to the assessment endpoint.

Extrapolations based on expert judgment are frequently required when assessors wish to use field data obtained from one geographic area and apply them to a different area of concern, or to extrapolate from the results of laboratory tests to more than one geographic region. In either case, risk assessors should consider variations between regions in environmental conditions, spatial scales and heterogeneities, and ecological forcing functions (see below).

Variations in environmental conditions in different geographic regions may alter stressor exposure and effects. If exposure to chemical stressors can be accurately estimated and are expected to be similar (e.g., see text note 4–20), the same species in different areas may respond similarly. For example, if the pesticide granular carbofuran were applied at comparable rates throughout the country, seed-eating birds could be expected to be similarly affected by the pesticide (Houseknecht, 1993). Nevertheless, the influence of environmental conditions on stressor exposure and effects can be substantial.

For biological stressors, environmental conditions such as climate, habitat, and suitable hosts play major roles in determining whether a biological stressor becomes established. For example, climate would prevent establishment of the Mediterranean fruit fly in the much colder northeastern United States. Thus, a thorough evaluation of environmental conditions in the area versus the natural habitat of the stressor is important. Even so, many biological stressors can adapt readily to varying environmental conditions, and the absence of natural predators or diseases may play an even more important role than abiotic environmental conditions.

For physical stressors that have natural counterparts, such as fire, flooding, or temperature variations, effects may depend on the natural variations in these parameters for a particular region. Thus, the comparability of two regions depends on both the pattern and range of natural disturbances.

Spatial scales and heterogeneities affect comparability between regions. Effects observed over a large scale may be difficult to extrapolate from one geographical location to another mainly because the spatial heterogeneity is likely to differ. Factors such as number and size of land-cover patches, distance between patches, connectivity and conductivity of patches (e.g., migration routes), and patch shape may be important. Extrapolations can be facilitated by using appropriate reference sites, such as sites in comparable ecoregions (Hughes, 1995).

Ecological forcing functions may differ between geographic regions. Forcing functions are critical abiotic variables that exert a major influence on the structure and function of ecological systems. Examples include temperature fluctuations, fire frequency, light intensity, and hydrologic regime. If these differ significantly between sites, it may be inappropriate to extrapolate stressor effects from one system to another.

The following references may be useful when assessing effects over different geographical areas: Bedford and Preston (1988), Detenbeck et al. (1992), Gibbs (1993), Gilbert (1987), Gosselink et al. (1990), Preston and Bedford (1988), and Risser (1988).

Empirical and Process-Based Approaches for Linking Measures of Effect to Assessment Endpoints. There are a variety of empirical and process-based approaches available to risk assessors depending on the scope of the assessment and the data and resources available. Empirical and process-based approaches include numerical extrapolations between effects measures and assessment endpoints. These linkages range in sophistication from applying an uncertainty factor to using a complex model requiring extensive measures of effects and measures of ecosystem and receptor characteristics as input. But even the most sophisticated quantitative models involve qualitative elements and assumptions and thus require professional judgment for evaluation. Individuals who use models and interpret their results should be familiar with the underlying assumptions and components contained in the model.

Empirical Approaches. Empirically based uncertainty factors or taxonomic extrapolations may be used when adequate effects databases are available but the understanding of underlying mechanisms of action or ecological principles is limited. When sufficient information on stressors and receptors is available, process-based approaches such as pharmacokinetic/pharmacodynamic models or population or ecosystem process models may be used. Regardless of the options used, risk assessors should justify and adequately document the approach selected.

Uncertainty factors are used to ensure that effects measures are sufficiently protective of assessment endpoints. Uncertainty factors are empirically derived numbers that are divided into measure of effects values to give an estimated stressor level that should not cause adverse effects to the assessment endpoint. Uncertainty factors have mostly been developed for chemicals because of the extensive ecotoxicologic databases available, especially for aquatic organisms. Uncertainty factors are useful when decisions must be made about stressors in a short time and with little information.

Uncertainty factors have been used to compensate for assessment endpoint/effect measures differences between endpoints (acute to chronic effects), between species, and between test situations (e.g., laboratory to field). Typically, uncertainty factors vary inversely with the quantity and type of effects measures data available (Zeeman, 1995). Uncertainty factors have been used in screening-level assessments of new chemicals (Nabholz, 1991), in assessing the risks of pesticides to aquatic and terrestrial organisms (Urban and Cook, 1986), and in developing benchmark dose levels for human health effects (U.S. EPA, 1995d).

In spite of their usefulness, uncertainty factors can also be misused, especially when used in an overly conservative fashion, as when chains of factors are multiplied together without sufficient justification. Like other approaches to bridging data gaps, uncertainty factors are often based on a combination of scientific analysis, scientific judgement and policy judgement (see section 4.1.3). It is important to differentiate among these three elements when documenting the basis for the uncertainty factors used.

Empirical data can be used to facilitate extrapolations between species to species, genera, families, or orders or functional groups (e.g., feeding guilds) (Suter, 1993a). Suter et al. (1983), Suter (1993a), and Barnthouse et al. (1987, 1990) developed methods to extrapolate toxicity among freshwater and marine fish and arthropods. As noted by Suter

(1993a), the uncertainties associated with extrapolating between orders, classes, and phyla tend to be very high. However, extrapolations can be made with fair certainty between aquatic species within genera and genera within families. Further applications of this approach (e.g., for chemical stressors and terrestrial organisms) are limited by a lack of suitable databases.

Dose-scaling or allometric regression has also been used to extrapolate the effects of a chemical stressor to another species. The method is used for human health risk assessment but has not been applied extensively to ecological effects (Suter, 1993a).

Allometric regression has been used with avian species (Kenaga, 1973) and to a limited extent for estimating effects to marine organisms based on their length. For chemical stressors, allometric relationships can enable an assessor to estimate toxic effects to species not commonly tested, such as native mammalian species. It is important that the assessor consider the taxonomic relationship between the known species and the species of interest. The closer the two are related, the more likely that the toxic response will be similar. Allometric approaches should not be applied to species that differ greatly in uptake, metabolism, or depuration of a chemical.

Process-Based Approaches. Process models for extrapolation are representations or abstractions of a system or process (Starfield and Bleloch, 1991) that incorporate causal relationships and provide a predictive capability that does not depend on the availability of existing stressor-response information as empirical models do (Wiegert and Bartell, 1994). Process models enable assessors to translate data on individual effects (e.g., mortality, growth, and reproduction) to potential alterations in specific populations, communities, or ecosystems. Such models can be used to evaluate risk hypotheses about the duration and severity of a stressor on an assessment endpoint that cannot be tested readily in the laboratory.

There are two major types of models: single-species population models and multispecies community and ecosystem models. Population models describe the dynamics of a finite group of individuals through time and have been used extensively in ecology and fisheries management and to assess the impacts of power plants and toxicants on specific fish populations (Barnthouse et al., 1987; Barnthouse et al., 1990). Population models are useful in answering questions related to short- or long-term changes of population size and structure and can be used to estimate the probability that a population will decline below or grow above a specified abundance (Ginzburg et al., 1982; Ferson et al., 1989). This latter application may be useful when assessing risks associated with biological stressors such as introduced or pest species. Excellent reviews of population models are presented by Barnthouse et al. (1986) and Wiegert and Bartell (1994). Emlen (1989) has reviewed population models that can be used for terrestrial risk assessment.

Proper use of the population models requires a thorough understanding of the natural history of the species under consideration, as well as knowledge of how the stressor influences its biology. Model input can include somatic growth rates, physiological rates, fecundity, survival rates of various classes within the population, and how these change when the population is exposed to the stressor and other environmental factors. In addition, the effects of population density on these parameters may be important (Hassell, 1986) and should be considered in the analysis of uncertainty.

Community and ecosystem models (e.g., Bartell et al., 1992; O'Neill et al., 1982) are particularly useful when the assessment endpoint involves structural (e.g., community composition) or functional (e.g., primary production) elements of the system potentially at risk. These models can also be useful when secondary effects are of concern. Changes in various community or ecosystem components such as populations, functional types, feeding guilds, or environmental processes can be estimated. By incorporating submodels describing the dynamics of individual system components, these models permit evaluation of risk to multiple assessment endpoints within the context of the larger environmental system.

Risk assessors should evaluate the degree of aggregation in population or multispecies model parameters that is appropriate based both on the input data available and on the desired output of the model. For example, if a decision is required about a particular species, a model that lumps species into trophic levels or feeding guilds will not be very useful. Assumptions concerning aggregation in model parameters should be included in the discussion of uncertainty.

4.3.2. Stressor-Response Profile

The final product of ecological response analysis is a summary profile of what has been learned. Depending on the risk assessment, the profile may be a written document, or a module of a larger process model. Alternatively, documentation may be deferred until risk characterization. In any case, the objective is to ensure that the information needed for risk characterization has been collected and evaluated. A useful approach in preparing the stressor-response profile is to imagine that it will be used by someone else to perform the risk characterization. Using this approach, the assessor may be better able to extract the information most important to the risk characterization phase. In addition, compiling the stressor-response profile provides an opportunity to verify that the assessment and measures of effect identified in the conceptual model were evaluated.

Risk assessors should address several questions in the stressor-response profile (text note 4–21). Depending on the type of risk assessment, affected ecological entities could include single species, populations, general trophic levels, communities, ecosystems, or landscapes. The nature of the effect(s) should be germane to the assessment endpoint(s). Thus if a single species is affected, the effects should represent parameters appropriate for that level of organization. Examples include effects on mortality, growth, and reproduction. Short- and long-term effects should be reported as appropriate. At the community level, effects could be summarized in terms of structure or function depending on the assessment endpoint. At the landscape level, there may be a suite of assessment endpoints and each should be addressed separately.

Examples of different approaches for displaying the intensity of effects as stressor-response curves or point estimates were provided in section 4.3.1.1. Other information such as the spatial area or time to recovery may be appropriate, depending on the scope of the assessment. Causal analyses are important, especially for assessments that include field observational data.

While ideally the stressor-response profile should express effects in terms of the assessment endpoint, this will not always be possible. Especially where it is necessary to use qualitative extrapolations between assessment endpoints and measures of effect, the stressor-response profile may only contain information on measures of effect. Under these circumstances, risk will be estimated using the measures of effects, and extrapolation to the assessment endpoints will occur during risk characterization.

Risk assessors need to be descriptive and candid about any uncertainties

associated with the ecological response analysis. If it was necessary to extrapolate from measures of effect to the assessment endpoint, describe both the extrapolation and its basis. Similarly, if a benchmark or similar reference dose or concentration was calculated, discuss the extrapolations and uncertainties associated with its development. For additional information on establishing reference concentrations, see Nabholz (1991), Urban and Cook (1986), Stephan et al. (1985), Van Leeuwen et al. (1992), Wagner and L-kke (1991), and Okkerman et al. (1993). Finally, the assessor should clearly indicate major assumptions and default values used in models.

At the end of the analysis phase, the stressor-response and exposure profiles are used to estimate risks. These profiles provide the opportunity to review what has been learned and to summarize this information in the most useful format for risk characterization. Whatever form the profiles take, they ensure that the necessary information is available for risk characterization.

5. Risk Characterization

Risk characterization (figure 5–1) is the final phase of ecological risk assessment. Its goals are to use the results of the analysis phase to estimate risk to the assessment endpoints identified in problem formulation (section 5.1), interpret the risk estimate (section 5.2), and report the results (section 5.3).

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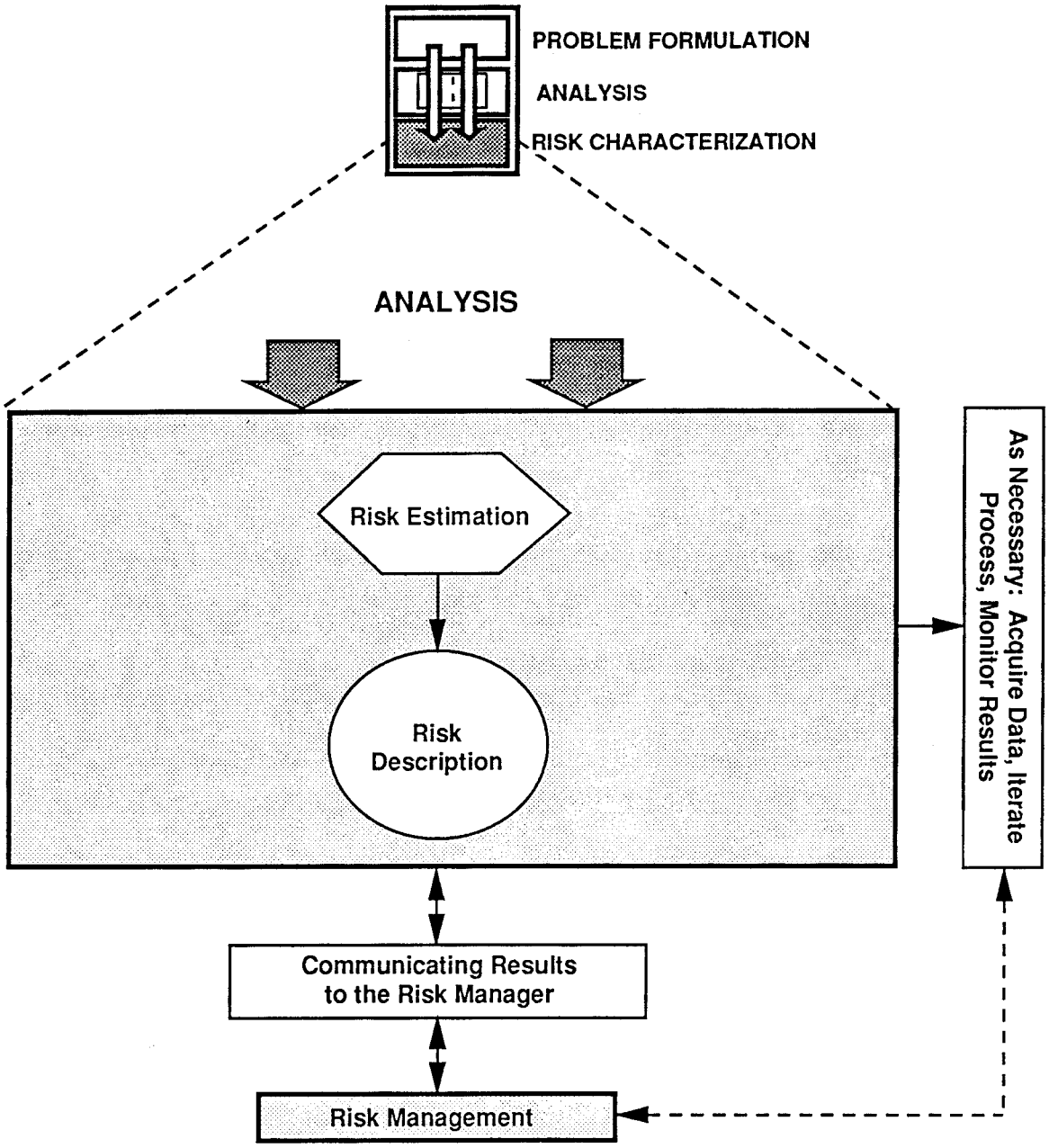

Figure 5-1. Risk characterization.

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Risk characterization is a major element of the risk assessment report. To be successful, it should provide clear information to the risk manager to use in environmental decision making (NRC, 1994; see section 6). If the risks are not sufficiently defined to support a management decision, the risk manager may elect to proceed with another iteration of the risk assessment process. Additional research or a monitoring program may improve the risk estimate or help to evaluate the consequences of a risk management decision.

5.1. Risk Estimation

Risk estimation determines the likelihood of adverse effects to assessment endpoints by integrating exposure and effects data and evaluating any associated uncertainties. The process uses exposure and stressor-response profiles which are developed according to the analysis plan (section 3.5). Risks can be estimated by one or more of the following approaches: (1) estimates expressed as qualitative categories, (2) estimates comparing single-point estimates of exposure and effects, (3) estimates incorporating the entire stressor-response relationship, (4) estimates incorporating variability in exposure and effects estimates, (5) estimates based on process models that rely partially or entirely on theoretical approximations of exposure and effects, and (6) estimates based on empirical approaches, including field observational data.

5.1.1. Risk Estimates Expressed as Qualitative Categories

In some cases, best professional judgment may be used to express risks qualitatively using categories such as low, medium, and high or yes and no. This approach is most frequently used when exposure and effects data are limited or not easily expressed in quantitative terms. A U.S. Forest Service assessment used qualitative categories because of limitations on both the exposure and effects data for the introduced species of concern as well as the resources available for the assessment. (text note 5–1)

5.1.2. Single-Point Estimates

When sufficient data are available to quantify exposure and effects estimates, the simplest approach for comparing the estimates is to use a ratio of two numbers (figure 5–2a). Typically, the ratio (or quotient) is expressed as an exposure concentration divided by an effects concentration. Quotients are commonly used for chemical stressors, where reference or benchmark toxicity values are widely available (text note 5–2).

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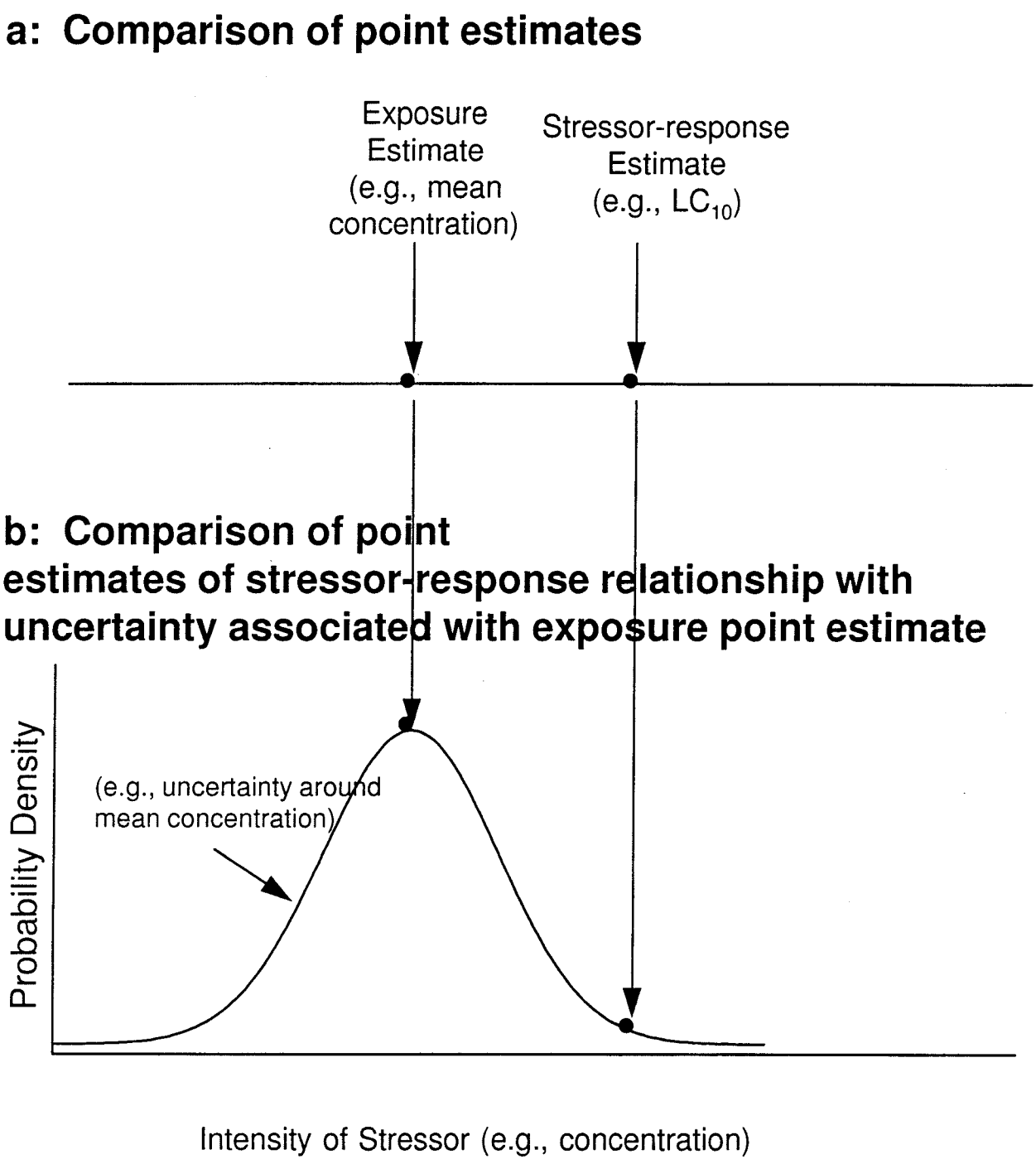

Figure 5-2. Risk estimation techniques. a. Comparison of exposure and stressor-response point estimates. b. Comparison of point estimates from the stressor-response relationship with uncertainty associated with an exposure point estimate.

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The principal advantages of the quotient method are that it is simple and quick to use and risk assessors and managers are familiar with its application. The quotient method provides an efficient, inexpensive means of identifying high or low risk situations that can allow risk management decisions to be made without the need for further information.

Quotients have also been used to integrate the risks of multiple chemical stressors. In this approach, quotients for the individual constituents in a mixture are generated by dividing each exposure level by a corresponding toxicity endpoint (e.g., an LC_{50}). Although the toxicity of a chemical mixture may be greater (synergism) or less (antagonism) than predicted from the toxicities of individual constituents of the mixture, a quotient addition approach assumes that toxicities are additive or close to additive, which may be true when the modes of action of chemicals in a mixture are similar (e.g., Könemann, 1981; Broderius et al., 1995; Hermens et al., 1984a,b; McCarty and Mackay, 1993; Sawyer and Safe, 1985).

For mixtures of chemicals having dissimilar modes of action, there is some evidence from fish acute toxicity tests with industrial organic chemicals that strict additivity or less-than-strict additivity is common, while antagonistic and synergistic responses are rare (Broderius, 1991). These experiences suggest that caution should be used when predicting that chemicals in a mixture will act independently of one another. However, these relationships observed with aquatic organisms may not be relevant for other endpoints, exposure scenarios, and species. When the mode of action for constituent chemicals are unknown, the assumptions and rationale concerning chemical interactions must be clearly stated.

The application of the quotient method is restricted by a number of limitations (see Smith and Cairns, 1993; Suter, 1993a). While a quotient can be useful in answering whether risks are high or low, it may not be helpful to a risk manager who needs to make a decision requiring a quantification of risks. For example, it is seldom useful to say that a risk mitigation approach will reduce a quotient value from 25 to 12, since this reduction cannot by itself be clearly interpreted in terms of effects on an assessment endpoint.

Another potential difficulty with the quotient method is that the point estimate of effect may not reflect the appropriate intensity of effect or exposure pattern for the assessment. For example, an LC_{50} derived from a 96-hour laboratory test using constant exposure levels may not be appropriate for an assessment of effects on reproduction resulting from short-term, pulsed exposures.

The quotient method cannot evaluate secondary effects. Interactions and effects beyond what is predicted from the simple quotient may be critical to characterizing the full extent of impacts from exposure to the stressors (e.g., bioaccumulation).

Finally, in most cases, the quotient method does not explicitly consider uncertainty (e.g., extrapolation from tested species to the species or community of concern). However, some uncertainties can be incorporated into single-point estimates to provide a statement of likelihood that the effects point estimate exceeds the exposure point estimate (figures 5–2b and 5–3). If exposure variability is quantified, then the point estimate of effects can be compared with a cumulative exposure distribution as described in text note 5–3. Further discussion of comparisons between point estimates of effects and distributions of exposure may be found in Suter et al., 1983.

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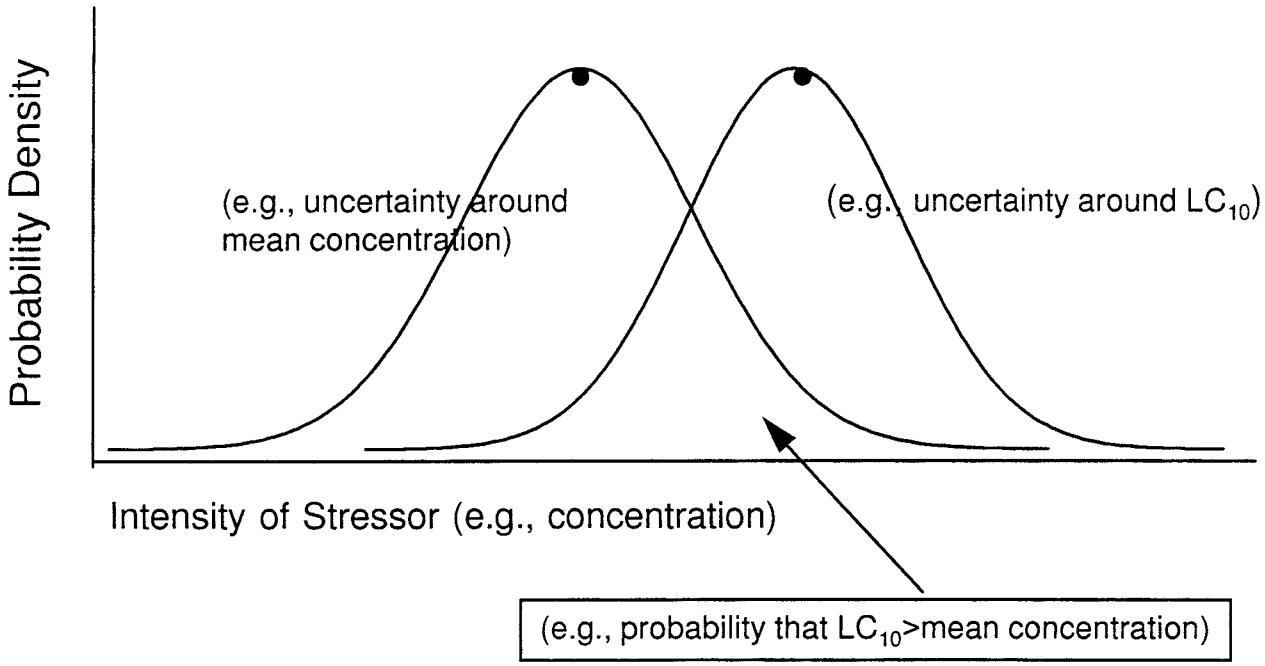

Figure 5-3. Risk estimation techniques: comparison of point estimates with associated uncertainties.

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In view of the advantages and limitations of the quotient method, it is important for risk assessors to consider the points listed below when evaluating quotient method estimates.

- How does the effect concentration relate to the assessment endpoint?
- What extrapolations are involved?
- How does the point estimate of exposure relate to potential spatial and temporal variability in exposure?
- Are data sufficient to provide confidence intervals on the endpoints?

5.1.3. Estimates Incorporating the Entire Stressor-Response Relationship

If the stressor-response profile described a curve relating the stressor level to the magnitude of response, then risk estimation can examine risks associated with many different levels of exposure (figure 5–4). These estimates are particularly useful when the risk assessment outcome is not based on exceedance of a predetermined decision rule such as a toxicity benchmark level.

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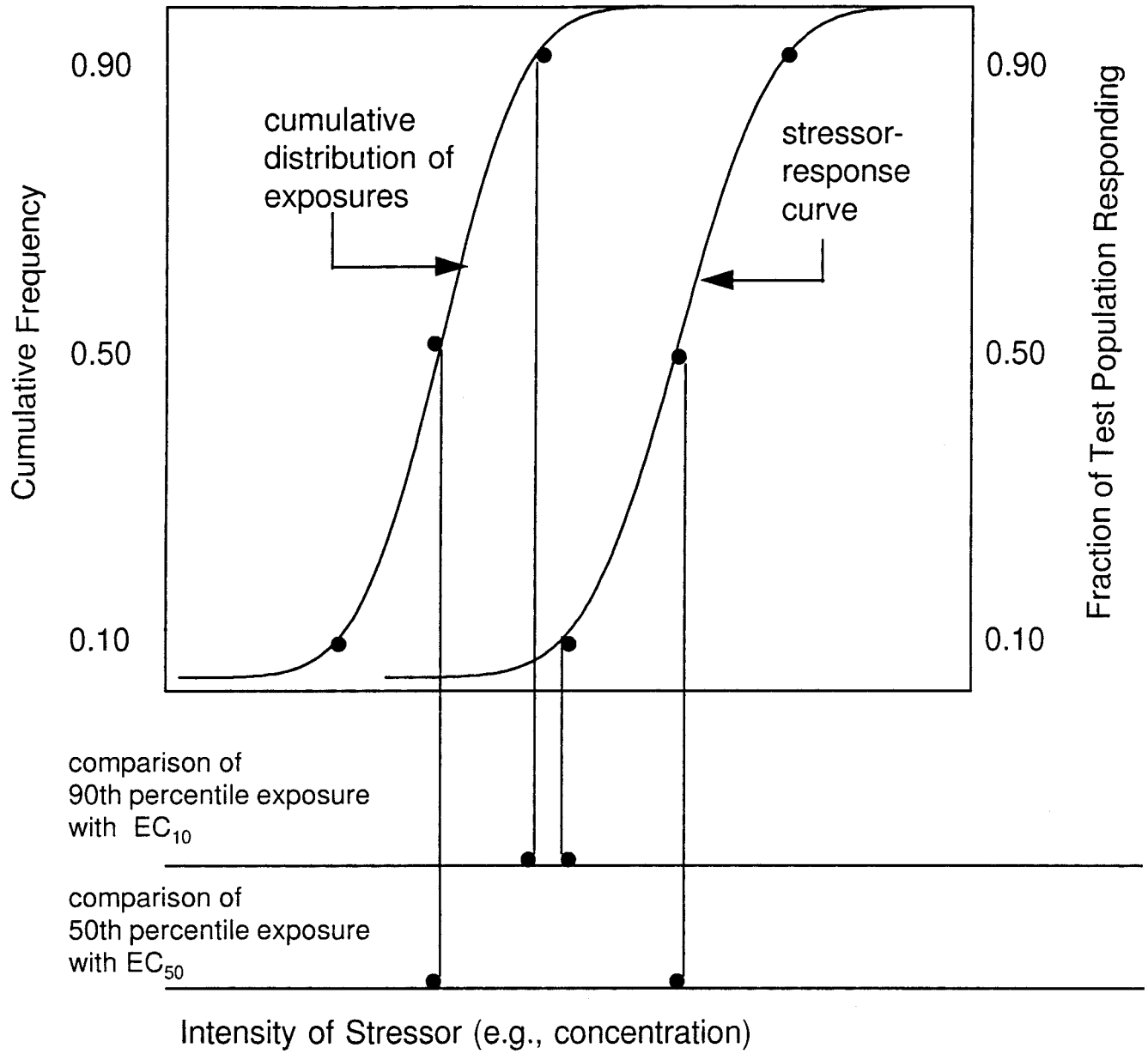

Figure 5-4. Risk estimation techniques: stressor-response curve versus a cumulative distribution of exposures.

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There are both advantages and limitations to comparing a stressor-response curve with an exposure distribution. The steepness of the effects curve shows the magnitude of change in effects associated with incremental changes in exposure, and the capability to predict changes in the magnitude and likelihood of effects for different exposure scenarios can be used to compare different risk management options. Also, uncertainty can be incorporated by calculating uncertainty bounds on the stressor-response or exposure estimates. While comparing exposure and stressor-response curves provides a predictive ability lacking in the quotient method, this approach shares the quotient method's limitations of not evaluating secondary effects, assuming that the exposure pattern used to derive the stressor-response curve is comparable to the environmental exposure pattern, and not explicitly considering uncertainties, such as extrapolations from tested species to the species or community of concern.

5.1.4. Estimates Incorporating Variability in Exposure or Effects

If the exposure or stressor-response profiles describe the variability in exposure or effects, then many different risk estimates can be calculated. Variability in exposure can be used to describe risks to moderately or highly exposed members of a population being investigated, while variability in effects can be used to describe risks to average or sensitive population members.

A major advantage of this approach is the capability to predict changes in the magnitude and likelihood of effects for different exposure scenarios, thus providing a means for comparing different risk management options. As noted above, comparing distributions also allows one to identify and quantify risks to different segments of the population. Limitations include the increased data requirements compared with previously described techniques and the implicit assumption that the full range of variability in the exposure and effects data is adequately represented. As with the quotient method, secondary effects are not readily evaluated with this technique. Thus, it is desirable to corroborate risks estimated by distributional comparisons with field studies or other lines of evidence. Text note 5–4 and figure 5–5 illustrate the use of cumulative exposure and effects distributions for estimating risk.

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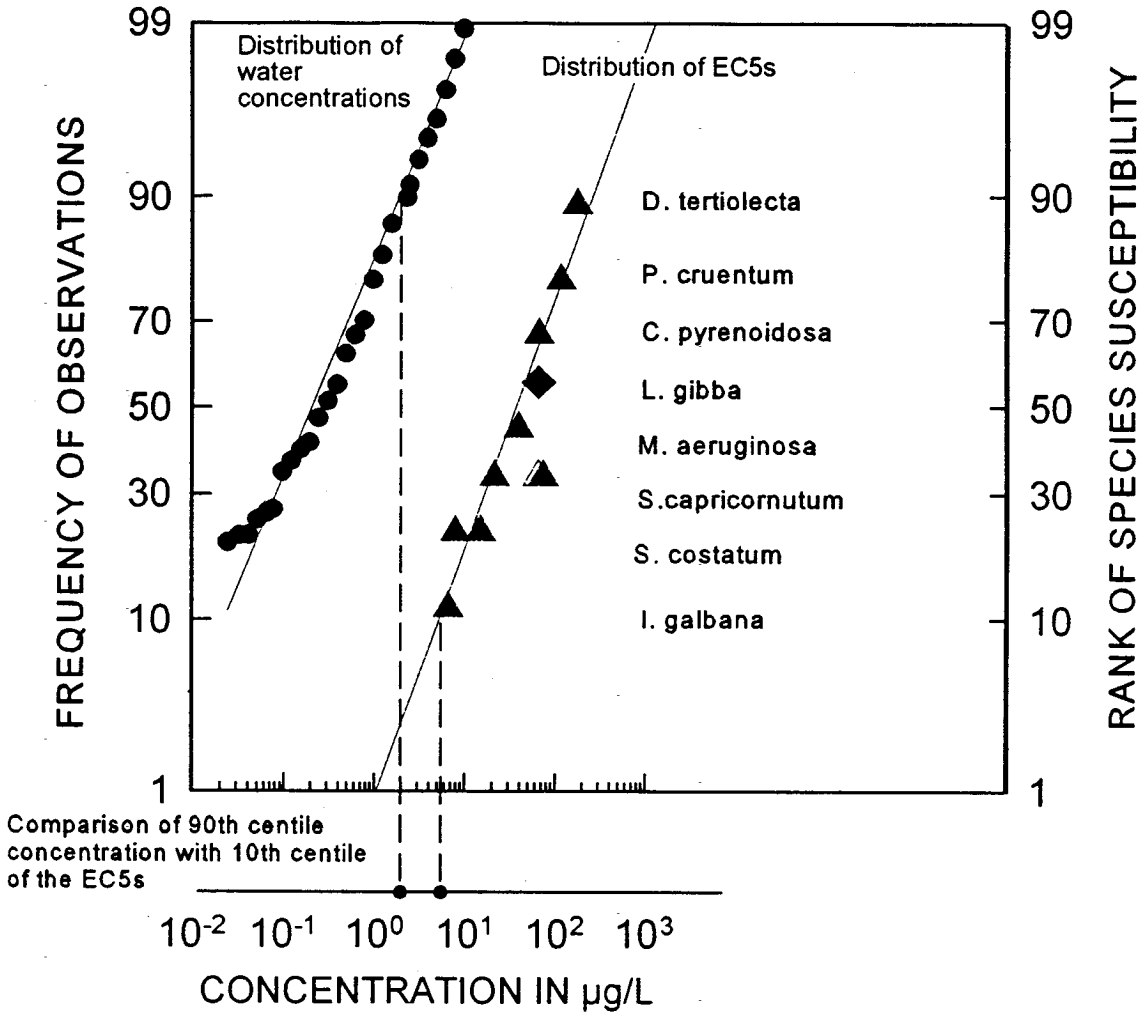

Figure 5-5. Risk estimation techniques: comparison of exposure distribution of an herbicide in surface waters with freshwater single-species toxicity data. See Text note 5-4 for further discussion. Redrawn from SETAC, 1994a.

