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Thursday
May 14, 1998

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Presidential Documents

Title 3—

The President

Proclamation 7094 of May 8, 1998

National Defense Transportation Day and National Transportation Week, 1998

By the President of the United States of America

A Proclamation

America's transportation system is the finest in the world. The web of streets, highways, bridges, and railroads that crisscross our Nation and our complex network of shipping lanes and air routes keep us connected to one another and the world. They enable us to move people and goods swiftly and efficiently across the country and around the globe and fuel the engine of our robust economy. Whether building subways, constructing new highways, or improving airplane safety, the dedicated and hardworking men and women of our national transportation system keep America moving.

As we look forward to a new century, we must build on our record of achievement. As always, our first priority must be the safety of those who use our Nation's transportation system. We have already made great progress in improving highway safety—the traffic fatality rate today is two-and-a-half times less than it was 30 years ago. However, by increasing seat belt use, ensuring that our children are properly secured in our vehicles, and lowering the threshold for drunk driving to a blood alcohol concentration of .08, we can further reduce the number of traffic accidents and the harm they cause.

We also must strive to keep our Nation's transportation system secure and our borders safe from terrorists and drug traffickers. Today, through improved training techniques and advanced technology, we have increased security at our airports, and programs such as the Coast Guard's Operation Frontier Shield have helped to seize tons of illegal drugs and abort numerous drug smuggling attempts.

While recognizing the many benefits we derive from our transportation system, we also acknowledge the need to use and develop it responsibly to ensure the protection of our environment. We are making progress in this goal as well: we have funded many projects to improve transit services and accommodations for bicyclists and pedestrians; we are turning historic railroad terminals into multimodal transportation centers; and funds from transportation programs have helped to support wetlands restoration projects and have aided communities in planning both transit projects and sustainable development. We must build on these efforts by also working to reduce the pollutants and greenhouse gases that our transportation system creates.

Recognizing the need for safety, security, and environmental stewardship in America's transportation system, we also must invest in our transportation infrastructure. Together with the Congress, my Administration has provided funding for construction projects in communities across the country, creating 700,000 new transportation-related jobs in the last 5 years. Our fiscal 1999 budget proposal for transportation infrastructure is 42 percent higher than the average level of investment from 1990 to 1993. The 240 trade agreements we have signed since 1993, including 27 ''open skies'' aviation agreements in the last 3 years, have opened markets around the world for American products. America's transportation system will enable us to seize these unprecedented opportunities for trade and economic growth.

In recognition of the importance of our Nation's transportation system to our national security and economic success, and in gratitude to the outstanding men and women who ensure its continued excellence, the United States Congress, by joint resolution approved May 16, 1957 (36 U.S.C. 160), has designated the third Friday in May of each year as ''National Defense Transportation Day'' and, by joint resolution approved May 14, 1962 (36 U.S.C. 166), declared that the week in which that Friday falls be designated ''National Transportation Week.''

NOW, THEREFORE, I, WILLIAM J. CLINTON, President of the United States of America, do hereby proclaim Friday, May 15, 1998, as National Defense Transportation Day and May 10 through May 16, 1998, as National Transportation Week. I urge all Americans to observe these occasions with appropriate ceremonies and activities, giving due recognition to the individuals and organizations that build, operate, and maintain this country's modern transportation systems.

IN WITNESS WHEREOF, I have hereunto set my hand this eighth day of May, in the year of our Lord nineteen hundred and ninety-eight, and of the Independence of the United States of America the two hundred and twenty-second.

William J. Clinton

[FR Doc. 98–13041
Filed 5–13–98; 8:45 am]
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Rules and Regulations

Federal Register
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Thursday, May 14, 1998

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 AGRICULTURE

Farm Service Agency

7 CFR Part 723

RIN 0560–AF14

Special Combinations for Tobacco Allotments and Quotas

AGENCY: Farm Service Agency, USDA.

ACTION: Interim Rule and Technical Correction.

SUMMARY: This notice corrects a reference contained in a final rule, published on February 24, 1998, (63 FR 9126) which amended the tobacco regulations. Also, to provide greater flexibility to tobacco farmers, this notice further amends the regulations to: allow for special farm combinations even where neither of the farms to be combined has a production flexibility contract (PFC) and to modify the consent requirements for the special combinations allowed under that section. In addition other corrections have been made to the regulation for purposes of clarity.

DATES: Effective: May 14, 1998. Comments must be received by July 13, 1998, to be assured of consideration.

ADDRESSES: Submit comments on the interim rule to: Director, Tobacco and Peanuts Division, USDA, FSA, STOP 0514, 1400 Independence Avenue, SW, Washington, DC 20013–0514. Comments may be faxed to (202) 690–2298. All written submissions made pursuant to this rule will be made available for public inspection in Room 5750 of the South Building, USDA, between the hours of 8:15 a.m. and 4:45 p.m., during regular Federal workdays.

FOR FURTHER INFORMATION CONTACT: Joe Lewis, Jr., Agricultural Program Specialist, Tobacco Branch, Tobacco and Peanuts Division, USDA, FSA, STOP 0514, 1400 Independence Avenue, SW, Washington, DC 20250–0514, telephone 202–720–0795.

SUPPLEMENTARY INFORMATION:

Executive Order 12866

This rule has been determined to be not significant and therefore was not reviewed by OMB under Executive Order 12866.

Regulatory Flexibility Act

The Regulatory Flexibility Act is not applicable to this interim rule since the Farm Service Agency (FSA) is not required by 5 U.S.C. 553 or any other provision of law to publish a notice of proposed rule making with respect to the subject matter of this rule.

Federal Assistance Program

The title and number of the Federal Assistance Program, as found in the Catalog of Federal Domestic Assistance, to which this rule applies are: Commodity Loans and Purchases—10.051.

Environmental Evaluation

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

Executive Order 12372

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

Executive Order 12988

This interim rule has been reviewed in accordance with Executive Order 12988. The provisions of this interim rule are not retroactive and preempt State laws to the extent that such laws are inconsistent with the provisions of this interim rule. Before any legal action is brought regarding determinations made under provisions of 7 CFR part 723, the administrative appeal provisions set forth at 7 CFR parts 780 and 711, as applicable, must be exhausted.

Paperwork Reduction Act

This interim rule does not contain new or revised information collection requirements that require approval by OMB under the Paperwork Reduction Act (44 U.S.C. 3507 *et seq*). A FR notice with a 60-day comment period for the information collections required in 7 CFR part 723 was published on September 25, 1997 (62 FR 50286). No comments were received. A request for revision and reinstatement has been submitted for approval.

Effective Date of Rule

It has been determined for purposes of all limitations that might apply, including any provisions of the Small Business Regulatory Enforcement Fairness Act of 1996 that might apply, that this rule should be effective immediately because the planting season for all kinds of tobacco began in early April and tobacco producers must make their final rotation and planting decisions. The nature of this interim rule and notice is to: (1) Correct a reference contained in a previous rule; (2) add greater flexibility for producers in combining farms for tobacco purposes only. As the rule simply provides for such flexibility and should not adversely affect anyone, it would be contrary to the public interest to delay the implementation date of the new regulations.

Background and Discussion

The final rule published on February 24, 1998, (63 FR 9126), adopted and modified the interim rule published on April 2, 1997 (62 FR 15599) which allowed, under § 723.209, for special combinations of flue-cured tobacco allotments and quotas on participating and nonparticipating farms with PFCs. Though the regulations, as modified through the February 24 rule were correct, the preamble to the February 24 publication incorrectly indicated that the special combinations allowed by that rule were limited to cases where the two farms being combined were owned by the same person. That was not the intention of the rule nor was such a limitation actually contained in the adopted regulations themselves. That erroneous reference in the February 24, 1998, preamble is hereby corrected. In addition, this rule adopts clarifying language for § 723.209 and further amends § 723.209 so as to explicitly

allow special combinations even if no PFC farm is involved. This will permit variances from normal combination rules that would otherwise apply under 7 CFR part 718. Such variances will allow for greater flexibility to farmers with special needs as might arise for tobacco-only combinations. There is a special need for farm combinations with respect to the tobacco program because it is one of the few programs with an existing farm-oriented poundage or quota system and because of limitations that exist with respect to the leasing of allotments and quotas. These special combinations allow for better farming practices, including crop rotation and mirror long-term practices in tobacco. The amendments to § 723.209 would, in addition, provide explicitly that for all special combinations allowed under § 723.209, the Deputy Administrator may waive consent requirements that would normally apply for combinations under the rules in 7 CFR part 718. Under the 7 CFR part 718 regulations, normally all of the owners and operators of both farms to be combined must consent to the combination. However, § 723.209 deals with limited and temporary, perhaps frequent, combinations that can involve tobacco farms that have many owners as the farms have been passed down among several generations. Locating, and obtaining a verifiable consent from all of the owners of tobacco farms for each such transaction can be very difficult and is not purposeful given that the farm will be continuing its basic operation in a manner similar to the way it has operated in the past.

List of Subjects in 7 CFR Part 723

Acreage allotments, Auction warehouses, Dealers, Domestic manufacturers, Marketing quotas, Penalties, Reconstitutions, Tobacco.

For the reasons set forth in the preamble, 7 CFR part 723 is amended as follows:

PART 723—[AMENDED]

1. The authority citation for 7 CFR part 723 continues to read as follows:

Authority: 7 U.S.C. 1301, 1311–1314, 1314–1, 1314b, 1314b–1, 1314b–2, 1314c, 1314d, 1314e, 1314f, 1314i, 1315, 1316, 1362, 1363, 1372–75, 1421, 1445–1 and 1445–2.

2. The heading for § 723.209 is revised and paragraph (c) is revised to read as follows:

§ 723.209 Determination of acreage allotments, marketing quotas, yields for combined farms; and special tobacco combinations.

* * * * *

(c) *Special tobacco combinations.* Notwithstanding other provision of this title, the Deputy Administrator may, upon proper application and to the extent deemed consistent with other obligations, permit farms, with respect to tobacco allotments and tobacco quotas, to be considered combined for purposes of this part and part 1464 of this title only without being combined for other purposes. This allowance shall apply for tobacco of all kinds and types and with respect to all farms even if one or more of the farms to be combined is the subject of a production flexibility contract (PFC) executed in connection with the program operated under the provisions of 7 CFR part 1412. Such special, limited combinations must otherwise meet the requirements of 7 CFR part 718 for combinations, except the signature (consent) requirements of § 718.201(a)(2) of that part. The Deputy Administrator may set such consent requirements for special farm combinations under this section as the Deputy Administrator believes necessary or appropriate. Further, in any case in which one of the farms is a PFC farm, none of the land on any PFC farm that would have been used for the production of tobacco can be used for the production of a ''PFC commodity'' as defined in this section. Such permission shall be conditioned upon the agreement of all interested parties that land on the PFC allotment or quota farm that would have been used for the production of tobacco shall not be used for the production of any PFC commodity. In the event that such production nonetheless occurs, the special tobacco combination may be made void, retroactive to the date of original approval. Such curative action will likely result in a finding of excess tobacco plantings and sanctions and remedies, which would likely include liability for penalties and other sanctions for excess marketings of tobacco. The Deputy Administrator may set such other conditions on the combinations as needed or deemed appropriate to serve the goals of the tobacco program and the goals of the PFC. The term *PFC commodity* for purposes of this section means wheat, corn, grain sorghum, barley, oats, upland cotton, and rice.

* * * * *

Signed at Washington, DC, on May 8, 1998.

Bruce R. Weber,

Acting Administrator,

Farm Service Agency.

[FR Doc. 98–12860 Filed 5–13–98; 8:45 am]

BILLING CODE 3410–05–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 39

[Docket No. 97–CE–72–AD; Amendment 39–10516; AD 98–10–05]

RIN 2120–AA64

Airworthiness Directives; Raytheon Aircraft Company Models B200, B200C, and B200T Airplanes

AGENCY: Federal Aviation Administration, DOT.

ACTION: Final rule.

SUMMARY: This amendment adopts a new airworthiness directive (AD) that applies to certain Raytheon Aircraft Company (Raytheon) Models B200, B200C, and B200T airplanes (formerly referred to as Beech Models B200, B200C, and B200T airplanes). This AD requires replacing the wiring for the engine fire detector system with fire resistant wiring. This AD is the result of the discovery during aircraft production of the potential for the existing engine fire detector system wiring on the affected airplanes to fail because of high heat and/or fire. The actions specified by this AD are intended to prevent failure of the engine fire detector system if high heat and/or fire stopped an electrical signal between the engine fire detectors and the engine fire warning annunciator lights located in the cockpit, which could result in passenger injury in the event of an airplane fire.

DATES: Effective June 27, 1998.

The incorporation by reference of certain publications listed in the regulations is approved by the Director of the Federal Register as of June 27, 1998.

ADDRESSES: Service information that applies to this AD may be obtained from the Raytheon Aircraft Company, P.O. Box 85, Wichita, Kansas 67201–0085. This information may also be examined at the Federal Aviation Administration (FAA), Central Region, Office of the Regional Counsel, Attention: Rules Docket No. 97–CE–72–AD, Room 1558, 601 E. 12th Street, Kansas City, Missouri 64106; or at the Office of the Federal Register, 800 North Capitol Street, NW, suite 700, Washington, DC.

FOR FURTHER INFORMATION CONTACT: Mr. Randy Griffith, Aerospace Engineer, Wichita Aircraft Certification Office, FAA, 1801 Airport Road, Mid-Continent Airport, Wichita, Kansas 67209; telephone: (316) 946–4145; facsimile: (316) 946–4407.

SUPPLEMENTARY INFORMATION:

Events Leading to the Issuance of This AD

A proposal to amend part 39 of the Federal Aviation Regulations (14 CFR part 39) to include an AD that would apply to certain Raytheon Models B200, B200C, and B200T airplanes was published in the **Federal Register** as a notice of proposed rulemaking (NPRM) on December 3, 1997 (62 FR 63914). The NPRM proposed to require replacing the wiring for the engine fire detector system with fire resistant wiring by incorporating Engine Fire Detector Harness Kit, part number 101–3208–1. Accomplishment of the proposed action as specified in the NPRM would be in accordance with Raytheon Mandatory Service Bulletin No. 2701, Issued: May, 1997.

The NPRM was the result of the discovery during aircraft production of the potential for the existing engine fire detector system wiring on the affected airplanes to fail because of high heat and/or fire.