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5.1.5. Estimates Based on Process Models

Process models are mathematical expressions that represent our understanding of the mechanistic operation of a system under evaluation. They can be useful tools both in the analysis phase (see section 4.1.2.) and the risk characterization phase of ecological risk assessment. For illustrative purposes, we distinguish between process models used for risk estimation that integrate exposure and effects information (text note 5–5) and process models used in the analysis phase that focus on either exposure or effects evaluations.

A major advantage of using process models for risk estimation is the ability to consider ''what if'' scenarios and to forecast beyond the limits of observed data that constrain risk estimation techniques based on empirical data. The process model can also consider secondary effects, unlike other risk estimation techniques such as the quotient method or comparisons of exposure and effect distributions. In addition, some process models may be capable of forecasting the combined effects of multiple stressors (e.g., Barnthouse et al., 1990).

Process model outputs may be point estimates or distributions. In either case, risk assessors should interpret these outputs with care. Process model outputs may imply a higher level of certainty than is appropriate and all too often are viewed without sufficient attention to underlying assumptions. The lack of knowledge on basic life histories for many species and incomplete knowledge on the structure and function of a particular ecosystem is often lost in the model output. Since process models are only as good as the assumptions on which they are based, they should be treated as hypothetical representations of reality until appropriately tested with empirical data. Comparing model results to field data provides a check on whether our understanding of the system was correct (Johnson, 1995) with respect to the risk hypotheses presented in problem formulation.

5.1.6. Field Observational Studies

Field observational studies (surveys) can serve as risk estimation techniques because they provide direct evidence linking exposure to stressors and effects. Field surveys measure biological changes in uncontrolled situations through collection of exposure and effects data at sites identified in problem formulation. A key issue with field surveys is establishing causal relationships between stressors and effects (section 4.3.1.2).

A major advantage of field surveys is that they provide a reality check on other risk estimates, since field surveys are usually more representative of both exposures and effects (including secondary effects) found in natural systems than are estimates generated from laboratory studies or theoretical models (text note 5–6). On the other hand, field data may not constitute reality if they are flawed due to poor experimental design, biased in sampling or analytical techniques, or fail to measure critical components of the system or random variations (Johnson, 1995). A lack of observed effects in a field survey may occur because the measurements are insufficiently sensitive to detect ecological effects, and, unless causal relationships are carefully examined, effects that are observed may be caused by factors unrelated to the stressor(s) of concern. Finally, field surveys taken at one point in time are usually not predictive; they describe effects associated with only one scenario (i.e., the one that exists).

5.2. Risk Description

After risks have been estimated, risk assessors need to integrate and interpret the available information into conclusions about risks to the assessment endpoints. In some cases, risk assessors may have quantified the relationship between assessment endpoints and measures of effect in the analysis stage (section 4.3.1.3). In other situations, qualitative links to assessment endpoints are part of the risk description. For example, if the assessment endpoints are survival of fish, aquatic invertebrates, and algae, risks may be estimated using a quotient method based on LC_{50c}. Regardless of the risk estimation technique, the technical narrative supporting the estimates is as important as the risk estimates themselves.

Risk descriptions include an evaluation of the lines of evidence supporting or refuting the risk estimate(s) and an interpretation of the adverse effects on the assessment endpoint.

5.2.1. Lines of Evidence

Confidence in the conclusions of a risk assessment may be increased by using several lines of evidence to interpret and compare risk estimates. These lines of evidence may be derived from different sources or by different techniques relevant to adverse effects on the assessment endpoints, such as quotient estimates, modeling results, field experiments, or field observations. (Note that the term ''weight of evidence'' is sometimes used in legal discussions or in other documents, e.g., Urban and Cook, 1986; Menzie et al., 1996. We use the phrase lines of evidence to emphasize that both qualitative evaluation and quantitative weightings may be used.)

Some of the factors that the risk assessor should consider when evaluating separate lines of evidence are:

- The relevance of evidence to the assessment endpoints
- The relevance of evidence to the conceptual model
- The sufficiency and quality of data and experimental designs used in key studies
- The strength of cause/effect relationships
- The relative uncertainties of each line of evidence and their direction.

This process involves more than just listing the factors that support or refute the risk. The risk assessor should carefully examine each factor and evaluate its contribution to the risk assessment.

For example, consider the two lines of evidence described for the carbofuran example (text notes 5–2 and 5–6): quotients and field studies. Both approaches are relevant to the assessment endpoint (survival of birds that forage in agricultural areas where carbofuran is applied), and both are relevant to the exposure scenarios described in the conceptual model (figure 3–2). However, the quotients are limited in their ability to express incremental risks (e.g., how much greater risk is expressed by a quotient of ''2'' versus a quotient of ''4''), while the field studies had some design flaws (text note 5–6). Nevertheless, because of the great preponderance of the data, the strong evidence of causal relationships from the field studies, and the consistency between these two lines of evidence, confidence in a conclusion of high risk to the assessment endpoint is supported.

Sometimes lines of evidence do not point toward the same conclusion. When they disagree, it is important to distinguish between true inconsistencies and those related to differences in statistical powers of detection. For example, a model may predict adverse effects that were not observed in a field survey. The risk assessor should ask whether the experimental design of the field study had sufficient power to detect the predicted difference or whether the endpoints measured were comparable with those used in the model.

Conversely, the model may have been unrealistic in its predictions. While it may be possible to use numerical weighting techniques for evaluating various lines of evidence, in most cases qualitative evaluations based on professional judgment are appropriate for sorting through conflicting lines of evidence. While iteration of the risk assessment process and collection of additional data may help resolve uncertainties, this option is not always available.

5.2.2. Determining Ecological Adversity

At this point in risk characterization, the changes expected in the assessment endpoints have been estimated and described. The next step is to interpret whether these changes are considered adverse. Adverse changes are those of concern ecologically or socially (section 1). Determining adversity is not always an easy task and frequently depends on the best professional judgment of the risk assessor.

Five criteria are proposed for evaluating adverse changes in assessment endpoints:

- Nature of effects.
- Intensity of effects.
- Spatial scale.
- Temporal scale.
- Potential for recovery.

The extent to which the five criteria are evaluated depends on the scope and complexity of the ecological risk assessment. However, understanding the underlying assumptions and science policy judgments is important even in simple cases. For example, when exceedance of a previously established decision rule such as a benchmark stressor level is used as evidence of adversity (e.g., see Urban and Cook, 1986, or Nabholz, 1991), the reasons why exceedences of the benchmark are considered adverse should be clearly understood.

To distinguish ecological changes that are adverse from those ecological events that are within the normal pattern of ecosystem variability or result in little or no significant alteration of biota, it is important to consider the nature and intensity of effects. For example, for an assessment endpoint involving survival, growth, and reproduction of a species, do predicted effects involve survival and reproduction or only growth? If survival of offspring will be affected, by what percentage will it diminish?

It is important for risk assessors to consider both the ecological and statistical contexts of an effect when evaluating intensity. For example, a statistically significant 1% decrease in fish growth (text note 5–7) may not be relevant to an assessment endpoint of fish population viability, and a 10% decline in reproduction may be worse for a population of slowly reproducing trees than for rapidly reproducing planktonic algae.

Natural ecosystem variation can make it very difficult to observe (detect) stressor-related perturbations. For example, natural fluctuations in marine fish populations are often large, with intra- and interannual variability in population levels covering several orders of magnitude. Furthermore, cyclic events (e.g., bird migration, tides) are very important in natural systems. Predicting the effects of anthropogenic stressors against this background of variation can be very difficult. Thus, a lack of statistically significant effects in a field study does not automatically mean that adverse ecological effects are absent. Rather, risk assessors must consider factors such as statistical power to detect differences, natural variability, and other lines of evidence in reaching their conclusions.

Spatial and temporal scales need to be considered in assessing the adversity of the effects. The spatial dimension encompasses both the extent and pattern of effect as well as the context of the effect within the landscape. Factors to consider include the absolute area affected, the extent of critical habitats affected compared with a larger area of interest, and the role or use of the affected area within the landscape.

Adverse effects to assessment endpoints vary with the absolute area of the effect. A larger affected area may be (1) subject to a greater number of other stressors, increasing the complications from stressor interactions; (2) more likely to contain sensitive species or habitats; or (3) more susceptible to landscape-level changes because many ecosystems may be altered by the stressors.

Nevertheless, a smaller area of effect is not always associated with lower risk. The function of an area within the landscape may be more important than the absolute area. Destruction of small but unique areas, such as critical wetlands, may have important effects on local wildlife populations. Also, in river systems, both riffle and pool areas provide important microhabitats that maintain the structure and function of the total river ecosystem. Stressors acting on some of these microhabitats may present a significant risk to the entire system.

Spatial factors are important for many species because of the linkages between ecological landscapes and population dynamics. Linkages between one or more landscapes can provide refugia for affected populations, and species may require adequate corridors between habitat patches for successful migration.

The temporal scale for ecosystems can vary from seconds (photosynthesis, prokaryotic reproduction) to centuries (global climate change). Changes within a forest ecosystem can occur gradually over decades or centuries and may be affected by slowly changing external factors such as climate. When interpreting ecological adversity, risk assessors should recognize that the time scale of stressor-induced changes operates within the context of multiple natural time scales. In addition, temporal responses for ecosystems may involve intrinsic time lags, so that responses from a stressor may be delayed. Thus, it is important to distinguish the long-term impacts of a stressor from the immediately visible effects. For example, visible changes resulting from eutrophication of aquatic systems (turbidity, excessive macrophyte growth, population decline) may not become evident for many years after initial increases in nutrient levels.

Considering the temporal scale of adverse effects leads logically to a consideration of recovery. Recovery is the rate and extent of return of a population or community to a condition that existed before the introduction of a stressor. (While this discussion deals with recovery as a result of natural processes, risk mitigation options may include restoration activities to facilitate or speed up the recovery process.) Because ecosystems are dynamic and even under natural conditions are constantly changing in response to changes in the physical environment (weather, natural catastrophes, etc.) or other factors, it is unrealistic to expect that a system will remain static at some level or return to exactly the same state that it was before it was disturbed (Landis et al., 1993). Thus, the attributes of a ''recovered'' system must be carefully defined. Examples might include productivity declines in an eutrophic system, reestablishment of a species at a particular density, species recolonization of a damaged habitat, or the restoration of health of diseased organisms.

Recovery can be evaluated in spite of the difficulty in predicting events in ecological systems (e.g., Niemi et al., 1990). For example, it is possible to distinguish changes that are usually reversible (e.g., recovery of a stream from sewage effluent discharge), frequently irreversible (e.g., establishment of introduced species), and always irreversible (e.g., species extinction). It is important for risk assessors to consider whether significant structural or functional

changes have occurred in a system that might render changes irreversible. For example, physical alterations such as deforestation in the coastal hills of Venezuela in recent history and Britain in the Neolithic period changed soil structure and seed sources such that forests cannot easily grow again (Fisher and Woodmansee, 1994).

Risk assessors should note natural disturbance patterns when evaluating the likelihood of recovery from anthropogenic stressors. Ecosystems that have been subjected to repeated natural disturbances may be more vulnerable to anthropogenic stressors (e.g., overfishing, logging of old-growth forest). Alternatively, if an ecosystem has become adapted to a disturbance pattern, it may be affected when the disturbance is removed (fire-maintained grasslands). The lack of natural analogues make it difficult to predict recovery from novel anthropogenic stressors (e.g., synthetic chemicals).

The relative rate of recovery can also be estimated. For example, fish populations in a stream are likely to recover much faster from exposure to a degradable chemical than from habitat alterations resulting from stream channelization. Risk assessors can use knowledge of factors such as the temporal scales of organisms' life histories, the availability of adequate stock for recruitment, and the interspecific and trophic dynamics of the populations in evaluating the relative rates of recovery. A fisheries stock or forest might recover in several decades, a benthic infaunal community in years, and a planktonic community in weeks to months.

Appendix E illustrates how the criteria for ecological adversity (nature and intensity of effects, spatial and temporal scales, and recovery) might be used in evaluating two cleanup options for a marine oil spill. This example also shows that recovery of a system depends not only on how quickly a stressor is removed but also on how any cleanup efforts affect the recovery.

5.3. Reporting Risks

When risk characterization is complete, the risk assessors should be able to estimate ecological risks, indicate the overall degree of confidence in the risk estimates, cite lines of evidence supporting the risk estimates, and interpret the adversity of ecological effects. Usually this information is included in a risk assessment report (sometimes referred to as a risk characterization report because of the integrative nature of risk characterization). This section describes elements that risk assessors should consider when preparing a risk assessment report.

Like the risk assessment itself, a risk assessment report may be brief or extensive depending on the nature of and the resources available for the assessment. While it is important to address the elements described below, risk assessors must judge the appropriate level of detail required. The report need not be overly complex or lengthy, depending on the nature of the risk assessment and the information required to support a risk management decision. In fact, it is important that information be presented clearly and concisely.

While the breadth of ecological risk assessment precludes providing a detailed outline of reporting elements, the risk assessor should consider the elements listed in text note 5–8 when preparing a risk assessment report.

To facilitate mutual understanding, it is critical that the risk assessment results are properly presented. Agency policy requires that risk characterizations be prepared ''in a manner that is clear, transparent, reasonable, and consistent with other risk characterizations of similar scope prepared across programs in the Agency'' (U.S. EPA 1995c). Ways to achieve such characteristics are described in text note 5–9.

After the risk assessment report is prepared, the results are discussed with risk managers. Section 6 provides information on communication between risk assessors and risk managers, describes the use of the risk assessment in a risk management context, and briefly discusses communication of risk assessment results from risk managers to the public.

6. Relating Ecological Information to Risk Management Decisions

After characterizing risks and preparing a risk assessment report (section 5), risk assessors discuss the results with risk managers (figure 5–1). Risk managers use risk assessment results along with other factors (e.g., economic or legal concerns) in making environmental decisions. The results also provide a basis for communicating risks to the public.

Mutual understanding between risk assessors and risk managers can be facilitated if the questions listed in text note 6–1 are addressed. Risk managers need to know what the major risks (or potential risks) are with respect to assessment endpoints and have an idea of whether the conclusions are supported by a large body of data or if there are significant data gaps. When there is insufficient information to characterize risk at an appropriate level of detail due to a lack of resources, a lack of a consensus on how to interpret information, or other reasons, the issues, obstacles, and correctable deficiencies should be clearly articulated for the risk manager's consideration.

In making a decision regarding ecological risks, risk managers use risk assessment results along with other information that may include social, economic, political, or legal issues. For example, the risk assessment may be used as part of a risk/benefit analysis, which may require translating resources (identified through the assessment endpoints) into monetary values. One difficulty with this approach is that traditional economic considerations may not adequately address things that are not considered commodities, intergenerational resource values or issues of long-term or irreversible effects (U.S. EPA, 1995b). Risk managers may also consider risk mitigation options or alternative strategies for reducing risks. For example, risk mitigation techniques such as buffer strips or lower field application rates can be used to reduce the exposure (and risk) of a new pesticide. Further, risk managers may consider relative as well as absolute risk, for example, by comparing the risk of a new pesticide to other pesticides currently in use. Finally, risk managers consider public opinion and political demands in their decisions. Taken together, these other factors may render very high risks acceptable or very low risks unacceptable.

Risk characterization provides the basis for communicating ecological risks to the public. This task is usually the responsibility of risk managers. Although the final risk assessment document (including its risk characterization sections) can be made available to the public, the risk communication process is best served by tailoring information to a particular audience. It is important to clearly describe the ecological resources at risk, their value, and the monetary and other costs of protecting (and failing to protect) the resources (U.S. EPA, 1995b).

Managers should clearly describe the sources and causes of risks, the potential adversity of the risks (e.g., nature and intensity, spatial and temporal scale, and recovery potential). The degree of confidence in the risk assessment, the rationale for the risk management decision, and the options for reducing risk are also important (U.S. EPA, 1995b). Other risk communication considerations are provided in text note 6–2.

Along with the discussions of risk and communications with the public, it is

important for risk managers to consider whether additional follow-on activities are required. Depending on the importance of the assessment, confidence level in the assessment results, and available resources, it may be advisable to conduct another iteration of the risk assessment (starting with problem formulation or analysis) in order to facilitate a final management decision. Another option is to proceed with the decision and develop a monitoring plan to evaluate the results of the decision (see section 1). For example, if the decision was to mitigate risks through exposure reduction, monitoring could help determine whether the desired reduction in exposure (and effects) was achieved.

7. Text Notes

Text Note 1–1. Related Terminology

The following terms overlap to varying degrees with the broad concept of ecological risk assessment used in these guidelines (see Appendix B for definitions):

- Hazard assessment.
- Comparative risk assessment.
- Cumulative ecological risk assessment.
- Environmental impact statement.

Text Note 1–2. Flexibility of the Framework Diagram

The framework process (figure 1–1) is a general representation of a complex and varied group of assessments, but this diagram should not be viewed as rigid and prescriptive. Rather, as illustrated by the examples below, broad applicability of the framework requires a flexible interpretation of the process.

- In problem formulation, an assessment may begin with a consideration of endpoints, stressors, or ecological effects. Problem formulation is frequently interactive and iterative rather than linear.
- In the analysis phase, it may be difficult to maintain a clear distinction between exposure and effects analyses in all but the simplest systems. Exposure and effects frequently become intertwined, as when an initial exposure leads to a cascade of additional exposures and effects. It is important that a risk assessment is based on an understanding of these complex relationships.
- Analysis and risk characterization are shown as separate phases. However, some models may combine the analysis of exposure and effects data with the integration of these data that occurs in risk characterization.

Text Note 1–3. The Iterative Nature of Ecological Risk Assessment

The ecological risk assessment process is by nature iterative. For example, it may take more than one pass through problem formulation to complete planning for the risk assessment, or information gathered in the analysis phase may suggest further problem formulation activities such as modification of the endpoints selected.

To maximize efficient use of limited resources, ecological risk assessments are frequently designed in sequential tiers that proceed from simple, relatively inexpensive evaluations to more costly and complex assessments. Initial tiers are based on conservative assumptions, such as maximum exposure and ecological sensitivity. When an early tier cannot define risk to support a management decision, a higher assessment tier is used that may require either additional data or applying more refined analysis techniques to available data. Iterations proceed until sufficient information is available to support a sound management decision, within the constraints of available resources.

Because a tiered approach can incorporate standardized decision points and supporting analyses, it can be particularly useful for multiple assessments of similar stressors or situations. However, it is difficult to generalize further concerning tiered risk assessments because they are used to answer so many different questions. Examples of organizations that use, are considering, or have advocated using tiered ecological risk assessments include the Canadian government (proposed, Gaudet, 1994), the European Community (E.C., 1993), industry (Cowan et al., 1995), the Aquatic Dialogue Group (SETAC 1994a), and the U.S. EPA Offices of Pesticide Programs (Urban and Cook, 1986), Pollution Prevention and Toxics (Lynch et al., 1994), and Superfund (document in preparation).

Text Note 2–1. Who Are Risk Managers?

Risk managers are individuals and organizations that take responsibility for, or have the authority to take action or require action, to mitigate an identified risk. The expression ''risk manager'' is often used to represent a decisionmaker in agencies like EPA or state environmental offices who has the authority to protect or manage a resource. However, risk managers often represent a diverse group of interested parties that influence the outcome of resource protection efforts. Particularly as the scope of environmental management expands to communities, the meaning of risk manager significantly expands to include decision officials in Federal, state, and local governments, as well as private-sector leaders in commercial, industrial, and private organizations. Risk managers may also include constituency groups, other interested parties, and the public. In situations where a complex of ecosystem values (e.g., watershed resources) is at risk from multiple stressors, many of these groups may act together as risk management teams. For additional insights on risk management and manager roles, see text notes 2–3 and 2–4.

Text Note 2–2. Who Are Risk Assessors?

Risk assessors are a diverse group of professionals who bring a needed expertise to a risk assessment. When a specific risk assessment process is well defined through regulations and guidance, one trained individual may be able to complete a risk assessment if needed information is available (e.g., premanufacture notice of a chemical). However, as more complex risk assessments become common, it will be rare that one individual can provide the necessary breadth of expertise. Every risk assessment team should include at least one professional who is knowledgeable and experienced in using the risk assessment process. Other team members bring specific expertise relevant to the location, the stressors, the ecosystem, and the scientific issues and other expertise as determined by the type of assessment.

Text Note 2–3. Questions Addressed by Risk Managers and Risk Assessors

Questions Principally for Risk Managers:

What is the nature of the problem and the best scale for the assessment?

What are the management goals and decisions needed, and how will risk assessment help?

What are the ecological values of concern?

What are the policy considerations (law, corporate stewardship, societal concerns, environmental justice)?

What precedents are set by previous risk assessments and decisions?

What is the context of the assessment (e.g., industrial, national park)?

What resources (e.g., personnel, time, money) are available?

What level of uncertainty is acceptable?

Questions Principally for Risk Assessors

What is the scale of the risk assessment?

What are the critical ecological endpoints and ecosystem and receptor characteristics?

How likely is recovery and how long will it take?

What is the nature of the problem: past, present, future?

What is our state of knowledge on the problem?

What data and data analyses are available and appropriate?

What are the potential constraints (e.g., limits on expertise, time, availability of methods and data)?

Text Note 2–4. The Role of Interested Parties

The involvement of all interested and affected parties, which ''stakeholder'' is commonly used to represent, is important to the development of management goals for some risk assessments. The greater the involvement, the broader the base of consensus about those goals. With strong consensus on management goals, decisions are more likely to be supported by all community groups during implementation of management plans. However, the context of this involvement can vary widely, and the ability to achieve consensus often decreases as the size of the management team increases. Where large diverse groups need to come to consensus, social science professionals and methods for consensus building become increasingly important. Interested parties become risk managers when they influence risk reduction. See additional discussion in text note 2–1 and section 2.2.

Text Note 2–5. Sustainability as a Management Goal

Sustainability is used repeatedly as a management goal in a variety of settings (see U.S. EPA, 1995b). To sustain is to prolong, to hold up under, or endure (Merriam-Webster, 1972). Sustainability and other concepts such as biotic or community integrity are very useful as guiding principles for management goals. However, in each case these principles must be explicitly interpreted to support a risk assessment. To do this, key questions need to be addressed: What does sustainability or integrity mean for the particular ecosystem? What must be protected to meet sustainable goals or system integrity? Which ecological resources and processes are to be sustained and why? How will we know we have achieved it? Answers to these questions serve to clarify the goals for a particular ecosystem. Concepts like sustainability and integrity do not meet the criteria for an assessment endpoint (see section 3.3.2).

Text Note 2–6. Management Goals for Waquoit Bay

Waquoit Bay is a small estuary on Cape Cod showing signs of degradation, including loss of eelgrass, fish, and shellfish and increasing macroalgae mats and fish kills. The management goal for Waquoit Bay was established through public meetings, preexisting goals from local organizations, and state and Federal regulations:

Reestablish and maintain water quality and habitat conditions in Waquoit Bay and associated freshwater rivers and ponds to (1) support diverse self-sustaining commercial, recreational, and native fish and shell fish populations, and (2) reverse ongoing degradation of ecological resources in the watershed.

To define this goal, it was interpreted into 10 objectives, two of which are:

- Reestablish a self-sustaining scallop population in the bay that can support a viable sport fishery.
- Reduce or eliminate nuisance macroalgal growth.

From these objectives, specific ecological resources in the bay were identified to provide the basis for the risk assessment, one of which is:

Areal extent and patch size of eelgrass beds.

Eelgrass was selected because scallops are dependent directly on eelgrass beds for survival and eelgrass is highly sensitive to excess macroalgal growth.

Text Note 2–7. Questions to Ask About Scope and Complexity

Is this risk assessment legally mandated, addressing a court-ordered decision, or providing guidance to a community?

Are decisions more likely based on assessments of a small area evaluated in-depth or a large-scale area in less detail?

What are the spatial and temporal boundaries of the problem?

What kinds of information are already available compared to what is needed?

How much time can be taken and how many resources are available?

What practicalities constrain data collection?

Is a tiered approach an option?

Text Note 3–1. Avoiding Potential Shortcomings Through Problem Formulation

The importance of problem formulation has been shown repeatedly in the Agency's analysis of ecological risk assessment case studies and in interactions with senior EPA managers and regional risk assessors (U.S. EPA, 1993a, 1994a). Consistent shortcomings identified in the case studies include (1) absence of clearly defined goals, (2) endpoints that are ambiguous and difficult to define and measure, and (3) failure to identify important risks. These and other shortcomings can be avoided through rigorous development of the products of problem formulation as described in this section of the guidelines.

Text Note 3–2. Uncertainty in Problem Formulation

In each product of problem formulation there are elements of uncertainty, a consideration of what is known and not known about a problem and its setting. The explicit treatment of uncertainty during problem formulation is particularly important because it will have repercussions throughout the remainder of the assessment. Uncertainty is discussed in section 3.4, Conceptual Models, because uncertainty in problem formulation is articulated in these models.

Text Note 3–3. Assessing Available Information: Questions to Ask Concerning Source, Stressor, and Exposure Characteristics, Ecosystem Characteristics, and Effects

Source and Stressor Characteristics

- What is the source? Is it anthropogenic, natural, point source, or diffuse nonpoint?
- What type of stressor is it: chemical, physical, or biological?
- What is the intensity of the stressor (e.g., the dose or concentration of a chemical, the magnitude or extent of physical disruption, the density or population size of a biological stressor)?
- What is the mode of action? How does the stressor act on organisms or ecosystem functions?

Exposure Characteristics

- With what frequency does a stressor event occur (e.g., is it isolated, episodic, or continuous; is it subject to natural daily, seasonal, or annual periodicity)?
- What is its duration? How long does it persist in the environment (e.g., for chemical, what is its half-life, does it bioaccumulate; for physical, is habitat alteration sufficient to prevent recovery; for biological, will it reproduce and proliferate)?
- What is the timing of exposure? When does it occur in relation to critical organism life cycles or ecosystem events (e.g., reproduction, lake overturn)?
- What is the spatial scale of exposure? Is the extent or influence of the stressor local, regional, global, habitat-specific, or ecosystemwide?

- What is the distribution? How does the stressor move through the environment (e.g., for chemical, fate and transport; for physical, movement of physical structures; for biological, life history dispersal characteristics)?

Ecosystems Potentially at Risk

- What are the geographic boundaries? How do they relate to functional characteristics of the ecosystem?
- What are the key abiotic factors influencing the ecosystem (e.g., climatic factors, geology, hydrology, soil type, water quality)?
- Where and how are functional characteristics driving the ecosystem (e.g., energy source and processing, nutrient cycling)?
- What are the structural characteristics of the ecosystem (e.g., species number and abundance, trophic relationships)?
- What habitat types are present?
- How do these characteristics influence the susceptibility (sensitivity and likelihood of exposure) of the ecosystem to the stressor(s)?
- Are there unique features that are particularly valued (e.g., the last representative of an ecosystem type)?
- What is the landscape context within which the ecosystem occurs?

Ecological Effects

- What are the type and extent of available ecological effects information (e.g., field surveys, laboratory tests, or structure-activity relationships)?
- Given the nature of the stressor (if known), which effects are expected to be elicited by the stressor?
- Under what circumstances will effects occur?

Text Note 3–4. Initiating a Risk Assessment: What's Different When Stressors, Effects, or Values Drive the Process?

The reasons for initiating a risk assessment also influence how the risk assessor proceeds through the process of problem formulation. When the assessment is initiated due to concerns about stressors, risk assessors use what is known about the characteristics of the stressor and its source to focus the assessment. Goals are articulated based on how the stressor is likely to cause risk to possible receptors that may become exposed. This information forms the basis for developing conceptual models and selecting assessment endpoints. When an observed effect is the basis for initiating the assessment, endpoints are normally established first. Often these endpoints involve affected ecological entities and their response. Goals for protecting the assessment endpoints are then established, which support the development of conceptual models. The models aid in the identification of the most likely stressor(s). Value-initiated risk assessments are driven up front by goals for the ecological value of concern. These values might involve ecological entities such as species, communities, ecosystems, or places. Based on these goals, assessment endpoints are selected first to serve as an interpretation of the goals. Once selected, the endpoints provide the basis for identifying an array of stressors that may be influencing them, and describing the diversity of potential effects. This information is then captured in the conceptual model(s).

Text Note 3–5. Salmon and Hydropower: Salmon as the Basis for an Assessment Endpoint

A hydroelectric dam is to be built on a river in the Pacific Northwest where anadromous fish such as salmon spawn. Assessment endpoints must be selected to assess potential ecological risk. Of the anadromous fish, salmon that spawn in the river are an appropriate choice because they meet the criteria for good assessment endpoints. Salmon fry and adults are important food sources for a multitude of aquatic and terrestrial species and are major predators of aquatic invertebrates (ecological relevance). Salmon are sensitive to changes in sedimentation and substrate pebble size, require quality cold water habitats, and have difficulty climbing fish ladders. Hydroelectric dams represent significant and normally fatal habitat alteration and physical obstacles to successful salmon breeding and fry survival (susceptibility). Finally, salmon support a large commercial fishery, some species are endangered, and they have ceremonial importance and are key food sources for Native Americans (basis for management goals). ''Salmon reproduction and population maintenance'' is a good assessment endpoint for this risk assessment, and if salmon populations are protected, other anadromous fish populations are likely to be protected as well. However, one assessment endpoint can rarely provide the basis for a risk assessment of complex ecosystems. These are better represented by a set of assessment endpoints.

Text Note 3–6. Cascading Adverse Effects: Primary (Direct) and Secondary (Indirect)

The interrelationships among entities and processes in ecosystems result in the potential for cascading effects: as one population, species, process, or other entity in the ecosystem is altered, other entities are affected as well. Primary, or direct, effects occur when a stressor acts directly on the assessment endpoint and causes an adverse response. Secondary, or indirect, effects occur when the response of an ecological entity to a stressor becomes a stressor to another entity. Secondary effects are not limited in number. They often are a series of effects among a diversity of organisms and processes that cascade through the ecosystem. For example, application of an herbicide on a wet meadow results in direct toxicity to plants. Death of the wetland plants leads to secondary effects such as loss of feeding habitat for ducks, breeding habitat for red-winged black birds, alteration of wetland hydrology that changes spawning habitat for fish, and so forth.

Text Note 3–7. Sensitivity and Secondary Effects: The Mussel-Fish Connection

Native freshwater mussels are endangered in many streams. Management efforts have focused on maintaining suitable habitat for mussels because habitat loss has been considered the greatest threat to this group. However, larval unionid mussels must attach to the gills of a fish host for one month during development. Each species of mussel must attach to a particular host species of fish. In situations where the fish community has been changed, perhaps due to stressors to which mussels are insensitive, the host fish may no longer be available. Mussel larvae will die before reaching maturity as a result. Regardless of how well managers restore mussel habitat, mussels will be lost from this system unless the fish community is restored. In this case, exposure to the absence of a critical resource is the source of risk.

TEXT NOTE 3–8.—EXAMPLES OF MANAGEMENT GOALS AND ASSESSMENT ENDPOINTS

Case	Regulatory context/management goal	Assessment endpoint
Assessing Risks of New Chemical Under Toxic Substances Control Act (Lynch et al., 1994).	Protect ''the environment'' from ''an unreasonable risk of injury'' (TSCA § 2[b] [1] and [2]); protect the aquatic environment. Goal was to exceed a concentration of concern by no more than 20 days a year.	Survival, growth, and reproduction of fish, aquatic invertebrates, and algae.
Special Review of Granular Carbofuran Based on Adverse Effects on Birds (Houseknecht, 1993).	Prevent * * * ''unreasonable adverse effects on the environment'' (FIFRA §§ 3[c][5] and 3[c][6]); using cost-benefit considerations. Goal was no regularly repeated bird kills.	Individual bird survival.
Modeling Future Losses of Bottomland Forest Wetlands (Brody et al., 1993).	National Environmental Policy Act may apply to environmental impact of new levee construction; also Clean Water Act § 404.	(1) Forest community structure and habitat value to wildlife species. (2) Species composition of wildlife community.
Pest Risk Assessment on Importation of Logs From Chile (USDA, 1993).	This assessment was done to help provide a basis for any necessary regulation of the importation of timber and timber products into the United States.	Survival and growth of tree species in the western United States.
Baird and McGuire Superfund Site (terrestrial component); (Burmaster et al., 1991; Callahan et al., 1991; Menzie et al., 1992).	Protection of the environment (CERCLA/SARA)	(1) Survival of soil invertebrates. (2) Survival and reproduction of song birds.
Waquoit Bay Estuary Watershed Risk Assessment.	Clean Water Act—wetlands protection; water quality criteria—pesticides; endangered species. National Estuarine Research Reserve, Massachusetts, Area of Critical Environmental Concern. Goal was to reestablish and maintain water quality and habitat conditions to support diverse self-sustaining commercial, recreational, and native fish, water-dependent wildlife, and shellfish, and reverse ongoing degradation.	(1) Estuarine eelgrass habitat abundance and distribution. (2) Estuarine fish species diversity and abundance. (3) Freshwater pond benthic invertebrate species diversity and abundance.

Text Note 3–9. Common Problems in Selecting Assessment Endpoints

- Endpoint is a goal (e.g., maintain and restore endemic populations).
- Endpoint is vague (e.g., estuarine integrity instead of eelgrass abundance and distribution).
- Ecological entity is better as a measure (e.g., measure emergence of midges for endpoint on feeding of fish).
- Ecological entity may not be as sensitive to the stressor (e.g., catfish versus salmon for sedimentation).
- Ecological resource is not exposed to the stressor (e.g., using insectivorous birds for avian risk of pesticide application to seeds).
- Ecological resources are irrelevant to the assessment (e.g., lake fish in salmon stream).
- Value of a species or attributes of an ecosystem are not fully considered (e.g., mussel-fish connection, see text note 3–7).
- Attribute is not sufficiently sensitive for detecting important effects (e.g., survival compared with recruitment for endangered species).