Interested persons have been afforded an opportunity to participate in the making of this amendment. No comments were received on the proposed rule or the FAA's determination of the cost to the public.

The FAA's Determination

After careful review of all available information related to the subject presented above, the FAA has determined that air safety and the public interest require the adoption of the rule as proposed except for minor editorial corrections. The FAA has determined that these minor corrections will not change the meaning of the AD and will not add any additional burden upon the public than was already proposed.

Cost Impact

The FAA estimates that 77 airplanes in the U.S. registry will be affected by this AD, that it will take approximately 4 workhours per airplane to accomplish the modification required by this AD, and that the average labor rate is approximately $60 an hour. Parts will be provided by the manufacturer at no cost to the owners/operators of the affected airplanes. Based on these figures, the total cost impact of this AD on U.S. operators is estimated to be $18,480, or $240 per airplane. These figures are based on the presumption that no owner/operator of the affected airplanes has incorporated this modification.

Raytheon has informed the FAA that approximately 40 kits have been shipped from the Raytheon Aircraft Authorized Service Center. Presuming that each of the 40 kits is incorporated on an affected airplane, this will reduce the cost impact of this AD by $9,600, from $18,480, to $8,880.

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 copy of the final 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, 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 a new airworthiness directive (AD) to read as follows:

98–10–05 Raytheon Aircraft Company: Amendment 39–10516; Docket No. 97–CE–72–AD.

Applicability: The following model and serial number airplanes, certificated in any category:

Model	Serial Nos.
B200	BB–1439, BB–1444 through BB–1447, BB–1449, BB–1450, BB–1452, BB–1453, BB–1455, BB–1456, and BB–1458 through BB–1512;
B200C	BL–139 and BL–140;
B200C (C–12R)	BW–1 through BW–5; and
B200T	BT–35 through BT–38.

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 within the next 200 hours time-in-service (TIS) after the effective date of this AD, unless already accomplished.

To prevent failure of the engine fire detector system if high heat and/or fire stopped an electrical signal between the engine fire detectors and the engine fire warning annunciator lights located in the cockpit, which could result in passenger injury in the event of an airplane fire, accomplish the following:

(a) Replace the existing engine fire protection system wiring with fire resistant wiring by incorporating Engine Fire Detector Harness Kit, part number 101–3208–1. Accomplish this replacement in accordance with the instructions included with the above kit, as referenced in Raytheon Mandatory Service Bulletin No. 2701, Issued: May, 1997.

(b) 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.

(c) An alternative method of compliance or adjustment of the compliance time that provides an equivalent level of safety may be approved by the Manager, Wichita Aircraft Certification Office (ACO), 1801 Airport Road, Room 100, Mid-Continent Airport, Wichita, Kansas 67209. The request shall be forwarded through an appropriate FAA Maintenance Inspector, who may add comments and then send it to the Manager, Wichita ACO.

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

(d) The replacement required by this AD shall be done in accordance with the instructions to Raytheon Engine Fire Detector

Harness Kit, part number 101–3208–1, as referenced in Raytheon Mandatory Service Bulletin No. 2701, Issued: May, 1997. This incorporation by reference was approved by the Director of the Federal Register in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. Copies may be obtained from Raytheon Aircraft Company, P.O. Box 85, Wichita, Kansas 67201–0085. Copies may be inspected at the FAA, Central Region, Office of the Regional Counsel, Room 1558, 601 E. 12th Street, Kansas City, Missouri, or at the Office of the Federal Register, 800 North Capitol Street, NW, suite 700, Washington, DC.

(e) This amendment becomes effective on June 27, 1998.

Issued in Kansas City, Missouri, on April 30, 1998.

Michael Gallagher,

Manager, Small Airplane Directorate, Aircraft Certification Service.

[FR Doc. 98–12507 Filed 5–13–98; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

15 CFR Part 921

[Docket #980427108–8108–01]

RIN 0694–AL16

National Estuarine Research Reserve System Regulations

AGENCY: Office of Ocean and Coastal Resource Management, National Ocean Service, National Oceanic and Atmospheric Administration, Commerce.

ACTION: Final rule.

SUMMARY: The National Oceanic and Atmospheric Administration (NOAA) is making a correction to its regulations concerning the National Estuarine Research Reserve System (NERRS) to clarify that certain types of financial assistance awards are not subject to specified limits on amounts. The Coastal Zone Protection Act of 1996 amended the Coastal Zone Management Act (CZMA) by, among other things, eliminating the state match requirement in cases where financial assistance was coming from proceeds of a natural resource damage action. In 1997, NOAA issued a rule to amend the NERRS regulations to conform to the statutory amendments. That rule specified that the state match requirement was eliminated in cases where natural resource damage proceeds were being used to fund NERRS activities. However, the rule did not address what the effects of other limits on financial assistance (caps on funding, rather than state match) would be in these cases. This final rule clarifies that, in cases where financial assistance is coming from natural resource damage funds, the caps on financial assistance to not apply.

EFFECTIVE DATE: May 14, 1998.

FOR FURTHER INFORMATION CONTACT: Mary O'Brien, Attorney-Adviser, Office of General Counsel, 1305 East-West Highway, Silver Spring, Maryland 20910. Telephone: 301–713–2967.

SUPPLEMENTARY INFORMATION:

I. Authority

This final rule is issued under the authority of the Coastal Zone Management Act, CZMA, 16 U.S.C. 1451 *et seq.*, as amended.

II. Background

Section 315 of the CZMA authorizes grants to states for the selection, designation, management, and use of National Estuarine Research Reserves. However, section 315 of the CZMA limits, in most cases, the proportion of federal financial assistance that may be provided to states for program activities. The 1996 amendments to the CZMA provided that notwithstanding these statutory limits, financial assistance provided from amounts recovered as a result of damage to natural resources located in the coastal zone may be used to pay 100 percent of the costs of activities carried out with the assistance. In 1997, NOAA issued a rule, the intent of which was to bring the program regulations into conformity with the statutory change.

Following NOAA's 1997 rule, questions arose as to the effects of the amendment on certain statutory and regulatory limits on amounts. While it was clear the amendments eliminated the match requirement in cases where financial assistance is coming from natural resource damage funds, questions remained as to the appropriate interpretation, in these cases, of provisions limiting the amount of financial assistance that may be granted to any one reserve for certain activities. Specifically, the statute provides a $5,000,000 cap on federal financial assistance for acquisition activities at any one reserve. The regulations contain not only that cap, but also a $100,000 cap on federal financial assistance for certain pre-designation activities (site selection, draft management plan and environmental impact statement preparation, and basic characterization studies).

The NERRS was established by Congress to provide for a system of representative estuarine ecosystems, with each site contributing to the biogeographical and typological balance of the system. It was envisioned that the completed system would ultimately contain 25–35 sites. Throughout the course of the program, there has been a need to ensure that limited appropriations are distributed equitably among reserve sites. Hence, the statute and the regulations provided caps to restrict the amount of funds that could be granted to any one site.

In the case of reserve activities being funded with amounts recovered as a result of natural resource damages, the concern that gave rise to the establishment of the caps does not exist. Natural resource damage funds do not come out of the NERRS appropriation. When such funds are used to establish a reserve or pay for reserve activities, there is no reduction in the appropriation and thus no effect, financial speaking, on other reserves in the system or on states wishing to advance reserve proposals. For this reason, it is not appropriate to apply the NERRS limits on federal financial assistance when activities are being funded from natural resource damage proceeds.

Congress recognized as much in the 1996 amendments to the CZMA. New section 315(e)(3)(C) explicitly stated that notwithstanding the 50 percent/ $5,000,000 cap, financial assistance provided from natural resource damage funds could be used to pay 100 percent of the costs of such activities. Congress did not address the $100,000 pre-designation cap, because that cap was established by regulation rather than by statute.

III. Discussion of Change

The purpose of this rule is to amend the regulations to clarify that, consistent with the changes made to the CZMA in 1996, the $5,000,000 and $100,000 limits on federal financial assistance for certain activities are not applicable with the funding for these activities is being provided from amounts recovered as a result of damage to natural resources.

IV. Rulemaking Requirements

A. This rule was determined to be ''not significant'' for purposes of Executive Order 12866.

B. This rule relates to public property, loans, grants, benefits, and contracts, and therefore, it is exempt from every requirement of section 553 of the Administrative Procedure Act, 5 U.S.C. 553, including notice and comment and delayed effective date.

C. Because a notice of proposed rulemaking is not required by 5 U.S.C.

553, or by any other law, a Regulatory Flexibility Analysis under the Regulatory Flexibility Act is not required and was not prepared.

D. This rule involves collections of information subject to the Paperwork Reduction Act and cleared by the Office of Management and Budget under control number 0648–0119. The estimated response times for these requirements are 480 hours for management program approval and 8 hours for program amendment and routine program changes. The response estimates shown include the time for reviewing instructions, searching existing data sources, gathering and maintaining needed data, and completing and reviewing the collection of information. Notwithstanding any other provision of the law, no person is required to respond to, nor shall any person be subject to penalty for failure to comply with, a collection of information, subject to the requirements of the PRA, unless that collection of information displays a currently valid OMB control number.

E. NOAA has concluded that this regulatory action does not constitute a major federal action significantly affecting the quality of the environment. Therefore, an environmental impact statement under the National Environmental Policy Act, 43 U.S.C. 4321 *et seq.* is not required.

F. This rule contains no mandates, under the provisions of Title II of the Unfunded Mandates Reform Act of 1995 (UMRA), Public Law 104–4, for state, local, or tribal governments or the private sector. Thus, this rule is not subject to the requirements of sections 202 and 205 of the UMRA.

G. NOAA has concluded that this regulatory action does not have sufficient federalism implications to warrant the preparation of a Federalism Assessment under Executive Order 12612.

List of Subjects in 15 CFR Part 921

Administrative practice and procedure, Coastal zone, Grant programs—Natural resources, Reporting and recordkeeping requirements.

Dated: May 11, 1998.

Nancy Foster,

Assistant Administrator for Ocean Services and Coastal Zone Management.

For the reasons set forth in the Preamble, 15 CFR part 921 is amended as follows:

PART 921—NATIONAL ESTUARINE RESEARCH RESERVE SYSTEM REGULATIONS

1. The authority citation for part 921 continues to read as follows:

Authority: Section 315 of the Coastal Zone Management Act, as amended (16 U.S.C. 1461).

2. Paragraph (f) of § 921.1 is amended by revising the fourth sentence to read as follows:

§ 921.1 Mission, goals and general provisions.

* * * * *

(f) * * * Notwithstanding any financial assistance limits established by this Part, when financial assistance is provided from amounts recovered as a result of damage to natural resources located in the coastal zone, such assistance may be used to pay 100 percent of all actual costs of activities carrier out with this assistance, as long as such funds are available. * * *

* * * * *

3. Paragraph (a) of § 921.10 is amended by adding a new sentence, after the third sentence, to read as follows:

§ 921.10 General.

(a) * * * Notwithstanding the above, when financial assistance is provided from amounts recovered as a result of damage to natural resources located in the coastal zone, such assistance may be used to pay 100 percent of all actual costs of activities carried out with this assistance, as long as such funds are available. * * *

4. Paragraph (b) of § 921.10 is amended by adding a new sentence, after the last sentence, to read as follows:

§ 921.10 General.

(b) * * * Notwithstanding the above, when financial assistance is provided from amounts recovered as a result of damage to natural resources located in the coastal zone, such assistance may be used to pay 100 percent of all actual costs of activities carrier out with this assistance, as long as such funds are available.

5. Section 921.20 is amended by revising the last sentence to read as follows:

§ 921.20 General

* * * In any case, the amount of Federal financial assistance provided to a coastal state with respect to the acquisition of lands and waters, or interests therein, for any one National Estuarine Research Reserve may not exceed an amount equal to 50 percent of the costs of the lands, waters, and interests therein or $5,000,000, whichever amount is less, except when the financial assistance is provided from amounts recovered as a result of damage to natural resources located in the coastal zone, in which case the assistance may be used to pay 100 percent of all actual costs of activities carrier out with this assistance, as long as such funds are available.

6. Section 921.31 is amended by revising the fourth sentence to read as follows:

§ 921.31 Supplemental acquisition and development awards.

* * * Acquisition awards for the acquisition of lands or waters, or interests therein, for any one reserve may not exceed an amount equal to 50 percent of the costs of the lands, waters, and interests therein of $5,000,000, whichever amount is less, except when the financial assistance is provided from amounts recovered as result of damage to natural resources located in the coastal zone, in which case the assistance may be used to pay 100 percent of all actual costs of activities carrier out with this assistance, as long as such funds are available. * * *

[FR Doc. 98–12880 Filed 5–13–98; 8:45 am]

BILLING CODE 3510–08–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 101

[Docket No. 98N–0274]

Food Labeling; Petitions for Nutrient Content and Health Claims, General Provisions

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is amending its regulations to define the conditions under which certain petitions for nutrient content and health claims shall be deemed to be denied and to codify the statutory timeframe within which the agency will complete rulemakings on such petitions. FDA is taking this action in response to the Food and Drug Administration Modernization Act of 1997 (FDAMA).

DATES: This regulation is effective May 14, 1998. Submit written comments by June 15, 1998.

ADDRESSES: Submit written comments to the Dockets Management Branch

(HFA–305), Food and Drug Administration, 12420 Parklawn Dr., rm. 1–23, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: Hilario R. Duncan, Center for Food Safety and Applied Nutrition (HFS–24), Food and Drug Administration, 200 C St. SW., Washington, DC 20204, 202–205–8281.

SUPPLEMENTARY INFORMATION: On November 21, 1997, President Clinton signed into law FDAMA (Pub. L. 105–115). Section 302 of FDAMA amended section 403(r)(4)(A)(i) of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 343(r)(4)(A)(i)) so that certain nutrient content claim and health claim petitions are deemed denied if FDA does not act by certain deadlines. In particular, under amended section 403(r)(4)(A)(i) of the act, if FDA fails to make a filing decision on either type of petition within 100 days of receipt of the petition by the agency, the petition shall be deemed to be denied unless an extension is mutually agreed upon by FDA and the petitioner. If the petition is deemed to be denied in this manner without filing, the petition shall not be made available to the public. In addition, if FDA fails to issue a proposed rule within 90 days of filing of either type of petition, that petition shall be deemed to be denied unless an extension is mutually agreed upon by FDA and the petitioner. Accordingly, FDA is amending §§ 101.69(m) and 101.70(j) (21 CFR 101.69(m) and 101.70(j)) to include the statutory language, i.e., ''Secretary'' is replaced with ''FDA'' in the appropriate places in the regulations. For consistency, FDA also is making a few editorial changes in § 101.69, i.e., replacing ''the Commissioner of Food and Drugs'' with ''FDA'' in the appropriate places in the regulation.