Text Note 3–10. What Are Risk Hypotheses and Why Are They Important?

Risk hypotheses are proposed answers to questions risk assessors have about what responses assessment endpoints (and measures) will show when they are exposed to stressors and how exposure will occur. Risk hypotheses clarify and codify relationships that are posited through the consideration of available data, information from scientific literature, and the best professional judgment by risk assessors developing the conceptual models. This explicit process opens the risk assessment to peer review and evaluation to ensure the scientific validity of the work. Risk hypotheses are not equivalent to statistical testing of null and alternative hypotheses. However, predictions generated from risk hypotheses can be tested in a variety of ways, including standard statistical approaches.

Text Note 3–11. Examples of Risk Hypotheses

Hypotheses include known information that sets the problem in perspective and the proposed relationships that need evaluation.

Stressor-initiated: Chemicals with a high K_{ow} tend to bioaccumulate. Premanufacture notice (PMN) chemical A has a K_{ow} of 5.5 and similar molecular structure as known chemical stressor B. Hypotheses: Based on the K_{ow} of chemical A, the mode of action of chemical B, and the food web of the target ecosystem, when the PMN chemical is released at a specified rate, it will bioaccumulate sufficiently in 5 years to cause developmental problems in wildlife and fish.

Effects-initiated: Bird kills were repeatedly observed in golf courses following the application of the pesticide carbofuran, which is highly toxic. Hypotheses: Birds die when they consume recently applied granulated carbofuran; as the level of application increases, the number of dead birds increases. Exposure occurs when dead and dying birds are consumed by other animals. Birds of prey and scavenger species will die from eating contaminated birds.

Ecological value-initiated: Waquoit Bay, Massachusetts, supports recreational boating and commercial and recreational shellfishing and is a significant nursery for fish. Large mats of macroalgae clog the estuary, most of the eelgrass has died, and scallops are gone. Hypotheses: Nutrient loading from septic systems, air pollution, and lawn fertilizers cause eelgrass loss by shading from algal growth, and direct toxicity from nitrogen compounds. Fish and shellfish populations are decreasing because of loss of eelgrass habitat and periodic hypoxia.

Text Note 3–12. What Are the Benefits of Developing Conceptual Models?

- The process of creating a conceptual model is a powerful learning tool.
- Conceptual models can be improved as knowledge increases.

• Conceptual models highlight what we know and don't know and can be used to plan future work.
• Conceptual models can be a powerful communication tool. They provide an explicit expression of our assumptions and understanding of a system for others to evaluate.
• Conceptual models provide a framework for prediction and are the template for generating more risk hypotheses.

Text Note 3–13. Uncertainty in Problem Formulation

Uncertainties in problem formulation are manifested in the quality of conceptual models. To describe uncertainty:
• Be explicit in defining assessment endpoints; include both entity and measurable attributes.
• Reduce or define variability by carefully defining boundaries for the assessment.
• Be open and explicit about the strengths and limitations of pathways and relationships depicted in the conceptual model.
• Identify and describe rationale for key assumptions made because of lack of knowledge, model simplification, approximation, or extrapolation.
• Describe data limitations.

Text Note 3–14. Examples of Assessment Endpoints and Measures (see also section 3.5.1)

Assessment Endpoint: Coho salmon breeding success and fry survival.

Measures of Effects

• Egg and fry response to low dissolved oxygen.
• Adult behavior in response to obstacles.
• Spawning behavior and egg survival in response to sedimentation.

Measures of Ecosystem and Receptor Characteristics

• Water temperature, water velocity, and physical obstructions.
• Abundance and distribution of suitable breeding substrate.
• Abundance and distribution of suitable food sources for fry.
• Feeding, resting, and reproductive cycles.
• Natural population structure (proportion of different size and age classes).
• Laboratory evaluation of reproduction, growth, and mortality.

Measures of Exposure

• Number and height of hydroelectric dams.
• Toxic chemical concentrations in water, sediment, and fish tissue.
• Nutrient and dissolved oxygen levels in ambient waters.

Text Note 3–15. Selecting What To Measure

Direct measurement of assessment endpoint responses is often not possible. Under these circumstances, the selection of a surrogate response measure is necessary. The selection of what, where, and how to measure determines whether the risk assessment is still relevant to management decisions about an assessment endpoint. For example, a risk assessment may be conducted to evaluate the potential risk of a pesticide used on seeds. Birds and mammals may be selected as the entities for assessment endpoints. However, to ensure that the organisms selected are susceptible to the pesticide, only those that eat seeds should be chosen. While insectivorous birds may serve as a good surrogate measure for determining the sensitivity of birds to the pesticide, they do not address issues of exposure. To evaluate susceptibility, the appropriate assessment endpoints in this case would be seed-eating birds and mammals. Problem formulations based on assessment endpoints that are both sensitive and likely to be exposed to the stressor will be relevant to management concerns. If assessment endpoints are not susceptible, their use in assessing risk can lead to poor management decisions.

Text Note 3–16. How Do Water Quality Criteria Relate to Assessment Endpoints?

Water quality criteria (U.S. EPA, 1986a) have been developed for the protection of aquatic life from chemical stressors. This text note shows how the elements of a water quality criterion correspond to management goals, assessment endpoints, and measures.

Regulatory Goal

• Clean Water Act, § 101: Protection of the chemical, physical, and biological integrity of the Nation's waters.

Program Management Objective

• Protect 99% of individuals in 95% of the species in aquatic communities from acute and chronic effects resulting from exposure to a chemical stressor.

Assessment Endpoints

• Survival of fish, aquatic invertebrate, and algal species under acute exposure.

• Survival, growth, and reproduction of fish, aquatic invertebrate, and algal species under chronic exposure.

Measures of Effect

• Laboratory LC_{50}s for at least eight species meeting certain requirements.
• Chronic NOAELs for at least three species meeting certain requirements.

Measures of Ecosystem and Receptor Characteristics

• Water hardness (for some metals).
• pH.

The water quality criterion is a benchmark level derived from a distributional analysis of single-species toxicity data. It is assumed that the species tested adequately represent the composition and sensitivities of species in a natural community.

Text Note 3–17. Data Quality Objectives (DQO) Process

The DQO process combines elements of both planning and problem formulation in its seven-step format.

Step 1—State the problem. Review existing information to concisely describe the problem to be studied.

Step 2—Identify the decision. Determine what questions the study will try to resolve and what actions may result.

Step 3—Identify inputs to the decision. Identify information and measures needed to resolve the decision statement.

Step 4—Define study boundaries. Specify time and spatial parameters and where and when data should be collected.

Step 5—Develop decision rule. Define statistical parameter, action level, and logical basis for choosing alternatives.

Step 6—Specify tolerable limits on decision errors. Define limits based on the consequences of an incorrect decision.

Step 7—Optimize the design. Generate alternative data collection designs and choose most resource-effective design that meets all DQOs.

Text Note 4–1. Data Collection and the Analysis Phase

Data needs are identified during problem formulation (the analysis plan step), and data are collected before the start of the analysis phase. These data may be collected for the specific purpose of a particular risk assessment, or they may be available from previous studies. If additional data needs are identified as the assessment proceeds, the analysis phase may be temporarily halted while they are collected or the assessor may choose to iterate the problem formulation again. Data collection methods are not described in these guidelines. However, the evaluation of data for the purposes of

risk assessment is discussed in section 4.2.

Text Note 4–2. The American National Standard for Quality Assurance

The Specifications and Guidelines for Quality Systems for Environmental Data Collection and Environmental Technology Programs (ASQC, 1994) recognizes several areas that are important to ensuring that environmental data will meet study objectives, including:

- Planning and scoping.
- Design of data collection operations.
- Implementation and monitoring of planned operations.
- Assessment and verification of data usability.

Text Note 4–3. Questions for Evaluating a Study's Utility for Risk Assessment

How do study objectives compare with those of the risk assessment?

Are the variables and conditions the study represents compared to those important to the risk assessment?

Was the study design adequate to meet its objectives?

Was the study conducted properly?

How were variability and uncertainty treated and reported?

Text Note 4–4. Considering the Degree of Aggregation in Models

Wiegert and Bartell (1994) suggest the following considerations for evaluating the proper degree of aggregation or disaggregation:

(1) Do not aggregate components with greatly disparate rates of fluxes;

(2) Do not greatly increase the disaggregation of the structural aspects of the model without a corresponding increase in the sophistication of the functional relationships and controls; and

(3) Disaggregate models only insofar as required by the goals of the model to facilitate testing.

Text Note 4–5. Questions for Source Description

Where does the stressor originate?

What environmental medium first receives stressors?

Does the source generate other constituents that will influence a stressor's eventual distribution in the environment?

Are there other sources of the same stressor?

Are there background sources?

Is the source still active?

Does the source produce a distinctive signature that can be seen in the environment, organisms or communities?

Additional Questions for Introduction of Biological Stressors

Is there an opportunity for repeated introduction or escape into the new environment?

Will the organism be present on a transportable item?

Are there mitigation requirements or conditions that would kill or impair the organism before entry, during transport, or at the port of entry?

Text Note 4–6. Questions To Ask in Evaluating Stressor Distribution

What are the important transport pathways?

What characteristics of the stressor influence transport?

What characteristics of the ecosystem will influence transport?

What secondary stressors will be formed?

Where will they be transported?

Text Note 4–7. General Mechanisms of Transport and Dispersal

Physical, Chemical and Biological Stressors

- By air current.
- In surface water (rivers, lakes, streams).
- Over and/or through the soil surface.
- Through ground water.

Primarily Chemical Stressors

- Through the food web.

Primarily Biological Stressors

- Splashing or raindrops.
- Human activity (boats, campers).
- Passive transmittal by other organisms.
- Biological vectors.

Text Note 4–8. Questions To Ask in Describing Contact or Co-Occurrence

Must the receptor actually contact the stressor for adverse effects to occur?

Must the stressor be taken up into a receptor for adverse effects to occur?

What characteristics of the receptors will influence the extent of contact or co-occurrence?

Will abiotic characteristics of the environment influence the extent of contact or co-occurrence?

Will ecosystem processes or community-level interactions influence the extent of contact or co-occurrence?

Text Note 4–9. Example of an Exposure Equation: Calculating a Potential Dose via Ingestion

$$ADD_{pot} = \sum_{k=1}^{m} \left(C_k \times FR_k \times NIR_k \right)$$

Where:

ADD_{pot}=Potential average daily dose (e.g., in mg/kg-day)

C_k=Average contaminant concentration in the kth type of food (e.g., in mg/kg wet weight)

FR_k=Fraction of intake of the kth food type that is from the contaminated area (unitless)

NIR_k=Normalized ingestion rate of the kth food type on a wet-weight basis (e.g., in g food/g body-weight-day).

m=Number of contaminated food types

Source: U.S. EPA, 1993c

Text Note 4–10. Measuring Internal Dose Using Biomarkers and Tissue Residues

Biomarkers, tissue residues, or other bioassessment methods may be useful in estimating or confirming exposure in cases where bioavailability is expected to be a significant issue, but the factors influencing it are not known. They can also be very useful when the metabolism and accumulation kinetics are important factors (McCarty and Mackay, 1993). These methods are most useful when they can be quantitatively linked to the amount of stressor originally contacted by the organism. In addition, they are most useful when the stressor-response relationship expresses the amount of stressor in terms of the tissue residues or biomarkers. Additional information and some considerations for their development can be found in Huggett et al. (1992).

Text Note 4–11. Questions Addressed by the Exposure Profile

How does exposure occur?

What is exposed?

How much exposure occurs? When and where does it occur?

How does exposure vary?

How uncertain are the exposure estimates?

What is the likelihood that exposure will occur?

Text Note 4–12. Questions for Stressor-Response Analysis

Does the assessment require point estimates or stressor-response curves?

Does the assessment require the establishment of a ''no-effect'' level?

Would cumulative effects distributions be useful?

Text Note 4–13. Qualitative Stressor-Response Relationships

The relationship between stressor and response can be described qualitatively, for instance, using categories of high, medium, and low, to describe the intensity of response given exposure to a stressor. For example, Pearlstine et al. (1985) assumed that seeds would not

germinate if they were inundated with water at the critical time. This stressor-response relationship was described simply as a yes or no. In most cases, however, the objective is to describe quantitatively the intensity of response associated with exposure, and in the best case, to describe how intensity of response changes with incremental increases in exposure.

Text Note 4–14. Median Effect Levels

Median effects are those effects elicited in 50% of the test organisms exposed to a stressor, typically chemical stressors. Median effect concentrations can be expressed in terms of lethality or mortality and are known as LC_{50} or LD_{50}, depending on whether concentrations (in the diet or in water) or doses (mg/kg) were used. Median effects other than lethality (e.g., effects on growth) are expressed as EC_{50} or ED_{50}. The median effect level is always associated with a time parameter (e.g., 24 or 48 hr). Because these tests seldom exceed 96 hr, their main value lies in evaluating short-term effects of chemicals. Stephan (1977) discusses several statistical methods to estimate the median effect level.

Text Note 4–15. No-Effect Levels Derived From Statistical Hypothesis Testing

Statistical hypothesis tests have typically been used with chronic toxicity tests of chemical stressors that evaluate multiple endpoints. For each endpoint, the objective is to determine the highest test concentration for which effects are not statistically different from the controls (the no observed adverse effect concentration, NOAEC) and the lowest concentration at which effects were statistically significant from the control (the lowest observed adverse effect concentration, LOAEC). The range between the NOAEC and the LOAEC is sometimes called the maximum acceptable toxicant concentration, or MATC. The MATC, which can also be reported as the geometric mean of the NOAEC and the LOAEC, provides a useful reference with which to compare toxicities of various chemical stressors.

Reporting the results of chronic tests in terms of the MATC or GMATC has been widely used within the Agency for evaluating pesticides and industrial chemicals (e.g., Urban and Cook, 1986; Nabholz, 1991).

Text Note 4–16. General Criteria for Causality (Adapted From Fox, 1991)

Criteria strongly affirming causality:

- Strength of association.
- Predictive performance.
- Demonstration of a stressor-response relationship.
- Consistency of association.

Criteria providing a basis for rejecting causality:

- Inconsistency in association.
- Temporal incompatibility.
- Factual implausibility.

Other relevant criteria:

- Specificity of association.
- Theoretical and biological plausibility.

Text Note 4–17. Koch's Postulates (Pelczar and Reid, 1972)

- A pathogen must be consistently found in association with a given disease.
- The pathogen must be isolated from the host and grown in pure culture.
- When inoculated into test animals, the same disease symptoms must be expressed.
- The pathogen must again be isolated from the test organism.

Text Note 4–18. Examples of Extrapolations to Link Measures of Effect to Assessment Endpoints

Every risk assessment has data gaps that must be addressed, but it is not always possible to obtain more information. When there is a lack of time, monetary resources, or a practical means to acquire more data, extrapolations such as those listed below may be the only way to bridge gaps in available data. Extrapolations may be:

- Between taxa (e.g., bluegill to rainbow trout).
- Between responses (e.g., mortality to growth or reproduction).
- From laboratory to field.
- Between geographic areas.
- Between spatial scales.
- From data collected over a short timeframe to longer-term effects.

Text Note 4–19. Questions Related to Selecting Extrapolation Approaches

How specific is the assessment endpoint?

Does the spatial or temporal extent of exposure suggest the need for additional receptors or extrapolation models?

Are the quantity and quality of the data available sufficient for planned extrapolations and models?

Is the proposed extrapolation technique consistent with ecological information?

How much uncertainty is acceptable?

Text Note 4–20. Questions To Consider When Extrapolating From Effects Observed in the Laboratory to Field Effects of Chemicals

Exposure factors:

How will environmental fate and transformation of the chemical effect exposure in the field?

How comparable are exposure conditions and the timing of exposure?

How comparable are the routes of exposure?

How do abiotic factors influence bioavailability and exposure?

How likely are preference or avoidance behaviors?

Effects factors:

What is known about the biotic and abiotic factors controlling populations of the organisms of concern?

To what degree are critical life stage data available?

How may exposure to the same or other stressors in the field have altered organism sensitivity?

Text Note 4–21. Questions Addressed by the Stressor-Response Profile

What ecological entities are affected?

What is the nature of the effect(s)?

What is the intensity of the effect(s)?

Where appropriate, what is the time scale for recovery?

What causal information links the stressor with any observed effects?

How do changes in measures of effects relate to changes in assessment endpoints?

What is the uncertainty associated with the analysis?

Text Note 5–1. Using Qualitative Categories to Estimate Risks of an Introduced Species

The importation of logs from Chile required an assessment of the risks posed by the potential introduction of the bark beetle, Hylurgus ligniperda (USDA, 1993). Experts to judged the potential for colonization and spread of the species, and their opinions were expressed as high, medium, or low as to the likelihood of establishment (exposure) or consequential effects of the beetle. Uncertainties were similarly expressed. A ranking scheme was then used to sum the individual elements into an overall estimate of risk (high, medium, or low). Narrative explanations of risk accompanied the overall rankings.

Text Note 5–2. Applying the Quotient Method

When applying the quotient method to chemical stressors, the effects concentration or dose (e.g., an LC_{50}, LD_{50}, EC_{50}, ED_{50}, NOAEL, or LOAEL) is frequently adjusted by uncertainty modifying factors prior to division into the exposure number (U.S. EPA, 1984; Nabholz, 1991; Urban and Cook, 1986; see section 4.3.1.3), although EPA used a slightly different approach in

estimating the risks to the survival of birds that forage in agricultural areas where the pesticide granular carbofuran is applied (Houseknecht, 1993). In this case, EPA calculated the quotient by dividing the estimated exposure levels of carbofuran granules in surface soils (number/ft^2) by the granules/LD_{50} derived from single-dose avian toxicity tests. The calculation yields values with units of LD_{50}/ft^2. It was assumed that a higher quotient value corresponded to an increased likelihood that a bird would be exposed to lethal levels of granular carbofuran at the soil surface. Minimum and maximum values for LD_{50}/ft^2 were estimated for songbirds, upland game birds, and waterfowl that may forage within or near 10 different agricultural crops.

Text Note 5–3. Comparing an Exposure Distribution With a Point Estimate of Effects

The EPA Office of Pollution Prevention and Toxics uses a Probabilistic Dilution Model (PDM3) to generate a distribution of daily average chemical concentrations based on estimated variations in stream flow in a model system. The PDM3 model compares this exposure distribution with an aquatic toxicity test endpoint to estimate how many days in a 1-year period the endpoint concentration is exceeded (Nabholz et al., 1993; U.S. EPA, 1988b). The frequency of exceedance is based on the duration of the toxicity test used to derive the effects endpoint. Thus, if the endpoint was an acute toxicity level of concern, an exceedance would be identified if the level of concern was exceeded for 4 days or more (not necessarily consecutive). The exposure estimates are conservative in that they assume instantaneous mixing of the chemical in the water column and no losses due to physical, chemical, or biodegradation effects.

Text Note 5–4. Comparing Cumulative Exposure and Effects Distributions for Chemical Stressors

Exposure distributions for chemical stressors can be compared with effects distributions derived from point estimates of acute or chronic toxicity values derived from different species (e.g., HCN, 1993; Cardwell et al., 1993; SETAC, 1994a; Solomon et al., 1996). Figure 5–5 shows a distribution of exposure concentrations of an herbicide compared with single-species algal toxicity data for the same chemical. The degree of overlap of the curves indicates the likelihood that a certain percentage of species may be adversely affected. For example, figure 5–5 indicates that the 10th percentile of algal species' EC_5 values is exceeded less than 10% of the time.

The predictive value of this approach is evident. The degree of risk reduction that could be achieved by changes in exposure associated with proposed risk mitigation options can be readily determined by comparing modified exposure distributions with the effects distribution curve.

When using effects distributions derived from single-species toxicity data, risk assessors should consider the following questions:

- Does the subset of species for which toxicity test data are available represent the range of species present in the environment?
- Are particularly sensitive (or insensitive) groups of organisms represented in the distribution?
- If a criterion level is selected—e.g., protect 95% of species—does the 5% of potentially affected species include organisms of ecological, commercial, or recreational significance?

Text Note 5–5. Estimating Risk With Process Models

Models that integrate both exposure and effects information can be used to estimate risk. During risk estimation, it is important that both the strengths and limitations of a process model approach be highlighted. Brody et al. (1993; see Appendix D) linked two process models to integrate exposure and effects information and forecast spatial and temporal changes in forest communities and their wildlife habitat value. While the models were useful for projecting long-term effects based on an understanding of the underlying mechanisms of change in forest communities and wildlife habitat, they could not evaluate all possible stressors of concern and were limited in the plant and wildlife species they could consider. Understanding both the strengths and limitations of models is essential for accurately representing the overall confidence in the assessment.

Text Note 5–6. An Example of Field Methods Used for Risk Estimation

Along with quotients comparing field measures of exposure with laboratory acute toxicity data (text note 5–2), EPA evaluated the risks of granular carbofuran to birds based on incidents of bird kills following carbofuran applications. Over 40 incidents involving nearly 30 species of birds were documented. Although reviewers identified problems with individual field studies (e.g., lack of appropriate control sites, lack of data on carcass-search efficiencies, no examination of potential synergistic effects of other pesticides, and lack of consideration of other potential receptors such as small mammals), there was so much evidence of mortality associated with carbofuran application that the study deficiencies did not alter the conclusions of high risk found by the assessment (Houseknecht, 1993).

Text Note 5–7. What Are Statistically Significant Effects?

Statistical testing is the ''statistical procedure or decision rule which leads to establishing the truth or falsity of a hypothesis. * * *'' (Alder and Roessler, 1972). Statistical significance is based on the number of data points, the nature of their distribution, whether inter-treatment variance exceeds intra-treatment variance in the data, and the a priori significance level (α). The types of statistical tests and the appropriate protocols (e.g., power of test) for these tests should be established as part of the analysis plan during problem formulation.

Text Note 5–8. Possible Risk Assessment Report Elements

- Describe risk assessor/risk manager planning results.
- Review the conceptual model and the assessment endpoints.
- Discuss the major data sources and analytical procedures used.
- Review the stressor-response and exposure profiles.
- Describe risks to the assessment endpoints, including risk estimates and adversity evaluations.
- Review and summarize major areas of uncertainty (as well as their direction) and the approaches used to address them.

fl Discuss the degree of scientific consensus in key areas of uncertainty.

fl Identify major data gaps and, where appropriate, indicate whether gathering additional data would add significantly to the overall confidence in the assessment results.

fl Discuss science policy judgments or default assumptions used to bridge information gaps, and the basis for these assumptions.

Text Note 5–9. Clear, Transparent, Reasonable, and Consistent Risk Characterizations

For clarity:

- Be brief; avoid jargon.
- Make language and organization understandable to risk managers and the informed lay person.
- Fully discuss and explain unusual issues specific to a particular risk assessment.

For transparency:

• Identify the scientific conclusions separately from policy judgments.

• Clearly articulate major differing viewpoints of scientific judgments.

• Define and explain the risk assessment purpose (e.g., regulatory purpose, policy analysis, priority setting).

• Fully explain assumptions and biases (scientific and policy).

For reasonableness:

• Integrate all components into an overall conclusion of risk that is complete, informative, and useful in decision making.

• Acknowledge uncertainties and assumptions in a forthright manner.

• Describe key data as experimental, state of the art, or generally accepted scientific knowledge.

• Identify reasonable alternatives and conclusions that can be derived from the data.

• Define the level of effort (e.g., quick screen, extensive characterization) along with the reason(s) for selecting this level of effort.

• Explain the status of peer review.

For consistency with other risk characterizations:

• Describe how the risks posed by one set of stressor(s) compare with the risks posed by a similar stressor(s) or similar environmental conditions.

• Indicate how the strengths and limitations of the assessment compare with past assessments.

Text Note 6–1. Questions Regarding Risk Assessment Results (Adapted From U.S. EPA, 1993d)

Questions principally for risk assessors to ask:

• Are the risks sufficiently well defined (and data gaps small enough) to support a risk management decision?

• Was the right problem analyzed?

• Was the problem adequately characterized?

Questions principally for risk managers to ask:

• What effects might occur?

• How adverse are the effects?

• How likely is it that effects will occur?

• When and where do the effects occur?

• How confident are you in the conclusions of the risk assessment?

• What are the critical data gaps, and will information be available in the near future to fill these gaps?

• Are more ecological risk assessment iterations required?

• How could monitoring help evaluate results of the risk management decision?

Text Note 6–2. Risk Communication Considerations for Risk Managers (U.S. EPA, 1995c)

• Plan carefully and evaluate the success of your communication efforts.

• Coordinate and collaborate with other credible sources.

• Accept and involve the public as a legitimate partner.

• Listen to the public's specific concerns.

• Be honest, frank, and open.

• Speak clearly and with compassion.

• Meet the needs of the media.

Text Note A–1. Stressor vs. Agent

Agent has been suggested as an alternative for the term stressor (Suter et al., 1994). Agent is thought to be a more neutral term than stressor, but agent is also associated with certain classes of chemicals (e.g., chemical warfare agents). In addition, agent has the connotation of the entity that is initially released from the source, whereas stressor has the connotation of the entity that causes the response. Agent is used in EPA's Guidelines for Exposure Assessment (U.S. EPA, 1992d) (i.e., with exposure defined as ''contact of a chemical, physical, or biological agent''). These two terms are considered to be nearly synonymous, but stressor is used throughout these guidelines for internal consistency.

Appendix A—Changes From EPA'S Ecological Risk Assessment Framework

EPA has gained much experience with the ecological risk assessment process since the publication of the Framework Report (U.S. EPA, 1992a) and has received many suggestions for modifications of both the process and the terminology. While EPA is not recommending major changes in the overall ecological risk assessment process, proposed modifications are summarized here to assist those who may already be familiar with the Framework Report. Changes in the diagram are discussed first, followed by changes in terminology and definitions.

A.1. Changes in the Framework Diagram

The revised framework diagram is shown in figure 1–2. Within each phase, rectangular boxes are used to designate inputs, hexagon-shaped boxes indicate actions, and circular boxes represent outputs. There have been only minor changes in the wording for the boxes outside of the risk assessment process (planning and communications between risk assessors and risk managers; acquire data, iterate process, monitor results). ''Iterate process'' was added to emphasize the iterative (and frequently tiered) nature of risk assessment.

The new diagram of problem formulation contains several changes. The hexagon encloses information about stressors, sources, and exposures, ecological effects, and the ecosystem at risk to better reflect the importance of integrating this information before selecting assessment endpoints and building conceptual models. The three products of problem formulation are enclosed in circles. Assessment endpoints are shown as a key product that drives conceptual model development. The conceptual model remains a central product of problem formulation. The analysis plan has been added as an explicit product of problem formulation to emphasize the need to plan data evaluation and interpretation before analyses begin. It is in the analysis plan that measures of ecological effects (measurement endpoints) are identified.

In the analysis phase, the left-hand side of figure 1–2 shows the general process of characterization of exposure, and the right-hand side shows the characterization of ecological effects. These two aspects of analysis must closely interact to produce compatible output that can be integrated in risk characterization. The dotted line and hexagon that includes both the exposure and ecological response analyses emphasize this interaction. In addition, the first three boxes in analysis now include the measures of exposure, effects, and ecosystem and receptor characteristics that provide input to the exposure and ecological response analyses.

Experience with the application of risk characterization as outlined in the Framework Report suggests the need for several modifications in this process. Risk estimation entails the integration of exposure and effects estimates along with an analysis of uncertainties. The process of risk estimation outlined in the Framework Report separates integration and uncertainty. The original purpose for this separation was to emphasize the importance of estimating uncertainty. This separation is no longer needed since uncertainty analysis is now explicitly addressed in most risk integration methods.

The description of risk is similar to the process described in the Framework Report. Topics included in the risk description include the lines of evidence that support causality and a determination of the ecological adversity of observed or predicted effects. Considerations for reporting risk assessment results are also described.

A.2. Changes in Definitions and Terminology

Except as noted below, these guidelines retain definitions used in the Framework Report (see Appendix B). Some definitions have been revised, especially those related to endpoints and exposure. Some changes in the classification of uncertainty from the Framework Report are also described in this section. It is likely that these terms will continue to generate considerable discussion among risk assessors.

A.2.1. Endpoint Terminology

The Framework Report uses the assessment and measurement endpoint terminology of Suter (1990) but offers no specific terms for measurements of stressor levels or ecosystem attributes. Experience has shown that stressor measurements are sometimes inappropriately called measurement endpoints; measurement endpoints should be ''* * * measurable responses to a stressor that are related to the valued characteristics chosen as assessment endpoints'' (U.S. EPA, 1992a; Suter, 1990; emphasis added). These guidelines replace measurement endpoint with measure of effect, which is defined as a measurable ecological characteristic that is related to the valued characteristic chosen as the assessment endpoint (Suter, 1990; U.S. EPA, 1992a). (An assessment endpoint is ''an explicit expression of the environmental value to be protected'' [U.S. EPA, 1992a].) Since data other than those required to evaluate responses (i.e., measures of effects) are required for an ecological risk assessment, two additional types of measures are used. Measures of exposure include stressor and source measurements, while measures of ecosystem and receptor characteristics include, for example, habitat measures, soil parameters, water quality conditions, or life history parameters that may be necessary to better characterize exposure or effects. Any of the three types of measures may be actual data (e.g., mortality), summary statistics (e.g., an LC_{50}), or estimated values (e.g., an LC_{50} estimated from a structure-activity relationship).

A.2.2. Exposure Terminology

These guidelines define exposure in a manner that is relevant to any chemical, physical, or biological entity. While the broad concepts are the same, the language and approaches vary depending on whether a chemical, physical, or biological entity is the subject of assessment. Key exposure-related terms and their definitions are:

- Source. A source is an entity or action that releases to the environment or imposes on the environment a chemical, physical, or biological stressor or stressors. Sources may include a waste treatment plant, a pesticide application, a logging operation, introduction of exotic organisms, or a dredging project.
- Stressor. A stressor is any physical, chemical, or biological entity that can induce an adverse response. This term is used broadly to encompass entities that cause primary effects and those primary effects that can cause secondary (i.e., indirect) effects. Stressors may be chemical (e.g., toxics or nutrients), physical (e.g., dams, fishing nets, or suspended sediments), or biological (e.g., exotic or genetically engineered organisms). While risk assessment is concerned with the characterization of adverse responses, under some circumstances a stressor may be neutral or produce effects that are beneficial to certain ecological components (see text note A–1). Primary effects may also become stressors. For example, a change in a bottomland hardwood plant community affected by rising water levels can be thought of as a stressor influencing the wildlife community. Stressors may also be formed through abiotic interactions; for example, the increase in ultraviolet light reaching the earth's surface results from the interaction of the original stressors released (chlorofluorocarbons) with the ecosystem (stratospheric ozone).
- Exposure. As discussed above, these guidelines use the term exposure broadly after the common definition of expose: ''to submit or subject to an action or influence'' (Merriam-Webster, 1972). Used in this way, exposure applies to physical and biological stressors as well as to chemicals (organisms are commonly said to be exposed to radiation, pathogens, or heat). Exposure is also applicable to higher levels of biological organization, such as exposure of a benthic community to dredging, exposure of an owl population to habitat modification, or exposure of a wildlife population to hunting. Although the operational definition of exposure, particularly the units of measure, depends on the stressor and receptor (defined below), the following general definition is applicable: Exposure is the contact or co-occurrence of a stressor with a receptor.
- Receptor. The receptor is the ecological component exposed to the stressor. This term may refer to tissues, organisms, populations, communities, and ecosystems. While either ''ecological component'' (U.S. EPA, 1992a) or ''biological system'' (Cohrssen and Covello, 1989) are alternative terms, ''receptor'' is usually clearer in discussions of exposure where the emphasis is on the stressor-receptor relationship. As discussed below, both disturbance and stress regime have been suggested as alternative terms for exposure. Neither term is used in these guidelines, which instead use exposure as broadly defined above.
- Disturbance. A disturbance is any event or series of events that disrupts ecosystem, community, or population structure and changes resources, substrate availability, or the physical environment (modified slightly from White and Pickett, 1985). Defined in this way, disturbance is clearly a kind of exposure (i.e., an event that subjects a receptor, the disturbed system, to the actions of a stressor). Disturbance may be a useful alternative to stressor specifically for physical stressors that are deletions or modifications (e.g., logging, dredging, flooding).
- Stress Regime. The term stress regime has been used in at least three distinct ways: (1) To characterize exposure to multiple chemicals or to both chemical and nonchemical stressors (more clearly described as multiple exposure, complex exposure, or exposure to mixtures), (2) as a synonym for exposure that is intended to avoid overemphasis on chemical exposures, and (3) to describe the series of interactions of exposures and effects resulting in secondary exposures, secondary effects, and, finally, ultimate effects (also known as risk cascade [Lipton et al., 1993]) or causal chain, pathway, or network (Andrewartha and Birch, 1984). Because of the potential for confusion and the availability of other clearer terms, this term is not used in these guidelines.

A.2.3. Uncertainty Terminology

The Framework Report divided uncertainty into conceptual model formation, information and data, stochasticity, and error. These guidelines discuss uncertainty throughout the process, focusing on the conceptual model (section 3.4.3), the analysis phase (section 4.1.3), and the incorporation of uncertainty in risk estimates (section 5.1). The bulk of the discussion appears in section 4.1.3, where the discussion is organized according to the following sources of uncertainty:

- Unclear communication.
- Descriptive errors.
- Variability.
- Data gaps.
- Uncertainty about a quantity's true value.

• Model structure uncertainty (process models).

• Uncertainty about a model's form (empirical models).

Appendix B.—Key Terms (Adapted From U.S. EPA, 1992a)

Agent—Any physical, chemical, or biological entity that can induce an adverse response (synonymous with stressor).

Assessment endpoint—An explicit expression of the environmental value that is to be protected. An assessment endpoint includes both an ecological entity and specific attributes of that entity. For example, salmon are a valued ecological entity; reproduction and population maintenance of salmon form an assessment endpoint.

Characterization of ecological effects—A portion of the analysis phase of ecological risk assessment that evaluates the ability of a stressor to cause adverse effects under a particular set of circumstances.

Characterization of exposure—A portion of the analysis phase of ecological risk assessment that evaluates the interaction of the stressor with one or more ecological entities. Exposure can be expressed as co-occurrence or contact, depending on the stressor and ecological component involved.

Community—An assemblage of populations of different species within a specified location in space and time.