Under amended section 403(r)(4)(A)(i) of the act, FDA also must publish a final rule within 540 days of receipt of the petition, or FDA is required to provide the relevant House and Senate legislative committees with the reasons for failing to do so. Accordingly, FDA is amending §§ 101.69(m) and 101.70(j) to state that rulemakings on health and certain nutrient content claim petitions shall be completed within 540 days of receipt of those petitions. The agency notes that § 101.70(j) provides that a final rule in response to a health claim petition will be published by FDA within 270 days of the date of publication of the proposal but that, for cause, the agency may extend the period for agency action no more than twice with each extension being for no more than 90 days. In view of amended section 403(r)(4)(A)(i) of the act, the agency advises that, to ensure final action shall be within 540 days of the date of receipt of the petition, the agency may be limited to only one such extension for cause, and such extension may be limited to fewer than 90 days.

Additionally, the agency is taking this opportunity to correct and clarify some inconsistent references in § 101.69 to FDA and to the Commissioner of Food and Drugs so that all references are to the FDA.

The agency has determined under 21 CFR 25.30(k) 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.

FDA has examined the economic implications of this final rule under Executive Order 12866. Executive Order 12866 directs agencies to assess all costs and benefits of available regulatory alternatives and, when regulation is necessary, to select the regulatory approach that maximizes net benefits (including potential economic, environmental, public health and safety effects; distributive impacts; and equity). Executive Order 12866 classifies a rule as significant if it meets any one of a number of specified conditions, including having an annual effect on the economy of $100 million or adversely affecting in a material way a sector of the economy, competition, or jobs, or if it raises novel legal or policy issues. The agency finds that this final rule is not a significant rule as defined by Executive Order 12866. No analysis is required for this rule under the Regulatory Flexibility Act (5 U.S.C. 601–612) because, as discussed in this document, FDA is issuing it without publishing a general notice of proposed rulemaking.

Finally, in accordance with the Small Business Regulatory Enforcement Fairness Act, the administrator of the Office of Information and Regulatory Affairs of the Office of Management and Budget has determined that this final rule is not a major rule for the purpose of congressional review.

This final rule contains no collections of information. Therefore, clearance by the Office of Management and Budget under the Paperwork Reduction Act of 1995 is not required.

Because the amendments set forth in this document incorporate the language of section 302 of FDAMA into §§ 101.69 and 101.70, FDA finds, for good cause, that notice and public procedure are unnecessary and, therefore, are not required under 5 U.S.C. 553. Nonetheless, under 21 CFR 10.40(e), FDA is providing an opportunity for comment on whether the regulations set forth in this document should be modified or revoked. Interested persons may, on or before June 15, 1998, submit to the Dockets Management Branch (address above) written comments regarding this final rule. Two copies of any comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with the docket number found in brackets in the heading of this document. Received comments may be seen in the office above between 9 a.m. and 4 p.m., Monday though Friday.

List of Subjects in 21 CFR Part 101

Food labeling, Nutrition, Reporting and recordkeeping requirements.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs, 21 CFR part 101 is amended as follows:

PART 101—FOOD LABELING

1. The authority citation for 21 CFR part 101 continues to read as follows:

Authority: 15 U.S.C. 1453, 1454, 1455; 21 U.S.C. 321, 331, 342, 343, 348, 371.

2. Section 101.69 is amended in paragraph (c) by removing ''FDA's Center for Food Safety and Applied Nutrition'' and adding in its place ''the Food and Drug Administration's (FDA) Center for Food Safety and Applied Nutrition''; in paragraph (d) by removing ''the Food and Drug Administration'' and adding in its place

''FDA''; and in paragraphs (l), (m)(4), (n)(3) and (n)(4), and (o)(3) and (o)(4) by removing ''the Commissioner of Food and Drugs'', wherever it appears, and adding in its place ''FDA''; by revising paragraph (m)(3); and by adding paragraphs (m)(4)(iii) and (m)(5) to read as follows:

§ 101.69 Petitions for nutrient content claims.

* * * * *

(m) * * *

(3) Within 100 days of the date of receipt of the petition, FDA will notify the petitioner by letter that the petition has either been filed or denied. If denied, the notification shall state the reasons therefor. If filed, the date of the notification letter becomes the date of filing for the purposes of section 403(r)(4)(A)(i) of the act. If FDA does not act within such 100 days, the petition shall be deemed to be denied unless an extension is mutually agreed upon by the FDA and the petitioner. A petition that has been denied, or has been deemed to be denied without filing, shall not be made available to the public. A filed petition shall be available to the public as provided under paragraph (g) of this section.

* * * * *

(4) * * *

(iii) If FDA does not act within 90 days of the filing date, the petition shall be deemed to be denied unless an extension is mutually agreed upon by FDA and the petitioner.

(5) If FDA issues a proposal, the rulemaking shall be completed within 540 days of the date of receipt of the petition.

* * * * *

3. Section 101.70 is amended by revising paragraph (j)(2), by adding paragraph (j)(3)(iii), and by revising paragraph (j)(4)(ii) to read as follows:

§ 101.70 Petitions for health claims.

* * * * *

(j) * * *

(2) Within 100 days of the date of receipt of the petition, FDA will notify the petitioner by letter that the petition has either been filed for comprehensive review or denied. The agency will deny a petition without reviewing the information contained in ''B. Summary of Scientific Data'' if the information in ''A. Preliminary Requirements'' is inadequate in explaining how the substance conforms to the requirements of § 101.14(b). If the petition is denied, the notification will state the reasons therefor, including justification of the rejection of any report from an authoritative scientific body of the U.S. Government. If filed, the date of the notification letter becomes the date of filing for the purposes of this regulation. If FDA does not act within such 100 days, the petition shall be deemed to be denied unless an extension is mutually agreed upon by FDA and the petitioner. A petition that has been denied, or has been deemed to be denied, without filing will not be made available to the public. A filed petition will be available to the public to the extent provided under paragraph (e) of this section.

(3) * * *

(iii) If FDA does not act within 90 days of the filing date, the petition shall be deemed to be denied unless an extension is mutually agreed upon by FDA and the petitioner.

(4) * * *

(ii) For cause, FDA may extend, no more than twice, the period in which it will publish a final rule; each such extension will be for no more than 90 days. FDA will publish a notice of each extension in the **Federal Register**. The document will state the basis for the extension, the length of the extension, and the date by which the final rule will be published, which date shall be within 540 days of the date of receipt of the petition.

Dated: May 6, 1998.

William B. Schultz,

Deputy Commissioner for Policy.

[FR Doc. 98–12832 Filed 5–13–98; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF LABOR

Mine Safety and Health Administration

30 CFR Part 100

RIN 1219–AB03

Civil Penalties; Correction

AGENCY: Mine Safety and Health Administration, Labor.

ACTION: Final rule; correction.

SUMMARY: This document corrects the RIN number to the final rule for criteria and procedures for proposed assessment of civil penalties published in the **Federal Register** on April 22, 1998.

EFFECTIVE DATE: May 14, 1998.

FOR FURTHER INFORMATION CONTACT: Patricia W. Silvey, Director, Office of Standards, Regulations, and Variances, MSHA, (703) 235–1910.

SUPPLEMENTARY INFORMATION: On April 22, 1998, (63 FR 20032) MSHA published a final rule on criteria and procedures for proposed assessment of civil penalties. This document corrects an error that appears on the front page of the notice. The RIN number 1219–AA49 is corrected to read 1219–AB03.

Patricia W. Silvey,

Director, Office of Standards, Regulations, and Variances.

[FR Doc. 98–12759 Filed 5–13–98; 8:45 am]

BILLING CODE 4510–43–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 9

[FRL–6013–2]

OMB Approval Numbers Under the Paperwork Reduction Act

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: In compliance with the Paperwork Reduction Act (PRA), this technical amendment amends the table that lists the Office of Management and Budget (OMB) control numbers issued under the PRA for the Urban Bus Rebuild Requirements.

EFFECTIVE DATE: This final rule is effective June 15, 1998.

FOR FURTHER INFORMATION CONTACT: William Rutledge, Engine Programs and Compliance Division (Mail Code 6403–J), U.S. Environmental Protection Agency, Washington, DC 20460. Telephone: (202) 564–9297.

SUPPLEMENTARY INFORMATION: EPA is today amending the table of currently approved information collection request (ICR) control numbers issued by OMB for various regulations. Today's amendment updates the table to list those information requirements promulgated under the Urban Bus Rebuild Requirements which appeared in the **Federal Register** on April 21, 1993 (58 FR 21359). The affected regulations are codified at 40 Code of Federal Regulations (CFR) §§ 85.1401 through 85.1415. EPA will continue to present OMB control numbers in a consolidated table format to be codified in 40 CFR part 9 of the Agency's regulations, and in each CFR volume containing EPA regulations. The table lists the section numbers with reporting and record keeping requirements, and the current OMB control numbers. This listing of the OMB control numbers and their subsequent codification in the CFR satisfy the requirements of the Paperwork Reduction Act (44 U.S.C. 3501 *et seq.*) and OMB's implementing regulations at 5 CFR part 1320.

This ICR was previously subject to public notice and comment prior to OMB approval. As a result, EPA finds that there is ''good cause'' under section 553(b)(B) of the Administrative Procedure Act (5 U.S.C. 553(b)(B)) to amend this table without prior notice and comment. Due to the technical nature of the table, further notice and comment would be unnecessary.

The Congressional Review Act, 5 U.S.C. 801 *et seq.*, as added by the Small Business Regulatory Enforcement Fairness Act of 1996, generally provides that before a rule may take effect, the agency promulgating the rule must submit a rule report, which includes a copy of the rule, to each House of the Congress and to the Comptroller General of the United States. However, section 808 provides that any rule for which the issuing agency for good cause finds that notice and public procedure thereon are impracticable, unnecessary or contrary to the public interest, shall take effect at such time as the agency promulgating the rule determines. 5 U.S.C. 808(2). As stated previously, EPA has made such a good cause finding, including the reasons therefor, and established an effective date of June 15, 1998. EPA will submit a report containing this rule and other required information to the U.S. Senate, the U.S. House of Representatives, and the Comptroller General of the United States prior to publication of the rule in the **Federal Register**. This rule is not a ''major rule'' as defined by 5 U.S.C. 804(2).

List of Subjects in 40 CFR Part 9

Environmental protection, Reporting and recordkeeping requirements.

Dated: May 5, 1998.

Richard D. Wilson,

Acting Assistant Administrator for Air and Radiation.

For the reasons set out in the preamble, part 9 of Title 40 of the Code of Federal Regulations is amended as follows:

PART 9—OMB APPROVALS UNDER THE PAPERWORK REDUCTION ACT [AMENDED]

1. The authority citation for part 9 continues to read as follows:

Authority: 7 U.S.C. 135 et seq., 136–136y; 15 U.S.C. 2001, 2003, 2005, 2006, 2601–2671; 21 U.S.C. 331j, 346a, 348; 31 U.S.C. 9701; 33 U.S.C. 1251 *et seq.*, 1311, 1313d, 1314, 1318, 1321, 1326, 1330, 1342, 1344, 1345 (d) and (e), 1361; E.O. 11735, 38 FR 21243, 3 CFR, 1971–1975 Comp. p. 973; 42 U.S.C. 241, 242b, 243, 246, 300f, 300g, 300g–1, 300g–2, 300g–3, 300g–4, 300g–5, 300g–6, 300j–1, 300j–2, 300j–3, 300j–4, 300j–9, 1857 *et seq.*, 6901–6992k, 7401–7671q, 7542, 9601–9657, 11023, 11048.

2. In § 9.1 the table is amended by adding the new entries under the indicated heading in numerical order to read as follows:

§ 9.1 OMB approvals under the Paperwork Reduction Act.

* * * * *

CONTROL OF AIR POLLUTION FROM MOTOR VEHICLES AND MOTOR VEHICLE ENGINES

40 CFR citation	OMB control No.
* * * * *	
85.1403	2060–0302
85.1404	2060–0302
85.1406	2060–0302
85.1407	2060–0302
85.1408	2060–0302
85.1409	2060–0302
85.1410	2060–0302
85.1411	2060–0302
85.1412	2060–0302
85.1413	2060–0302
85.1414	2060–0302
85.1415	2060–0302
* * * * *	

[FRDoc. 98–12852 Filed 5–13–98; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 52

[AZ–007–FON FRL–6010–3]

Finding of Failure To Submit Required State Implementation Plans for Carbon Monoxide; Arizona; Phoenix Carbon Monoxide Nonattainment Area

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: Under the Clean Air Act (Act), EPA is taking final action to find that the State of Arizona has failed to make required State Implementation Plan (SIP) submittals for the metropolitan Phoenix carbon monoxide (CO) nonattainment area. These required submittals are the serious area plan requirements for attainment of the CO national ambient air quality standards (NAAQS). The deadline for these submittals was February 28, 1998.

This final action triggers the 18-month time clock for mandatory application of sanctions and 2-year time clock for a Federal Implementation Plan under the Act. This action is consistent with the Act's mechanism for assuring timely SIP submissions.

EFFECTIVE DATE: April 27, 1998.

FOR FURTHER INFORMATION CONTACT: Frances Wicher, Office of Air Planning (AIR–2), Air Division, U.S. EPA, Region 9, 75 Hawthorne Street, San Francisco, California, 94105–3901, telephone (415) 744–1248.

SUPPLEMENTARY INFORMATION:

I. Background

A. Serious Area CO Planning Requirements for the Phoenix Metropolitan Area

Under sections 107(d)(1)(C) and 186(a) of the Clean Air Act (Act or CAA), the Phoenix metropolitan area was designated nonattainment and classified as ''moderate'' for carbon monoxide. The nonattainment designation and classification are codified in 40 CFR part 81. See 56 FR 56694 (November 6, 1991). Moderate CO nonattainment areas were given until December 31, 1995 to attain the CO NAAQS.