Comparative risk assessment—A process that generally uses an expert judgment approach to evaluate the relative magnitude of effects and set priorities among a wide range of environmental problems (e.g., U.S. EPA, 1993b). Some applications of this process are similar to the problem formulation portion of an ecological risk assessment in that the outcome may help select topics for further evaluation and help focus limited resources on areas having the greatest risk reduction potential. In other situations, a comparative risk assessment is conducted more like a preliminary risk assessment. For example, EPA's Science Advisory Board used expert judgment and an ecological risk assessment approach to analyze future ecological risk scenarios and risk management alternatives (U.S. EPA, 1995a).

Conceptual model—The conceptual model describes a series of working hypotheses of how the stressor might affect ecological entities. The conceptual model also describes the ecosystem potentially at risk, the relationship between measures of effect and assessment endpoints, and exposure scenarios.

Cumulative distribution function (CDF)—Cumulative distribution functions are particularly useful for describing the likelihood that a variable will fall within different ranges of x. F(x) (i.e., the value of y at x in a CDF plot) is the probability that a variable will have a value less than or equal to x (figure B–1).

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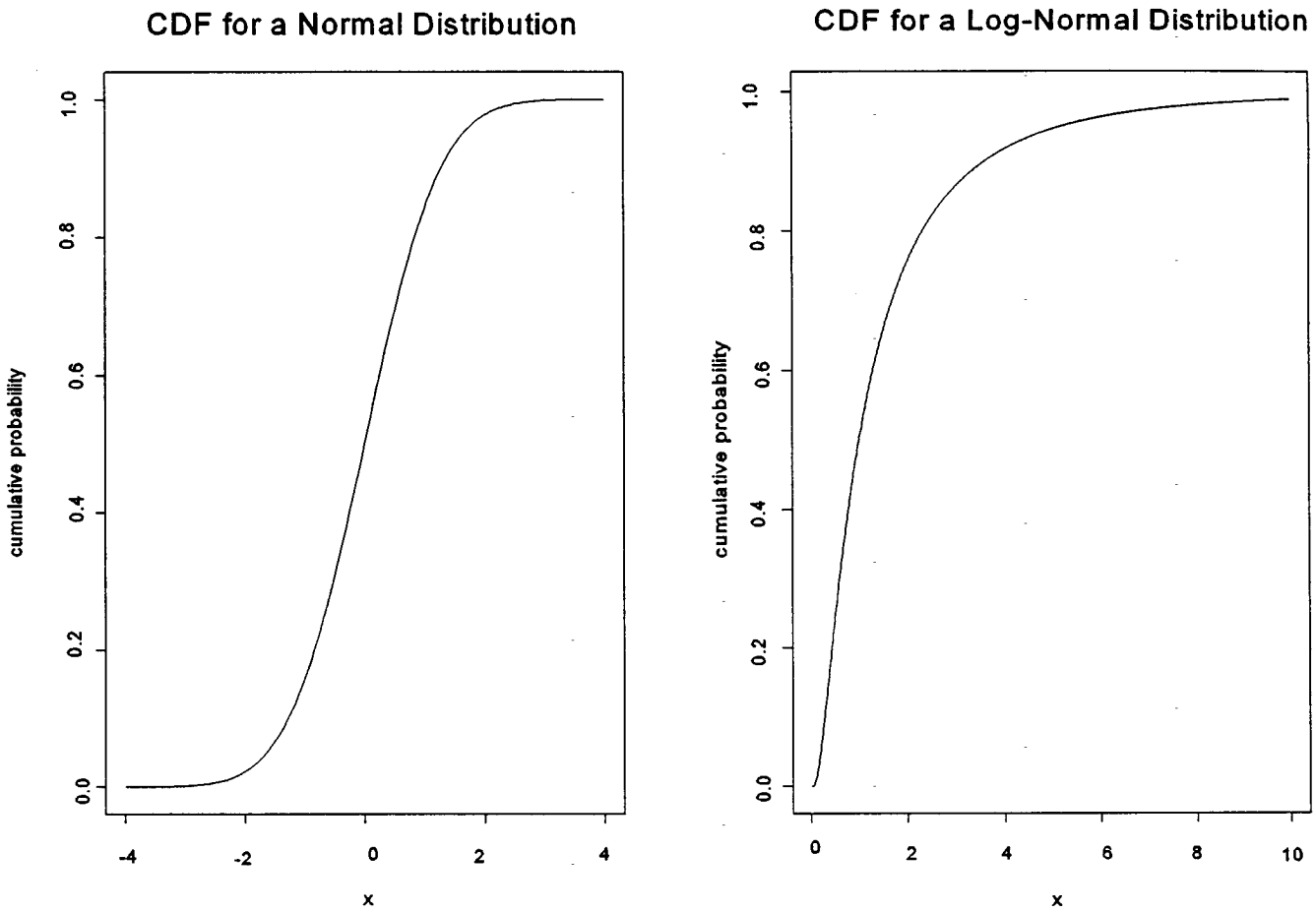

Figure B-1. Plots of Cumulative Distribution Function (CDF)

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Cumulative ecological risk assessment—A process that involves consideration of ''the aggregate ecologic risk to the target entity caused by the accumulation of risk from multiple stressors'' (Bender, 1996).

Disturbance—Any event or series of events that disrupts ecosystem, community, or population structure and changes resources, substrate availability, or the physical environment (modified from White and Pickett, 1985).

Ecological entity—A general term that may refer to a species, a group of species, an ecosystem function or characteristic, or a specific habitat. An ecological entity can be one component of an assessment endpoint.

Ecological risk assessment—The process that evaluates the likelihood that adverse ecological effects may occur or are occurring as a result of exposure to one or more stressors.

Ecosystem—The biotic community and abiotic environment within a specified location in space and time.

Environmental impact statement—Assessments are required under the National Environmental Policy Act (NEPA) to fully evaluate environmental effects associated with proposed major Federal actions. Like ecological risk assessments, environmental impact statements (EIS) typically require a ''scoping process'' analogous to problem formulation, an analysis by multidisciplinary teams, and a presentation of uncertainties (CEQ, 1986, cited in Suter, 1993a). By virtue of special expertise, EPA may cooperate with other agencies by preparing EISs or otherwise participating in the NEPA process.

Exposure—The contact or co-occurrence of a stressor with a receptor.

Exposure profile—The product of characterization of exposure in the analysis phase of ecological risk assessment. The exposure profile summarizes the magnitude and spatial and temporal patterns of exposure for the scenarios described in the conceptual model.

Exposure scenario—A set of assumptions concerning how an exposure may take place, including assumptions about the exposure setting, stressor characteristics, and activities that may lead to exposure.

Hazard assessment—This term has been used to mean either (1) evaluating the intrinsic effects of a stressor (U.S. EPA, 1979) or (2) defining a margin of safety or quotient by comparing a toxicologic effects concentration with an exposure estimate (SETAC, 1987).

Lines of evidence—Information derived from different sources or by different techniques that can be used to interpret and compare risk estimates. While this term is similar to the term ''weight of evidence,'' it does not necessarily imply assignment of quantitative weightings to information.

Lowest observed adverse effect level (LOAEL)—The lowest level of a stressor evaluated in a test that causes statistically significant differences from the controls.

Maximum acceptable toxic concentration (MATC)—For a particular ecological effects test, this term is used to mean either the range between the NOAEL and the LOAEL or the geometric mean of the NOAEL and the LOAEL for a particular test. The geometric mean is also known as the chronic value.

Measure of ecosystem and receptor characteristics—A measurable characteristic of the ecosystem or receptor that is used in support of exposure or effects analysis.

Measure of effect—A measurable ecological characteristic that is related to the valued characteristic chosen as the assessment endpoint.

Measure of exposure—A measurable stressor characteristic that is used to help quantify exposure.

Measurement endpoint—See ''measure of effect.''

Median lethal concentration (LC_{50})—A statistically or graphically estimated concentration that is expected to be lethal to 50% of a group of organisms under specified conditions (ASTM, 1990).

No observed adverse effect level (NOAEL)—The highest level of a stressor evaluated in a test that does not cause statistically significant differences from the controls.

Population—An aggregate of individuals of a species within a specified location in space and time.

Primary effect—An effect where the stressor acts on the ecological component of interest itself, not through effects on other components of the ecosystem (synonymous with direct effect; compare with definition for secondary effect).

Probability density function (PDF)—Probability density functions are particularly useful in describing the relative likelihood that a variable will have different particular values of x. The probability that a variable will have a value within a small interval around x can be approximated by multiplying f(x) (i.e., the value of y at x in a PDF plot) by the width of the interval (figure B–2).

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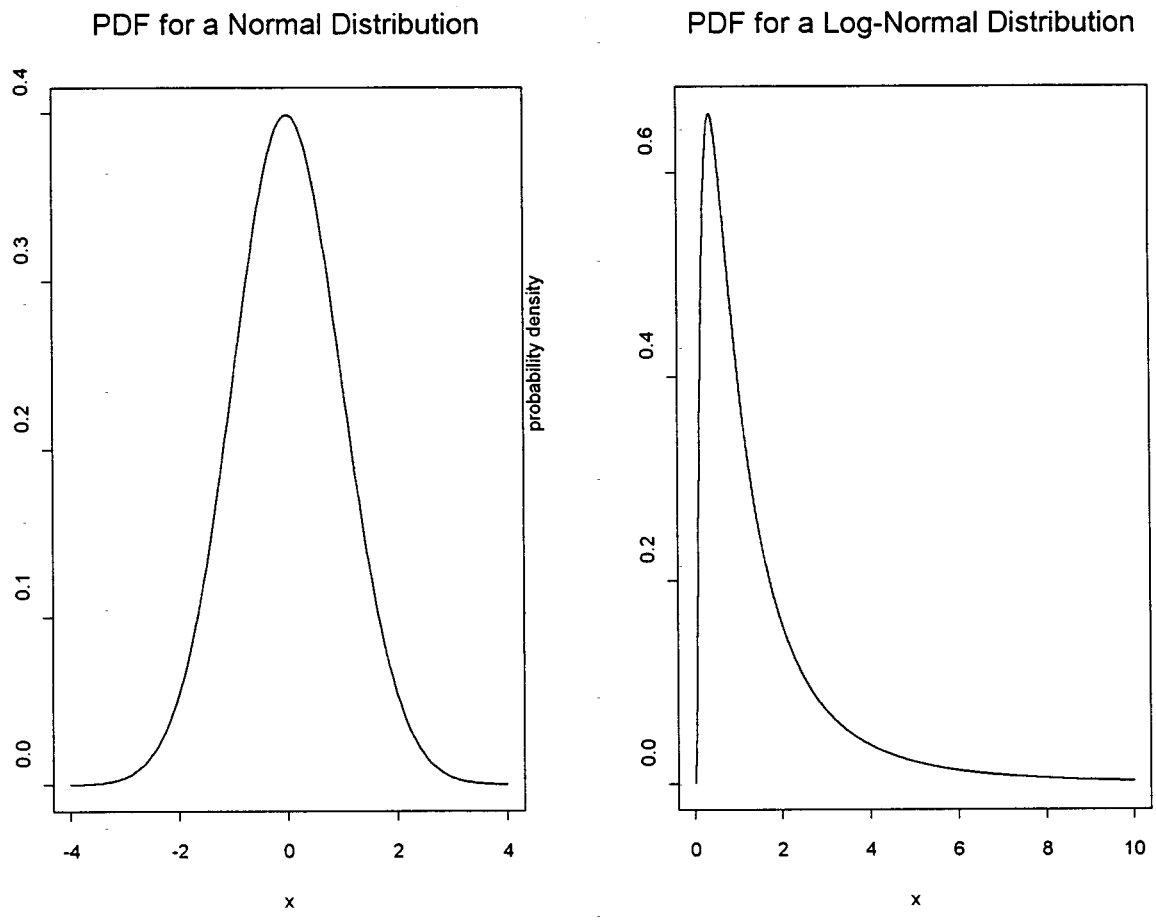

Figure B-2. Plots of Probability Density Functions (PDF)

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Receptor—The ecological entity exposed to the stressor.

Recovery—The rate and extent of return of a population or community to a condition that existed before the introduction of a stressor. Due to the dynamic nature of ecological systems, the attributes of a ''recovered'' system must be carefully defined.

Relative risk assessment—A process similar to comparative risk assessment. It involves estimating the risks associated with different stressors or management actions. To some, relative risk connotes the use of quantitative risk techniques, while comparative risk approaches more often rely on expert judgment. Others do not make this distinction.

Risk characterization—A phase of ecological risk assessment that integrates the exposure and stressor response profiles to evaluate the likelihood of adverse ecological effects associated with exposure to a stressor. The adversity of effects is discussed, including consideration of the nature and intensity of the effects, the spatial and temporal scales, and the potential for recovery.

Secondary effect—An effect where the stressor acts on supporting components of the ecosystem, which in turn have an effect on the ecological component of interest (synonymous with indirect effects; compare with definition for primary effect).

Source—An entity or action that releases to the environment or imposes on the environment a chemical, physical, or biological stressor or stressors.

Source term—As applied to chemical stressors, the type, magnitude, and patterns of chemical(s) released.

Stress regime—The term stress regime has been used in at least three distinct ways: (1) to characterize exposure to multiple chemicals or to both chemical and nonchemical stressors (more clearly described as multiple exposure, complex exposure, or exposure to mixtures), (2) as a synonym for exposure that is intended to avoid overemphasis on chemical exposures, and (3) to describe the series of interactions of exposures and effects resulting in secondary exposures, secondary effects, and, finally, ultimate effects (also known as risk cascade [Lipton et al., 1993]) or causal chain, pathway, or network (Andrewartha and Birch, 1984).

Stressor—Any physical, chemical, or biological entity that can induce an adverse response (synonymous with agent).

Stressor-response profile—The product of characterization of ecological effects in the analysis phase of ecological risk assessment. The stressor-response profile summarizes the data on the effects of a stressor and the relationship of the data to the assessment endpoint.

Trophic levels—A functional classification of taxa within a community that is based on feeding relationships (e.g., aquatic and terrestrial green plants comprise the first trophic level and herbivores comprise the second).

Appendix C.—Conceptual Model Examples

Conceptual model diagrams are visual representations of the conceptual

models. They may be based on theory and logic, empirical data, mathematical models, and probability models. These diagrams are useful tools for communicating important pathways in a clear and concise way. They can be used to ask new questions about relationships that help generate plausible risk hypotheses. Further discussion of conceptual models is found in section 3–4.

Flow diagrams like those shown in figures C–1 through C–3 are typical conceptual model diagrams. When constructing flow diagrams like these, it is helpful to use distinct and consistent shapes to distinguish among stressors, assessment endpoints, responses, exposure routes, and ecosystem processes. Although flow diagrams are often used to illustrate conceptual models, there is no set configuration for conceptual model diagrams. Pictorial representations of the processes of an ecosystem can be more effective (e.g., Bradley and Smith, 1989).

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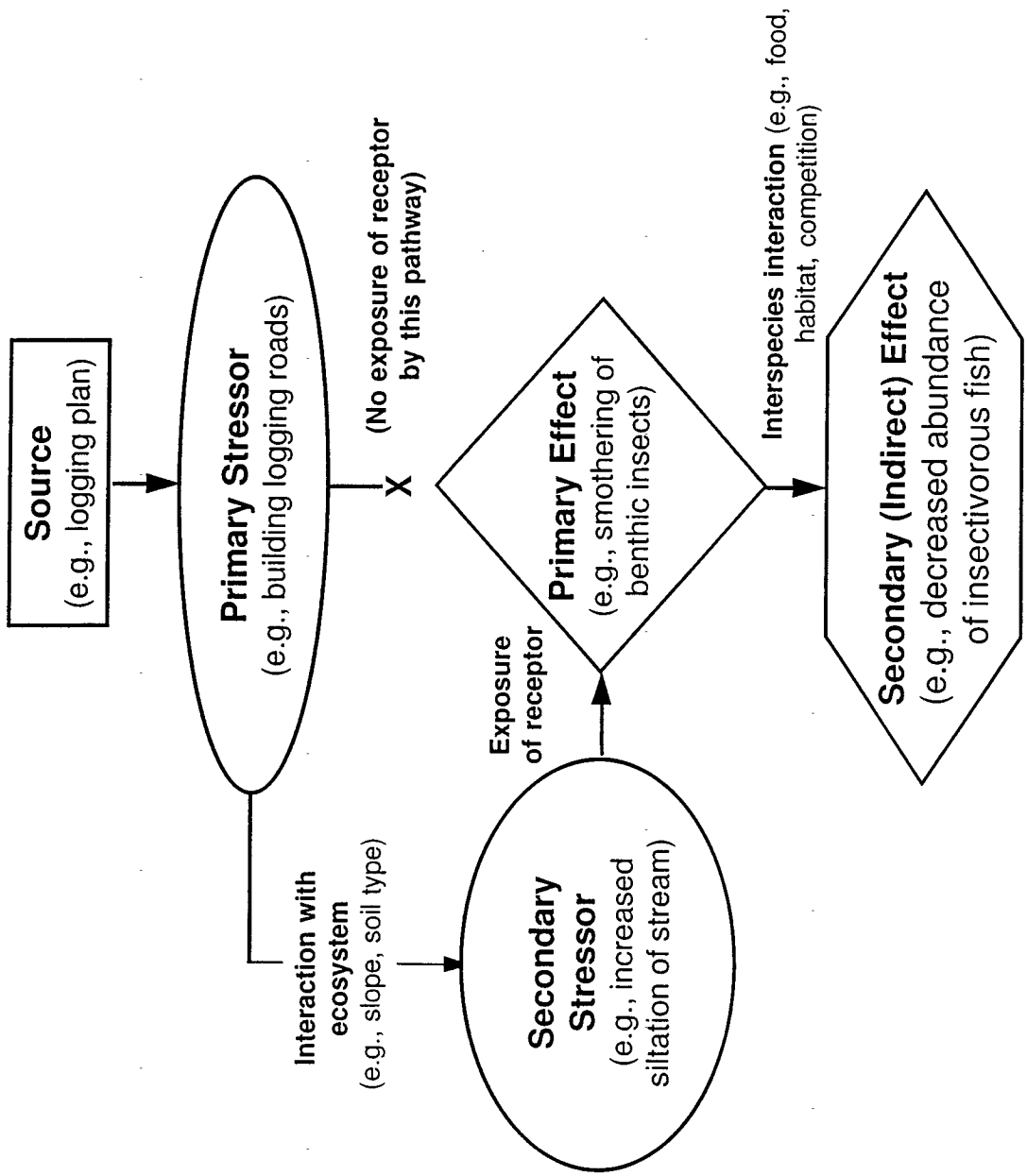


Figure C-1. Conceptual model for logging.

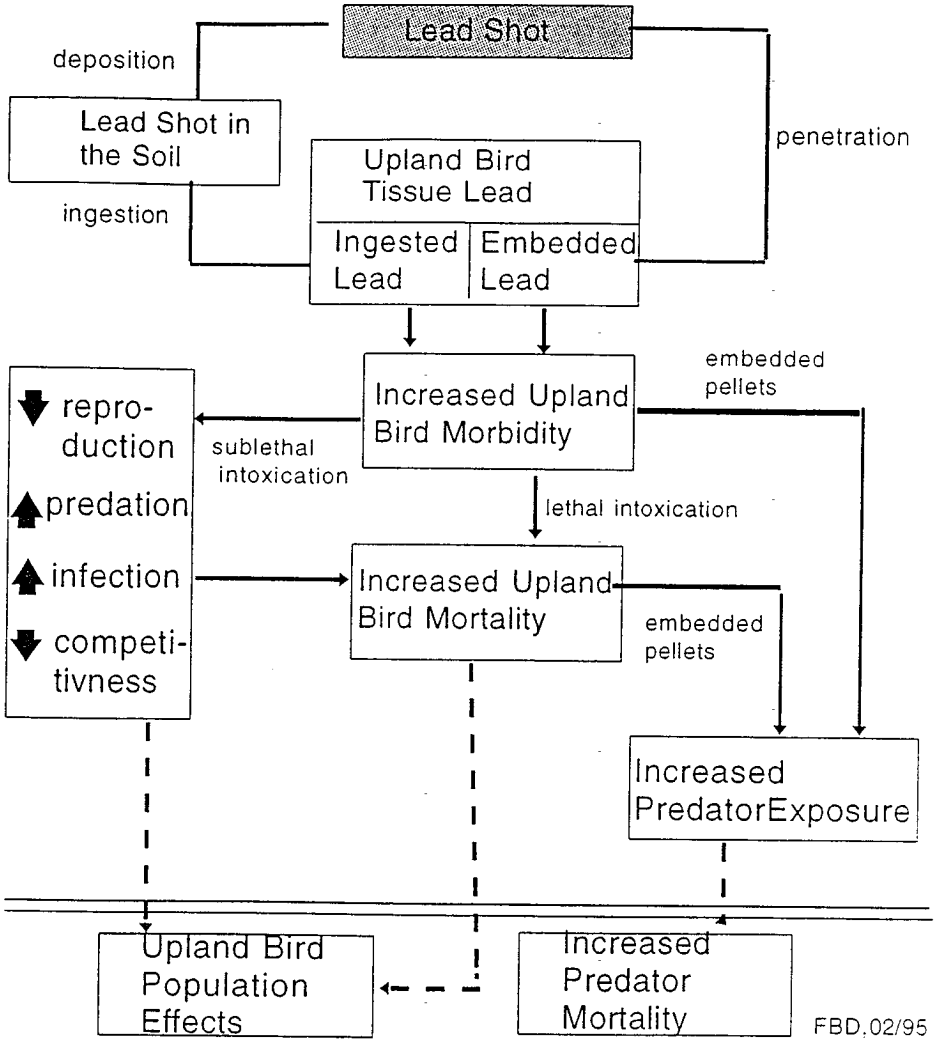


Figure C-2. Conceptual model for tracking stress associated with lead shot through upland ecosystems. Reprinted from *Environmental Toxicology and Chemistry* by Kendall et al. (1996) with permission of the Society of Environmental Toxicology and Chemistry (copyright 1996).

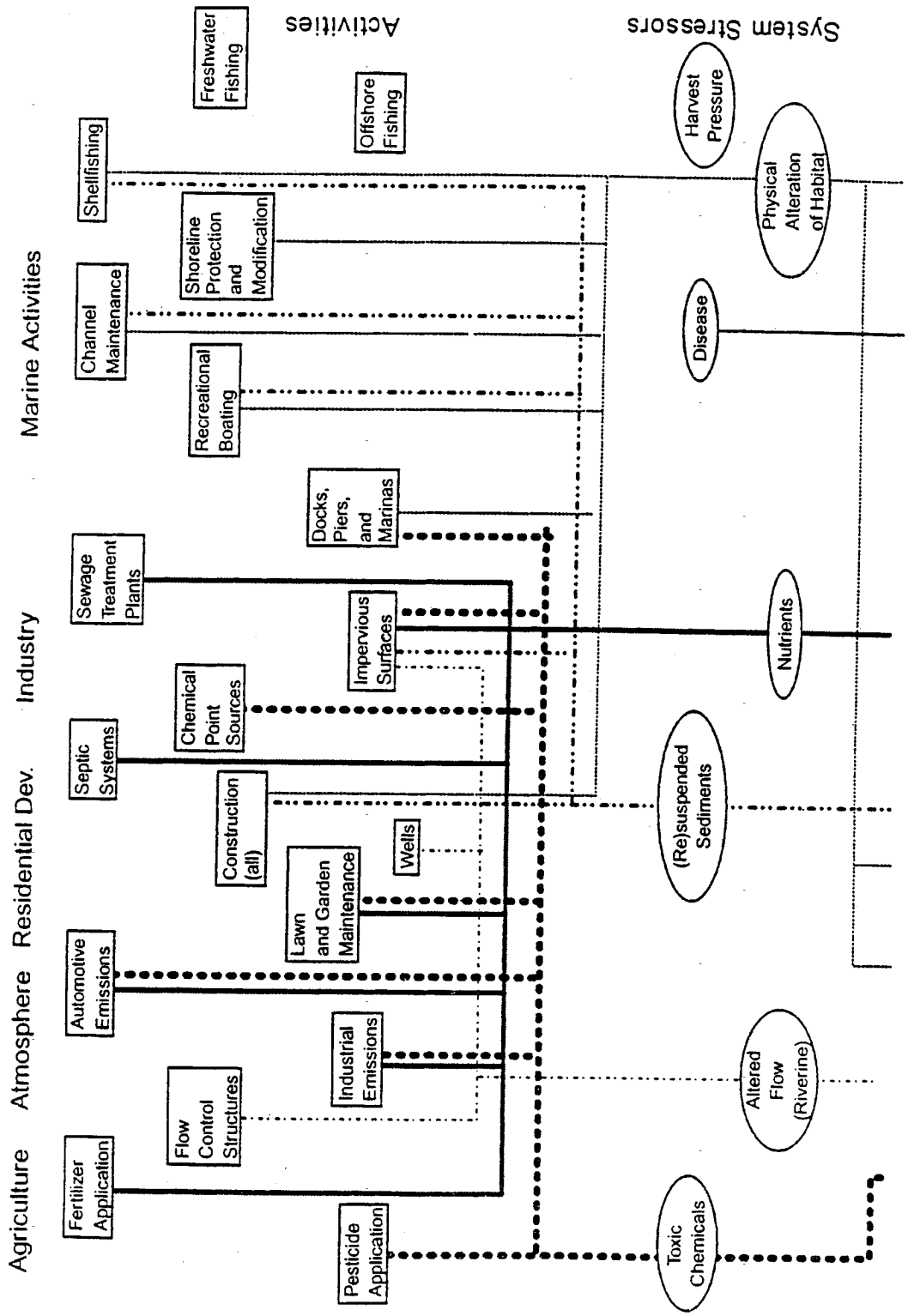
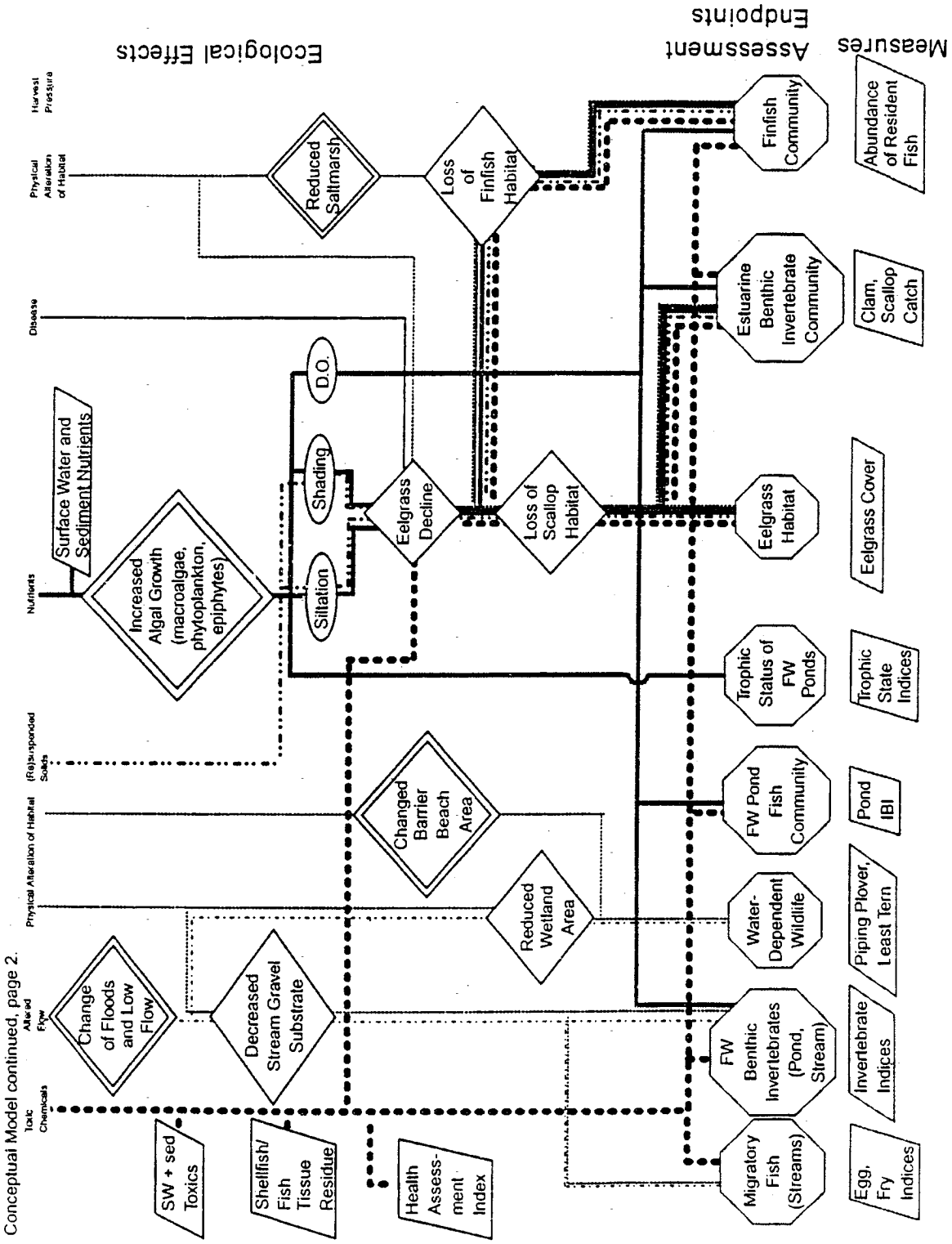


Figure C-3. Waquoit Bay watershed conceptual model.



Conceptual Model continued, page 2.

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Figure C–1 illustrates the relationship between a primary physical stressor (logging roads) and an effect on an assessment endpoint (fecundity in insectivorous fish). This simple diagram illustrates that building logging roads (which could be considered a stressor or a source) in ecosystems where slope, soil type, low riparian cover, and other ecosystem characteristics lead to the erosion of soil, which enters streams and smothers the benthic organisms (exposure pathway is not explicit in this diagram). Because of the dependence of insectivorous fish on benthic organisms, the fish are believed to be at risk from the building of logging roads. Each arrow in this diagram represents a hypothesis about the proposed relationship (e.g., human action and stressor, stressor and effect, primary effect to secondary effect). Each risk hypothesis provides insights into the kinds of data that will be needed to verify that the hypothesized relationships are valid.

Figure C–2 is a conceptual model used by Kendall et al. (1996) to track a contaminant through upland ecosystems. In this example, upland birds are exposed to lead shot when it becomes embedded in their tissue after being shot and by ingesting lead accidentally when feeding on the ground. Both are hypothesized to result in increased morbidity (e.g., lower reproduction and competitiveness and higher predation and infection) and mortality, either directly (lethal intoxication) or indirectly (effects of morbidity leading to mortality). These effects are believed to result in changes in upland bird populations and, due to hypothesized exposure of predators to lead, to increase predator mortality. This example shows multiple exposure pathways for effects on two assessment endpoints. Each arrow contains within it assumptions and hypotheses about the relationship depicted that provide the basis for identifying data needs and analyses.

Figure C–3 is a conceptual model adapted from the Waquoit Bay watershed risk assessment. At the top of the model, multiple human activities that occur in the watershed are shown in rectangles. Those sources of stressors are linked to stressor types depicted in ovals. Multiple sources are shown to contribute to an individual stressor, and each source may contribute to more than one stressor. The stressors then lead to multiple ecological effects depicted again in rectangles. Some rectangles are double-lined to indicate effects that can be directly measured for data analysis. Finally, the effects are linked to particular assessment endpoints. The connections show that one effect can result in changes in many assessment endpoints. To fully depict exposure pathways and types of effects, specific portions of this conceptual model would need to be expanded to illustrate those relationships.

Appendix D.—Analysis Phase Examples

The analysis phase process is illustrated here for a chemical, physical, and biological stressor. These examples do not represent all possible approaches but illustrate the analysis phase process using information from actual assessments.

D.1. Special Review of Granular Formulations of Carbofuran Based on Adverse Effects on Birds

Figure D–1 is based on an assessment of the risks of carbofuran to birds under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) (Houseknecht, 1993). Carbofuran is a broad-spectrum insecticide and nematicide applied primarily in granular form on 27 crops as well as forests and pineseed orchards. The assessment endpoint was survival of birds that forage in agricultural areas where carbofuran is applied.

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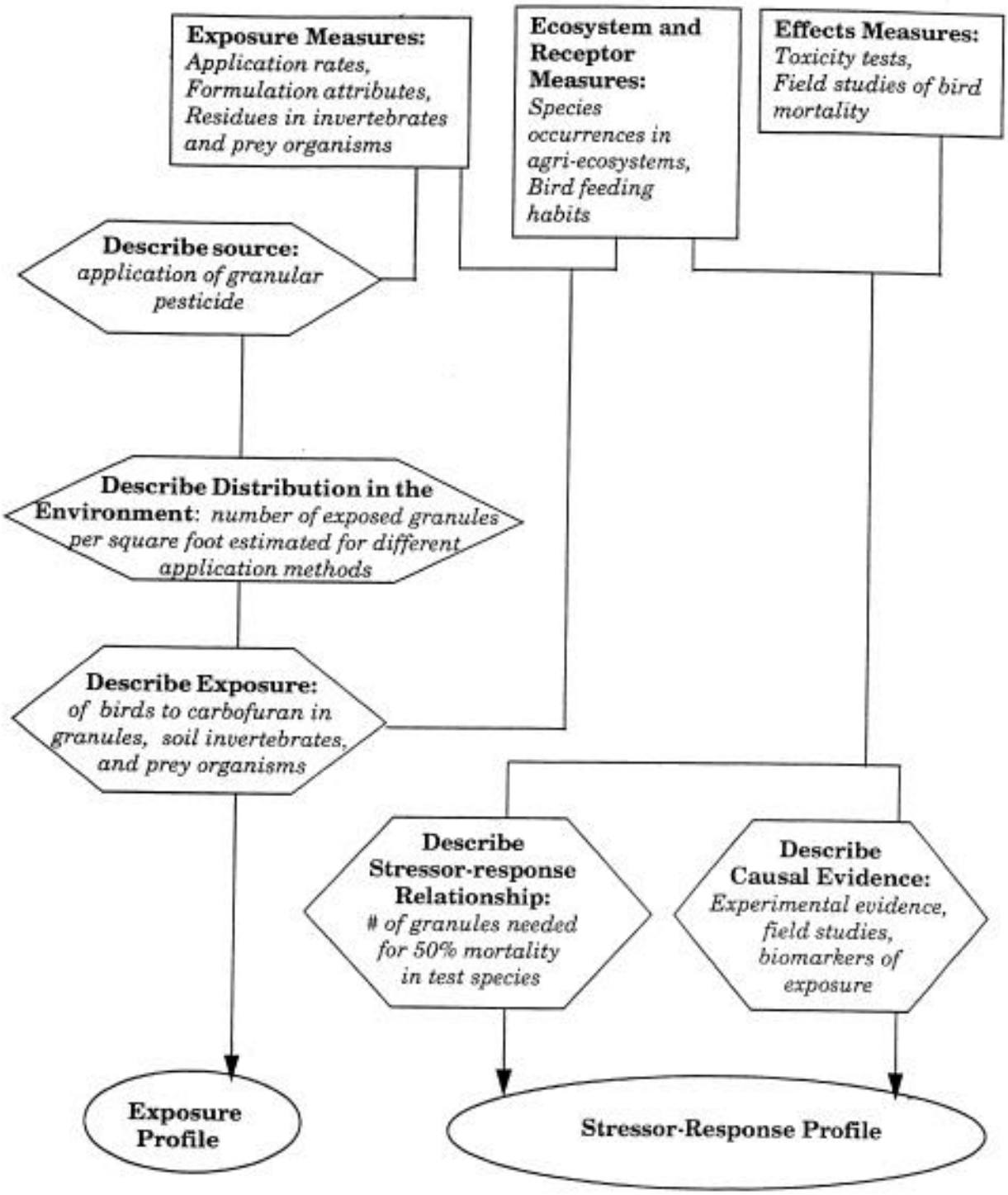

Figure D-1. Example of the analysis phase process: special review of carbofuran. Rectangular boxes indicate inputs, hexagon-shaped boxes indicate actions, and circular boxes indicate outputs.