The Act provides that moderate areas that the Administrator finds have failed to attain by their moderate area deadlines are reclassified to serious by operation of law, CAA section 186(b)(2). Reclassified areas are then required to submit revised SIPs to address the

serious area CO requirements. These planning requirements are set forth in CAA section 187(b).

On July 29, 1996, EPA published a final reclassification of the metropolitan Phoenix CO nonattainment area to serious (61 FR 39343). The reclassification became effective 30 days later on August 28, 1996. Under the schedule established by the Administrator pursuant to CAA section 187(f) in the reclassification notice, the State of Arizona was required to submit a serious area plan addressing the CO NAAQS for the area by February 28, 1998, 18 months after the effective date of the reclassification.

These requirements, as they pertain to the Phoenix nonattainment area, include:

(a) A demonstration of attainment of the CO NAAQS as expeditiously as practicable but no later than December 31, 2000 including annual emission reductions as are necessary to attain the standard by that date (CAA sections 187(a)(7) and 186(a)(1));

(b) A forecast of vehicle miles traveled (VMT) for each year before the attainment year and provisions for annual updates of these forecasts (CAA section 187(a)(2)(A));

(c) A comprehensive, accurate, and current inventory of actual emissions from all sources (CAA section 187(a)(1));

(d) Adopted contingency measures (CAA sections 172(c)(9) and 187(a)(3)), and

(e) Adopted transportation control measures and strategies to offset any growth in CO emissions from growth in VMT or number of vehicle trips (CAA sections 187(b)(2)).[1]

B. Consequences of a Failure to Submit Finding

The Maricopa Association of Governments, the Arizona Department of Environmental Quality, and the Maricopa County Environmental Services Department have been working on the serious area CO plan since the Phoenix area was reclassified in July, 1996. These efforts have included development of an emission inventory, regional and ''hotspot'' air quality modeling, and evaluation of candidate control measures.

Notwithstanding the significant efforts by these agencies, the State has failed to meet the February 28, 1998 deadline for the required SIP submittals; therefore, EPA is required to find that the State of Arizona has failed to make the required SIP submittals for the Phoenix area CO nonattainment area.

The CAA establishes specific consequences if EPA finds that a state has failed to meet certain requirements of the CAA. Of particular relevance here is CAA section 179(a)(1), the mandatory sanctions provision. Section 179(a) sets forth four findings that form the basis for application of a sanction. The first finding, that a State has failed to submit a plan required under the CAA, is the finding relevant to this rulemaking.

If Arizona has not made the required complete submittals within 18 months of the effective date of today's rulemaking, pursuant to CAA section 179(a) and 40 CFR 52.31, the offset sanction identified in CAA section 179(b) will be applied in the affected area. If the State has still not made complete submittals 6 months after the offset sanction is imposed, then the highway funding sanction will apply in the affected area, in accordance with 40 CFR 52.31.[2] In addition, CAA section 110(c) provides that EPA must promulgate a federal implementation plan (FIP) no later than 2 years after a finding under section 179(a).

The 18-month clock will stop and the sanctions will not take effect if, within 18 months after the date of the finding, EPA finds that the State has made a complete submittal of a plan addressing the serious area CO requirements for Phoenix area. In addition, EPA will not promulgate a FIP if the State makes the required SIP submittals and EPA takes final action to approve the submittals within 2 years of EPA's findings (section 110(c)(1) of the Act).

II. Final Action

A. Rule

EPA is making a finding of failure to submit for the Phoenix CO nonattainment area, due to failure of the State to submit SIP revisions addressing the Clean Air Act's serious area plan requirements for the CO standard.

B. Effective Date under the Administrative Procedures Act

Because EPA is issuing this action as a rulemaking, the Administrative Procedures Act (APA) applies.

The action will be effective on the date this action is signed, April 27, 1998. Under the APA, 5 U.S.C. 553(d)(3), agency rulemaking may take effect before 30 days after the date of publication in the **Federal Register** if an agency has good cause to mandate an earlier effective date. This action concerns SIP submittals that are already overdue and the State and general public are aware of applicable provisions of the CAA relating to overdue SIPs. In addition, this action simply starts a ''clock'' that will not result in sanctions for 18 months and that the State may ''turn off'' through the submission of complete SIP submittals. These reasons support an effective date prior to 30 days after the date of publication.

C. Notice-and-Comment Under the Administrative Procedures Act

This action is a final agency action but is not subject to the notice-and-comment requirements of the APA, 5 U.S.C. 533(b). EPA believes that because of the limited time provided to make findings of failure to submit regarding SIP submittals, Congress did not intend such findings to be subject to notice-and-comment rulemaking. However, to the extent such findings are subject to notice-and-comment rulemaking, EPA invokes the good cause exception pursuant to the APA, 5 U.S.C. 553(d)(3). Notice and comment are unnecessary because no EPA judgment is involved in making a nonsubstantive finding of failure to submit SIPs required by the CAA. Furthermore, providing notice and comment would be impracticable because of the limited time provided under the statute for making such determinations. Finally, notice and comment would be contrary to the public interest because it would divert Agency resources from the critical substantive review of submitted SIPs. See 58 FR 51270, 51272, note 17 (October 1, 1993); 59 FR 39832, 39853 (August 4, 1994).

III. Administrative Requirements

A. Executive Order 12866

The Office of Management and Budget (OMB) has exempted this action from review under Executive Order 12866.

B. Regulatory Flexibility Act

Under the Regulatory Flexibility Act (RFA), 5 U.S.C. 600 *et seq.*, EPA must prepare a regulatory flexibility analysis

[1] Serious CO nonattainment areas are also required to adopt and implement enhanced vehicle inspection and maintenance programs, see CAA section 187(a)(6). Arizona has already made the required submission of this program and EPA approved the program on May 8, 1995 (60 FR 22519).

[2] In a 1994 rulemaking, EPA established the Agency's selection of the sequence of these two sanctions: the offset sanction under section 179(b)(2) shall apply at 18 months, followed 6 months later by the highway sanction under section 179(b)(1) of the Act. EPA does not choose to deviate from this presumptive sequence in this instance. For more details on the timing and implementation of the sanctions, see 59 FR 39832 (August 4, 1994), promulgating 40 CFR 52.31, ''Selection of sequence of mandatory sanctions for findings made pursuant to section 179 of the Clean Air Act.''

assessing the impact of any proposed or final rule on small entities. 5 U.S.C. 603 and 604. Alternatively, EPA may certify that the rule will not have a significant impact on a substantial number of small entities. Small entities include small business, small not-for-profit enterprises and government entities with jurisdiction over populations of less than 50,000.

As discussed in section III.C. below, findings of failure to submit required SIP revisions do not by themselves create any new requirements. Therefore, I certify that today's action does not have a significant impact on small entities.

C. Unfunded Mandates Act

Under sections 202, 203, and 205 of the Unfunded Mandates Reform Act of 1995 (''Unfunded Mandates Act'') signed into law on March 22, 1995, EPA must undertake various actions in association with proposed or final rules that include a Federal mandate that may result in estimated costs of $100 million or more to the private sector, or to State, local, or tribal governments in the aggregate.

In addition, under the Unfunded Mandates Act, before EPA establishes any regulatory requirements that may significantly or uniquely affect small governments, including tribal governments, EPA must have developed, under section 203, a small government agency plan.

EPA has determined that today's action is not a Federal mandate. The CAA provision discussed in this notice requires states to submit SIPs. This notice merely provides findings that Arizona has not met that requirement. This notice does not, by itself, require any particular action by any State, local, or tribal government, or by the private sector.

For the same reasons, EPA has determined that this rule contains no regulatory requirements that might significantly or uniquely affect small governments.

D. Submission to Congress and the General Accounting Office

The Congressional Review Act, 5 U.S.C. 801 *et seq.*, as added by the Small Business Regulatory Enforcement Fairness Act of 1996, generally provides that before a rule may take effect, the agency promulgating the rule must submit a rule report, which includes a copy of the rule, to each House of the Congress and to the Comptroller General of the United States. However, section 808 provides that any rule for which the issuing agency for good cause finds (and incorporates the finding and a brief statement of reasons therefor in the rule) that notice and public procedure thereon are impracticable, unnecessary or contrary to the public interest, shall take effect at such time as the agency promulgating the rule determines. 5 U.S.C. 808(2). As stated previously, EPA has made such a good cause finding, including the reasons therefor, and established an effective date of April 27, 1998. EPA will submit a report containing this rule and other required information to the U.S. Senate, the U.S. House of Representatives, and the Comptroller General of the United States prior to publication of the rule in the **Federal Register**. This rule is not a ''major rule'' as defined by 5 U.S.C. 804(2).

E. Paperwork Reduction Act

This rule does not contain any information collection requirements which require OMB approval under the Paperwork Reduction Act (44 U.S.C. 3501 *et seq.*).

F. Judicial Review

Under CAA Section 307(b)(1), a petition to review today's action may be filed in the Court of Appeals for the appropriate circuit by July 13, 1998. Filing a petition for reconsideration by the Administrator of this final rule does not affect the finality of this rule for the purposes of judicial review nor does it extend the time within which a petition for judicial review may be filed, and shall not postpone the effectiveness of such rule or action. This action may not be challenged later in proceedings to enforce its requirements. See section 307(b)(2) of the Act.

List of Subjects in 40 CFR Part 52

Environmental protection, Air pollution control, Carbon monoxide, Intergovernmental relations.

Authority: 42 U.S.C. 7401 *et seq.*

Dated: April 27, 1998.

Felicia Marcus,

Regional Administrator, Region IX.

[FR Doc. 98–12853 Filed 5–13–98; 8:45 am]

BILLING CODE 6560–50–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Care Financing Administration

Centers for Disease Control and Prevention

42 CFR Part 493

[HCFA–2239–F]

RIN 0938–AH82

CLIA Program; Simplifying CLIA Regulations Relating to Accreditation, Exemption of Laboratories Under a State Licensure Program, Proficiency Testing, and Inspection

AGENCY: Health Care Financing Administration (HCFA), and Centers for Disease Control and Prevention (CDC), HHS.

ACTION: Final rule.

SUMMARY: This final rule responds to selected comments received on a final rule with a comment period implementing the Clinical Laboratory Improvement Amendments of 1988, which was published in the **Federal Register** on February 28, 1992, in the areas of proficiency testing and inspections for clinical laboratories. In responding to these comments, we accommodate, when possible, the Administration's regulatory reform initiative by reducing duplicative material, emphasizing outcome-oriented results, and simplifying regulations. In that regard, we also are streamlining our regulations in the areas of State exemption, and granting deemed status to laboratories accredited by an approved accreditation organization.

EFFECTIVE DATE: These regulations are effective on June 15, 1998.

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FOR FURTHER INFORMATION CONTACT: Judy Yost, (410) 786–3531.

SUPPLEMENTARY INFORMATION:

I. Background

On February 28, 1992, we published in the **Federal Register**, at 57 FR 7002, final regulations with an opportunity for public comment, ''Regulations Implementing the Clinical Laboratory Improvement Amendments of 1988 (CLIA),'' that set forth requirements for laboratories that are subject to CLIA. CLIA requirements apply to any laboratory that examines human specimens for the diagnosis, prevention, or treatment of any disease or impairment of, or the assessment of the health of, human beings. The regulations at 42 CFR part 493 establish uniform requirements for all laboratories regardless of location, size, or type. A laboratory must meet these Federal requirements, or a laboratory may meet the requirements if it is either accredited by a private, nonprofit accreditation organization approved by HCFA, and holds a valid CLIA certificate, or it is located in a State that HCFA has granted an exemption from CLIA requirements because the State has in effect laws that provide for requirements equal to or more stringent than CLIA requirements.

On July 31, 1992, we published in the **Federal Register**, at 57 FR 33992, a final rule that established the criteria used to approve accreditation organizations and State licensure programs. These regulations are found in subpart E of part 493 and are based on statutory requirements in section 353 (e) and (p) of the Public Health Service Act.

II. Provisions of the Final Regulations

These regulations respond to public comments received on the February 28, 1992 rule concerning the inspection of laboratories and the regulatory use of proficiency testing. In responding to the concerns of the commenters, we accommodate, whenever possible, the Administration's regulatory reform commitment by:

(1) Eliminating duplicative material and reorganizing regulations concerning accreditation by a private, nonprofit accreditation organization and exemption from CLIA requirements under an approved State licensure program (subpart E of part 493); (2) emphasizing education in proficiency testing to improve laboratory performance (subpart H of part 493); and (3) focusing on an outcome-oriented approach in laboratory inspections (subpart Q of part 493).

A. Accreditation of a Laboratory by a Private, Nonprofit Accreditation Organization or Exemption From CLIA Requirements Under an Approved State Laboratory Program (Subpart E)

Based on the requirements in section 353(e) and (p) of the Public Health Service Act and regulations in part 493, subpart E, HCFA has approved six accreditation organizations. They are: American Association of Blood Banks, American Osteopathic Association, American Society for Histocompatability and Immunogenetics, College of American Pathologists, Commission on Office Laboratory Accreditation, and Joint Commission on Accreditation of Healthcare Organizations. We have also approved three State licensure programs for CLIA exemption of licensed laboratories within the State: Washington, New York, and Oregon.

The existing regulations in subpart E contain duplicative information, which we are eliminating by restructuring subpart E and consolidating requirements. The revised subpart better reflects the process involved and better organizes the information required from organizations and States to obtain HCFA approval. This restructuring does not change the current requirements, but only redesignates them into a more customer-oriented document, making them easier for users to understand. In this process, we use new section numbers, but retain all the requirements in subpart E.

B. Participation in Proficiency Testing for Laboratories Performing Tests of Moderate Complexity (Including the Subcategory of Provider-performed Microscopy), High Complexity, or Any Combination of These Tests (Subpart H)

Proficiency testing (PT) is the testing of laboratory samples, the values of which are unknown to the laboratory, to assess the accuracy of the laboratory's results. PT serves as a test performance indicator, as well as provides invaluable feedback. Under the CLIA regulations, laboratories test PT samples three times a year for the tests the laboratory performs, which are listed in subpart I of part 493. Samples for these three testing events are provided and graded by HCFA-approved PT programs. A laboratory's performance is described as satisfactory performance, unsatisfactory performance, or unsuccessful performance. Satisfactory performance occurs when a laboratory attains a passing score for all analytes, subspecialties, or specialties. Unsatisfactory performance occurs when a laboratory fails to attain the minimum satisfactory score for an analyte, subspecialty, or specialty for a testing event. Unsuccessful performance occurs when a laboratory fails to attain the minimum satisfactory score for an analyte, subspecialty, or specialty for two consecutive or two of three consecutive testing events.