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The analysis phase focused on birds that may incidentally ingest granules as they forage or that may eat other animals that contain granules or residues. Measures of exposure included application rates, attributes of the formulation (e.g., size of granules), and residues in prey organisms. Measures of the ecosystem and receptors included an inventory of bird species that may be exposed following applications for 10 crops. The birds' respective feeding behaviors were considered in developing routes of exposure. Measures of effect included laboratory toxicity studies and field investigations of bird mortality.

The source of the chemical was application of the pesticide in granular form. The distribution of the pesticide in agricultural fields was estimated based on the application rate. The number of exposed granules was estimated from literature data. Based on a review of avian feeding behavior, seed-eating birds were assumed to ingest any granules left uncovered in the field. The intensity of exposure was summarized as the number of exposed granules per square foot.

The stressor-response relationship was described using the results of toxicity tests. These data were used to construct a toxicity statistic expressed as the number of granules needed to kill 50% of the test birds (i.e., granules per LD_{50}), assuming 0.6 mg of active ingredient (AI) per granule and average body weights for the birds tested. Field studies were used to document the occurrence of bird deaths following applications and provide further causal evidence. Carbofuran residues and cholinesterase levels were used to confirm that exposure to carbofuran caused the deaths.

D.2. Modeling Losses of Bottomland-Forest Wetlands

Figure D–2 is based on an assessment of the ecological consequences (risks) of long-term changes in hydrologic conditions (water-level elevations) for three habitat types in the Lake Verret Basin of Louisiana (Brody et al., 1989, 1993; Connor and Brody, 1989). The project was intended to provide a habitat-based approach for assessing the environmental impacts of Federal water projects under the National Environmental Policy Act and Section 404 of the Clean Water Act. Output from the models provided risk managers with information on how changes in water elevation might alter the ecosystem. The primary anthropogenic stressor addressed in this assessment was artificial levee construction for flood control, which contributes to land subsidence by reducing sediment deposition in the floodplain. Assessment endpoints included forest community structure and habitat value to wildlife species and the species composition of the wildlife community.

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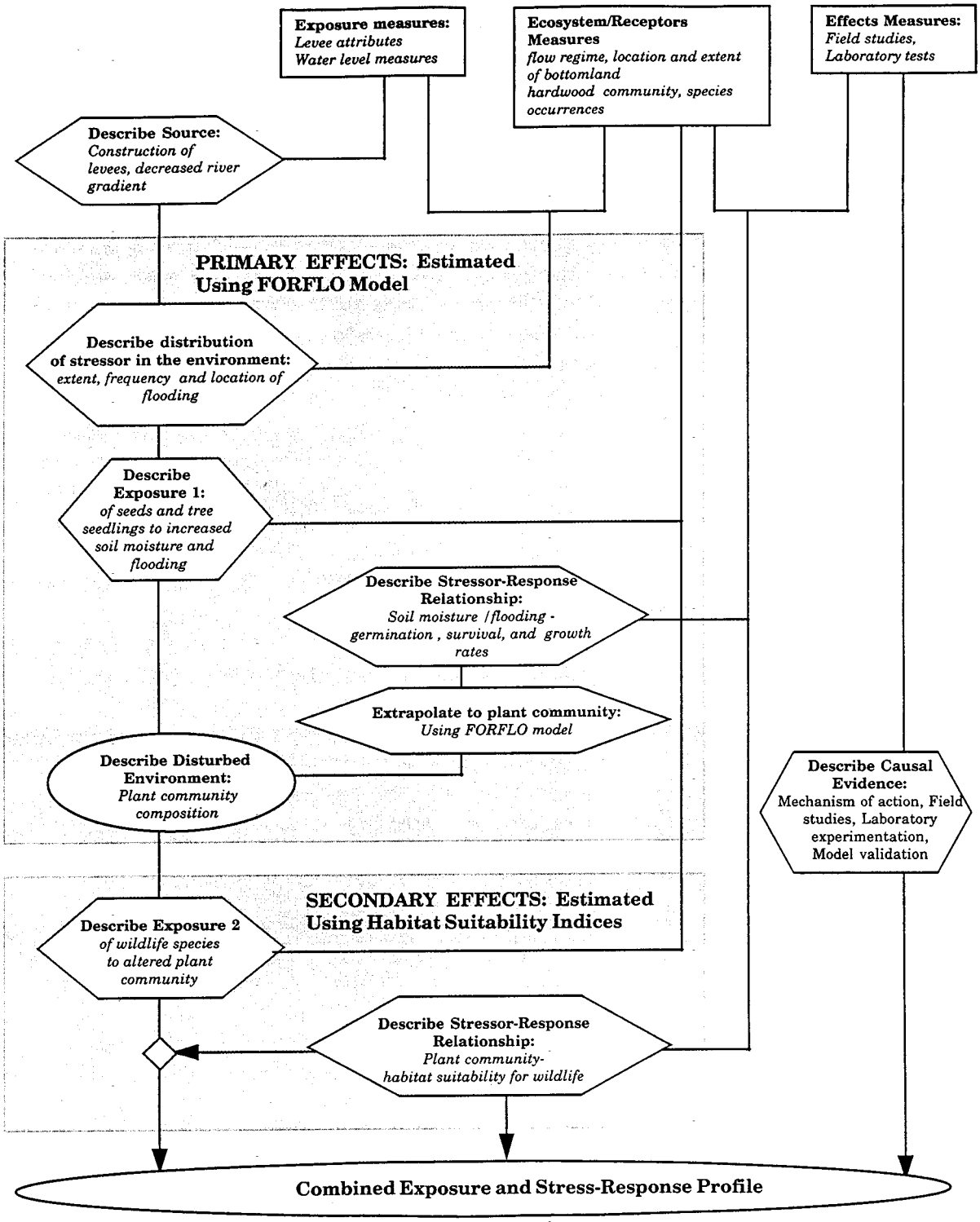

Figure D-2. Example of the analysis phase process: modeling losses of bottomland hardwoods. Rectangular boxes indicate inputs, hexagon-shaped boxes indicate actions, and circular boxes indicate outputs.

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The analysis phase began by considering primary (direct) effects of water-level changes on plant community composition and habitat characteristics. Measures of exposure included the attributes and placement of the levees and water-level measurements. Ecosystem and receptor measures included location and extent of bottomland-hardwood communities, plant species occurrences within these communities, and information on the historic flow regimes. Effects measures included laboratory studies of plant response to moisture and field measurements along moisture gradients.

While the principal stressor under evaluation was the construction of levees, the decreased gradient of the river due to sediment deposition at its mouth also contributed to increased water levels. The extent and frequency of flooding were simulated by the FORFLO model based on estimates of net subsidence rates from levee construction and decreased river gradient. Seeds and seedlings of the tree species were assumed to be exposed to the altered flooding regime. Stressor-response relationships describing plant response to moisture (e.g., seed germination, survival) were embedded within the FORFLO model. This information was used by the model to simulate changes in plant communities: The model tracks the species type, diameter, and age of each tree on simulated plots from the time the tree enters the plot as a seedling or sprout until it dies. The FORFLO model calculated changes in the plant community over time (from 50 to 280 years). The spatial extent of the three habitat types of interest—wet bottomland hardwoods, dry bottomland hardwoods, and cypress-tupelo swamp—was mapped onto a Geographic Information System (GIS) along with the hydrological information. Then the changes projected by FORFLO were manually linked to the GIS to show how the spatial distribution of different communities would change. Evidence that flooding would actually cause these changes included comparisons of model predictions with field measurements, the laboratory studies of plant response to moisture, and knowledge of the mechanisms by which flooding elicits changes in plant communities.

Secondary (indirect) effects on wildlife associated with changes in the habitat provided by the plant community formed the second part of the analysis phase. Important measures included life-history characteristics and habitat needs of the wildlife species. Effects on wildlife were inferred by evaluating the suitability of the plant community as habitat. Specific aspects of the community structures calculated by the FORFLO model provided the input to this part of the analysis. For example, the number of snags was used to evaluate habitat value for woodpeckers. Resident wildlife (represented by five species) were assumed to co-occur with the altered plant community. Habitat value was evaluated by calculating the Habitat Suitability Index (HSI) for each habitat type multiplied by the habitat type's area.

A combined exposure and stressor-response profile is shown in figure D–2; these two elements were combined with the models used for the analysis and then used directly in risk characterization.

D.3. Pest Risk Assessment of Importation of Logs From Chile

Figure D–3 is based on the assessment of potential risks to U.S. forests due to the incidental introduction of insects, fungi, and other pests inhabiting logs harvested in Chile and transported to U.S. ports (USDA, 1993). This risk assessment was used to determine whether actions to restrict or regulate the importation of Chilean logs were needed to protect U.S. forests and was conducted by a team of six experts under the auspices of the U.S. Department of Agriculture Forest Service. Stressors include insects, forest pathogens (e.g., fungi), and other pests. The assessment endpoint was the survival and growth of tree species (particularly conifers) in the western United States. Damage that would affect the commercial value of the trees as lumber was clearly of interest.

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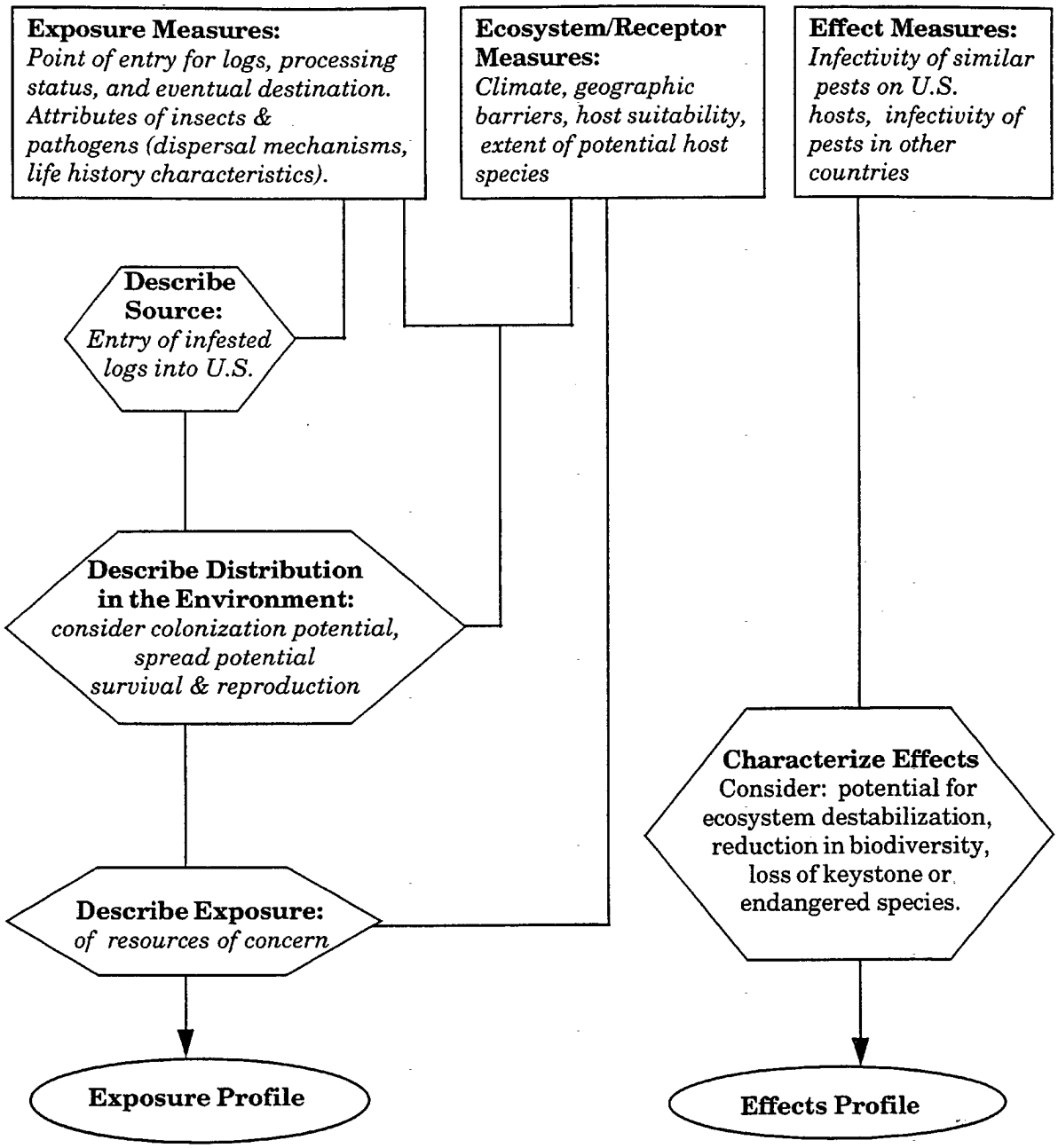

Figure D-3. Example of the analysis phase process: pest risk assessment of the importation of logs from Chile. Rectangular boxes indicate inputs, hexagon-shaped boxes indicate actions, and circular boxes indicate outputs.

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The analysis phase was carried out by eliciting professional opinions from a team of experts. Exposure measures used by the team included distribution information for the imported logs and attributes of the insects and pathogens such as dispersal mechanisms and life history characteristics. Ecosystem and receptor measures included the climate of the United States, location of geographic barriers, knowledge of host suitability, and ranges of potential host species. Effect measures included knowledge of the infectivity of these pests in other countries and the infectivity of similar pests on U.S. hosts.

This information was used by the risk assessment team to evaluate the potential for exposure. They began by evaluating the likelihood of entry of infested logs into the United States. The distribution of the organisms given entry was evaluated by considering the potential for colonization and spread beyond the point of entry as well as the likelihood of organisms surviving and reproducing. The potential for exposure was summarized by assigning each of the above elements a judgment-based value of high, medium, or low.

The evaluation of ecological effects was also conducted based on collective professional judgment. Of greatest relevance to this guidance was the consideration of environmental damage potential, defined as the likelihood of ecosystem destabilization, reduction in biodiversity, loss of keystone species, and reduction or elimination of endangered or threatened species. (The team also considered economic damage potential and social and political influences; however, these guidelines consider those factors to be part of the risk management process.) Again, each consideration was assigned a value of high, medium, or low to summarize the potential for ecological effects.

Appendix E.—Criteria for Determining Ecological Adversity: A Hypothetical Example (Adapted from Harwell et al., 1994)

As a result of a collision at sea, an oil tanker releases 15 million barrels of #2 fuel oil 3 km offshore. It is predicted that prevailing winds will carry the fuel onshore within 48 to 72 hours. The coastline has numerous small embayments that support an extensive shallow, sloping subtidal community and a rich intertidal community. A preliminary assessment determined that if no action were taken, significant risks to the communities would result. Additional risk assessments were conducted to determine which of two options should be used to clean up the oil spill.

Option 1 is to use a dispersant to break up the slick, which would reduce the likelihood of extensive onshore contamination but would cause extensive mortality to the phytoplankton, zooplankton, and ichthyoplankton, which are important for commercial fisheries. Option 2 is to try to contain and pump off as much oil as possible; this option anticipates that a shift in wind direction will move the spill away from shore and allow for natural dispersal at sea. If this does not happen, the oil will contaminate the extensive sub- and intertidal mud flats, rocky intertidal communities, and beaches and pose an additional hazard to avian and mammalian fauna. It is assumed there will be a demonstrable change beyond natural variability in the assessment endpoints (e.g., structure of planktonic, benthic, and intertidal communities). What is the adversity of each option?

- Nature and severity of the effect. For both options, the magnitude of change in the assessment endpoints is likely to be severe. Planktonic populations often are characterized by extensive spatial and temporal variability. Nevertheless, within the spatial boundaries of the spill, the use of dispersants is likely to produce complete mortality of all planktonic forms within the upper 3 m of water. For benthic and intertidal communities that generally are stable and have less spatial and temporal variability than planktonic forms, oil contamination will likely result in severe impacts on survival and chronic effects lasting for several years. Thus, under both options, changes in the assessment endpoints will probably exceed the natural variability for threatened communities in both space and time.
- Spatial scale. The areal extent of impacts is similar for each of the options. While extensive, the area of impact constitutes a small percentage of the landscape. This leaves considerable area available for replacement stocks and creates significant fragmentation of either the planktonic or inter- and subtidal habitats. Ecological adversity is reduced because the area is not a mammalian or avian migratory corridor.
- Temporal scale and recovery. Based on experience with other oil spills, it is assumed that the effects are reversible over some time period. The time needed for reversibility of changes in phytoplankton and zooplankton populations should be short (days to weeks) given their rapid generation times and easy immigration from adjacent water masses. Similarly, although ichthyoplankton do not reproduce, they typically experience extensive natural mortality, and immigration is readily available from surrounding water masses. On the other hand, the time needed for reversibility of changes in benthic and intertidal communities is likely to be long (years to decades). First, the stressor (oil) would be likely to persist in sediments and on rocks for several months to years. Second, the life histories of the species comprising these communities span 3 to 5 years. Third, the reestablishment of benthic intertidal community and ecosystem structure (hierarchical composition and function) often requires decades.

Both options result in (1) assessment endpoint effects that are of great severity, (2) exceedances of natural variability for those endpoints, and (3) similar estimates of areal impact. What distinguishes the two options is temporal scale and reversibility. In this regard, changes to the benthic and intertidal ecosystems are considerably more adverse than those to the plankton. On this basis, the option of choice would be to disperse the oil, effectively preventing it from reaching shore where it would contaminate the benthic and intertidal communities.

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Monday
September 9, 1996

Part III

Consumer Product Safety Commission

16 CFR Parts 1615 and 1616

Flammable Fabrics Act: Children's Sleepwear (Sizes 0–6x, 7–14) Flammability Standards; Final Rule

CONSUMER PRODUCT SAFETY COMMISSION

16 CFR Parts 1615 and 1616

Standard for the Flammability of Children's Sleepwear: Sizes 0 Through 6X; Standard for the Flammability of Children's Sleepwear: Sizes 7 Through 14

AGENCY: Consumer Product Safety Commission.

ACTION: Final amendments.

SUMMARY: The Commission issues final amendments of the flammability standards for children's sleepwear in sizes 0 through 6X and sizes 7 through 14. The amendments issued below revise the definition of ''children's sleepwear'' in the standard for sizes 0 through 6X to exclude from the requirements of that standard: garments sized for infants nine months of age or younger; and tight-fitting sleepwear garments. The amendments also revise the definition of ''children's sleepwear'' in the standard for sizes 7 through 14 to exclude tight-fitting sleepwear garments.[1] The amendments define the term ''tight-fitting garment'' in terms of maximum dimensions at specified locations on garments in sizes for children older than 9 months through children's size 14.

The Commission issues these amendments because it finds that the existing children's sleepwear standards are not limited to those sleepwear garments which present an unreasonable risk of burn deaths and injuries. The Commission concludes that the amendments will afford consumers a wider selection of sleepwear garments for children without diminishing the protection provided by the children's sleepwear standards.

DATES: The amendments will become effective on January 1, 1997.

FOR FURTHER INFORMATION CONTACT: Patricia Fairall, Division of Regulatory Management, Office of Compliance, Consumer Product Safety Commission, Washington, DC 20207; telephone (301) 504–0400, extension 1369.

SUPPLEMENTARY INFORMATION:

A. Provisions of Final Amendments

By publication of this notice of final rulemaking, the Commission amends the Standard for the Flammability of Children's Sleepwear: Sizes 0 through 6X (16 CFR part 1615) and the Standard for the Flammability of Children's Sleepwear: Sizes 7 through 14 (16 CFR part 1616). The amendments issued below exempt sleepwear garments sized for children nine months of age and younger and ''tight-fitting'' sleepwear garments sized for children older than nine months to children's size 14 from all requirements of the children's sleepwear flammability standards. The term ''tight-fitting garment'' is defined by specifying maximum dimensions for the chest, waist, seat, upper arm, thigh, wrist, and ankle of the garment for each size from 9–12 months through children's size 14.

The amendments issued below are similar to proposed amendments published in the Federal Register of October 25, 1994 (59 FR 53616). The final amendments differ from the proposal by:

- Increasing the size of infant garments exempted from the current standard for sizes 0 through 6X;
- Changing some of the maximum dimensions specified for tight-fitting garments in children's sizes 6X through 14; and
- Eliminating the requirement for a permanent label on tight-fitting sleepwear garments to advise the purchaser that those garments are not flame-resistant.

The differences between the proposed and final amendment are discussed in detail under the heading G. Comments on the Proposed Amendments.

The amendments issued below become effective on January 1, 1997. The Commission's finding that this effective date is in the public interest and the reasons for that finding are set forth under the heading H. Effective Date. Elsewhere in this issue of the Federal Register, the Commission has published a notice to continue through March 9, 1998 a stay of enforcement for close-fitting garments which are labeled and promoted as underwear.

B. Background

The Flammable Fabrics Act (FFA) (15 U.S.C. 1191 *et seq.*) authorizes the issuance of flammability standards for products of wearing apparel made from fabric to protect the public from unreasonable risks of the occurrence of fire leading to death, injury, or significant property damage.

In 1971, the Secretary of Commerce issued a flammability standard for children's sleepwear in sizes 0 through 6X under the authority of section 4 of the FFA (15 U.S.C. 1193). The standard was issued to protect young children from death and serious burn injuries which had been associated with ignition of sleepwear garments, such as nightgowns and pajamas, by small open-flame sources. The standard for sleepwear in sizes 0 through 6X became effective in 1972 and is now codified at 16 CFR part 1615.

In 1973, authority to issue flammability standards under provisions of the FFA was transferred from the Department of Commerce to the Consumer Product Safety Commission by section 30(b) of the Consumer Product Safety Act (CPSA) (15 U.S.C. 2079(b)). In 1974, the Commission issued a flammability standard for children's sleepwear in sizes 7 through 14. That standard became effective in 1975 and is now codified at 16 CFR part 1616.

The safety requirements of the two standards are nearly identical. They prescribe a test which requires that specimens of fabrics, seams, and trim of children's sleepwear garments must self-extinguish after exposure to a small open flame. Both standards require manufacturers of children's sleepwear subject to their provisions to test prototypes of sleepwear garments with acceptable results before beginning production. Both standards also require manufacturers to sample and test garments from regular production. Failure to comply with the sampling and testing requirements of the standards is a violation of section 3 of the FFA (15 U.S.C. 1192). The standards do not require or prohibit the use of any particular type of fabric or garment design as long as the manufacturer successfully completes the prescribed prototype and production testing.

C. Garments Subject to the Sleepwear Standards

Both standards define the term ''children's sleepwear'' to mean ''any product of wearing apparel'' in the sizes covered by the standard ''such as nightgowns, pajamas, or similar or related items, such as robes, intended to be worn primarily for sleeping or activities related to sleeping.'' As originally issued and as amended below, both standards exclude diapers and underwear from their coverage. See 16 CFR 1615.1(a) and 1616.2(a).

Under this definition, the coverage of the sleepwear standards is not limited to children's pajamas, nightgowns, and robes, but also includes other garments ''intended primarily for sleeping or activities related to sleeping.'' 16 CFR 1615.1(a), 1616.2(a) During the time that the standards have been in effect, the Commission staff has responded to a large number of inquiries from manufacturers and importers of children's garments about whether particular products are ''children's

[1] The Commission voted 2–1 to issue these amendments of the children's sleepwear flammability standards, Chairman Ann Brown dissenting.

sleepwear'' subject to the standards; or ''underwear,'' which is specifically excluded from the standards; or ''daywear,'' ''playwear,'' or other categories of non-sleepwear garments, each of which is outside the scope of the standards.

To provide guidance to the children's garment industry on the scope of the sleepwear standards, in 1984 the Commission issued policy statements which discuss the factors the Commission will consider when determining whether a garment is intended to be worn primarily for sleeping or related activities.(1)[2] These policy statements are codified at 16 CFR 1615.64 and 1616.65. Additionally, the staff developed a pamphlet describing and illustrating various styles of sleepwear and non-sleepwear garments. This pamphlet was revised from time to time, most recently in 1989.(2)

During the past several years, many consumers have expressed a desire to obtain children's garments made from 100 percent untreated cotton fabric for use as sleepwear. Although the standards do not prohibit any specific type of fabric in the production of children's sleepwear, 100 per cent cotton fabric cannot pass the flammability tests in the standards unless treated with a flame retardant. The Commission also received information indicating that many parents were dressing their children in underwear, large T-shirts, or other garments made of 100 percent untreated cotton rather than traditional sleepwear manufactured to comply with the sleepwear flammability standards.

These actions by manufacturers and consumers resulted in an increasing number of children sleeping in garments which did not comply with the children's sleepwear standards. In view of this trend, the Commission decided in 1991 to re-examine the scope of the children's sleepwear standards and to consider amending the definitions of the term ''children's sleepwear'' in the two standards. The Commission began this rulemaking proceeding in 1993.

D. Statutory Provisions

Section 4 of the FFA (15 U.S.C. 1193) authorizes the Commission to issue or amend a flammability standard for a product of wearing apparel if the Commission finds that a new or amended standard is needed to protect the public against the unreasonable risk of the occurrence of fire leading to death, injury, or significant property damage.

Section 4(g) of the FFA (15 U.S.C. 1193(g)) requires publication in the Federal Register of an advance notice of proposed rulemaking (ANPR) to begin a proceeding for the issuance or amendment of a flammability standard. The ANPR must describe the product and the risk of injury under consideration; summarize the regulatory alternatives being considered; provide information about existing standards which may be relevant; invite interested parties to submit an existing standard to the Commission for publication as the proposed standard or a statement of intention to develop or modify a voluntary standard to address the risk of injury under consideration; and solicit written comments on the risk of injury and regulatory alternatives under consideration.

If the Commission decides to continue the proceeding after consideration of comments and submissions received in response to the ANPR, section 4(i) of the FFA (15 U.S.C. 1193(i)) requires publication in the Federal Register of a notice of proposed rulemaking (NPR). The NPR must set forth the text of the proposed standard or amendment and a preliminary regulatory analysis containing a discussion of the anticipated benefits and costs of the proposed rule and other regulatory alternatives considered by the Commission. Section 4(d) of the FFA (15 U.S. C. 1193(d)) specifies that the NPR must provide interested persons the opportunity to submit written comments and to request a public hearing for oral presentation of data and opinions concerning the proposal.

To issue a final standard or amendment, section 4(j) of the FFA (15 U.S.C. 1193(j)) requires the Commission to publish a notice of final rulemaking setting forth the text of the final rule and the Commission's final regulatory analysis of costs, benefits, and regulatory alternatives. Additionally, section 4(b) of the FFA (15 U.S.C. 1193(b)) requires the notice of final rulemaking to contain findings that the standard or amendment is needed to protect the public from the unreasonable risk of death, injury, or significant property damage from fires associated with the product under consideration; is reasonable, technologically practicable, and appropriate; and is limited to those fabrics or products which have been determined to present an unreasonable risk of death, injury, or significant property damage.

E. Publication of ANPR

The Commission began this proceeding by publication of an ANPR in the Federal Register of January 13, 1993 (58 FR 4111).(4) The ANPR identified the products under consideration as children's sleepwear garments in sizes 0 through 14, and the risk of injury as death or personal injury from fires resulting from ignition of children's sleepwear by small open-flame sources.

The ANPR also described the regulatory alternatives being considered by the Commission. Briefly summarized, the alternatives were:

(1) Amend the children's sleepwear standards to exempt tight-fitting sleepwear garments and sleepwear garments in infant sizes. Children's sleepwear garments exempted from the requirements of the sleepwear standard would be subject to the provisions of the Standard for the Flammability of Clothing Textiles (16 CFR Part 1610). That standard prohibits the manufacture, importation, or sale of garments which are ''dangerously flammable because of rapid and intense burning,'' but does not require garments to self-extinguish when exposed to a small open-flame ignition source.

(2) Issue an enforcement policy statement to announce that the Commission will not apply the requirements of the children's sleepwear standards to tight-fitting sleepwear garments and garments in infant sizes if those garments met the requirements of the clothing textiles flammability standard.

The ANPR also contained information about other flammability standards for children's sleepwear; solicited information about relevant voluntary standards and statements of intention to develop or modify a voluntary standard; and invited interested persons to submit written comments on the ANPR.

On the same date the Commission published the ANPR, the Commission announced that it would not enforce the children's sleepwear standards in cases involving garments currently being used as sleepwear if those garments are skin-tight or nearly skin-tight, relatively free of ornamentation, made from fabrics such as rib knit, interlock knit, or waffle knit, and labeled as ''underwear.'' 58 FR 4078(5)

In response to the ANPR, the Commission received more than 2,100 written comments from individuals, firms, and organizations. (More than a third of the comments were identical form letters with space for the

[2] Numbers in parentheses identify reference documents in the List of Relevant Documents at the end of this notice. Requests for inspection of any of these documents should be made at the Commission's Public Reading Room, 4330 East-West Highway, room 419, Bethesda Maryland 20814, or by calling the Office of the Secretary at (301) 504–0800.

commenter's name.) Comments were received from all 50 states, the District of Columbia, Puerto Rico, the U.S. Virgin Islands, and from United States citizens living abroad.(3), (6), (7) Almost all of these comments favored modification of the standards to exempt some or all children's sleepwear garments from their requirements.

In addition to the information provided by commenters, the Commission also considered information developed or obtained by the Commission staff. That information included injury data(10); information about flammability characteristics of various fabrics and garments(8), (11); and a review of children's sleepwear flammability standards issued by Australia, Canada, New Zealand and the United Kingdom.(9), (11)

From its review of burn injury data, the Commission estimates that on average, about 1,150 children younger than 15 years of age were treated each year in hospital emergency rooms for burn injuries associated with clothing during the period from 1980 through 1993. Of that total, the Commission estimates that each year, about 90 burn injuries to children were associated with sleepwear, about 860 were associated with day wear, and about 200 were associated with other types of clothing or unspecified types of clothing.(10)

On average, each year about four children younger than fifteen years of age died from fires associated with clothing of all types.(10)

Available information also shows that most thermal burn injuries associated with sleepwear involved females, whereas most burn injuries associated with day wear involved males. Thermal burn injuries from nightwear were usually associated with nightgowns or pajamas that probably were not tight-fitting.(10)

In 1978, the Commission staff reviewed information about deaths and injuries associated with sleepwear to children younger than one year of age. Ten cases involved injuries associated with sleepwear. However, nine of these cases involved whole-house conflagrations, and the other involved a home-made garment.(11) Thus, none of these cases involved risks of injury which the sleepwear standards were intended to address.

F. Proposed Amendments

After consideration of comments received in response to the ANPR, information compiled by the staff, and information presented at an oral briefing by the staff, the Commission decided to propose amending the children's sleepwear standards.

The Commission published a notice to propose amending the children's sleepwear standards by exempting infant garments and tight-fitting garments from their requirements on October 25, 1994. (59 FR 53616)(20)

Section 4 of the FFA (15 U.S.C. 1193) authorizes the agency to issue or amend mandatory requirements for the flammability of wearing apparel only when such requirements are ''*needed to adequately protect the public* against *unreasonable risk of the occurrence of fire* leading to death, injury, or significant property damage.'' (Emphasis added.) Section 4 of the FFA also requires that in order to issue or amend a standard, the Commission must find, among other things, that the standard or amendment is ''limited'' to include only those garments which have been determined to present an ''unreasonable risk'' of burn deaths or injuries, or significant property damage. Consequently, the Commission concluded that if the children's sleepwear standards currently apply to garments which do not present an unreasonable risk of fire leading to death, injury, or significant property damage, the scope of the standards could be narrowed to remove those garments from the coverage of the standards.

That notice proposed to amend the children's sleepwear flammability standards by exempting:

(1) Garments intended for children six months of age and younger from the standard for sizes 0 through 6X; and

(2) ''Tight-fitting'' sleepwear garments from the standard for sizes 0 through 6X and the standard for sizes 7 through 14.

The proposed exemption for infant garments was stated in terms of maximum dimensions for the chest and length of the garment. The maximum dimensions specified were selected by considering body sizes of children approximately six months old, as set forth in ASTM standard D 4910–89, ''Standard Tables of Body Measurements for Infants, Ages 0 to 18 months,'' published by ASTM (formerly the American Society for Testing and Materials). (12)

The proposed amendments also required that an exempted infant garment must be labeled to indicate that the garment is intended for use by a child six months of age or younger.

In addition, the proposed amendments stated that garments in sizes for infants six months of age or younger must meet the applicable requirements of the flammability standards for clothing textiles and vinyl plastic film (16 CFR parts 1610 and 1611).

The proposed amendments defined the term ''tight-fitting garment'' by specifying maximum dimensions for the following parts of the garment: Chest, waist, seat, upper arm, thigh, wrist, and ankle. The proposed amendments also required that an exempted tight-fitting garment must be labeled to indicate its size. The maximum dimensions specified by the proposed amendments for tight-fitting garments in sizes for children six to 24 months old were selected by considering body sizes of children approximately six months old set forth in a proposed revision of ASTM standard D 4910. (12) The proposed maximum dimensions for tight-fitting garments in sizes 2 through 6X were based on dimensions specified in a draft ASTM standard tentatively designated ''Standard Table of Body Measurements for Pre-School Children Sizes 2—6X/7.''(12) Maximum dimensions specified by the proposed amendments for tight-fitting garments in sizes 7 through 14 were based on a report of an anthropometric study of children ranging in age from infancy to the age of 18 years, conducted in 1977 by the University of Michigan. (12)

To be eligible for the exemption from the requirements of the children's sleepwear standards, the proposal specified that a tight-fitting garment be labeled to indicate its size. The proposed amendments also required that when offered for sale to consumers, exempted garments in sizes for 6-to-9 months and larger must be clearly and conspicuously labeled with a statement to advise consumers that the garment is not flame-resistant and should be tight-fitting for the safety of the child.

Finally, the proposed amendments required that sleepwear garments exempted from the flammability requirements as ''tight-fitting'' garments must comply with applicable provisions of the flammability standards for clothing textiles and vinyl plastic film (16 CFR parts 1610 and 1611).