Comments Concerning Regulatory Use of PT

In response to the concerns of commenters received on the final rule published February 28, 1992, we are emphasizing our existing policy that uses PT as an outcome indicator of laboratory performance and for educational purposes. We found that the commenters' recommendations were consistent with our regulatory reform initiative.

Comment: Many commenters recommended that we use PT performance more for educational purposes than for punitive actions. Commenters stated that PT is an excellent mechanism for assisting laboratories to identify and solve problems, evaluate personnel, and improve test performance; however, while PT is a valuable educational tool, it has limitations that should preclude it from use as the sole indicator for regulatory intervention.

Response: We agree with the commenters. We allow a laboratory to undertake education or training, or both, to correct initial unsuccessful PT performance for each laboratory specialty in which it performs PT. An educational focus for an initial occurrence of unsuccessful PT affords the laboratory further opportunity to undertake training of its personnel, or to obtain technical assistance, or both, to identify, correct, and prevent the problems that led to PT failures. We are revising subpart H to clarify and emphasize HCFA's educational approach. This approach will not release the laboratory from its responsibility to perform patient testing accurately and reliably. It is, however,

less punitive than some laboratories' initial perception of the PT actions we would impose, and provides an incentive, as well as a mechanism for laboratories to improve their performance.

The enforcement provisions in § 493.1838 give a laboratory the opportunity to train personnel or to obtain technical assistance, or both, when the laboratory has performed PT unsuccessfully. We are adding a new paragraph (c) to § 493.803, which sets forth the educational emphasis of PT, to respond to comments received on PT requirements. These regulatory additions unify commenters' recommendations with the Administration's Reinventing Government initiative by focusing on education as a correction to the problem, as opposed to punitive measures.

Comment: Commenters recommended that HCFA use PT performance as an index of performance or a screening tool to identify potential problems. Commenters also suggested that we impose stricter sanctions (that is, that we remove from a laboratory's certificate the laboratory's authorization to test a specific analyte) when a laboratory demonstrates an unwillingness or inability to correct the problems that caused the failure.

Response: We agree with the commenters. We have also established some exceptions at § 493.803(c) that encompass the commenters' suggestions. We would take more assertive actions when there is an immediate jeopardy to patient health and safety, when a laboratory demonstrates an inability or unwillingness to provide evidence that it has taken steps to correct its PT problem(s), or if it has a history of noncompliance with CLIA requirements other than proficiency testing (for example, a laboratory that has had condition level deficiencies in quality control).

C. Inspection—Subpart Q

We are revising part 493 subpart Q, Inspections, in response to commenters' concerns. We are also reconstructing this subpart into a more concise format, using succinct, easier to understand language. Additionally, we are redirecting the HCFA inspection process to focus more on outcomes, rather than a solely process-oriented review of a laboratory. These actions also follow the Administration's Reinventing Government initiative in that the onsite survey is less process dependent.

1. Alternate Quality Assessment Survey

Comment: We received comments requesting that we inspect laboratories onsite every 2 years, but provide a ''paper inspection'' that the laboratory would complete between biennial onsite inspections.

Response: We believe that it would be a prudent use of our resources, and a sensible means of allowing greater flexibility than the program currently provides, to have an inspection scheme that gears itself to the variations we see in laboratory compliance. For those laboratories that we believe pose potential risks to public health and safety, judging from their compliance history, we continue to believe that regular onsite inspections present the most viable course of assuring ourselves that these laboratories maintain compliance with CLIA requirements. On the other hand, for those laboratories that have a sustained record of maintaining compliance, the need to have a constantly recurring onsite presence is not as compelling.

We believe that the statute specifically authorizes our focussed use of limited inspection resources. Specifically, section 353(g)(2) of the Public Health Service Act calls for inspections to be performed on a biennial basis, ''or with such other frequency as the Secretary determines to be necessary to assure compliance'' with CLIA standards. We believe that the use of the Alternate Quality Assurance Survey allows us to be in a position to inspect onsite with less frequency than we have before, while still assuring that those laboratories that require the closest supervision will continue to receive it. This approach would further the statutory mandate that we have a schedule for inspections that enables us to ensure facility compliance with program requirements.

With input from our partners in the State survey agencies and our regional office surveyors, we will review and evaluate information, such as the type and number of deficiencies (if any) cited at the last onsite inspection, proficiency testing performance, and complaints lodged against the laboratory. We consider information of this type in determining whether a laboratory may be a candidate for this self-inspection (the Alternate Quality Assessment Survey). We believe that a self-inspection process will motivate laboratories to improve their performance. It is also an example of the Reinventing Government initiative put into practice.

A laboratory may receive the Alternate Quality Assessment Survey in lieu of an onsite inspection. Based on a review of the completed Alternate Quality Assessment Survey form and information submitted by the laboratory, should we conclude that, for any reason, the laboratory is not performing in a manner expected by the statute and regulations, we will follow the Alternate Quality Assessment Survey with an onsite inspection to verify that the laboratory is in compliance with CLIA requirements. A laboratory will not receive the Alternate Quality Assessment Survey for two consecutive certification cycles.

We will monitor and evaluate the effectiveness of the Alternate Quality Assessment Survey process through verification inspections of approximately 5 percent of the laboratories receiving the self-survey questionnaire. We will adjust the self assessment process, as indicated.

2. Outcome-oriented Survey Process

Comment: Among the commenters' recommendations were indications that our February 28, 1992 regulations implementing the CLIA requirements may not be applicable to all functions of all laboratories. We were reminded that certain standards might not be required for every type of testing performed; for example, the requirements for specimen preparation and storage of specimens would not directly apply to most point-of-care testing and, typically, have minimum impact on the quality of testing in this setting. Although HCFA surveyors have not held laboratories to requirements that are not applicable to a particular laboratory's testing activities, there was a concern from the commenters that the surveyors would interrupt direct patient care and spend an inordinate amount of time performing a line-by-line comparison of regulations that would not apply to the type of testing performed by the entity.

Response: In an effort to be responsive to those concerns, we are enhancing our inspection or survey process by focusing on outcomes. The outcome-oriented survey is the onsite inspection mechanism that is used for all laboratories. Onsite inspections are performed for: initial surveys for newly regulated laboratories; validation inspections of accredited or CLIA-exempt laboratories, laboratories that do not qualify for the Alternate Quality Assessment Survey; and for alternate cycles for those laboratories completing the Alternate Quality Assessment Survey. The emphasis of the survey is on the quality of the laboratory's performance and is based on a review of the laboratory's oversight and monitoring of its preanalytical,

analytical, and postanalytical testing processes using the quality assurance requirements in the regulations. Surveyors will review laboratory performance from the perspective of the effect on patient care rather than a line-by-line comparison for regulatory compliance. While we will look at outcomes as indicators of compliance, should we identify noncompliance with requirements set forth in the CLIA rules, we will cite deficiencies and, if necessary, impose sanctions. Our improvements to the survey mechanism are also in line with the Administration's Reinventing Government initiative by focusing on outcomes, as opposed to process.

In summary, on commenters' recommendations, we are providing to laboratories an onsite survey process that is less process dependent and more outcome-oriented, as well as a self-evaluative assessment (the Alternate Quality Assessment Survey), to motivate laboratories toward self-monitoring of their overall performance.

3. Specific Comments and Responses on Issues Concerning Inspection of Laboratories

We received 114 comments concerning subpart Q, Inspections. Many of the commenters raised identical or closely related issues, and we combined them, when appropriate.

Comment: We received numerous comments regarding announced versus unannounced inspections. Some commenters believed that only a physician office laboratory should have announced inspections, especially when direct patient care is provided. They believed that it would be a waste of the inspector's time if, at the time of the inspection, the laboratory was closed, the director unavailable, or the laboratory was not conducting testing. Other commenters believed that the option for announced inspections should be provided to all laboratories. These commenters believed that, even if given advance notice of an inspection, a laboratory would still not be able to ''falsify'' documentation or other data that would not be readily identified by a competent inspector. Another group of commenters stated that follow-up inspections should be unannounced. One commenter believed that we should set standards limiting agency discretion to conduct unannounced inspections. Still another commenter believed that ''warrants'' should be required when the laboratory owner does not give advance consent for his or her laboratory to be inspected.

Response: We agree with commenters who recommended announced inspections for all laboratories. We have instituted a policy of announced inspections for all initial and recertification inspections, which allows a laboratory the latitude to include multiple members of the staff in the inspection process for the educational value. Announced, routine inspections are more efficient, in that the laboratory can make previous testing records more accessible before the inspection, and these inspections are also less intrusive when the laboratory is a health care facility providing direct patient care.

We are revising subpart Q by eliminating the modifiers ''announced and unannounced'' and keeping only the unqualified term ''inspections.'' This is in accordance with section 353(g)(1) of the Public Health Service Act, which clearly provides for either announced or unannounced inspections. This provision applies to all laboratories, in keeping with the site-neutral intent of the CLIA statute. However, we are maintaining our policy that all complaint and follow-up inspections are unannounced and are conducted during routine hours of operation. Because these inspections are most probably for cause, laboratories are evaluated during normal operating conditions so that an appropriate assessment can be made.

We disagree with the commenter who believed that we should develop standards limiting agency discretion to conduct unannounced inspections. The law allows the Secretary to determine when announced or unannounced inspections should be conducted and does not call for standards to be developed limiting this provision. We believe that the survey procedures and instructions contained in the HCFA State Operations Manual (HCFA Pub. 7) adequately outline situations in which an announced or unannounced inspection should be conducted.

We disagree with the commenter who suggested that we require a ''warrant'' when the laboratory owner does not give advance consent for the laboratory to be inspected. The law provides us with the authority to enter a laboratory for the purpose of conducting an inspection. If an owner, director, or any employee of the laboratory refuses our reasonable request for permission to inspect the laboratory and its operations, the laboratory may be subject to revocation of its CLIA certificate, as provided in section 353(i)(1)(E) of the Public Health Service Act and § 493.1840 of the regulations.

Comment: A few commenters said the word ''will'' should be changed to ''may'' in the following context: ''HHS will conduct announced or unannounced surveys'' at § 493.1776(a) (now found at § 493.1775(b)).

Response: We agree with the commenters. However, as previously explained, we are removing the specific words ''announced'' and ''unannounced,'' and the pertinent portion of § 493.1775(b) now reads, '' * * * HCFA or a HCFA agent may conduct an inspection at any time during the laboratory's hours of operation * * *'' to be consistent with the rest of the subpart.

Comment: One commenter believed that CLIA requires yearly inspections, while other commenters recommended that we conduct inspections every other year onsite with a paper inspection in alternate years.

Response: Section 353(g)(1) of the Public Health Service Act requires inspections on a biennial basis or with such other frequency that the Secretary determines necessary to ensure compliance with the CLIA requirements. We conduct complaint inspections, as necessary, after we determine that the complaint alleges a violation of CLIA requirements. We agree with the commenters' recommendation for onsite inspections to be alternated with a self-evaluative survey. We have developed a self-assessment form, the Alternate Quality Assessment Survey, to be used in alternate cycles for laboratories with a history of compliance because there is less need to have a constantly recurring presence in those laboratories.

Comment: Some commenters suggested that inspections be conducted by professional organizations. There was concern that surveyors would not be knowledgeable about specialty testing or regulatory requirements, and might inappropriately apply requirements. Another group of commenters believed that cytology inspections should be conducted by a qualified pathologist and cytotechnologist.

Response: Inspections for laboratories holding certificates of compliance are performed by HCFA regional office laboratory consultants or State survey agency personnel, or both, and stress an outcome-oriented focus. In addition to mandatory participation at a HCFA-sponsored laboratory surveyor training program and one-on-one training with an experienced surveyor, we also provide written guidelines to assist surveyors in evaluating laboratory compliance with Federal regulations. This training provides the surveyor with comprehensive, detailed information regarding the regulations, outcome-oriented survey process, and surveyor

guidelines, all of which complement their technical background. Training is also provided at the State and Federal regional levels on an on-going basis. Moreover, we have a contract in place with an organization of cytology professionals, which provides specialized reviews of selected cytology laboratories. The individuals who participate in these reviews are qualified as general supervisors and technical supervisors in cytology. This contract has been in effect since 1989.

HCFA also has approved six professional organizations as accrediting bodies under CLIA. These organizations sought deeming authority for their programs, which were equal to, or more stringent than, the CLIA requirements taken as a whole. A laboratory may, therefore, choose to apply for a certificate of accreditation; in which case, a HCFA-approved accreditation organization would serve as its inspecting agency for CLIA.

Comment: One organization believed that it is inappropriate for a surveyor to interview an employee during an inspection, and if a disgruntled employee makes false or specious comments against his or her employer, it may impugn the reputation of the laboratory director.

Response: We disagree. Any interviews conducted during the course of an inspection are to assist the surveyor in gathering information for the determination of the laboratory's compliance with the applicable requirements under part 493. Any pertinent information received during an inspection is verified, and determination of a facility's compliance is based on all elements of the inspection process, not just individual interviews.

Comment: Another group of commenters was concerned that patient records will be reviewed during the course of the inspection and believed that patient privacy may be compromised.

Response: We understand the commenters' concerns; however, laboratory surveyors are health care professionals who are familiar with the need for patient privacy. Confidentiality of patient and laboratory information is also reinforced during surveyor training sessions. Laboratory surveyors appreciate and respect patient confidentiality. Therefore, we do not believe patient privacy would be compromised.

Comment: A few commenters believed that we should only conduct inspections for cause. One commenter believed that complaints should be better defined. Another commenter believed that complaints should be verified before a complaint inspection is conducted.

Response: Section 353(g)(2) of the Public Health Service Act requires that we conduct inspections biennially or with such frequency as the Secretary determines is necessary. For those laboratories with a history of compliance, there is less need to have a constantly recurring onsite presence, and we have developed a self-evaluative survey, the Alternate Quality Assessment Survey, to be used in alternate cycles. We believe the use of the Alternate Quality Assessment Survey allows us to be in a position to inspect onsite with less frequency than we have before, while still ensuring that those laboratories that require the closest supervision will continue to receive it.