In a separate notice also published on October 25, 1994 (59 FR 53584), the Commission extended until further notice the stay of enforcement of the children's sleepwear standards published in 1993 for cases involving skin-tight or nearly skin-tight garments similar in design and manufacture to underwear, provided those garments were labeled and marketed as underwear. (21)

G. Comments on the Proposed Amendments

In response to the proposal to amend the sleepwear standards, the

Commission received 39 written comments. Some commenters submitted more than one comment.(22)–(61) Commenters included individual consumers, students, a physician, a retired Federal employee, manufacturers and importers of children's sleepwear and other children's garments, an association of manufacturers of children's sleepwear, the American Burn Association, the Coalition for American Trauma Care, Fire Prevention Canada, the International Association of Fire Chiefs, the National Cotton Council of America, and the Learn Not to Burn Foundation of the National Fire Protection Association.

Additionally, on April 25, 1995, members of the Commission staff conducted a public meeting with manufacturers and importers of children's sleepwear and other children's garments, consumers, and other interested persons to discuss the proposed amendments.(81)

The following is a summary of the principal issues raised by the written comments and at the public meeting, and the Commission's resolution of those issues.

1. Revocation of the Standards

A comment from one manufacturer of children's garments expresses the view that available injury information does not establish that any children's sleepwear garments present an unreasonable risk of burn deaths or injuries to children. This comment urges the Commission to revoke the standards in their entirety. (25)

When the Department of Commerce issued the flammability standard for sizes 0 through 6X, it considered injury data collected by the National Bureau of Standards (now the National Institute of Standards and Technology) through the Flammable Fabrics Accident Case and Testing System (FFACTS). From 1967 through January 1973, FFACTS obtained information about 434 cases involving burn injuries associated with sleepwear, 101 of which involved children younger than six years of age. Although FFACTS incidents do not constitute a probability sample, they document instances in which children were injured in fires involving sleepwear before issuance of the standard for sizes 0 through 6X. (70)

Unlike FFACTS, the National Electronic Injury Surveillance System (NEISS) gathers information about injuries by using a probability sample. For that reason, NEISS data can be reliably projected into national estimates of injuries associated with products. From burn injuries to children associated with children's sleepwear during the years 1980 through 1994 reported by NEISS, the Commission estimates that during that time period, on average, about 90 children younger than 15 years of age were treated in hospital emergency rooms each year for burns associated with children's sleepwear. (70)

The estimated number of burn injuries associated with children's sleepwear in the years following issuance of the sleepwear standards has been relatively low. This indicates that the sleepwear standards have been relatively successful. Therefore, the Commission does not believe that available injury information supports revocation of the children's sleepwear standards in their entirety.

A comment from one consumer questions whether use of children's sleepwear manufactured from man-made fabrics to comply with the sleepwear standards may increase the risk of sudden-infant-death syndrome (SIDS). (22) The Commission has reviewed medical publications concerning SIDS and has found no references which implicate a specific type of fabric or clothing as a contributing factor to SIDS. (73)

2. Exemption for Infant Garments

The proposed amendments contained provisions to exempt garments for infants six months of age and younger from the requirements of the sleepwear standard for sizes 0 through 6X. The proposed amendments limited the exemption for infant garments to those not exceeding specified dimensions for the chest and overall length of the garment. Those dimensions were selected using information about the body size of children approximately six months old.

Before proposing that exemption, the Commission reviewed information about burn deaths and injuries to children one year of age and younger associated with sleepwear. That information included a study completed in 1978 of 66 burn injuries to children younger than one year old associated with clothing. In ten cases, the clothing involved was specifically identified as sleepwear. Nine of those cases involved whole-house fires; the other involved a home-made garment. The Commission concluded that none of these cases involved risks of injury which the sleepwear standard was intended to address. (11)

The Commission also considered information about children's physical and mental development. That information shows that most children are not capable of moving themselves until they are about seven months old. For that reason, children six months of age and younger are not likely to come within range of small open-flame ignition sources when an adult is not present. (12)

A comment from the Children's Sleepwear Coalition (a group of children's sleepwear manufacturers and suppliers) objects to the proposal to exempt sleepwear garments for infants six months of age and younger. This comment states that infants are unable to defend themselves from risks of burn injury, and could be exposed to ignition sources by adults. Such exposure could occur if adults smoke in their presence, or place them near a kitchen range or other open flame source. (30) Comments from two individual manufacturers of children's sleepwear object to the proposed exemption for similar reasons. (45), (54)

Comments from two manufacturers of children's sleepwear, an importer of children's garments, and the National Cotton Council urge the Commission to expand the scope of the exemption to include garments for children one year of age and younger. (25), (28), (33), (47) In support of this position, the comments cite the absence of injuries associated with sleepwear to children younger than one year of age.

Comments from two manufacturers and one importer of children's garments state that the proposed amendment to exempt infant sleepwear garments was not consistent with industry practices for the sizing of infant clothing. (23), (35), (53) Two of these comments state that the maximum dimensions based on body measurements of children six months of age would have the effect of exempting some, but not all, infant garments. Garments in sizes 0 to three months (or infants ''small'' size) and three to six months (or infants ''medium'' size) would be exempted by the proposal, but not garments in sizes six to nine months (or infants ''large'' size). These comments recommend that the exemption apply to garments intended for infants nine months of age and younger, thereby exempting all sleepwear garments in infant sizes. (35), (53)

A comment from one manufacturer of children's garments observed that infants grow rapidly. This comment states that a garment having the maximum dimensions for exemption as an ''infant garment'' in the proposed amendment would fit a six-month-old child for only a short period of time. This comment states that most parents purchase children's garments with the expectation that their children will be able to wear them for a reasonable period of time. (23)

At the Commission's public meeting on April 25, 1995, several manufacturers of children's garments stated that parents typically buy garments one size larger than the age of their children.(81)

After consideration of all of these comments, the Commission concludes that the proposed exemption of ''infant garments'' should be included in the final amendments, with some modification. The amendment of the standard for sizes 0 through 6X issued below defines the term ''infant garment'' as one which is ''sized for a child nine months of age or younger.''

The Commission proposed to exempt garments for children six-months of age and younger because information about child development indicates that until they reach the age of seven months, most infants are not capable of moving by themselves.(12) Consequently, infants six months of age and younger are at minimal risk of exposing their clothing to an ignition source. And, available injury information reveals an absence of burn injuries associated with sleepwear to children younger than one year of age which might have been prevented or reduced by the sleepwear standard.(10), (11)

The Commission recognizes that many parents and other adults purchase infant garments one or two sizes larger than the age of the intended wearer, due in part to the rapid rate at which infants grow. By revising the definition of ''infant garment'' to include garments sized for children nine months of age and younger, the amendment issued below exempts garments in sizes frequently purchased for children approximately six months of age and younger. Exemption of garments sized for infants nine months of age and younger also makes allowance for those infants who are slightly larger than the average six-month old, and assures that a garment purchased for a six-month old will fit the infant for a reasonable length of time. Additionally, this modification of the proposed amendment makes the size of exempted ''infant garments'' more compatible with the range of sizes used by manufacturers of infant garments.

The amendments issued below specify that the maximum length for a one-piece infant garment shall not exceed 64.8 centimeters (25.75 inches). The maximum dimension for the length of either piece of a two-piece infant garment is 40 centimeters (15.75 inches). These dimensions were selected by considering body sizes of children approximately nine months old set forth in ASTM standard D 4910–95 ''Standard Tables of Body Measurements for Infants, Sizes 0 to 24 months,'' published by ASTM (formerly the American Society for Testing and Materials). No maximum dimension is specified for the chest of an infant garment exempted by the final amendments because the safety of infant garments is not dependent on a tight fit.

Exempted garments must comply with the flammability standards for clothing textiles and vinyl plastic film (16 CFR parts 1610 and 1611), and bear a label stating the size of the garment in terms of months of age. If the label is not visible when the garment is offered for sale, the size of the garment, in months, must appear legibly on the package.

3. Exemption for Tight-Fitting Garments

Comments from the National Cotton Council (33), (40), (48), five firms which manufacture or import children's sleepwear or other children's garments (28), (31), (34), (35), (42), (53), and a student research group (29) generally support issuance of final amendments to exempt tight-fitting children's sleepwear garments from the requirements of the sleepwear flammability standards. (Some of these comments recommend changes to specific provisions of the proposal, which are discussed below.)

Comments supporting an exemption for tight-fitting garments made from fabrics which are not flame-resistant state that those garments provide protection to children from unreasonable risks of burn injuries for the following reasons:

(1) Incident data do not show burn injuries associated with tight-fitting sleepwear;

(2) If exposed to an ignition source, tight-fitting garments are not easily ignited because the body absorbs some of the heat from the ignition source;

(3) If these garments are ignited, the wearer becomes aware of ignition almost immediately; and

(4) If ignited, these garments burn slowly because oxygen to support combustion is available on only one side of the garment.

Comments supporting issuance of final amendments for tight-fitting garments also observe that flammability standards for children's sleepwear in effect in Canada, Australia, and New Zealand exempt tight-fitting pajamas.(33), (40), (48)

In addition, a study cited in the proposal shows that no burn deaths associated with children's sleepwear have been reported in Canada since 1987.(33), (63)

Comments from the Children's Sleepwear Coalition (30), (58), five individual manufacturers of children's sleepwear (45), (46), (54)–(56), (59), a student research group (27), the Learn Not to Burn Foundation of the National Fire Protection Association (32), (78), the International Association of Fire Fighters (36), Fire Prevention Canada (37), and the Coalition for American Trauma Care (60) assert that the current low rate of children's deaths associated with ignition of clothing is evidence that the children's sleepwear standards have been effective. These comments express concern that exempting tight-fitting sleepwear garments and thereby allowing them to be made from fabrics which are not flame-retardant will expose children to an increased risk of burn deaths and injuries.

Before proposing the amendments, the Commission considered available data which show a measurable reduction in burn deaths associated with all types of clothing, including children's sleepwear, during the past 20 years. (10), (11). Additionally, information about burn injuries associated with all types of children's clothing from 1980 through 1994 shows that children's sleepwear has been associated with a relatively small proportion of those injuries. From its evaluation of this injury information, the Commission concludes that the children's sleepwear standards have contributed to the relatively low level of reported burn injuries associated with sleepwear. However, existing injury information does not support the assertion that amendment of the standards to exempt tight-fitting garments made from fabrics which do not pass the flammability test in the children's sleepwear standards will expose children to a greater risk of burn injuries.

Flammability standards for children's sleepwear issued by Canada and three other countries exempt tight-fitting garments. In 1993, the government of Canada advised the Commission that a proposed five-year study of burn injuries to assess the effectiveness of the Canadian sleepwear standard was discontinued before the end of the five-year period because of a lack of reported burn cases.(63)

When the Commission began this proceeding in 1993, it also announced that it would not enforce the children's sleepwear standards in cases involving garments which are skin-tight or nearly skin-tight and are similar in fabric and design to underwear.(5) That stay was continued at the time the Commission published the proposed amendments of the standards.(21) The garments covered by the stay of enforcement have somewhat larger dimensions than the ''tight-fitting'' garments defined in the proposed amendments.

On the basis of injuries reported to the National Electronic Injury Surveillance System (NEISS), the Commission estimates that about 2,520 children were treated in hospital emergency rooms for burn injuries associated with clothing during the years 1993 and 1994. During the years 1991 and 1992, the Commission estimates that approximately 2,760 children were treated in hospital emergency rooms for burn injuries associated with clothing.(62) Thus, burn injuries associated with the general category of children's clothing have not increased since the Commission issued the stay of enforcement.

During the years 1993 and 1994, the Commission received no reports of any burn injury to a child younger than 15 years of age associated with a garment which was identified as one covered by the stay of enforcement. (62)

Additionally, a Canadian study of 174 burn injuries cases associated with clothing involving children nine years of age or younger found that closeness of fit and the presence or absence of an adult at the time of injury were significantly associated with the severity of the burn injury. Fiber content was not included as a variable in this study. Burns tended to be more severe in cases associated with loose-fitting clothing and the absence of an adult.(11)

Accordingly, the Commission concludes that amending the standards to exempt tight-fitting sleepwear garments made from fabrics which are not flame-resistant will not create an unreasonable risk of burn injuries to children.(8), (10), (11), (62), (65)

4. Definition of ''Tight-Fitting Garment''

The proposed amendments defined the term ''tight-fitting garment'' as one which did not exceed specified dimensions in the chest, seat, upper arm, thigh, wrist, and ankle for each size ranging from 6-to-9 months through children's size 14.

A comment from one manufacturer of children's garments observes that the maximum dimensions specified for size 6 in the proposal were larger than the maximum dimensions specified for size 7.(28) The Commission agrees that the maximum dimensions for size 7 should be larger than the maximum dimensions for size 6. In the amendments issued below, maximum dimensions increase continuously from the smallest to the largest sizes of garments.

Other comments express the view that the maximum dimensions specified in the proposal for all sizes are too small. One manufacturer states that the amendments should exempt garments which fit ''reasonably close to the body,'' such as children's polo pajamas, rather than define the exempted garments by maximum dimensions intended to result in a ''skin-tight'' fit.(25) An importer suggests that the maximum dimensions specified for chest, seat, and thigh in all sizes should be increased by one or two inches.(35)

Before proposing amendments to exempt tight-fitting garments, the Commission reviewed technical literature indicating that tight-fitting garments are less likely to contact an ignition source, and if ignited to burn less rapidly, than loose-fitting clothing.(8) The Commission also considered burn injury data indicating that injuries associated with close-fitting garments are generally less severe than those associated with loose-fitting garments.(11)

Research on the flammability of wearing apparel indicates that fit and fiber are both important factors affecting a garment's flammability. The existing provisions of the children's sleepwear standards address the risk of burn injury by specifying a test for flame-resistance. Garments made from fabrics which pass the flammability test of the children's sleepwear standards do not present an unreasonable risk of injury, regardless of their fit. Similarly, tight-fitting garments exempted by the amendments issued below do not present an unreasonable risk of burn injury, even if they are made from fabrics which do not pass the flammability test of the children's sleepwear standards.

Section 4(b) of the FFA requires that an amendment of a flammability standard must be ''stated in objective terms.'' The term ''tight-fitting garment'' in the amendments issued below is defined by maximum dimensions at specified locations on the garment for each size. Although these dimensions include adjustments to provide a continuous increase in dimensions from the smallest to largest sizes, the dimensions and points of measurement are substantially similar to those in the notice of proposed rulemaking.

The final amendments also include language in the definition of ''tight-fitting garment'' to assure that the garment will conform closely to the contour of the body. Provisions of §§ 1615.1(o)(3) through (7) and 1616.2(m)(3) through (7) require that the torso of such garments must fit closely from chest to waist and from waist to seat; that the sleeves must taper from upper arm to wrist; and that the legs must taper from thigh to ankle.

Comments from three manufacturers of children's garments recommend adjustment of the maximum dimensions to allow for fabric shrinkage after laundering.(25), (28), (31) One of these comments states that if the maximum dimensions do not include an allowance for shrinkage, manufacturers may be required to wash garments before offering them for sale or to use other means to control shrinkage. This comment states that those measures would be ''expensive,'' but does not provide quantitative information about the extent of the additional costs.(28) At the public meeting on April 25, 1995, one importer recommended that the Commission allow an additional 10 per cent to the maximum dimensions for shrinkage.(81)

The maximum dimensions for ''tight-fitting garments'' in the amendments issued below have not been increased to allow for shrinkage after laundering or to provide a margin of tolerance for manufacturing variation. Garment shrinkage depends on the type of fiber or fiber-blend, method of construction, and finishing process used in the production of the fabric, and the laundering conditions to which the garment is exposed after wearing. Increasing the maximum dimensions to allow for shrinkage could reduce the likelihood that garments will be tight-fitting when worn by children.(72)

Garments made from knit fabrics have the ability to stretch and adapt to the shape of the body. For this reason, they are suitable, although not necessarily required, for production of ''tight-fitting garments'' exempted from the children's sleepwear standards by the amendments issued below.(72) Additionally, as indicated by one comment, various means are available to manufacturers to control shrinkage, although they may result in higher production costs.(28)

5. Labeling

The proposed amendments included in the definition of ''tight-fitting garment'' a requirement that when displayed for sale to consumers, the garment must be clearly and conspicuously labeled with the statement: ''Garment is not flame-resistant. For child's safety, garment should be tight fitting. Loose-fitting clothing is more likely to contact an ignition source and burn.''

Comments from a manufacturer and an importer of children's garments stated that the proposed labeling statement was too lengthy.(25), (35) At the Commission's public meeting on April 25, 1995, manufacturers also expressed the view that the proposed labeling statement was too negative.(81)

A comment from the National Cotton Council states that children's garments currently bear labels stating size, information about the manufacturer,

fiber content, country of origin, and care instructions. This comment states that the addition of the language specified by the proposed amendments would require an unsuitably large label for tight-fitting sleepwear garments.(33)

The same comment suggests that an educational effort to provide safety information to consumers about tight-fitting sleepwear by use of hang tags on garments and signs at retail stores would be a less expensive way to convey safety information about tight-fitting sleepwear garments to consumers. At the public meeting in April 1995 and in a subsequent written comment, the National Cotton Council stated that it would work cooperatively with the Commission to develop an information and education campaign to inform consumers that garment design is an important factor in burn injuries associated with children's sleepwear, and that snug-fitting sleepwear that fits close to the body is a safer choice than loose-fitting garments.(48), (81) Individual manufacturers of children's garments have also indicated their willingness to participate in such an effort.

The amendments issued below do not include the proposed labeling statement for tight-fitting sleepwear garments exempted from the flammability requirements of the children's sleepwear standards. The Commission concludes that a well-designed and broadly disseminated information and education campaign, developed with guidance from the Commission, will be a better means to inform consumers about appropriate selection and use of the tight-fitting garments exempted from the sleepwear standards by the amendments issued below. Such a campaign can help consumers understand why sleepwear garments which are not flame-resistant are being offered for sale and the importance of a tight fit for those garments; that other children's sleepwear garments which are not tight-fitting but are manufactured to comply with the sleepwear standards remain available for purchase; and that loose-fitting garments which are not flame-resistant (such as those made from untreated cotton and cotton blends) should not be used for children's sleepwear.

The Commission expects that point-of-sale materials directed to consumers, including hang-tags on garments, labeling statements on packaging, and store signs, will be an important component of the sleepwear industry's information and education effort. The Commission also expects that another part of this effort will be directed at retailers to emphasize the necessity for separation of children's nonsleepwear garments such as underwear, daywear, and playwear from sleepwear garments manufactured to comply with the standards and tight-fitting sleepwear garments exempted from those standards by the amendments issued below. Separation of non-sleepwear garments from children's sleepwear is necessary to assure that consumers will not inadvertently purchase a loose-fitting, non-sleepwear garment which is not flame-resistant when shopping for children's sleepwear.

H. Effective Date

Section 4(b) of the FFA (15 U.S.C. 1293(b)) provides that an amendment of a flammability standard shall become effective twelve months after publication of the notice of final rulemaking unless the Commission makes a finding for good cause that an earlier or later effective date is in the public interest and publishes the reasons for that finding.

On May 23, 1996, members of the Commission staff met with representatives of manufacturers, importers, and retailers of children's garments, the National Cotton Council, and other interested parties to discuss technical issues related to the Commission's decision to amend the children's sleepwear standards. At this meeting, representatives of the National Cotton Council and some manufacturers claimed that the amendments should become effective upon publication. They observed that the amendments do not impose any additional requirements on firms, but instead exempt certain garments from the requirements of the children's sleepwear standards that do not present an unreasonable risk of burn injury. These proponents of an immediate effective date asserted that many firms are able to begin marketing the newly exempted sleepwear garments within a short time after issuance of the final amendments.

Representatives of several importers claimed that their businesses would need several months or more after publication of the final amendments to draft specifications, place orders, and receive merchandise from overseas suppliers. Similarly, representatives of some domestic manufacturers stated that they would need time to devise specifications for fabrics, place orders with fabric suppliers, and receive fabrics to be used in production of the sleepwear garments that will be exempted from the requirements of the sleepwear standards.

After considering all information concerning an appropriate effective date, the Commission concludes that the amendments issued below shall become effective on January 1, 1997. The Commission finds for good cause that a short delay in the effective date, less than the one year specified by the FFA, is in the public interest because it balances the need of some firms for a period of transition in which to make those adjustments necessary to market the sleepwear garments exempted by the amendments with the interest of other firms in marketing those products as soon as possible.

The Commission is aware that many of the firms favoring a delayed effective date are producers or importers of children's sleepwear manufactured to comply with the sleepwear flammability standards. The Commission recognizes the important role which complying sleepwear plays in preventing burn injuries. The regulations governing the flammability of material used to make children's sleepwear garments other than garments covered by these amendments will continue to apply to garments such as robes and nightgowns. However, a delay in the effective date of the amendments issued below beyond January 1, 1997, postpones the availability of tight-fitting cotton and cotton-blend sleepwear garments, and prolongs the period during which consumers seeking untreated cotton sleepwear for their children may purchase alternative garments which pose greater flammability risks. For these reasons, the Commission concludes that an effective date of January 1, 1997, is appropriate to: (1) Provide a transition period for manufacturers and importers of complying sleepwear garments who wish to sell garments permitted by these amendments; and (2) allow all companies to take advantage of the amendments within a reasonable period of time.

The Commission has also extended the stay of enforcement of the sleepwear standards for 18 months for close-fitting garments labeled and promoted as underwear. The Commission has taken this action to minimize costs to manufacturers, distributors, and retailers of children's sleepwear and other garments which may result from adjustments of inventories of both sleepwear and non-sleepwear garments which are subject to the stay of enforcement.(67)

I. Final Regulatory Analysis and Required Findings

Section 4(j) of the FFA (15 U.S.C. 1193(j)) requires that a notice of final rulemaking must include a final regulatory analysis containing:

• A discussion of potential benefits and costs of the final rule, including those which cannot be quantified, and an identification of those persons likely to receive its benefits and bear its costs;

• A description of any alternatives to the final rule which were considered by the Commission together with a summary description of their potential benefits and costs and a brief explanation of why these alternatives were not chosen; and

• A summary of significant issues raised by comments on the preliminary analysis, and the Commission's assessment of those issues.

• Additionally, section 4(j) requires that the final rule must include the Commission's findings that:

• The benefits expected from the rule bear a reasonable relationship to its costs;

• It imposes the least burdensome requirement which prevents or adequately reduces the risk of injury for which it is promulgated.

1. Potential Benefits of the Amendments

The amendments issued below will provide consumers a wider choice of children's sleepwear. Specifically, the amendments will allow garments intended for children younger than nine months of age and tight-fitting garments in sizes as large as children's size 14 to be made from untreated cotton and cotton blends, which may not currently be used in the production of children's sleepwear. Although a dollar value cannot be placed on this benefit, the Commission is aware that large numbers of consumers have expressed a desire for children's sleepwear made from cotton rather than the man-made fibers used to produce most sleepwear garments manufactured to comply with the children's sleepwear flammability standards.(6), (29), (34), (42), (66), (67)

The amendments will permit consumers to dress their children for sleeping in the tight-fitting sleepwear garments exempted from the requirements of the standards instead of loose-fitting underwear, playwear, or daywear garments. This, in turn, could reduce the risks of burn injuries and deaths to children because tight-fitting sleepwear garments present a lower fire risk to children than loose garments which are not flame-resistant and do not comply with the children's sleepwear standards. The extent to which such a substitution will occur is not known, and therefore any resulting benefit is not quantifiable.(67)

Manufacturers who elect to produce the garments in infant sizes and tight-fitting garments exempted from the children's sleepwear standards will benefit from a wider choice of fabrics and the elimination of requirements for sampling, testing, and recordkeeping under the sleepwear standards. The Commission is not able to predict the extent to which manufacturers will elect to produce sleepwear garments exempted by the amendments issued below. For that reason, the benefits to manufacturers from increased choice of fabric and elimination of sampling, testing, and recordkeeping costs cannot be quantified.(67)

2. Potential Costs of the Amendments

Potential costs of the amendments include those related to temporary disruptions in the production process as manufacturers make changes needed to produce garments exempted by the amendments. According to industry sources, those changes could include recalibration of cutting and sewing machines. Some costs may be associated with modification of packaging, but they are expected to be negligible. To minimize disruptions in the production process, the Commission has extended a stay of enforcement for close-fitting garments labeled and promoted for sale as underwear for 18 months to allow manufacturers, distributors, and retailers to dispose of existing inventories of those garments.(67)

Because the Commission cannot predict the extent to which manufacturers will elect to produce the sleepwear garments exempted from the requirements of the children's sleepwear standards, the Commission is unable to quantify the costs to manufacturers which may result.(67) However, the amendments do not require manufacturers to produce the exempted garments. Consequently, the Commission anticipates that only those firms which find it profitable to produce the exempted garments will incur the costs required to begin making them.

The amendments issued below permit the manufacture of certain children's sleepwear garments which will not pass the flammability test in the children's sleepwear standards. Consequently, the potential costs of the amendments include the possibility of increased societal costs resulting from any burn injuries which may be associated with the exempted garments.(67) However, during the three-year period in which the stay of enforcement for close-fitting garments has been in effect, the Commission has received no reports of burn injuries associated with ignition of those garments.(62) Additionally, Canada's experience with sleepwear standards which contain provisions similar to those in the amendments issued below indicates the risk of increased burn injuries is extremely low.(63) And if consumers dress their children for sleeping in the tight-fitting garments exempted by the amendments instead of loose-fitting T-shirts and other loose-fitting garments which are not flame-resistant and do not comply with the children's sleepwear standards, risks of burn injuries to children are expected to decrease.(67)

3. Alternatives to the Amendments

a. *Make no change to the standards.* The existing children's sleepwear flammability standards have contributed to the relatively low level of burn injuries to children associated with clothing.(10) Additionally, information is available to demonstrate that a number of burn injuries to children younger than six years of age were associated with sleepwear before the flammability standard for sizes 0 through 6X became effective.(70) If the Commission made no change to the standards, the level of protection against risks of burn injuries to children associated with children's sleepwear would not be altered.

However, if the Commission does not amend the standards, consumers will be unable to purchase children's sleepwear garments made from untreated cotton and cotton blends. Some consumers have expressed a strong desire to purchase such garments for their children to wear while sleeping.(6), (29), (34), (42), (66), (67) In addition, if the Commission does not make changes to the standards, problems related to their enforcement in cases where garments resemble children's sleepwear but are marketed and sold as underwear or playwear are expected to continue.(68) This has been a problem in the past which the changes to the standard are expected to alleviate. And, to satisfy their desire for cotton sleepwear for their children, more people may turn to looser-fitting substitutes which are not flame-resistant and present a greater risk of burn injury.

b. *Continue the stay of enforcement without amending the standards.* On January 13, 1993, the Commission announced that it would not enforce the children's sleepwear standards in cases involving close fitting garments which are similar in design and construction to underwear, relatively free of ornamentation, and are labeled and marketed as underwear. The Commission continued this stay of enforcement when it published the notice of proposed rulemaking on October 25, 1994. During the period that this stay of enforcement has been in effect, the Commission has not observed any burn injuries to children associated

with the garments covered by the stay of enforcement.(62)

However, the tight-fitting garments exempted by the amendments issued below fit more closely than the garments subject to the stay of enforcement. Additionally, those tight-fitting garments can be marketed as children's sleepwear. Consequently, the Commission anticipates the exempted tight-fitting garments would provide better protection against risks of burn injuries than the garments covered by the stay of enforcement.(67)

4. Issues Raised by Comments on the Preliminary Regulatory Analysis

a. *Potential benefits.* A comment from a manufacturer of children's garments asserts that issuance of final amendments to exempt garments in infant sizes and close-fitting garments from the children's sleepwear standards may result in a decrease, rather than an increase in consumers' choice of sleepwear garments. This comment states that retailers devote a limited amount of shelf space to children's sleepwear. If consumers demonstrate a significant preference for cotton sleepwear garments exempted from the requirements of the standards, this comment claims that retailers will stock fewer garments manufactured to comply with the sleepwear standards, and may eventually stop selling those garments.(59)

As stated above, in 1993 the Commission published a stay of enforcement of the sleepwear standards in cases involving skin-tight or nearly skin-tight garments which are similar in design to the tight-fitting garments exempted by the amendments issued below. Available marketing data shows that during 1992, the last year before the stay, sales of traditional children's sleepwear manufactured to comply with the flammability standards were approximately 123.6 million units. During 1994, the second year of the stay of enforcement, sales of traditional children's sleepwear were 123.5 million units.(66)

The Commission concludes that available information about sales of children's sleepwear does not support the assertion that the amendments issued below will result in reduced choice to consumers. Additionally, many parents and children may prefer the comfort of looser-fitting garments made from flame-resistant fabrics over the tight-fitting garments made from cotton or cotton blends. Certain styles of sleepwear, such as nightgowns, robes, and traditional pajamas will still be required to be made from fabrics which pass the tests of the sleepwear standards. The Commission does not expect consumers to cease purchasing these styles of sleepwear.

b. *Potential costs.* A comment from the American Burn Association states that the Commission's preliminary regulatory analysis underestimated the number of burn injuries which may result from the proposed amendments and consequently the costs to society for treatment of those injuries. This comment observes that in the notice proposing the amendments, the Commission estimated that each year about 1,150 children were treated in hospital emergency rooms for burn injuries associated with clothing of all types. The comment asserts that the true number of emergency room visits may be as high as 4,000 a year, citing a study published in the May-June 1995 issue of the Journal of Burn Care and Rehabilitation.(38)

The Commission observes that the study cited by this comment reviewed cases involving children referred to burn centers for burn injuries of all types, and was not limited to burns associated with ignition of clothing or sleepwear. Accordingly, the estimates of children's burn injuries treated in emergency rooms made in this comment are not comparable to those made by the Commission in the notice of proposed rulemaking.(10) Additionally, the study cited in this comment does not contain any information from which to predict the likely effect of the proposed amendments on the number of children's burn injuries associated with sleepwear.

A comment from The Learn Not to Burn Foundation of the National Fire Protection Association asserts that increased burn injuries to children are likely to result if the Commission issues final amendments of the children's sleepwear standards.(32) That comment sets forth the following rationale: At present, children's cotton garments suitable for use as sleepwear are ''sufficiently expensive'' that they are purchased primarily by consumers with higher incomes. Higher-income consumers are more likely to have behaviors that offset the increased risk of burn injury presented by sleepwear garments which do not comply with the flammability standards. The proposed amendments will reduce the cost of the exempted sleepwear garments, thereby making them available to lower-income consumers. According to this comment, ''low income correlates negatively with all measures of fire risk.''

However, recent marketing and injury information does not support the expectations expressed in this comment. As noted in the response to an earlier comment, since the stay of enforcement of the children's sleepwear standards was issued in 1993, sales of traditional sleepwear manufactured to comply with the standards has remained relatively constant. During the same period of time, sales of children's underwear garments increased from 476 million units in 1992 to 502.4 million units in 1994. One trade publication attributes this gain in sales of children's underwear to the use of some of these garments for sleeping.(66) Underwear and playwear garments subject to the stay of enforcement are sold by high-volume retailers and discounters at lower prices than sleepwear which complies with the children's sleepwear flammability standards.(87) Consequently, these garments have been available to both higher- and lower-income consumers. Again, during the time the stay has been in effect, the Commission has received no reports of burn injuries associated with the garments identified as subject to the stay.(62)

c. *Regulatory alternatives.* A comment from a retired Federal employee states that as an alternative to the exemption of infant garments from the standards, the Commission should consider elimination of requirements for testing seam and trim, but continue to require the fabric used in those garments to meet the flammability requirements of the standard for sizes 0 through 6X. The comment states that such a change would have a negligible effect on safety.(26)

The suggestion in this comment would relieve manufacturers of garments in infant sizes from some, but not all, of the requirements of the standard for sizes 0 through 6X. However, if fabric used in those garments remained subject to the flammability requirements of that standard, untreated cotton and cotton blends could not be used.

As noted above, one of the principal benefits of the amendments issued below is to provide consumers with a greater choice of sleepwear garments by permitting the use of those fabrics for production of certain types of children's sleepwear. The Commission concludes that the alternative suggested by this comment would significantly reduce the potential benefits of the amendments issued below, without a corresponding reduction in their potential costs.(10)

For these reasons, the Commission affirms the conclusion of its preliminary and final regulatory analysis that the amendments are not likely to increase societal costs resulting from burn injuries to children associated with sleepwear.

5. Findings

After considering all information concerning benefits and costs of the amendments, including comments on the preliminary regulatory analysis, the Commission finds the benefits of the amendments issued below bear a reasonable relationship to their costs. Although these benefits are not quantifiable, they include increased choice to consumers in children's sleepwear garments. To the extent that consumers choose the tight-fitting sleepwear garments permitted by the amendments rather than loose-fitting garments which are not flame-resistant, risks of burn injuries to children may be reduced.

The costs of the amendments include some disruption to the children's sleepwear industry, and the possibility of increased societal costs of treating burn injuries associated with the garments exempted by the amendments. By establishing an effective date of January 1, 1997, and extending the stay of enforcement for certain close-fitting children's underwear and playwear, the Commission has minimized costs associated with disruption of the children's sleepwear industry. For the reasons set forth in the discussion of potential costs of the amendments and comments on the preliminary regulatory analysis, the Commission concludes that the potential costs of the amendment, although unquantifiable, are minimal.

The Commission also finds that the amendments issued below impose the least burdensome requirements which adequately reduce the risks of burn injuries to children associated with sleepwear. The Commission has considered the possibilities of withdrawing the proposed amendment, with or without extending the stay of enforcement for certain close-fitting children's underwear and playwear. For the reasons set forth above in the discussion of regulatory alternatives, the Commission finds that none of the alternatives considered will provide the increased choice to consumers at as low a level of risk as the amendments issued below.

J. Other Statutory Findings

Section 4(b) of the FFA (15 U.S.C. 1193(b)) states that each flammability standard or amendment shall be based on findings that the standard or amendment is: Reasonably needed to protect the public against an unreasonable risk of the occurrence of fire leading to death or personal injury, or significant property damage; reasonable, technologically appropriate, and practicable; and limited to those fabrics, related materials, or products of wearing apparel or interior furnishing which have been determined to present an unreasonable risk of fire leading to death, personal injury, or significant property damage.

After considering all of the information received during this rulemaking proceeding, the Commission finds that to the extent that the Standard for the Flammability of Children's Sleepwear: Sizes 0 Through 6X (16 CFR part 1615) and the Standard for the Flammability of Children's Sleepwear: Sizes 7 Through 14 (16 CFR part 1616) are applicable to garments intended for children nine months of age or younger or to the tight-fitting garments described in the amendments issued below, those standards are not: (i) Reasonably necessary to protect the public from risks of fire leading to death, personal injury, or significant property damage; or (ii) limited to the garments which present that unreasonable risk. After considering the same information, the Commission also finds that the amendments issued below are reasonable, technologically practicable, and appropriate.