A complaint is an allegation against a laboratory by any individual for any perceived or real violation of the CLIA requirements. For example, there may be a complaint that a laboratory is operating without a certificate or that a laboratory is performing testing outside of the certificate it holds. Inspectors are instructed to determine if the complaint involves CLIA requirements or regulations under the jurisdiction of another agency. If the complaint involves a violation of State or other Federal law that is under the jurisdiction of another agency (for example, the Occupational Safety and Health Administration), we refer the complaint to the appropriate State or agency for investigation. If the complaint is an alleged violation of the CLIA requirements, we may conduct an unannounced onsite inspection focusing on the alleged violations.

Comment: A commenter wanted the phrase ''including allegations that individuals other than physicians are performing microscopic exams'' added at § 493.1776(a)(2). Another group of commenters believed that we should conduct unannounced inspections to substantiate which individuals are performing testing.

Response: When a complaint alleges that an individual performing tests is not qualified, we investigate the laboratory's compliance with the CLIA personnel qualification requirements. It is our policy to conduct unannounced complaint inspections. To clarify this policy we are moving § 493.1776(a)(2) to § 493.1775(b) and also referencing this in § 493.1773(f).

Comment: Some commenters objected to ''onsite proficiency testing'' as part of the inspection process as being inappropriate based on the complications involved in testing PT samples and suggested that we delete § 493.1777(b)(1).

Response: We disagree with the commenters. Section 493.1777(b)(1), now § 493.1773(b)(1), provides the surveyor with the authority to require a laboratory to perform testing, which may include analysis of PT samples from a HCFA-approved PT program, as part of the inspection. We are aware of the complications referred to by the commenters. Although the option of requiring a laboratory to perform testing on PT samples exists, it is not routinely employed by surveyors. If it were employed, it would be structured to address complications expressed by the commenters.

Comment: One commenter believed that we should require onsite (proficiency) testing during routine inspections for laboratories holding a certificate of waiver.

Response: Section 353(d)(2)(C) of the Public Health Service Act specifically exempts laboratories performing only waived tests from routine inspections and all quality standards including PT. We, therefore, may not require this testing or routinely inspect waived testing.

Comment: A few commenters suggested that we add the following language to § 493.1775, ''States may coordinate the Medicare/Medicaid compliance surveys for skilled nursing facilities, nursing facilities, and intermediate care facilities for the mentally retarded with CLIA compliance activities.''

Response: We encourage coordination of inspections under the Medicare, Medicaid, and CLIA programs. Due to separate laws and funding, resources, expertise, and availability, we can do no more than encourage inspectors from different programs to coordinate inspections to reduce the burden on facilities. Thus, we are making no change to the regulations.

Comment: Commenters also suggested that we change § 493.1775(d) to read: ''* * *payments for laboratory services to the laboratory or * * * '' to ensure that a suspension of Medicare payments for laboratory services by a provider could not result in the suspension of payments for any non-laboratory services.

Response: We are moving this requirement from § 493.1775(d) to § 493.1773(g). As stated above, CLIA and Medicare/Medicaid are separate programs. Actions we take under the CLIA program may result in a laboratory being unable to perform certain tests. We notify the Medicare and Medicaid programs, as appropriate, of any action we take to suspend, limit or revoke the

CLIA certificate, which may have an impact on the facility's overall participation in Medicare/Medicaid.

Comment: One commenter suggested that we change § 493.1780(b)(4)(ii) to ensure that inspection reports from accreditation bodies are readily available to inspectors.

Response: The current regulations require that an accrediting organization submit pertinent information to HCFA, which includes inspection reports from the accreditation organization's surveys. We find that performing validation inspections without prior knowledge of the organization's findings offers a more unbiased approach for our surveyors than performing inspections with prior knowledge. Therefore, inspection reports from accreditation organizations are not normally made available to surveyors before they perform validation inspections. However, these reports are used in the comparability review of the organization's inspection.

Comment: Some commenters urged us to approve the College of American Pathologists as an accrediting organization, so that laboratories that are accredited by this organization will meet CLIA requirements.

Response: HCFA approved the College of American Pathologists as an accreditation organization (see notice published February 9, 1995 in the **Federal Register** at 60 FR 7774). Five other organizations have also been approved as accreditation organizations: American Association of Blood Banks; American Osteopathic Association; American Society for Histocompatibility and Immunogenetics; Commission on Office Laboratory Accreditation; and Joint Commission on Accreditation of Health Care Organizations.

Comment: Several commenters indicated that it is possible for mobile laboratories providing services in more than one State to operate under one certificate. They questioned which State would have the responsibility to inspect the laboratories.

Response: When a mobile laboratory provides service in more than one State under one certificate, the State in which the laboratory's home base is located has the responsibility to ascertain compliance with the regulations. This may involve contacting other State survey agencies and coordinating survey activity or scheduling the survey to coincide with testing performed in the State in which the home base is located.

Comment: Another commenter suggested that we inspect a mobile laboratory when it reaches a specific mileage limit.

Response: Section 353(g)(2) of the Public Health Service Act requires that we conduct inspections on a biennial basis or with such other frequency as the Secretary determines to be necessary to assure compliance with CLIA requirements and standards. While there is latitude in determining frequency of inspection, we believe the assurance of accurate testing is independent of mileage traveled. Therefore, we will continue to inspect mobile laboratories with the same frequency as other types of laboratories.

Conforming Changes

To avoid the continued use of an overly long term in the text of the regulations, we are adding a definition for the term, ''State licensure program,'' which means a State laboratory licensure or approval program.

III. Waiver of Proposed Rulemaking

We ordinarily publish a notice of proposed rulemaking in the **Federal Register** and invite prior public comment on proposed rules. The notice of proposed rulemaking includes a reference to the legal authority under which the rule is proposed, and the terms and substances of the proposed rule or a description of the subjects and issues involved. This procedure can be waived, however, if an agency finds good cause that a notice-and-comment procedure is impracticable, unnecessary, or contrary to the public interest and incorporates a statement of the finding and its reasons in the rule issued.

With regard to all elements of this regulation except one, we are responding to comments we received in previous rulemaking documents and, in response to earlier rules. Accordingly, a final rule is justified. The one exception concerns the rewritten subpart E. But here, since we are making no substantive changes, but merely condensing and reorganizing content, we believe that it is unnecessary and not in the public interest to delay the effectiveness of this clarification, as would happen were we to issue a proposed rule.

Therefore, we find good cause to waive the notice of proposed rulemaking and to issue this final rule.

IV. Redesignation Table

The following table is a guide to readers in identifying the source of requirements in the final rule.

Existing section	New section
493.501(a) introductory text	493.551(a)
493.501(a)(1)	493.551(a)(1)
493.501(a)(2)	493.551(a)(2)
493.501(b) introductory text	493.551(b)
493.501(b)(1)	493.551(a)(3)
493.501(b)(2)	493.551(a)(3)
493.501(b)(3)	493.551(b)(1)
493.501(b)(4)	493.551(b)(2)
493.501(c) introductory text	493.553(a)
493.501(c)(1)	493.557(a)(1)
493.501(c)(2)	493.553(a)(1)
493.501(c)(3)	493.553(a)(2) (i)–(iv) & (vi)
493.501(c)(4)	493.553(a)(3)
493.501(c)(5)	493.557(a)(2)
493.501(c)(6)	493.557(a)(3) (i)–(iii)
493.501(c)(7)	493.553(a)(4)
493.501(c)(8)	493.553(a)(5)
493.501(c)(9)	493.553(a)(6)
493.501(c)(10)	493.557(a)(4)
493.501(c)(11)	493.557(a)(5)
493.501(c)(12)	493.553(a)(2)(v)
493.501(d) introductory text	493.553(b)
493.501(d)(1)	493.553(b)(1)
493.501(d)(2)	493.553(b)(2)

Existing section	New section
493.501(d)(3)	493.553(b)(3)
493.501(d)(4)	493.553(c)
493.501(d)(5)	493.553(d)
493.501(d)(6)	493.561(a)(1)
493.501(d)(7)	493.561(b) (1)–(3)
493.501(d)(8)	493.561(a)(2)
493.501(e) introductory text	493.559(a)
493.501(e)(1)	493.559(b)(1)
493.501(e)(2)	493.559(b)(4)
493.501(e)(3)	493.559(b)(2)(ii)
493.501(e)(4)	493.559(b)(5)
493.503(a)	493.551(b)(3)
493.503(b)(1)	493.551(b)(4)
493.503(b)(2)	493.551(b)(4)
493.503(b)(3)	493.551(b)(5)–(6)
493.503(b)(4)	493.551(b)(6)
493.504	493.551(c)
493.506(a)	493.559(b)(2)(i) & 493.557(a)(1)
493.506(b)(1)	493.555(a)
493.506(b)(2)(i)	493.557(a)(3) (i)–(iii)
493.506(b)(2)(ii)	493.555(b)
493.506(b)(2)(iii)	493.557(a)(6)
493.506(b)(2)(iv)	493.557(a)(7)
493.506(b)(2)(v)	493.557(a)(8)
493.506(b)(2)(vi)	493.557(a)(9)
493.506(b)(2)(vii)	493.557(a)(10)
493.506(b)(2)(viii)	493.557(a)(11)
493.506(b)(3)(i)	493.555(c)(1)
493.506(b)(3)(ii)	493.555(c)(2)
493.506(b)(3)(iii)	493.555(c)(3)(i)
493.506(b)(3)(iv)	493.555(c)(4)
493.506(b)(3)(v)	493.555(c)(5)
493.506(b)(3)(vi)	493.557(b)(12)(i)–(ii)
493.506(b)(3)(vii)	493.557(b)(13)
493.506(b)(3)(viii)	493.557(b)(14)
493.507(a) introductory text	493.563(a)(1)
493.507(a)(1)	493.563(b)
493.507(a)(2)	493.563(c)
493.507(b)	493.565
493.507(c)	493.567
493.507(d)	493.569
493.507(e)	493.571
493.507(f)	493.563(e) + (d)
493.509(a)	493.573(a)
493.509(b)	493.573(b)
493.509(c)	493.573(c)
493.509(d)	493.573(d)
493.511(a)(1)	493.575(a)(1)
493.511(a)(2)	493.575(a)(3)
493.511(a)(3)	493.575(a)(4) & (a)(4)(i)
493.511(b)	493.575(b)(1)
493.511(c)	493.575(b)(2)
493.511(d) introductory text	493.575(c)
493.511(d)(1)	493.575(c)(1)
493.511(d)(2)	493.575(c)(2)
493.511(d)(3)–(4)	493.575(c)(3)
493.511(d)(5)	493.575(c)(4)
493.511(e)	493.575(d)
493.511(f)	493.575(e)
493.511(g)	493.575(f)
493.511(h)	493.575(g)(1) & (g)(3)
493.511(i)	493.575(h)(1)
493.511(j)	493.575(k)
493.513(a) introductory text	493.553(c) & 493.551(a)
493.513(a)(1)–(2)	493.551(a)(1)
493.513(a)(3)	493.551(a)(2)
493.513(a)(4)	493.557(b)(1)
493.513(a)(5)	493.557(b)(2)
493.513(a)(6)	493.557(b)(3)
493.513(a)(7)	493.557(b)(4)
493.513(a)(8)	493.557(b)(5)
493.513(b)(1)–(2)	493.551(a)(3)
493.513(c) introductory text	493.553(a)
493.513(c)(1)	493.553(a)(1)

Existing section	New section
493.513(c)(2)	493.553(a)(2)(i)–(vi)
493.513(c)(3)	493.557(b)(1)
493.513(c)(4)	493.553(a)(3)
493.513(c)(5)	493.553(a)(4)
493.513(c)(6)	493.553(a)(5)
493.513(c)(7)	493.553(a)(6)
493.513(c)(8)	493.553(b)(6)
493.513(d)(1)	493.557(b)(7)
493.513(d)(2)	493.557(b)(8)(i)–(iii)
493.513(e)	493.553(b)(1)
493.513(f)	493.553(b)(2)
493.513(g)	493.553(b)(3)
493.513(h)	493.561(c)
493.513(i)	493.553(d)
493.513(j)	493.561(a)(1)
493.513(k)	493.559(a)
493.513(k)(1)	493.559(b)(1)
493.513(k)(2)	493.559(b)(4)
493.513(k)(3)	493.559(b)(3)
493.513(k)(4)	493.559(b)(5)
493.513(l)	493.557(b)(14)
493.513(m)	493.561(a)(2)
493.515 (a)(1)	493.555(a)
493.515(a)	493.555 introductory text
493.515(a)(2)	493.555(b)
493.515(a)(2)(ii)	493.557(b)(9)
493.515(a)(2)(iii)	493.557(b)(10)
493.515(a)(3) introductory text	493.555(c) introductory text
493.515(a)(3)(i)	493.555(c)(1)
493.515(a)(3)(ii)	493.555(c)(2)
493.515(a)(3)(iii)	493.555(c)(4)
493.515(a)(3)(iv)	493.557(b)(11)
493.515(a)(3)(v)	493.557(b)(12)
493.515(a)(3)(vi)	493.557(b)(13)
493.515(a)(3)(vii)	493.555(c)(3)(ii)
493.515(a)(3)(viii)	493.555(c)(5)
493.517(a)	493.563(a)(2)(i)–(ii)
493.517(a)(1)	493.563(b)(1)(2)
493.517(a)(2)	493.563(c)(1)–(2)
493.517(b)(1)	493.565(a)
493.517(b)(2)	493.565(b)
493.517(b)(3)	493.565(c)
493.517(c)	493.567(b)
493.517(d)	493.569(b)
493.517(e)	493.571(b) and (c)
493.517(f)	493.563(f)
493.519(a)	493.573(a)
493.519(b)	493.573(b)
493.519(c)(1)	493.573(c)(1)
493.519(c)(2)	493.573(c)(2)
493.519(d) introductory text	493.573(d)(1)(ii)
493.519(d)(1)–(4)	493.573(d)(2)(i)–(iv)
493.521(a)(1)	493.575(a)(2)
493.521(a)(2)	493.575(a)(3)
493.521(a)(3)	493.575(a)(4) & (4)(ii)
493.521(b)	493.575(b)(1)
493.521(c)	493.575(b)(2)
493.521(d)	493.575(c)
493.521(e)	493.575(d)
493.521(f)	493.575(e)
493.521(g)	493.575(i)
493.521(h)	493.575(h)
493.521(i)	493.575(f)
493.521(j)	493.575(g)(2)–(3)
493.521(k)	493.575(j)(1)–(2)
493.521(l)	493.575(k)
493.1775(a)	493.1773(a); 493.1775(a)
493.1775(b)(1)	493.1773(b)(2)
493.1775(b)(2)	493.1773(b)(4)
493.1775(b)(3)	493.1773(b)(3)
493.1775(b)(4)(1)–(ii)	493.1773(f); 493.1775(b)(1)–(4)
493.1775(b)(4)(iii)–(iv)	493.1775(a)
493.1775(b)(5)	493.1773(b)(5)
493.1775(c)	493.1773(d)

Existing section	New section
493.1775(d)	493.1773(g)
493.1776(a) introductory text	493.1773(a); 493.1775(a) & (b)
493.1776(a)(1)–(4)	493.1773(f); 493.1775(a)
493.1776(a)(4) (uncoded text)	deleted; redundant
493.1776(b)(1)	493.1773(b)(2)
493.1776(b)(2)	493.1773(b)(4)
493.1776(b)(3)	493.1773(b)(3)
493.1776(b)(4)	493.1773(f); 493.1775(b)(1)–(4)
493.1776(b)(5)	493.1773(b)(5)
493.1776(c)	493.1773(d)
493.1776(d)	493.1773(g)
493.1777 introductory text	493.1773(a), (f); 493.1777(a)–(c)
493.1777(a)	493.1777(a)–(b)
493.1777(b)	493.1773(b)
493.1777(c)	493.1773(c)
493.1777(d)	deleted; redundant
493.1777(e)	493.1773(d)
493.1777(f)	493.1773(e)
493.1777(g)	493.1773(g)
493.1780(a)	493.1773(a); 493.1780(a)
493.1780(b)	493.1773(a), (f); 493.1780(b)
493.1780(c)	493.1773(b)
493.1780(d)	493.1773(c)
493.1780(e)	deleted; redundant
493.1780(f)	493.1773(d)
493.1780(g)	493.1773(g); 493.1780(c)

V. Regulatory Impact Statement

A. General

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, all clinical laboratories are considered to be small entities. Individuals and States are not included in the definition of a small entity.