K. Future Activities

The Commission will continue to monitor closely and thoroughly information from all available sources concerning burn injuries to children from sleepwear and other garments. If at any time, the Commission detects an increase in burn deaths or injuries to children associated with any of the garments exempted by these amendments, it will take any appropriate action, including initiation of rulemaking to broaden the scope of the children's sleepwear flammability standards.

The Commission will also monitor the information and education campaign undertaken by manufacturers of children's sleepwear and other garments to assure that it accurately and effectively informs consumers about the children's sleepwear flammability standards, garments manufactured to comply with those standards, and the garments exempted from those standards by the amendments issued below.

L. Stay of Enforcement

The stay of enforcement which was issued on January 13, 1993, and continued on October 25, 1994, will end on March 9, 1998. A separate notice published elsewhere in this issue of the Federal Register provides additional details about the stay of enforcement and its termination date.

M. Impact on Small Businesses

In accordance with section 605(b) of the Regulatory Flexibility Act (5 U.S.C. 605(b)), the Commission hereby certifies that the amendments to the children's sleepwear standards issued below will not have a significant economic impact on a substantial number of small entities, including small businesses.

At this time, about 65 firms manufacture or import traditional children's sleepwear garments, i.e., nightgowns, pajamas, and robes.(66). The number of firms in the children's sleepwear industry has not changed substantially in the past several years.(15) About 45 of these firms have fewer than 500 employees and are considered to be small businesses.(83) None of the firms which are small businesses market children's sleepwear exclusively. In addition to traditional children's sleepwear, these firms also manufacture or import other types of garments such as infantwear, children's underwear and playwear, and in some cases, adult underwear and lingerie.(83)

For many years, the market for traditional children's sleepwear has been relatively small but constant. In 1970, the year before promulgation of the first children's sleepwear standard, sales of all new children's sleepwear garments amounted to about 1.4 garments per child younger than 14 years of age.(83) From 1992 through 1994, sales volume has been about 124 million units, about two garments per child each year.(84) This sales information reflects a strong preference for traditional sleepwear by some consumers.

However, if one assumes that most children use several garments each year for sleeping, a logical inference is that children are using many garments other than traditional nightgowns and pajamas for sleeping.

The amendments issued below exempt sleepwear garments sized for children nine months of age and younger and certain tight-fitting sleepwear garments from the requirements of the children's sleepwear standards. The tight-fitting sleepwear garments exempted by the amendments are similar in fit and appearance to long underwear.

A decision to produce or import the exempted garments would entail minimal costs for any current manufacturer or importer of children's sleepwear, regardless of size, for several reasons. First, these firms have an existing customer base for the sleepwear and other garments which they currently distribute. Second, in the children's sleepwear industry, design

and fabric choices are under continuous reassessment; consumer demand and production costs are important considerations when deciding on the design and fabric to be used. Usually, only minor capital costs are involved in making changes to design or material used to produce these garments.(83)

Firms which decide to produce or import garments exempted from the sleepwear standards by the amendments issued below will be able to use untreated fabrics made from cotton and cotton blends which cannot pass the flammability test of the standards. Additionally, they will avoid costs of testing and recordkeeping imposed by the standards.

However, no firm is required to produce or import exempted garments. Firms which decide that demand for the garments exempted by the amendments does not justify the costs of producing or importing them will not be required to make any changes to their current practices.(67)

For these reasons, the Commission concludes that the final amendments will not likely have a significant economic impact on a substantial number of small entities, including small businesses.(83)

N. Environmental Considerations

The amendments issued below fall within the categories of Commission actions described at 16 CFR 1021.5(c) that have little or no potential for affecting the human environment. The amendments are not expected to have a significant effect on production processes or on the types or amounts of materials used for construction or packaging of children's sleepwear. The amendments will not render existing inventories unsalable, or require destruction of existing goods. The Commission has no information indicating any special circumstances in which these amendments may affect the human environment. For that reason, neither an environmental assessment nor an environmental impact statement is required.(67)

List of Subjects in 16 CFR Parts 1615 and 1616

Clothing, Consumer protection, Flammable materials, Infants and children, Labeling, Records, Textiles, Warranties.

Conclusion

Therefore, pursuant to the authority of section 30(b) of the Consumer Product Safety Act (15 U.S.C. 2079(b)) and section 4 of the Flammable Fabrics Act (15 U.S.C. 1193), the Commission hereby amends title 16 of the Code of Federal Regulations, Chapter II, Subchapter D, parts 1615 and 1616 to read as follows:

PART 1615—STANDARD FOR THE FLAMMABILITY OF CHILDREN'S SLEEPWEAR: SIZES 0 THROUGH 6X

1. The authority for part 1615 continues to read as follows:

Authority: Sec. 4, 67 Stat. 112, as amended, 81 Stat. 569–570; 15 U.S.C. 1193.

2. In § 1615.1, Paragraphs (c) through (m) are redesignated paragraphs (d) through (n), respectively.

3. Section 1615.1 is amended by revising paragraph (a) and adding new paragraphs (c) and (o) to read as follows:

§ 1615.1 Definitions.

(a) *Children's Sleepwear* means any product of wearing apparel up to and including size 6X, such as nightgowns, pajamas, or similar or related items, such as robes, intended to be worn primarily for sleeping or activities related to sleeping, except:

(1) Diapers and underwear;

(2) ''Infant garments,'' as defined by section 1615.1(c), below; and

(3) ''Tight-fitting garments,'' as defined by section 1615.1(o), below.

* * * * *

(c) *Infant garment* means a garment which:

(1) Is sized for a child nine months of age or younger;

(2) If a one-piece garment, does not exceed 64.8 centimeters (25.75 inches) in length; if a two-piece garment, has no piece exceeding 40 centimeters (15.75 inches) in length;

(3) Complies with all applicable requirements of the Standard for the Flammability Clothing Textiles (16 CFR Part 1610) and the Standard for the Flammability Vinyl Plastic Film (16 CFR part 1611); and

(4) Bears a label stating the size of the garment, expressed in terms of months of age. For example, ''0 to 3 mos.'' or ''9 mos.'' If the label is not visible to the consumer when the garment is offered for sale at retail, the same information must appear legibly on the package of the garment.

* * * * *

(o) *Tight-fitting garment* means a garment which:

(1) In each of the sizes listed below does not exceed the maximum dimension specified below for the chest, waist, seat, upper arm, thigh, wrist, or ankle:

	Chest	Waist	Seat	Upper arm	Thigh	Wrist	Ankle
Size 9–12 mos							
Maximum dimension:							
Centimeters	48.3	48.3	48.3	14.3	26.7	10.5	13
(inches)	(19)	(19)	(19)	(5⅝)	(10½)	(4⅛)	(5⅛)
Size 12–18 mos							
Maximum dimension:							
Centimeters	49.5	49.5	50.8	14.9	28.3	10.5	13.1
(inches)	(19½)	(19½)	(20)	(5⅞)	(11⅛)	(4⅛)	(5⅛)
Size 18–24 mos							
Maximum dimension:							
Centimeters	52.1	50.8	53.3	15.6	29.5	11	13.6
(inches)	(20½)	(20)	(21)	(6⅛)	(11⅝)	(4¼)	(5⅜)

	Chest	Waist	Seat	Upper arm	Thigh	Wrist	Ankle
Size 2							
Maximum dimension:							
Centimeters	52.1	50.8	53.3	15.6	29.8	11.4	14
(inches)	(20½)	(20)	(21)	(6⅛)	(11¾)	(4½)	(5½)
Size 3							
Maximum dimension:							
Centimeters	53.3	52.1	56	16.2	31.4	11.7	14.9
(inches)	(21)	(20½)	(22)	(6⅜)	(12⅜)	(4⅝)	(5⅞)
Size 4							
Maximum dimension:							
Centimeters	56	53.3	58.4	16.8	33.0	12.1	15.9
(inches)	(22)	(21)	(23)	(6⅝)	(13)	(4¾)	(6¼)
Size 5							
Maximum dimension:							
Centimeters	58.4	54.6	61.0	17.5	34.6	12.4	16.8
(inches)	(23)	(21½)	(24)	(6⅞)	(13⅝)	(4⅞)	(6⅝)
Size 6							
Maximum dimension:							
Centimeters	61.0	55.9	63.5	18.1	36.2	12.7	17.8
(inches)	(24)	(22)	(25)	(7⅛)	(14¼)	(5)	(7)
Size 6X							
Maximum dimension:							
Centimeters	62.9	57.2	65.4	18.7	37.8	13.0	18.7
(inches)	(24¾)	(22½)	(25¾)	(7⅜)	(14⅞)	(5⅛)	(7⅜)

NOTE: Maximum dimensions are calculated by placing the garment on a horizontal, flat surface with the outer surface of the garment exposed, measuring the distances between the points specified below; and multiplying that value by two:

Chest—measure distance from arm pit to arm pit.

Waist—on one-piece garment, measure at the narrowest location between arm pits and crotch. On two-piece garment, measure width at the bottom of the upper piece, and the top of the lower piece.

Seat—on one-piece garment, measure at widest location between waist and crotch. On two-piece garment, take this measurement on lower piece only.

Upper arm—measure at a line perpendicular to the sleeve. Extending from the outer edge of the sleeve to the arm pit.

Thigh—measure at a line perpendicular to the leg extending from the outer edge of the leg to the crotch.

Wrist—measure the width of the end of the sleeve, if intended to extend to the wrist.

Ankle—measure the width of the end of the leg, if intended to extend to the ankle.

(2) Has no item of fabric, ornamentation or trim, such as lace, appliques, or ribbon, which extends more than 6 millimeters (¼ inch) from the point of attachment to the outer surface of the garment;

(3) Has sleeves which do not exceed the maximum dimension for the upper arm at any point between the upper arm and the wrist, and which diminish in width gradually from the upper arm to the wrist;

(4) Has legs which do not exceed the maximum dimension for the thigh at any point between the thigh and the ankle, and which diminish in width gradually from the thigh to the ankle;

(5) In the case of a one-piece garment, has a width which does not exceed the maximum dimension for the chest at any point between the chest and the waist and which diminishes gradually from the chest to the waist; and has a width which does not exceed the maximum dimension for the seat at any point between the seat and the waist and which diminishes gradually from the seat to the waist;

(6) In the case of a two-piece garment has an upper piece with a width which does not exceed the maximum dimension for the chest at any point between the chest and the bottom of that piece and which diminishes gradually from the chest to the bottom of that piece; in the case of an upper piece with fastenings, has the lowest fastening within 15 centimeters (6 inches) of the bottom of that piece;

(7) In the case of a two-piece garment, has a lower piece with a width which does not exceed the maximum dimension for the seat at any point between the seat and the top of the lower piece and which diminishes gradually from the seat to the top of that piece;

(8) Complies with all applicable requirements of the Standard for the Flammability of Clothing Textiles (16 CFR part 1610) and the Standard for the Flammability of Vinyl Plastic Film (16 CFR part 1611); and

(9) Bears a label stating the size of the garment in terms of age in months, or by child's size; for example: ''Size 9 to 12 mos.'' or ''Size 2.'' If the label is not visible to the consumer when the garment is offered for sale at retail, the same information must appear legibly on the package of the garment.

PART 1616—STANDARD FOR THE FLAMMABILITY OF CHILDREN'S SLEEPWEAR: SIZES 7 THROUGH 14

1. The authority for part 1616 continues to read as follows:

Authority: Sec. 4, 67 Stat. 112, as amended, 81 Stat. 569–570; 15 U.S.C. 1193.

2. Section 1616.2 is amended by revising paragraph (a) and adding a new paragraph (m), to read as follows:

§ 1616.2 Definitions.

In addition to the definitions given in section 2 of the Flammable Fabrics Act, as amended (sec. 2, 81 Stat. 586; 15 U.S.C. 1191), the following definitions apply for the purposes of this Standard:

(a) Children's sleepwear means any product of wearing apparel size 7 through 14, such as nightgowns, pajamas, or similar or related items, such as robes, intended to be worn primarily for sleeping or activities related to sleeping, except:

(1) Diapers and underwear; and

(2) ''Tight-fitting garments'' as defined by section 1616.2(m), below.

* * * * *

(m) *Tight-fitting garment* means a garment which:

(1) in each of the sizes listed below does not exceed the maximum dimension specified below for the chest, waist, seat, upper arm, thigh, wrist, or ankle:

	Chest	Waist	Seat	Upper arm	Thigh	Wrist	Ankle
Size 7 Boys [1]							
Maximum dimension:							
Centimeters	63.5	58.4	66	18.7	37.2	13.0	18.7
(inches)	(25)	(23)	(26)	(7⅜)	(14⅝)	(5⅛)	(7⅜)
Size 7 Girls							
Maximum dimension:							
Centimeters	63.5	58.4	67.3	18.7	38.7	13.0	18.7
(inches)	(25)	(23)	(26½)	(7⅜)	(15¼)	(5⅛)	(7⅜)
Size 8 Boys [1]							
Maximum dimension:							
Centimeters	66	59.7	67.3	19.4	38.4	13.3	19.1
(inches)	(26)	(23½)	(26½)	(7⅝)	(15⅛)	(5¼)	(7½)
Size 8 Girls							
Maximum dimension:							
Centimeters	66	59.7	71.1	19.4	41.3	13.3	19.1
(inches)	(26)	(23½)	(28)	(7⅝)	(16¼)	(5¼)	(7½)
Size 9 Boys [1]							
Maximum dimension:							
Centimeters	68.6	61.0	69.2	20	39.7	13.7	19.4
(inches)	(27)	(24)	(27¼)	(7⅞)	(15⅝)	(5⅜)	(7⅝)
Size 9 Girls							
Maximum dimension:							
Centimeters	68.6	61.0	73.7	20	42.6	13.7	19.4
(inches)	(27)	(24)	(29)	(7⅞)	(16¾)	(5⅜)	(7⅝)
Size 10 [1] Boys							
Maximum dimension:							
Centimeters	71.1	62.2	71.1	20.6	41.0	14	19.7
(inches)	(28)	(24½)	(28)	(8⅛)	(16⅛)	(5½)	(7¾)
Size 10 Girls							
Maximum dimension:							
Centimeters	71.1	62.2	76.2	20.6	43.8	14	19.7
(inches)	(28)	(24½)	(30)	(8⅛)	(17¼)	(5½)	(7¾)
Size 11 [1] Boys							
Maximum dimension:							
Centimeters	73.7	63.5	73.7	21	42.2	14.3	20
(inches)	(29)	(25)	(29)	(8¼)	(16⅝)	(5⅝)	(7⅞)

	Chest	Waist	Seat	Upper arm	Thigh	Wrist	Ankle
Size 11 Girls							
Maximum dimension:							
Centimeters	73.7	63.5	78.7	21	45.1	14.3	20
(inches)	(29)	(25)	(31)	(8¼)	(17¾)	(5⅝)	(7⅞)
Size 12 Boys [1]							
Maximum dimension:							
Centimeters	76.2	64.8	76.2	21.6	43.5	14.6	20.3
(inches)	(30)	(25½)	(30)	(8½)	(17⅛)	(5¾)	(8)
Size 12 Girls							
Maximum dimension:							
Centimeters	76.2	64.8	81.3	21.6	46.7	14.6	20.3
(inches)	(30)	(25½)	(32)	(8½)	(18½)	(5¾)	(8)
Size 13 Boys							
Maximum dimension:							
Centimeters	78.7	66	78.7	22.2	44.8	14.9	20.6
(inches)	(31)	(26)	(31)	(8¾)	(17⅝)	(5⅞)	(8⅛)
Size 13 Girls							
Maximum dimension:							
Centimeters	78.7	66	83.8	22.2	47.6	14.9	20.6
(inches)	(31)	(26)	(33)	(8¾)	(18¾)	(5⅞)	(8⅛)
Size 14 Boys [1]							
Maximum dimension:							
Centimeters	81.3	67.3	81.3	22.9	46	15.2	21
(inches)	(32)	(26½)	(32)	(9)	(18⅛)	(6)	(8¼)
Size 14 Girls							
Maximum dimension:							
Centimeters	81.3	67.3	86.4	22.9	49.5	15.2	21
(inches)	(32)	(26½)	(34)	(9)	(19½)	(6)	(8¼)

[1] Garments not explicitly labeled and promoted for wear by girls must not exceed these maximum dimensions.

NOTE: Maximum dimensions are calculated by placing the garment on a horizontal, flat surface, with the outer surface of the garment exposed; measuring the distances at the points specified below; and multiplying that value by two:

Chest—measure distance from arm pit to arm pit.

Waist—on one-piece garment, measure at narrowest location between arm pits and crotch; on two-piece garment, measure width at the bottom of the upper piece, and at the top of the lower piece.

Seat—on one-piece garment, measure at widest location between waist and crotch. On two-piece garment, take this measurement on the lower piece only.

Upper arm—measure at a line perpendicular to the sleeve extending from the outer edge of the sleeve to the arm pit.

Thigh—measure at a line perpendicular to the leg extending from the outer edge of the leg to the crotch.

Wrist—measure the width of the end of the sleeve, if intended to extend to the wrist.

Ankle—measure the width of the end of the leg, if intended to extend to the ankle.

(2) Has no item of fabric, ornamentation or trim, such as lace, appliques, or ribbon, which extends more than 6 millimeters (¼ inch) from the point of attachment to the outer surface of the garment;

(3) Has sleeves which do not exceed the maximum dimension for the upper arm at any point between the upper arm and the wrist and which diminish in width gradually from the upper arm to the wrist;

(4) Has legs which do not exceed the maximum dimension for the thigh at any point between the thigh and the ankle, and which diminish gradually in width between the thigh and the ankle;

(5) In the case of a one-piece garment, has a width which does not exceed the maximum dimension for the chest at any point between the chest and the waist and which diminishes gradually from the chest to the waist; and has a width which does not exceed the maximum dimension for the seat at any point between the seat and the waist and which diminishes gradually from the seat to the waist;

(6) In the case of a two-piece garment, has an upper piece with a width which does not exceed the maximum distance for the chest at any point between the chest and the bottom of that piece and which diminishes gradually from the chest to the bottom of that piece; in the case of an upper piece with fastenings, has the lowest fastening within 15 centimeters (6 inches) of the bottom of that piece;

(7) In the case of a two-piece garment, has a lower piece with a width which does not exceed the maximum

dimension for the seat at any point between the seat and the top of the lower piece and which diminishes gradually from the seat to the top of that piece;

(8) Complies with all applicable requirements of the Standard for the Flammability of Clothing Textiles (16 CFR part 1610) and the Standard for the Flammability of Vinyl Plastic Film (16 CFR part 1611); and

(9) Bears a label stating the size of the garment; for example ''Size 7.'' If the label is not visible to the consumer when the garment is offered for sale at retail, the garment size must appear legibly on the package of the garment.

Effective date: These amendments shall become effective on January 1, 1997, and shall be applicable to garments which are introduced into commerce on or after that date.

Dated: August 29, 1996.

Todd A. Stevenson,

Deputy Secretary, Consumer Product Safety Commission.

List of Relevant Documents

1. Federal Register notice ''Flammability Standards for Children's Sleepwear; Statements of Enforcement Policy'' published by the Consumer Product Safety Commission; 4 pages; March 20, 1984 (49 FR 10249).
2. Supplemental CPSC Staff Guide to the Enforcement Policy Statements of the Flammability Standard for Children's Sleepwear—Garment Diagrams and Assessments, published by the Division of Regulatory Management, Consumer Product Safety Commission; 27 pages; 1989.
3. Memorandum from Terrance R. Karels, ECPA, to the Commission, entitled ''Children's Sleepwear Project''; 12 pages; July 19, 1994.
4. Federal Register notice ''Standards for the Flammability of Children's Sleepwear: Sizes 0 Through 6X and 7 Through 14; Advance Notice of Proposed Rulemaking,'' published by the Consumer Product Safety Commission; 4 pages; January 13, 1993 (58 FR 4111).
5. Federal Register notice ''Standards for the Flammability of Children's Sleepwear: Sizes 0 Through 6X and 7 Through 14; Stay of Enforcement,'' published by the Consumer Product Safety Commission; 1 page; January 13, 1993 (58 FR 4078).
6. Tabular summaries of comments and staff responses to comments to the Advance Notice of Proposed Rulemaking; 50 pages; July 19, 1994.
7. ''Statement by The Children's Sleepwear Coalition In Response to the Consumer Product Safety Commission's Advance Notice of Proposed Rulemaking''; 10 pages; March 25, 1993.
8. Memorandum from Linda Fansler, ESME, to Terrance R. Karels, ECPA, entitled ''Technical Rationale Supporting Tight-Fitting Children's Sleepwear Garments''; 11 pages; March 14, 1994.
9. Memorandum from Linda Fansler, ESME, to Terrance R. Karels, ECPA, entitled ''Recent Conversation Between Staff of Consumer and Corporate Affairs Canada and Commission Staff''; 4 pages; July 17, 1992.
10. Memorandum from Dr. Terry L. Kissinger, EPHA, to Terrance R. Karels, ECPA, entitled ''Injury Data Related to the Children's Sleepwear Standards''; 13 pages; February 8, 1994.
11. Memorandum from Dr. Terry L. Kissinger, EPHA, to Terrance R. Karels, ECPA, entitled ''Results of Review of Available Literature,'' and attachments; 21 pages; April 1, 1994.
12. Memorandum from George Sweet, EPHF, to Terrance R. Karels, ECPA, entitled ''Human Factors Issues Regarding Sleepwear,'' and attachment; 8 pages; March 8, 1994.
13. Memorandum from George Sweet, EPHF, to Terrance R. Karels, ECPA, entitled ''Garments Intended for Infants''; 4 pages; July 8, 1994.
14. ''Preliminary Regulatory and Regulatory Flexibility Analyses for the Proposed Amendments to the Children's Flammability Standards,'' by Anthony C. Homan, Directorate for Economic Analysis; 7 pages; June, 1994.
15. ''Market Sketch—Children's Sleepwear,'' by Anthony C. Homan, Directorate for Economic Analysis; 14 pages; March, 1992.
16. Memorandum from Eva S. Lehman, HSPS, to Terrance R. Karels, ECPA, entitled ''Toxicological Evaluation of Fabrics Used in Children's Sleepwear''; 3 pages; June 7, 1994.
17. Memorandum from Patricia Fairall, CERM, to Terrance Karels, ECPA, entitled ''Compliance History—Enforcement of Children's Sleepwear''; 6 pages; April 20, 1994.
18. Memorandum from James F. Hoebel, Acting Director, ESME, to Terrance R. Karels, ECPA, entitled ''Amendments to Children's Sleepwear Standards''; 3 pages; July 7, 1994.
19. Memorandum from Dr. Terry L. Kissinger, EPHA, to Terrance R. Karels, ECPA, entitled ''Proposed Amendment to Children's Sleepwear Standards''; 7 pages; July 15, 1994.
20. Federal Register notice ''Standard for the Flammability of Children's Sleepwear: Sizes 0 Through 6X; Standard for the Flammability of Children's Sleepwear: Sizes 7 Through 14; Proposed amendments'' published by the Consumer Product Safety Commission; 11 pages; October 25, 1994 (59 FR 53616).
21. Federal Register notice ''Continuation of Stay of Enforcement of Standards for the Flammability of Children's Sleepwear, Sizes 0 Through 6X and 7 Through 14'' published by the Consumer Product Safety Commission; 1 page; October 25, 1994 (59 FR 53584).
22. Comment on proposed amendments from Aline Farr; 1 page; September 14, 1994.
23. Comment on proposed amendments from Leonard Schwab, the Schwab Company; 7 pages; November 29, 1994.
24. Comment on proposed amendments from Kay M. Villa, American Textile Manufacturers Institute; 1 page; December 22, 1994.
25. Comment on proposed amendments from Carl Schlosser, Salant Children's Apparel Group; 5 pages; December 28, 1994.
26. Comment on proposed amendments from John F. Krasny; 2 pages; January 4, 1995.
27. Comment on proposed amendments from student research group, Florida International University; 2 pages; January 4, 1995.
28. Comment on proposed amendments from Steven E. Loftin, the William Carter Company; 2 pages; January 5, 1995.
29. Comment on proposed amendments from student research group; 2 pages; January 6, 1995.
30. Comment on proposed amendments from Gerald L. Colliers, the Children's Sleepwear Coalition; 6 pages; January 8, 1995.
31. Comment on proposed amendments from Mary-beth Boughton, Oneita Industries; 2 pages; January 9, 1995.
32. Comment on proposed amendments from James McMullen, Learn Not to Burn Foundation, National Fire Protection Association; 2 pages; January 13, 1995.
33. Comment on proposed amendments from Phillip J. Wakelyn, Ph.D., National Cotton Council of America; 7 pages; January 9, 1995.
34. Comment on proposed amendments from John Wigodsky, Fruit of the Loom; 1 page; January 5, 1995.
35. Comment on proposed amendments from Julie Goldscheider, Impact Imports International, Inc.; 3 pages; January 9, 1995.
36. Comment on proposed amendments from Alfred K. Whitehead, International Association of Fire Fighters; 1 page; July 31, 1995.
37. Comment on proposed amendments from Frank Albert, Fire Prevention Canada; 2 pages; August 1, 1995.
38. Comment on proposed amendments from Andrew M. Munster, M.D., American Burn Association; 2 pages; August 29, 1995.
39. Comment on proposed amendments from Ramsey J. Choucair, M.D., Shriners Hospitals for Crippled Children, Burns Institute; 2 pages; August 30, 1995.
40. Comment on proposed amendments from Phillip J. Wakelyn, Ph.D., National Cotton Council of America; 2 pages; September 8, 1995.
41. Comment on proposed amendments from Anthony R. O'Neill, National Fire Protection Association, with enclosures; 7 pages; October 23, 1995.
42. Comment on proposed amendments from Carl Schlosser, Salant Children's Apparel Group; 1 page; October 10, 1995.
43. Comment on proposed amendments from Mary Jane Murray; 1 page; undated.
44. Comment on proposed amendments from Tim Ackerman, T & G Associates, Inc., with enclosure; 3 pages; October 25, 1995.
45. Comment on proposed amendments from John McCarthy, Kid Duds, with enclosure; 3 pages; October 30, 1995.
46. Comment on proposed amendments from Leigh Ann Schwarzkopf, Kid Duds, with enclosure; 8 pages; January 5, 1996.
47. Comment on proposed amendments from Phillip J. Wakelyn, Ph.D., National Cotton Council of America; 2 pages; October 30, 1995.
48. Comment on proposed Amendments from Phillip. J. Wakelyn, Ph.D., National

Cotton Council of America, with enclosures; 5 pages; December 18, 1995.

49. Comment on proposed Amendments from Phillip. J. Wakelyn, Ph.D., National Cotton Council of America, with enclosure; 3 pages; December 21, 1995.

50. Comment on proposed amendments from Leonard S. Bernstein, Candlesticks, Inc.; 2 pages; October 31, 1995.

51. Comment on proposed amendments from Leonard S. Bernstein, Candlesticks, Inc., with enclosure; 3 pages; December 14, 1995.

52. Comment on proposed amendments from Leonard S. Bernstein, Candlesticks, Inc.; 1 page; January 10, 1996.

53. Comment on proposed amendments from Mary-beth Boughton, Oneita Industries; 2 pages; November 6, 1995.

54. Comment on proposed amendments from G. L. Collier, I–C Manufacturing Company, with enclosure; 5 pages; December 30, 1995.

55. Comment on proposed amendments from Hy Grubman, InnerWorld; 1 page; December 28, 1995.

56. Comment on proposed amendments from Jack Brownstein, Waterbury Garment Corporation, with enclosure; 2 pages; January 3, 1996.

57. Comment on proposed amendments from Craig V. Mayer, P.E.; 2 pages; January 5, 1996.

58. Comment on proposed amendments from Gerald L. Collier, Children's Sleepwear Coalition; 5 pages; January 24, 1996.

59. Comment on proposed amendments from Stephen Schnitzer and Marvin Sandberg, PCA Apparel; 5 pages; February 6, 1996.

60. Comment on proposed amendments from The Coalition for American Trauma Care; 2 pages; February 6, 1996.

61. Comment on proposed amendments from Cressie Goff, Sew Sweet Stitches, and Carol Grider, R.N., with enclosures; 3 pages; February 21, 1996.

62. Memorandum from Terry L. Kissinger, Ph.D., EHHA, to Terrance R. Karels, ECPA, entitled ''Injury Data Related to the Children's Sleepwear Standards''; 13 pages; July 12, 1995.

63. Letter from Carole LaCombe, Director, Product Safety Canada, to Eric C. Peterson, Executive Director, Consumer Product Safety Commission, concerning Canadian standards for the flammability of children's sleepwear; 3 pages; September 13, 1993.

64. Memorandum from Linda Fansler, ES, concerning telephone conversation between staff of the Consumer Product Safety Commission and staff of Consumer and Corporate Affairs Canada on June 18, 1992, concerning the Canadian standards for the flammability of children's sleepwear; 3 pages.

65. Memorandum from Linda Fansler, ESME, to Terrance R. Karels, ECPA, entitled ''Tight Fitting Children's Sleepwear''; 5 pages; July 14, 1995.

66. Memorandum from Terrance R. Karels, Project Manager, to Warren J. Prunella, Associate Executive Director for Economic Analysis, entitled ''Sleepwear Market Update''; 2 pages; October 6, 1995.

67. Final Regulatory Analysis for amendments of the children's sleepwear standards by Terrance R. Karels; 8 pages; July 1995.

68. Memorandum from David Schmeltzer, Assistant Executive Director for Compliance, to Terrance Karels, Project Manager, entitled ''Sleepwear Briefing Package''; 4 pages; August 24, 1995.

69. Memorandum from Patricia Fairall, Compliance Officer, to Terrance Karels, Project Manager, entitled ''Compliance Discussion of the Proposed Amendments to the Children's Sleepwear Standards''; 2 pages; June 26, 1995.

70. Memorandum from Terry L. Kissinger, Ph.D., EHHA, to Terrance R. Karels, ECPA, entitled ''Response to Public Comments Received after Publication of the Notice of Proposed Rulemaking''; 8 pages; July 12, 1995.

71. Memorandum from George Sweet, EPHF, to Terrance R. Karels, ECPA, entitled ''Human Factors Responses to Sleepwear NPR Comments''; 7 pages; May 5, 1995.

72. Memorandum from Linda Fansler, ESME, to Terrance R. Karels, ECPA, entitled ''Response to Comments''; 3 pages; July 14, 1995.

73. Memorandum from Suad Nakamura, Ph.D., EHPS, to Terrance R. Karels, Project Manager, entitled ''Children's Sleepwear—Response to Comments on the Notice of Proposed Rulemaking''; 2 pages; July 19, 1995.

74. Memorandum from Patricia Fairall, Compliance Officer, to Terrance R. Karels, Program Manager, entitled ''Response to Comments from Proposed Amendments to the Children's Sleepwear Standards published in the Federal Register on October 25, 1994''; 5 pages; June 26, 1995.

75. Memorandum from Terry L. Kissinger, Ph.D., EHHA, to Terrance R. Karels, ECPA, entitled ''Response to Letter from John Krasny to James Hoebel''; 5 pages; August 3, 1995.

76. Memorandum from George Sweet, ESHA, to Terrance R. Karels, ECPA, entitled ''Issues involved in amendment the sleepwear flammability regulation: Sizing and Labeling''; 3 pages; September 20, 1995.

77. Memorandum from Karen G. Krushaar, OIPA, to Terrance R. Karels, ECPA, entitled ''Children's Sleepwear Informational Campaign''; 2 pages; July 11, 1995.

78. Position statement of the National Fire Protection Association and the Learn Not to Burn Foundation in Opposition to the Proposed Amendment of the Children's Sleepwear Standards; 5 pages; July 1995.

79. Letter from John F. Krasny to J. F. Hoebel concerning paper by Vickers, Krasny, and Tovey entitled ''Some Apparel Fire Hazard Parameters''; 2 pages; July 17, 1995.

80. Memorandum from Linda Fansler, ESME, concerning telephone conversation with John Krasny on September 20, 1995; 2 pages.

81. Log of public meeting conducted on April 25, 1995, concerning proposed amendments of the children's sleepwear flammability standards; 4 pages.

82. Memorandum from James F. Hoebel, Chief Engineer for Fire Hazards, to Terrance R. Karels, Project Manager, entitled ''Children's Sleepwear''; 3 pages; October 10, 1995.

83. Memorandum from Warren J. Prunella, Associate Executive Director for Economic Analysis, to file concerning small business effects of proposed amendments to the children's sleepwear flammability standards; 3 pages; February 17, 1995.

84. Memorandum from Warren J. Prunella, Associate Executive Director for Economic Analysis, to Eric A. Rubel, General Counsel, concerning requirements for Congressional review of final amendments to the children's sleepwear standards; 3 pages; undated.

85. Vote sheet to accompany briefing package on children's sleepwear flammability standards; 2 pages; October 11, 1995.

86. Memorandum from Terrance R. Karels, Project Manager, and Ronald L. Medford, Assistant Executive Director for Hazard Identification and Reduction entitled ''Questions Regarding Children's Sleepwear Amendments,'' with attachments; 21 pages; January 30, 1996.

[FR Doc. 96–22697 Filed 9–6–96; 8:45 am]

BILLING CODE 6355–01–P

federal register

Monday
September 9, 1996

Part IV

Department of Education

Federal Pell Grant Program; Notice

DEPARTMENT OF EDUCATION

Federal Pell Grant Program

AGENCY: Department of Education.

ACTION: Notice; deadline dates for receipt of applications, reports, and other documents for the 1996–97 award year.

SUMMARY: The Secretary announces the deadline dates for receiving documents from persons applying for grants under, and from institutions participating in, the Federal Pell Grant Program in the 1996–97 award year.

FOR FURTHER INFORMATION CONTACT: Jacquelyn C. Butler, Program Specialist, Pell and State Grant Section, Grants Branch, Policy Development Division, Policy, Training, and Analysis Service, Office of Postsecondary Education, U.S. Department of Education, 600 Independence Avenue, S.W. (ROB–3, Room 3045), Washington, DC 20202–5447. Telephone: (202) 708–4607. Individuals who use a telecommunications device for the deaf may call the Federal Information Relay Service at 1–800–730–8913 between 9 a.m. and 8 p.m., Eastern time, Monday through Friday.

SUPPLEMENTARY INFORMATION: The Federal Pell Grant Program, administered by the U.S. Department of Education (Department), provides grants to students attending eligible institutions of higher education to help them pay for their educational costs. The program supports Goals 2000, the President's strategy for moving the Nation toward the National Education Goals, by enhancing opportunities for postsecondary education. The National Education Goals call for increasing the rate at which students graduate from high school and pursue high quality postsecondary education and for supporting life-long learning. Authority for the Federal Pell Grant Program is contained in section 401 of the Higher Education Act of 1965, as amended, 20 U.S.C. 1070a.

Deadline Dates

The following tables provide the deadline dates for the Federal Pell Grant Program for the 1996–97 award year.