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. Such an 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.

B. Provisions of the Final Regulations

This rule has been drafted in response to comments pertaining to proficiency testing and the CLIA inspection process. As our responses to commenters' concerns were developed, it became apparent that we were also fulfilling the Administration's regulatory reform initiative. This initiative directs us to revise regulations that are outdated or otherwise in need of reform. We have, therefore, also included subpart E of part 493 in this rule.

Subpart E

Subpart E of part 493 provides for the accreditation of a laboratory by an accreditation organization, and the exemption of laboratories within a particular State from CLIA requirements when the accreditation organization or State applies requirements that are equal to, or more stringent than, the CLIA requirements taken as a whole. Subpart E contains requirements for State licensure programs, accreditation organizations, laboratories seeking deemed status by virtue of accreditation by a HCFA-approved accreditation organization, and laboratories that operate within a State that HCFA has determined maintains requirements that are equal to or more stringent than the CLIA requirements. We are revising subpart E by removing duplicative information. We are reorganizing subpart E to distinguish accreditation organization and State licensure program responsibilities from those of laboratories. We are combining common requirements for accreditation organizations and State licensure programs. These actions will accommodate the Administration's regulatory reform initiative. We are making no substantive changes to the content or the intent. Therefore, we are not imposing additional burden. The relief established by reorganizing and combining like requirements is not quantifiable, but it should aid in the submission of materials for approvals and reapprovals.

Subpart H

The changes we are making in § 493.803(c) reflect HCFA's policy of an educational focus for proficiency testing. We are clarifying existing enforcement options in response to comments received concerning PT sanctions. In this rule, subpart H provides that, if a laboratory is initially unsuccessful in PT, it must obtain technical assistance, or undertake training of personnel, or both, rather than having HCFA impose principal or alternative sanctions. This affords the laboratory an additional opportunity to correct the problem that caused the PT failure, encouraging quality testing in a more positive manner. We believe that a laboratory should have ample opportunity to investigate the reason for its initial failure, to obtain the necessary technical assistance or training, or both, to correct the problems that caused the failure and implement a plan of action, which should prevent reoccurrence. This requirement also exists in subpart R, Enforcement Procedures. Principal and alternative sanctions may apply if the laboratory refuses to correct its problems, has repeated compliance problems, or immediate jeopardy exists. While this educational approach has always been a viable option, based on comments received on previous rulemaking, we believe that it is important to clarify that this option exists and will be exercised. We are revising the regulation accordingly.

We are not imposing any additional burden with this clarification; we are

only identifying which of our enforcement actions or options we implement in a particular circumstance.

Subpart Q

We are eliminating redundant information by restructuring and organizing all generic requirements for an onsite inspection into one section of the regulations. In addition we have implemented the commenter-recommended laboratory self-inspection process (the Alternate Quality Assessment Survey). Although an onsite inspection may not be performed, the survey agency personnel must still review and evaluate the self-inspection responses submitted by the laboratory and take any necessary action. While travel and onsite time is eliminated for inspections of these laboratories, the laboratory surveyors, however, may realize little or no reduction in the time spent on the overall process. We expect laboratories that perform the Alternate Quality Assessment Survey to benefit from the educational aspects realized by performing this self evaluative survey and minimized disruption to their activities.

Our onsite survey process, which is outcome-oriented, concentrates on a review of each laboratory's specific testing activities and its impact on patient health and safety. We are unable to predict the long term effects because they are dependent upon each individual laboratory's compliance and testing activities. Although it is difficult to quantify the financial impact due to the variability from laboratory to laboratory, we expect that our collective efforts to streamline and clarify the regulations may reduce the laboratory costs associated with CLIA in many cases, without diminishing quality.

C. Conclusion

For these reasons, we have determined, and the Secretary certifies, that this regulation does not result in a significant impact on a substantial number of small entities and does not have a significant effect on the operations of a substantial number of small rural hospitals. Therefore, we are not preparing analyses for either the RFA or section 1102(b) of the Act.

D. OMB Review

In accordance with the provisions of Executive Order 12866, this regulation was reviewed by the Office of Management and Budget.

E. Collection of Information Requirements

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

Section 493.803 and subpart Q (newly revised §§ 493.1771 through 493.1780 previously numbered §§ 493.1775 through 493.1780) are currently approved under OMB approval number 0938–0612 with an expiration date of April 30, 2001. Subpart E (newly revised sections §§ 493.551, 493.553, 493.555, 493.557, 493.559, and 493.561, which were previously contained in §§ 493.501, 493.506, 493.513 and 493.515) is currently approved under OMB approval number 0938–0686 with an expiration of April 30, 1999.

Section 493.803 contains the requirement that a laboratory must successfully participate in a PT program approved by HCFA for the specialties, subspecialties, and analytes listed in the regulation, if these tests are performed by the laboratory. The burden associated with this requirement is the testing of PT specimens and recording the results.

Subpart Q sets forth conditions and standards for inspection of laboratories. The burden associated with inspections of laboratories, or alternative mechanisms to determine compliance, consists of retrieving records and documentation necessary for the inspector to ascertain compliance, participating in entrance and exit conferences for onsite inspections, responding to a statement of deficiencies that may result from an inspection, and documenting any corrective action.

Subpart E sets forth the requirements and process for a private, nonprofit accreditation organization voluntarily seeking approval under the CLIA program and a State licensure program voluntarily seeking exemption for its laboratories within the State from the CLIA program. The burden associated with these sections is the compilation of specific information that must be submitted for evaluation as well as the requirements for providing ongoing information.

Description of Respondents

Respondents for § 493.803 and subpart Q, §§ 493.1771 through 493.1780 fall in the categories of: small businesses or organizations, businesses or other for-profit, non-profit institutions, State and local governments, and Federal agencies.

Respondents for subpart E, §§ 493.551, 493.553, 493.555, 493.557, 493.559, and 493.561 are private nonprofit accreditation organizations and State licensure programs.

ESTIMATED ANNUAL REPORTING AND RECORDKEEPING BURDEN

CFR section	Annual number of respondents	Annual frequency	Average burden per response in hours	Annual burden in hours
Subpart E 493.551 through 493.561	11	varies, as needed	192	2112
Subpart H 493.803	63,600	3 events	1	190,800
Subpart Q 493.1771 through 493.1780	36,918	biennial	4	4,618

Persons interested in commenting on these currently approved information collections should send comments to the following address: Health Care Financing Administration, Office of Information Services, Information Technology Investment Management Group, Room C2–26–17, 7500 Security Boulevard, Baltimore, Maryland, 21244–1850. Attn: HCFA–2239–F.

List of Subjects in 42 CFR Part 493

Grant programs-health, Health facilities, Laboratories, Medicaid, Medicare, Reporting and recordkeeping requirements.

42 CFR chapter IV is amended as follows:

PART 493—LABORATORY REQUIREMENTS

1. The authority citation for part 493 is revised to read as follows:

Authority: Sec. 353 of the Public Health Service Act, secs. 1102, 1861(e), the sentence following sections 1861(s)(11) through 1861(s)(16) of the Social Security Act (42 U.S.C. 263a, 1302, 1395x(e), the sentence following 1395x(s)(11) through 1395x(s)(16)).

Subpart A—General Provisions

§ 493.2 [Amended]

2. Section 493.2 is amended by adding in alphabetical order the following definition of *State licensure program:*

* * * * *

State licensure program means a State laboratory licensure or approval program.

* * * * *

Subpart E—Accreditation by a Private, Nonprofit Accreditation Organization or Exemption Under an Approved State Laboratory Program

§§ 493.501 through 493.521 [Removed]

3. Sections 493.501 through 493.521 are removed.

4. In subpart E, new §§ 493.551, 493.553, 493.555, 493.557, 493.559, 493.561, 493.563, 493.565, 493.567, 493.569, 493.571, 493.573, and 493.575 are added to read as follows:

Sec.
493.551 General requirements for laboratories.
493.553 Approved process (application and reapplication) for accreditation organizations and State licensure programs.
493.555 Federal review of laboratory requirements.
493.557 Additional submission requirements.
493.559 Publication of approval of deeming authority or CLIA exemption.
493.561 Denial of application or reapplication.
493.563 Validation inspections—Basis and focus.
493.565 Selection for validation inspection—laboratory responsibilities.
493.567 Refusal to cooperate with validation inspection.
493.569 Consequences of a finding of noncompliance as a result of a validation inspection.
493.571 Disclosure of accreditation, State and HCFA validation inspection results.
493.573 Continuing Federal oversight of private nonprofit accreditation organizations and approved State licensure programs.
493.575 Removal of deeming authority or CLIA exemption and final determination review.

§ 493.551 General requirements for laboratories.

(a) *Applicability*. HCFA may deem a laboratory to meet all applicable CLIA program requirements through accreditation by a private nonprofit accreditation program (that is, grant deemed status), or may exempt from CLIA program requirements all State licensed or approved laboratories in a State that has a State licensure program established by law, if the following conditions are met:

(1) The requirements of the accreditation organization or State licensure program are equal to, or more stringent than, the CLIA condition-level requirements specified in this part, and the laboratory would meet the condition-level requirements if it were inspected against these requirements.

(2) The accreditation program or the State licensure program meets the requirements of this subpart and is approved by HCFA.

(3) The laboratory authorizes the approved accreditation organization or State licensure program to release to HCFA all records and information required and permits inspections as outlined in this part.

(b) *Meeting CLIA requirements by accreditation*. A laboratory seeking to meet CLIA requirements through accreditation by an approved accreditation organization must do the following:

(1) Obtain a certificate of accreditation as required in subpart D of this part.

(2) Pay the applicable fees as required in subpart F of this part.

(3) Meet the proficiency testing (PT) requirements in subpart H of this part.

(4) Authorize its PT organization to furnish to its accreditation organization the results of the laboratory's participation in an approved PT program for the purpose of monitoring the laboratory's PT and for making the annual PT results, along with explanatory information required to interpret the PT results, available on a reasonable basis, upon request of any person. A laboratory that refuses to authorize release of its PT results is no longer deemed to meet the condition-level requirements and is subject to a full review by HCFA, in accordance with subpart Q of this part, and may be subject to the suspension or revocation of its certificate of accreditation under § 493.1840.

(5) Authorize its accreditation organization to release to HCFA or a HCFA agent the laboratory's PT results that constitute unsuccessful participation in an approved PT program, in accordance with the definition of ''unsuccessful participation in an approved PT program,'' as specified in § 493.2 of this part, when the laboratory has failed to achieve successful participation in an approved PT program.

(6) Authorize its accreditation organization to release to HCFA a notification of the actions taken by the organization as a result of the unsuccessful participation in a PT program within 30 days of the initiation of the action. Based on this notification, HCFA may take an adverse action against a laboratory that fails to participate successfully in an approved PT program.

(c) *Withdrawal of laboratory accreditation*. After an accreditation organization has withdrawn or revoked its accreditation of a laboratory, the laboratory retains its certificate of accreditation for 45 days after the laboratory receives notice of the withdrawal or revocation of the accreditation, or the effective date of any action taken by HCFA, whichever is earlier.

§ 493.553 Approval process (application and reapplication) for accreditation organizations and State licensure programs.

(a) *Information required*. An accreditation organization that applies or reapplies to HCFA for deeming authority, or a State licensure program that applies or reapplies to HCFA for exemption from CLIA program requirements of licensed or approved laboratories within the State, must provide the following information:

(1) A detailed comparison of the individual accreditation, or licensure or approval requirements with the comparable condition-level requirements; that is, a crosswalk.

(2) A detailed description of the inspection process, including the following:

(i) Frequency of inspections.

(ii) Copies of inspection forms.

(iii) Instructions and guidelines.

(iv) A description of the review and decision-making process of inspections.

(v) A statement concerning whether inspections are announced or unannounced.

(vi) A description of the steps taken to monitor the correction of deficiencies.

(3) A description of the process for monitoring PT performance, including action to be taken in response to unsuccessful participation in a HCFA-approved PT program.

(4) Procedures for responding to and for the investigation of complaints against its laboratories.

(5) A list of all its current laboratories and the expiration date of their accreditation or licensure, as applicable.

(6) Procedures for making PT information available (under State confidentiality and disclosure requirements, if applicable) including explanatory information required to interpret PT results, on a reasonable basis, upon request of any person.