BILLING CODE 4000–01–P

A. Deadline Dates for Application Processing and Receipt of Student Aid Reports (SARs) or Institutional Student Information Records (ISIRs)

Who Submits?	What is Submitted?	Where is it Submitted?	What is the Deadline Date?
Student	A paper original Free Application for Federal Student Aid (FAFSA) or renewal application (Renewal FAFSA)	Multiple Data Entry (MDE) Servicer listed on the student's application	June 30, 1997
Student	FAFSA Express	Central Processing System (CPS)	June 30, 1997
Student thru institution	An electronic original or renewal application (EDExpress)	CPS	*June 30, 1997
Student	SAR corrections, confirmations, and duplicate requests	MDE Servicer listed on the student's SAR	August 15, 1997
Student thru institution	ISIR corrections, confirmations, and duplicate requests	CPS	*August 15, 1997
Student	Valid SAR	Institution	The earlier of: - the student's last date of enrollment; or - August 29, 1997
Student thru CPS to institution	Valid ISIR	Institution receives ISIR from the CPS	The earlier of: - the student's last date of enrollment; or - August 29, 1997
Student	Verification documents	Institution	The earlier of: - 60 days after the student's last date of enrollment; or - August 29, 1997

* The deadline for submitting electronic transactions is prior to midnight (Central Time) on the deadline date. Transmissions must be completed and the records must be accepted for processing before midnight to meet the deadline. Transmissions started but not completed until after midnight are not considered on time.

B. Deadline Dates for Reporting Federal Pell Grant Student Payment Data

Who Submits?	What is Submitted?	Where is it Submitted?	What is the Deadline Date?
Institution	At least one acceptable student Payment Data record must be submitted for each Federal Pell Grant recipient at the institution by: -Recipient Data Exchange (Tape); or -Floppy Disk Data Exchange; or -Electronic Data Exchange**	1. Institutions transmitting student Payment Data using Recipient Data Exchange or Floppy Disk Data Exchange submit through: Regular Mail: U.S. Department of Education Application & Pell Processing Systems Division, PSS P.O. Box 10800 Herndon, Virginia 20172-7009 or Commercial Courier: U.S. Department of Education Application & Pell Processing Systems Division, PSS c/o PRC Inc. G-T01 PGRFMS/DMS 12001 Sunrise Valley Drive Reston, Virginia 20191-3411 2. Institutions transmitting student Payment Data using Electronic Data Exchange submit through: Title IV Wide Area Network	An institution is required to submit student Payment Data not later than 30 calendar days after the institution: -makes a payment; or -becomes aware of the need to make an adjustment to previously reported student Payment Data or expected student Payment Data. (Following this chart is a detailed discussion explaining an institution's responsibility for reporting student Payment Data.)
			After September 30, 1997 only if: -downward adjustment of previously reported award; or -initial audit or program review finding per 34 CFR part 690.83.
		U.S. Department of Education Institutional Financial Management Division, AFMS P.O. Box 23791 Washington, DC 20026-0791	Administrative relief based on an administrative error by the Department or Departmental contractors: January 31, 1998

**Transmission of student Payment Data using Electronic Data Exchange must be started prior to midnight on the deadline date.

BILLING CODE 4000–01–C

Deadline for Reporting Federal Pell Grant Student Payment Data

In the 1995–96 award year, institutions were required to report student ''Payment Data'' to the Department by fixed reporting periods. (Student Payment Data include both the Federal Pell Grant payment that an institution makes to a student and the Federal Pell Grant payment it expects to make to that student for an award year.) Thus, for example, an institution was required to report student Payment Data to the Department by October 15, 1995 if it paid a Federal Pell Grant to a student at any time during the period of July 1, 1995 through October 15, 1995.

For the 1996–97 award year, the Secretary has changed the period for reporting student Payment Data to the Department. Reporting periods are not fixed but are based on the date an institution pays a Federal Pell Grant to a student. Under this reporting requirement, an institution must submit to the Department Payment Data for a student not later than 30 calendar days after the institution makes a payment to the student. In addition, if the institution becomes aware that previously reported payments or expected payments, *i.e.*, Payment Data, for a student are no longer accurate, the institution must submit accurate Payment Data for that student to the Department not later than 30 calendar days after becoming aware of the change.

The following two examples illustrate the new reporting requirement. As a first example, a student enrolls for the fall 1996 semester at an institution. The institution pays that student his Federal Pell Grant award for that semester on September 5, 1996. The institution must submit that student's Payment Data to the Department not later October 5, 1996.

As a second example, a student enrolls for the fall 1996 semester as a full-time student, and the institution expects the student to enroll as a full-time student for the spring 1997 semester. The institution pays that student his Federal Pell Grant award for the fall 1996 semester on September 5, 1996. The institution submits that student's Payment Data to the Department on October 1, 1996. On January 15, 1997 the student enrolls in the spring 1997 semester as a half-time student. The institution must submit to the Department revised Payment Data for that student not later February 14, 1997.

Because some institutions have not yet received computer software necessary to submit student Payment Data to the Department and this notice is being published after the beginning of the 1996–97 award year, the Secretary understands that not all institutions will initially report student Payment Data within the 30-day reporting period. Therefore, the Secretary will not take adverse actions against an institution that does not initially submit student Payment Data within the 30-day reporting period during the first three months of the 1996–97 award year.

Proof of Delivery

The Department accepts as proof, if the documents were submitted by mail or by non-U.S. Postal Service courier, one of the following:

(1) A legible mail receipt with the date of mailing stamped by the U.S. Postal Service.

(2) A legibly-dated U.S. Postal Service postmark.

Note: The U.S. Postal Service does not uniformly provide a dated postmark. Before relying on this method of proof of mailing, an institution should check with the post office at which it mails its submission. An institution is strongly encouraged to use First Class Mail.

(3) A dated shipping label, invoice, or receipt from a commercial courier.

(4) Other proof of mailing or delivery acceptable to the Secretary.

The Department accepts hand deliveries at the address stated in the previous chart between 8 a.m. and 4:30 p.m. Eastern Time on days other than Saturday, Sunday, or Federal holidays.

An institution that transmits its student Payment Data information via the EDE Electronic Payments service must ensure that its transmission is completed before midnight (local time at the institution's EDE destination point) on September 30, 1997.

Other Sources for Detailed Information on the Application and Automated Processes

A more detailed discussion of the student application process for the Federal Pell Grant Program is contained in the *1996–97 Student Guide, Funding Your Education,* the *1996–97 Counselor's Handbook for High Schools,* the *1996–97 Counselor's Handbook for Postsecondary Schools, A Guide to 1996–97 SARs and ISIRs* (Action Letter #8 March 1996), and the *1996–97 Federal Student Financial Aid Handbook.* A more detailed discussion of the institutional reporting requirement for student Payment Data for the Federal Pell Grant Program is contained in the *1996–97 Federal Student Financial Aid Handbook.*

Applicable Regulations

The regulations applicable to this program are the Federal Pell Grant Program regulations in 34 CFR part 690, the Student Assistance General Provisions regulations in 34 CFR part 668, and the Institutional Eligibility regulations in 34 CFR part 600.

(Catalog of Federal Domestic Assistance No. 84.063, Federal Pell Grant Program)

(Authority: 20 U.S.C. 1070a)

Dated: August 23, 1996.

David A. Longanecker,

Assistant Secretary for Postsecondary Education.

[FR Doc. 96–22811 Filed 9–6–96; 8:45 am]

BILLING CODE 4000–01–P

federal register

Monday
September 9, 1996

Part V

The President

Executive Order 13017—Advisory Commission on Consumer Protection and Quality in the Health Care Industry

Federal Register
Vol. 61, No. 175
Monday, September 9, 1996

Presidential Documents

Title 3—

The President

Executive Order 13017 of September 5, 1996

Advisory Commission on Consumer Protection and Quality in the Health Care Industry

By the authority vested in me as President by the Constitution and the laws of the United States of America, including the Federal Advisory Committee Act, as amended (5 U.S.C. App.), it is hereby ordered as follows:

Section 1. *Establishment.* (a) There is established the Advisory Commission on Consumer Protection and Quality in the Health Care Industry (the ''Commission''). The Commission shall be composed of not more than 20 members to be appointed by the President. The members will be consumers, institutional health care providers, health care professionals, other health care workers, health care insurers, health care purchasers, State and local government representatives, and experts in health care quality, financing, and administration.

(b) The Secretary of Health and Human Services and the Secretary of Labor shall serve as Co-Chairs of the Commission. The Co-Chairs shall report through the Vice President to the President.

Sec. 2. *Functions.* (a) The Commission shall advise the President on changes occurring in the health care system and recommend such measures as may be necessary to promote and assure health care quality and value, and protect consumers and workers in the health care system. In particular, the Commission shall:

(1) Review the available data in the area of consumer information and protections for those enrolled in health care plans and make such recommendations as may be necessary for improvements;

(2) Review existing and planned work that defines, measures, and promotes quality of health care, and help build further consensus on approaches to assure and promote quality of care in a changing delivery system; and

(3) Collect and evaluate data on changes in availability of treatment and services, and make such recommendations as may be necessary for improvements.

(b) For the purpose of carrying out its functions, the Commission may hold hearings, establish subcommittees, and convene and act at such times and places as the Commission may find advisable.

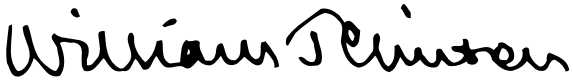
Sec. 3. *Reports.* The Commission shall make a preliminary report to the President by September 30, 1997. A final report shall be submitted to the President 18 months after the Commission's first meeting.

Sec. 4. *Administration.* (a) To the extent permitted by law, the heads of executive departments and agencies, and independent agencies (collectively ''agencies'') shall provide the Commission, upon request, with such information as it may require for the purposes of carrying out its functions.

(b) Members of the Commission may receive compensation for their work on the Commission not to exceed the daily rate specified for Level IV of the Executive Schedule (5 U.S.C. 5315). While engaged in the work of the Commission, members appointed from among private citizens of the United States may be allowed travel expenses, including per diem in lieu of subsistence, as authorized by law for persons serving intermittently in the Government service (5 U.S.C. 5701-5707) to the extent funds are available for such purposes.

(c) To the extent permitted by law and subject to the availability of appropriations, the Department of Health and Human Services shall provide the Commission with administrative services, funds, facilities, staff, and other support services necessary for the performance of the Commission's functions. The Secretary of Health and Human Services shall perform the administrative functions of the President under the Federal Advisory Committee Act, as amended (5 U.S.C. App.), with respect to the Commission.

Sec. 5. *General Provision*. The Commission shall terminate 30 days after submitting its final report, but not later than 2 years from the date of this order, unless extended by the President.



THE WHITE HOUSE,
September 5, 1996.

[FR Doc. 96–23187
Filed 9–6–96; 10:28 am]
Billing code 3195–01–P

Reader Aids

Federal Register

Vol. 61, No. 175

Monday, September 9, 1996

CUSTOMER SERVICE AND INFORMATION

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Public Laws Update Services (numbers, dates, etc.) **523–6641**
For additional information **523–5227**

Presidential Documents

Executive orders and proclamations **523–5227**
The United States Government Manual **523–5227**

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TDD for the hearing impaired **523–5229**

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FEDERAL REGISTER PAGES AND DATES, SEPTEMBER

46373–46528 3
46529–46698 4
46699–47018 5
47019–47408 6
47409–47660 9

CFR PARTS AFFECTED DURING SEPTEMBER

At the end of each month, the Office of the Federal Register publishes separately a List of CFR Sections Affected (LSA), which lists parts and sections affected by documents published since the revision date of each title.

3 CFR

Administrative Orders:

Memorandums:
August 30, 1996 46695

Presidential Determinations:
No. 96–42 of August 24, 1996 46699
No. 96–43 of August 27, 1996 46529

Executive Orders:
13017 of September 5, 1996 47659

4 CFR

Proposed Rules:
7 47240

5 CFR

317 46531
412 46531

Proposed Rules:
316 47450

7 CFR

12 47019
911 46701
915 46701
1075 47038

Proposed Rules:
457 46401
1079 46571
1137 47092
1160 47093

8 CFR

3 .....46373, 47550
103 .....46373, 47039, 47550
210 46534
242 .....46373, 47550
245a 46534
264 46534
274a 46534
299 46534

9 CFR

Proposed Rules:
319 47453
381 47453

10 CFR

Ch. 1 46537

12 CFR

3 47358
208 47358
225 47358
325 47358

Proposed Rules:
225 47242

14 CFR

39 .....46538, 46540, 46541, 46542, 46703, 46704, 47041, 47046, 47047, 47049, 47051, 47409, 47410
71 .....47051, 47052, 47053, 47411
97 .....46706, 46707, 46711
1215 46713

Proposed Rules:
39 .....46572, 46574, 46576, 46742, 47459, 47462
71 .....46743, 46744, 47465, 47466

16 CFR

1615 .....47412, 47634
1616 .....47412, 47634

17 CFR

249 47412

20 CFR

655 46988

21 CFR

136 46714
137 46714
139 46714
173 .....46374, 46376
177 .....46543, 46716
178 .....46544, 46545
510 46547
520 46719
522 46548
606 47413
610 47413
801 47550
803 47550
804 47550
807 47550
820 47550
897 47550

22 CFR

Proposed Rules:
514 46745

24 CFR

247 47380
573 47404
880 47380
884 47380
3500 46510

Proposed Rules:
3500 46523

26 CFR

1 46719
602 46719

27 CFR

Proposed Rules:
9 46403

178 47095

28 CFR

0 46720

29 CFR

506 46988

30 CFR

935 46548
944 46550
946 46552
Proposed Rules:
917 46577

32 CFR

706 46378
801 46379
Proposed Rules:
318 47467

33 CFR

165 47054

34 CFR

Proposed Rules:
75 47550
76 47550
77 47550
271 47550
272 47550
607 47550
642 47550
648 47550
662 47550
663 47550
664 47550
682 47398

35 CFR

Proposed Rules:
133 46407
135 46407

36 CFR

1 46554
7 46379
15 46554

38 CFR

4 46720
Proposed Rules:
16 47469

40 CFR

52 ..... 47055, 47057, 47058
63 46906
81 47058
82 47012
261 46380
300 47060
Proposed Rules:
35 46748
52 ..... 47099, 47100
59 46410
64 46418
70 46418
71 46418
81 47100
270 46748
271 46748
300 ..... 46418, 46749, 46753

42 CFR

417 46384
482 47423
Proposed Rules:
418 46579

43 CFR

4 47434

44 CFR

64 46732

45 CFR

2400 46734

46 CFR

10 47060
12 47060

47 CFR

1 46557
25 46557
51 47284
52 47284
68 47434
73 ..... 46563, 47434, 47435, 47436
80 46563
95 46563
Proposed Rules:
Ch. 1 46419
1 ..... 46420, 46603, 46755
22 46420
25 46420
73 ..... 46430, 46755, 47470, 471, 47472

48 CFR

1506 47064
1515 47065
1534 47064
1536 47064
1542 47064
1545 47064
1552 ..... 47064, 47065
1807 47068
1808 47068
1809 47068
1810 47068
1811 47068
1812 47068
1814 47068
1828 47068
1835 47068
1842 47068
1845 47082
1852 ..... 47068, 47082
1853 47082
1871 47068
Proposed Rules:
1 47390
3 47390
4 47390
5 47384
9 47390
11 47384
12 ..... 47384, 47390
13 47384
14 47390
15 47390
19 47390
33 47390
37 47390
43 47390
52 ..... 47384, 47390
53 47390
203 47100
212 47101
215 47100
219 47101
225 47101
226 47101
227 47101
233 47101
252 ..... 47100, 47101
501 46607
504 46607
507 46607
510 46607
511 46607
512 46607
514 46607
515 46607
538 46607
539 46607
543 46607
546 46607
552 46607
570 46607
Proposed Rules:
Ch. 34 47550

49 CFR

538 46740
571 47086
575 47437
583 46385
1039 47446
Proposed Rules:
531 46756

50 CFR

32 46390
622 47446
660 47089
679 ..... 46399, 46570, 47089
Proposed Rules:
17 ..... 46430, 46608, 47105
21 46431
648 ..... 47106, 47472, 47473
679 47108

REMINDERS

The items in this list were editorially compiled as an aid to Federal Register users. Inclusion or exclusion from this list has no legal significance.

RULES GOING INTO EFFECT TODAY

COMMERCE DEPARTMENT

National Oceanic and Atmospheric Administration

Endangered and threatened species:

Umpqua River cutthroat trout; published 8-9-96

Fishery conservation and management:

Gulf of Alaska groundfish; published 8-9-96

ENERGY DEPARTMENT

Acquisition regulations:

Miscellaneous amendments; Federal regulatory reform; published 8-9-96

ENVIRONMENTAL PROTECTION AGENCY

Clean Air Act:

State operating permits programs--

Tennessee; published 7-11-96

FEDERAL COMMUNICATIONS COMMISSION

Common carrier services:

Telephone network, connection of terminal equipment--

Technical amendments; published 9-9-96

Radio stations; table of assignments:

California; published 8-6-96

Colorado et al.; published 8-15-96

HOUSING AND URBAN DEVELOPMENT DEPARTMENT

Fair housing:

Complaint processing; subpoena provision removed; published 8-8-96

INTERIOR DEPARTMENT

Hearings and Appeals Office, Interior Department

Administrative procedures:

Hearings and appeals procedures; published 9-9-96

NUCLEAR REGULATORY COMMISSION

Production and utilization facilities; domestic licensing:

Nuclear power plants--

Codes and standards; subsections IWE and IWL; published 8-8-96

SECURITIES AND EXCHANGE COMMISSION

Securities:

Form BD amendments

Compliance date suspension; published 9-9-96

TRANSPORTATION DEPARTMENT

Federal Aviation Administration

Airworthiness directives:

AlliedSignal Inc.; published 8-19-96

Fokker; published 8-5-96

TRANSPORTATION DEPARTMENT

National Highway Traffic Safety Administration

Motor vehicle safety standards:

Air brake systems--

Long-stroke brake chambers; published 7-11-96

TREASURY DEPARTMENT

Internal Revenue Service

Income taxes:

Section 355 distributions by U.S. corporations to foreign persons; treatment; published 8-14-96

COMMENTS DUE NEXT WEEK

AGRICULTURE DEPARTMENT

Agricultural Marketing Service

Almonds grown in California; comments due by 9-19-96; published 8-20-96

Marketing orders; expenses and assessment rates; comments due by 9-16-96; published 8-16-96

Oranges and grapefruit grown in Texas; comments due by 9-20-96; published 8-21-96

AGRICULTURE DEPARTMENT

Animal and Plant Health Inspection Service

Exportation and importation of animals and animal products:

Foreign ≥regions≥ criteria based on risk class levels, etc.; comments due by 9-16-96; published 7-11-96

AGRICULTURE DEPARTMENT

Federal Crop Insurance Corporation

Administrative regulations:

Crop insurance coverage for production of agricultural commodity on highly erodible land or converted wetland; comments due by 9-20-96; published 7-23-96

AGRICULTURE DEPARTMENT

Farm Service Agency

Federal claims collection; administrative offset; comments due by 9-16-96; published 8-30-96

AGRICULTURE DEPARTMENT

Rural Business-Cooperative Service

Federal claims collection; administrative offset; comments due by 9-16-96; published 8-30-96

AGRICULTURE DEPARTMENT

Rural Housing Service

Federal claims collection; administrative offset; comments due by 9-16-96; published 8-30-96

AGRICULTURE DEPARTMENT

Rural Utilities Service

Federal claims collection; administrative offset; comments due by 9-16-96; published 8-30-96

AGRICULTURE DEPARTMENT

Acquisition regulations:

Federal regulatory review; comments due by 9-16-96; published 7-16-96

COMMERCE DEPARTMENT

National Oceanic and Atmospheric Administration

Fishery conservation and management:

Summer flounder; comments due by 9-16-96; published 8-26-96

Summer flounder, scup, and black sea bass; comments due by 9-19-96; published 8-23-96

Marine mammals:

Endangered fish or wildlife--

Anadramous Atlantic salmon in seven Maine rivers; comments due by 9-17-96; published 8-27-96

Incidental taking--

Naval activities; USS Seawolf submarine shock testing; comments due by 9-17-96; published 8-2-96

Naval activities; USS Seawolf submarine shock testing; correction; comments due by 9-17-96; published 8-23-96

COMMODITY FUTURES TRADING COMMISSION

Reporting requirements:

Options and futures large trader reports; daily filing requirements; comments due by 9-16-96; published 7-18-96

DEFENSE DEPARTMENT

Acquisition regulations:

Petroleum products; comments due by 9-20-96; published 7-22-96

Small Business Adminsitration; certificates of competency processing; comments due by 9-20-96; published 7-22-96

ENVIRONMENTAL PROTECTION AGENCY

Air programs:

Fuel and fuel additives--

Diesel fuel sulfur requirement exemption; Alaska; comments due by 9-18-96; published 8-19-96

Diesel fuel sulfur requirement exemption; Alaska; comments due by 9-18-96; published 8-19-96

Air quality implementation plans; approval and promulgation; various States:

Missouri; comments due by 9-20-96; published 8-21-96

Hazardous waste program authorizations:

Indiana; comments due by 9-19-96; published 8-20-96

Superfund program:

National oil and hazardous substances contingency plan--

National priorities list update; comments due by 9-16-96; published 8-15-96

National priorities list update; comments due by 9-16-96; published 8-15-96

National priorities list update; comments due by 9-20-96; published 8-21-96

National priorities list update; comments due by 9-20-96; published 8-21-96

FEDERAL COMMUNICATIONS COMMISSION

Radio services, special:

Private land mobile services--
Public safety radio requirements through 2010 calendar year; comments due by 9-20-96; published 5-20-96
Radio stations; table of assignments:
Arkansas; comments due by 9-16-96; published 9-3-96
Colorado; comments due by 9-16-96; published 8-6-96
Hawaii; comments due by 9-16-96; published 8-6-96
Oklahoma; comments due by 9-16-96; published 8-6-96

FEDERAL EMERGENCY MANAGEMENT AGENCY
Disaster assistance:
Temporary housing assistance; mobile homes and travel trailers; inventory divestiture; comments due by 9-20-96; published 8-21-96

FEDERAL RESERVE SYSTEM
Reimbursement for providing financial records (Regulation S):
Recordkeeping requirements for certain financial records; comments due by 9-20-96; published 8-21-96

HEALTH AND HUMAN SERVICES DEPARTMENT
Children and Families Administration
Aid to Families with Dependent Children under title IV-A of the Social Security Act; child support cooperation and referral; comments due by 9-16-96; published 7-17-96

HEALTH AND HUMAN SERVICES DEPARTMENT
Food and Drug Administration
Food additives:
Adhesive coatings and components--
Dimethyl 1,4-cyclohexanedi-carboxylate; comments due by 9-16-96; published 8-15-96
Labeling of drug products (OTC):
Orally ingested drug products containing calcium, magnesium, and potassium (OTC); comments due by 9-20-96; published 7-22-96
Sodium content (OTC); labeling provisions; comments due by 9-20-96; published 7-22-96

HOUSING AND URBAN DEVELOPMENT DEPARTMENT
Public and Indian housing:
Public housing development program; Federal regulatory review; comments due by 9-20-96; published 7-22-96

INTERIOR DEPARTMENT
Indian Affairs Bureau
Land and water:
Rights-of-way over Indian lands; comments due by 9-16-96; published 7-18-96
Practice and procedure:
Administrative action appeals; Federal regulatory review; comments due by 9-19-96; published 6-21-96

INTERIOR DEPARTMENT
Land Management Bureau
Patent preparation and issuance; comments due by 9-16-96; published 8-16-96

INTERIOR DEPARTMENT
Fish and Wildlife Service
Endangered and threatened species:
Anadramous Atlantic salmon in seven Maine rivers; comments due by 9-17-96; published 8-27-96
Copperbelly water snake; comments due by 9-16-96; published 7-16-96

INTERIOR DEPARTMENT
Natural resource damage assessments
Type B procedures; comments due by 9-16-96; published 7-16-96

JUSTICE DEPARTMENT
Bankruptcy Reform Act:
Standing trustees; qualifications and standards; comments due by 9-16-96; published 7-18-96

LABOR DEPARTMENT
Occupational Safety and Health Administration
Construction and general industry safety and health standards:
Federal regulatory reform; comments due by 9-20-96; published 7-22-96

LIBRARY OF CONGRESS
Copyright Office, Library of Congress
Digital audio recording devices and media; statements of account; verification; comments due by 9-16-96; published 6-18-96

PERSONNEL MANAGEMENT OFFICE
Health benefits, Federal employees:
Leave without pay or insufficient pay; payment of premiums; comments due by 9-20-96; published 7-22-96

TRANSPORTATION DEPARTMENT
Coast Guard
Ports and waterways safety:
Los Angeles-Long Beach, CA; safety zone; comments due by 9-19-96; published 7-19-96

TRANSPORTATION DEPARTMENT
Federal Aviation Administration
Airworthiness directives:
Beech; comments due by 9-17-96; published 8-9-96
Boeing; comments due by 9-16-96; published 7-17-96
British Aerospace; comments due by 9-16-96; published 7-17-96
Fokker; comments due by 9-16-96; published 8-6-96
Hamilton Standard; comments due by 9-16-96; published 8-2-96
Jetstream; comments due by 9-16-96; published 8-7-96
Lockheed; comments due by 9-16-96; published 8-6-96
Sikorsky; comments due by 9-17-96; published 7-19-96
Class D airspace; comments due by 9-20-96; published 8-27-96
Class E airspace; comments due by 9-16-96; published 9-5-96

TRANSPORTATION DEPARTMENT
National Highway Traffic Safety Administration
Motor vehicle safety standards:
Occupant crash protection--
Air bags; reduction of dangerous impacts, especially on children; comments due by 9-20-96; published 8-6-96
School bus manufacturers and school transportation providers; public meeting; comments due by 9-16-96; published 6-19-96

TREASURY DEPARTMENT
Comptroller of the Currency
National banks lending limits; comments due by 9-16-96; published 7-17-96

TREASURY DEPARTMENT
Internal Revenue Service
Income taxes:
Extraordinary dividends; distributions to corporate shareholders; comments due by 9-16-96; published 6-18-96
Securities dealers; mark-to-market; equity interests in related parties and dealer-customer relationship; comments due by 9-18-96; published 6-20-96
Structure; definition; comments due by 9-18-96; published 6-20-96

VETERANS AFFAIRS DEPARTMENT
Medical benefits:
Homeless providers grant and per diem program; comments due by 9-16-96; published 7-16-96

CFR CHECKLIST

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An asterisk (*) precedes each entry that has been issued since last week and which is now available for sale at the Government Printing Office.

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4	(869–028–00003–7)	5.50	Jan. 1, 1996
5 Parts:			
1–699	(869–028–00004–5)	26.00	Jan. 1, 1996
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1200–End, 6 (6 Reserved)	(869–028–00006–1)	25.00	Jan. 1, 1996
7 Parts:			
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27–45	(869–028–00008–8)	11.00	Jan. 1, 1996
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52	(869–028–00010–0)	5.00	Jan. 1, 1996
53–209	(869–028–00011–8)	17.00	Jan. 1, 1996
210–299	(869–028–00012–6)	35.00	Jan. 1, 1996
300–399	(869–028–00013–4)	17.00	Jan. 1, 1996
400–699	(869–028–00014–2)	22.00	Jan. 1, 1996
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900–999	(869–028–00016–9)	30.00	Jan. 1, 1996
1000–1199	(869–028–00017–7)	35.00	Jan. 1, 1996
1200–1499	(869–028–00018–5)	29.00	Jan. 1, 1996
1500–1899	(869–028–00019–3)	41.00	Jan. 1, 1996
1900–1939	(869–028–00020–7)	16.00	Jan. 1, 1996
1940–1949	(869–028–00021–5)	31.00	Jan. 1, 1996
1950–1999	(869–028–00022–3)	39.00	Jan. 1, 1996
2000–End	(869–028–00023–1)	15.00	Jan. 1, 1996
8	(869–028–00024–0)	23.00	Jan. 1, 1996
9 Parts:			
1–199	(869–028–00025–8)	30.00	Jan. 1, 1996
200–End	(869–028–00026–6)	25.00	Jan. 1, 1996
10 Parts:			
0–50	(869–028–00027–4)	30.00	Jan. 1, 1996
51–199	(869–028–00028–2)	24.00	Jan. 1, 1996
200–399	(869–028–00029–1)	5.00	Jan. 1, 1996
400–499	(869–028–00030–4)	21.00	Jan. 1, 1996
500–End	(869–028–00031–2)	34.00	Jan. 1, 1996
11	(869–028–00032–1)	15.00	Jan. 1, 1996
12 Parts:			
1–199	(869–028–00033–9)	12.00	Jan. 1, 1996
200–219	(869–028–00034–7)	17.00	Jan. 1, 1996
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600–End	(869–028–00038–0)	31.00	Jan. 1, 1996
13	(869–028–00039–8)	18.00	Mar. 1, 1996
14 Parts:			
1–59	(869–028–00040–1)	34.00	Jan. 1, 1996
60–139	(869–028–00041–0)	30.00	Jan. 1, 1996
140–199	(869–028–00042–8)	13.00	Jan. 1, 1996
200–1199	(869–028–00043–6)	23.00	Jan. 1, 1996
1200–End	(869–028–00044–4)	16.00	Jan. 1, 1996
15 Parts:			
0–299	(869–028–00045–2)	16.00	Jan. 1, 1996
300–799	(869–028–00046–1)	26.00	Jan. 1, 1996
800–End	(869–028–00047–9)	18.00	Jan. 1, 1996
16 Parts:			
0–149	(869–028–00048–7)	6.50	Jan. 1, 1996
150–999	(869–028–00049–5)	19.00	Jan. 1, 1996
1000–End	(869–028–00050–9)	26.00	Jan. 1, 1996
17 Parts:			
1–199	(869–028–00052–5)	21.00	Apr. 1, 1996
200–239	(869–028–00053–3)	25.00	Apr. 1, 1996
240–End	(869–028–00054–1)	31.00	Apr. 1, 1996
18 Parts:			
1–149	(869–028–00055–0)	17.00	Apr. 1, 1996
150–279	(869–028–00056–8)	12.00	Apr. 1, 1996
280–399	(869–028–00057–6)	13.00	Apr. 1, 1996
400–End	(869–028–00058–4)	11.00	Apr. 1, 1996
19 Parts:			
1–140	(869–028–00059–2)	26.00	Apr. 1, 1996
141–199	(869–028–00060–6)	23.00	Apr. 1, 1996
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20 Parts:			
1–399	(869–028–00062–2)	20.00	Apr. 1, 1996
400–499	(869–028–00063–1)	35.00	Apr. 1, 1996
500–End	(869–028–00064–9)	32.00	Apr. 1, 1996
21 Parts:			
1–99	(869–028–00065–7)	16.00	Apr. 1, 1996
100–169	(869–028–00066–5)	22.00	Apr. 1, 1996
170–199	(869–028–00067–3)	29.00	Apr. 1, 1996
200–299	(869–028–00068–1)	7.00	Apr. 1, 1996
300–499	(869–028–00069–0)	50.00	Apr. 1, 1996
500–599	(869–028–00070–3)	28.00	Apr. 1, 1996
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800–1299	(869–028–00072–0)	30.00	Apr. 1, 1996
1300–End	(869–028–00073–8)	14.00	Apr. 1, 1996
22 Parts:			
1–299	(869–028–00074–6)	36.00	Apr. 1, 1996
300–End	(869–028–00075–4)	24.00	Apr. 1, 1996
23	(869–028–00076–2)	21.00	Apr. 1, 1996
24 Parts:			
0–199	(869–028–00077–1)	30.00	May 1, 1996
200–219	(869–028–00078–9)	14.00	May 1, 1996
220–499	(869–028–00079–7)	13.00	May 1, 1996
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1700–End	(869–028–00083–5)	14.00	May 1, 1996
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26 Parts:			
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50–299	(869–028–00100–9)	14.00	Apr. 1, 1996
300–499	(869–028–00101–7)	25.00	Apr. 1, 1996

Title	Stock Number	Price	Revision Date
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600–End	(869–028–00103–3)	8.00	Apr. 1, 1996
27 Parts:			
1–199	(869–028–00104–1)	44.00	Apr. 1, 1996
200–End	(869–028–00105–0)	13.00	Apr. 1, 1996
28 Parts:			
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43-end	(869-026-00109-0)	22.00	July 1, 1995
29 Parts:			
0–99	(869–028–00108–4)	26.00	July 1, 1996
100–499	(869–028–00109–2)	12.00	July 1, 1996
500–899	(869–026–00112–0)	36.00	July 1, 1995
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30 Parts:			
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31 Parts:			
0–199	(869–026–00122–7)	15.00	July 1, 1995
200–End	(869–026–00123–5)	25.00	July 1, 1995
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33 Parts:			
1–124	(869–026–00130–8)	20.00	July 1, 1995
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1–299	(869–026–00133–2)	25.00	July 1, 1995
300–399	(869–026–00134–1)	21.00	July 1, 1995
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36 Parts			
1–199	(869–026–00137–5)	15.00	July 1, 1995
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37	(869–026–00139–1)	20.00	July 1, 1995
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1, 1–1 to 1–10		13.00	[3] July 1, 1984
1, 1–11 to Appendix, 2 (2 Reserved)		13.00	[3] July 1, 1984
3–6		14.00	[3] July 1, 1984
7		6.00	[3] July 1, 1984
8		4.50	[3] July 1, 1984
9		13.00	[3] July 1, 1984
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42 Parts:			
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43 Parts:			
1–999	(869–026–00166–9)	23.00	Oct. 1, 1995
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45 Parts:			
1–199	(869–022–00170–7)	22.00	Oct. 1, 1995
200–499	(869–026–00171–5)	14.00	Oct. 1, 1995
500–1199	(869–026–00172–3)	23.00	Oct. 1, 1995
1200–End	(869–026–00173–1)	26.00	Oct. 1, 1995
46 Parts:			
1–40	(869–026–00174–0)	21.00	Oct. 1, 1995
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47 Parts:			
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[1] Because Title 3 is an annual compilation, this volume and all previous volumes should be retained as a permanent reference source.

[2] The July 1, 1985 edition of 32 CFR Parts 1–189 contains a note only for Parts 1–39 inclusive. For the full text of the Defense Acquisition Regulations in Parts 1–39, consult the three CFR volumes issued as of July 1, 1984, containing those parts.

[3] The July 1, 1985 edition of 41 CFR Chapters 1–100 contains a note only for Chapters 1 to 49 inclusive. For the full text of procurement regulations in Chapters 1 to 49, consult the eleven CFR volumes issued as of July 1, 1984 containing those chapters.

[4] No amendments to this volume were promulgated during the period Apr. 1, 1990 to Mar. 31, 1996. The CFR volume issued April 1, 1990, should be retained.

[5] No amendments to this volume were promulgated during the period July 1, 1991 to June 30, 1996. The CFR volume issued July 1, 1991, should be retained.