(b) *HCFA action on an application or reapplication*. If HCFA receives an application or reapplication from an accreditation organization, or State licensure program, HCFA takes the following actions:

(1) HCFA determines if additional information is necessary to make a determination for approval or denial of the application and notifies the accreditation organization or State to afford it an opportunity to provide the additional information.

(2) HCFA may visit the accreditation organization or State licensure program offices to review and verify the policies and procedures represented in its application and other information, including, but not limited to, review and examination of documents and interviews with staff.

(3) HCFA notifies the accreditation organization or State licensure program indicating whether HCFA approves or denies the request for deeming authority or exemption, respectively, and the rationale for any denial.

(c) *Duration of approval*. HCFA approval may not exceed 6 years.

(d) *Withdrawal of application*. The accreditation organization or State licensure program may withdraw its application at any time before official notification, specified at § 493.553(b)(3).

§ 493.555 Federal review of laboratory requirements.

HCFA's review of an accreditation organization or State licensure program includes, but is not limited to, an evaluation of the following:

(a) Whether the organization's or State's requirements for laboratories are equal to, or more stringent than, the condition-level requirements for laboratories.

(b) The organization's or State's inspection process to determine the comparability of the full inspection and complaint inspection procedures and requirements to those of HCFA, including, but not limited to, inspection frequency and the ability to investigate and respond to complaints against its laboratories.

(c) The organization's or State's agreement with HCFA that requires it to do the following:

(1) Notify HCFA within 30 days of the action taken, of any laboratory that has—

(i) Had its accreditation or licensure suspended, withdrawn, revoked, or limited;

(ii) In any way been sanctioned; or

(iii) Had any adverse action taken against it.

(2) Notify HCFA within 10 days of any deficiency identified in an accredited or CLIA-exempt laboratory if the deficiency poses an immediate jeopardy to the laboratory's patients or a hazard to the general public.

(3) Notify HCFA, within 30 days, of all newly—

(i) Accredited laboratories (or laboratories whose areas of specialty/subspecialty testing have changed); or

(ii) Licensed laboratories, including the specialty/subspecialty areas of testing.

(4) Notify each accredited or licensed laboratory within 10 days of HCFA's withdrawal of the organization's deeming authority or State's exemption.

(5) Provide HCFA with inspection schedules, as requested, for validation purposes.

§ 493.557 Additional submission requirements.

(a) *Specific requirements for accreditation organizations*. In addition to the information specified in §§ 493.553 and 493.555, as part of the approval and review process, an accreditation organization applying or reapplying for deeming authority must also provide the following:

(1) The specialty or subspecialty areas for which the organization is requesting deeming authority and its mechanism for monitoring compliance with all requirements equivalent to condition-level requirements within the scope of the specialty or subspecialty areas.

(2) A description of the organization's data management and analysis system with respect to its inspection and accreditation decisions, including the kinds of routine reports and tables generated by the systems.

(3) Detailed information concerning the inspection process, including, but not limited to the following:

(i) The size and composition of individual accreditation inspection teams.

(ii) Qualifications, education, and experience requirements that inspectors must meet.

(iii) The content and frequency of training provided to inspection personnel, including the ability of the organization to provide continuing education and training to inspectors.

(4) Procedures for removal or withdrawal of accreditation status for laboratories that fail to meet the organization's standards.

(5) A proposed agreement between HCFA and the accreditation organization with respect to the notification requirements specified in § 493.555(c).

(6) Procedures for monitoring laboratories found to be out of compliance with its requirements. (These monitoring procedures must be used only when the accreditation organization identifies noncompliance. If noncompliance is identified through validation inspections, HCFA or a HCFA agent monitors corrections, as authorized at § 493.565(d)).

(7) A demonstration of its ability to provide HCFA with electronic data and reports in compatible code, including the crosswalk specified in § 493.553(a)(1), that are necessary for effective validation and assessment of the organization's inspection process.

(8) A demonstration of its ability to provide HCFA with electronic data, in compatible code, related to the adverse actions resulting from PT results constituting unsuccessful participation in PT programs as well as data related to the PT failures, within 30 days of the initiation of adverse action.

(9) A demonstration of its ability to provide HCFA with electronic data, in compatible code, for all accredited laboratories, including the area of specialty or subspecialty.

(10) Information defining the adequacy of numbers of staff and other resources.

(11) Information defining the organization's ability to provide adequate funding for performing required inspections.

(12) Any facility-specific data, upon request by HCFA, which includes, but is not limited to, the following:

(i) PT results that constitute unsuccessful participation in a HCFA-approved PT program.

(ii) Notification of the adverse actions or corrective actions imposed by the accreditation organization as a result of unsuccessful PT participation.

(13) An agreement to provide written notification to HCFA at least 30 days in advance of the effective date of any proposed change in its requirements.

(14) An agreement to disclose any laboratory's PT results upon reasonable request by any person.

(b) *Specific requirements for a State licensure program*. In addition to requirements in §§ 493.553 and 493.555, as part of the approval and review process, when a State licensure program applies or reapplies for exemption from the CLIA program, the State must do the following:

(1) Demonstrate to HCFA that it has enforcement authority and administrative structures and resources adequate to enforce its laboratory requirements.

(2) Permit HCFA or a HCFA agent to inspect laboratories in the State.

(3) Require laboratories in the State to submit to inspections by HCFA or a HCFA agent as a condition of licensure or approval.

(4) Agree to pay the cost of the validation program administered in that State as specified in §§ 493.645(a) and 493.646(b).

(5) Take appropriate enforcement action against laboratories found by HCFA not to be in compliance with requirements equivalent to CLIA requirements.

(6) Submit for Medicare and Medicaid payment purposes, a list of the specialties and subspecialties of tests performed by each laboratory.

(7) Submit a written presentation that demonstrates the agency's ability to furnish HCFA with electronic data in compatible code, including the crosswalk specified in § 493.553(a)(1).

(8) Submit a statement acknowledging that the State will notify HCFA through electronic transmission of the following:

(i) Any laboratory that has had its licensure or approval revoked or withdrawn or has been in any way sanctioned by the State within 30 days of taking the action.

(ii) Changes in licensure or inspection requirements.

(iii) Changes in specialties or subspecialties under which any licensed laboratory in the State performs testing.

(9) Provide information for the review of the State's enforcement procedures for laboratories found to be out of compliance with the State's requirements.

(10) Submit information that demonstrates the ability of the State to provide HCFA with the following:

(i) Electronic data and reports in compatible code with the adverse or corrective actions resulting from PT results that constitute unsuccessful participation in PT programs.

(ii) Other data that HCFA determines are necessary for validation and assessment of the State's inspection process requirements.

(11) Agree to provide HCFA with written notification of any changes in its licensure/approval and inspection requirements.

(12) Agree to disclose any laboratory's PT results in accordance with a State's confidentiality requirements.

(13) Agree to take the appropriate enforcement action against laboratories found by HCFA not to be in compliance with requirements comparable to condition-level requirements and report these enforcement actions to HCFA.

(14) If approved, reapply to HCFA every 2 years to renew its exempt status and to renew its agreement to pay the cost of the HCFA-administered validation program in that State.

§ 493.559 Publication of approval of deeming authority or CLIA exemption.

(a) *Notice of deeming authority or exemption.* HCFA publishes a notice in the **Federal Register** when it grants deeming authority to an accreditation organization or exemption to a State licensure program.

(b) *Contents of notice.* The notice includes the following:

(1) The name of the accreditation organization or State licensure program.

(2) For an accreditation organization:

(i) The specific specialty or subspecialty areas for which it is granted deeming authority.

(ii) A description of how the accreditation organization provides reasonable assurance to HCFA that a laboratory accredited by the organization meets CLIA requirements equivalent to those in this part and would meet CLIA requirements if the laboratory had not been granted deemed status, but had been inspected against condition-level requirements.

(3) For a State licensure program, a description of how the laboratory requirements of the State are equal to, or more stringent than, those specified in this part.

(4) The basis for granting deeming authority or exemption.

(5) The term of approval, not to exceed 6 years.

§ 493.561 Denial of application or reapplication.

(a) *Reconsideration of denial.* (1) If HCFA denies a request for approval, an accreditation organization or State licensure program may request, within 60 days of the notification of denial, that HCFA reconsider its original application or application for renewal, in accordance with part 488, subpart D.

(2) If the accreditation organization or State licensure program requests a reconsideration of HCFA's determination to deny its request for approval or reapproval, it may not submit a new application until HCFA issues a final reconsideration determination.

(b) *Resubmittal of a request for approval— accreditation organization.* An accreditation organization may resubmit a request for approval if a final reconsideration determination is not pending and the accreditation program meets the following conditions:

(1) It has revised its accreditation program to address the rationale for denial of its previous request.

(2) It demonstrates that it can provide reasonable assurance that its accredited facilities meet condition-level requirements.

(3) It resubmits the application in its entirety.

(c) *Resubmittal of request for approval—State licensure program.* The State licensure program may resubmit a request for approval if a final reconsideration determination is not pending and it has taken the necessary action to address the rationale for any previous denial.

§ 493.563 Validation inspections—Basis and focus.

(a) *Basis for validation inspection*—(1) *Laboratory with a certificate of accreditation.* (i) HCFA or a HCFA agent may conduct an inspection of an accredited laboratory that has been issued a certificate of accreditation on a representative sample basis or in response to a substantial allegation of noncompliance.

(ii) HCFA uses the results of these inspections to validate the accreditation organization's accreditation process.

(2) *Laboratory in a State with an approved State licensure program.* (i) HCFA or a HCFA agent may conduct an inspection of any laboratory in a State with an approved State licensure program on a representative sample basis or in response to a substantial allegation of noncompliance.

(ii) The results of these inspections are used to validate the appropriateness of the exemption of that State's licensed or approved laboratories from CLIA program requirements.

(b) *Validation inspection conducted on a representative sample basis.* (1) If HCFA or a HCFA agent conducts a validation inspection on a representative sample basis, the inspection is comprehensive, addressing all condition-level requirements, or it may be focused on a specific condition-level requirement.

(2) The number of laboratories sampled is sufficient to allow a reasonable estimate of the performance of the accreditation organization or State.

(c) *Validation inspection conducted in response to a substantial allegation of noncompliance.* (1) If HCFA or a HCFA agent conducts a validation inspection in response to a substantial allegation of noncompliance, the inspection focuses on any condition-level requirement that HCFA determines to be related to the allegation.

(2) If HCFA or a HCFA agent substantiates a deficiency and determines that the laboratory is out of compliance with any condition-level requirement, HCFA or a HCFA agent conducts a full CLIA inspection.

(d) *Inspection of operations and offices.* As part of the validation review process, HCFA may conduct an onsite inspection of the operations and offices to verify the following:

(1) The accreditation organization's representations and to assess the accreditation organization's compliance with its own policies and procedures.

(2) The State's representations and to assess the State's compliance with its own policies and procedures, including verification of State enforcement actions taken on the basis of validation inspections performed by HCFA or a HCFA agent.

(e) *Onsite inspection of an accreditation organization.* An onsite inspection of an accreditation organization may include, but is not limited to, the following:

(1) A review of documents.

(2) An audit of meetings concerning the accreditation process.

(3) Evaluation of accreditation inspection results and the accreditation decision-making process.

(4) Interviews with the accreditation organization's staff.

(f) *Onsite inspection of a State licensure program.* An onsite inspection of a State licensure program office may include, but is not limited to, the following:

(1) A review of documents.

(2) An audit of meetings concerning the licensure or approval process.

(3) Evaluation of State inspection results and the licensure or approval decision-making process.

(4) Interviews with State employees.

§ 493.565 Selection for validation inspection—laboratory responsibilities.

A laboratory selected for a validation inspection must do the following:

(a) Authorize its accreditation organization or State licensure program, as applicable, to release to HCFA or a HCFA agent, on a confidential basis, a copy of the laboratory's most recent full, and any subsequent partial inspection.

(b) Authorize HCFA or a HCFA agent to conduct a validation inspection.

(c) Provide HCFA or a HCFA agent with access to all facilities, equipment, materials, records, and information that HCFA or a HCFA agent determines have a bearing on whether the laboratory is being operated in accordance with the requirements of this part, and permit HCFA or a HCFA agent to copy material or require the laboratory to submit material.

(d) If the laboratory possesses a valid certificate of accreditation, authorize HCFA or a HCFA agent to monitor the correction of any deficiencies found through the validation inspection.

§ 493.567 Refusal to cooperate with validation inspection.

(a) *Laboratory with a certificate of accreditation.* (1) A laboratory with a certificate of accreditation that refuses to cooperate with a validation inspection by failing to comply with the requirements in § 493.565—

(i) Is subject to full review by HCFA or a HCFA agent, in accordance with this part; and

(ii) May be subject to suspension, revocation, or limitation of its certificate of accreditation under this part.

(2) A laboratory with a certificate of accreditation is again deemed to meet the condition-level requirements by virtue of its accreditation when the following conditions exist:

(i) The laboratory withdraws any prior refusal to authorize its accreditation organization to release a copy of the laboratory's current accreditation inspection, PT results, or notification of any adverse actions resulting from PT failure.

(ii) The laboratory withdraws any prior refusal to allow a validation inspection.

(iii) HCFA finds that the laboratory meets all the condition-level requirements.

(b) *CLIA-exempt laboratory.* If a CLIA-exempt laboratory fails to comply with the requirements specified in § 493.565, HCFA notifies the State of the laboratory's failure to meet the requirements.

§ 493.569 Consequences of a finding of noncompliance as a result of a validation inspection.

(a) *Laboratory with a certificate of accreditation.* If a validation inspection results in a finding that the accredited laboratory is out of compliance with one or more condition-level requirements, the laboratory is subject to—

(1) The same requirements and survey and enforcement processes applied to laboratories that are not accredited and that are found out of compliance following an inspection under this part; and

(2) Full review by HCFA, in accordance with this part; that is, the laboratory is subject to the principal and alternative sanctions in § 493.1806.

(b) *CLIA-exempt laboratory.* If a validation inspection results in a finding that a CLIA-exempt laboratory is out of compliance with one or more condition-level requirements, HCFA directs the State to take appropriate enforcement action.

§ 493.571 Disclosure of accreditation, State and HCFA validation inspection results.

(a) *Accreditation organization inspection results.* HCFA may disclose accreditation organization inspection results to the public only if the results are related to an enforcement action taken by the Secretary.

(b) *State inspection results.* Disclosure of State inspection results is the responsibility of the approved State licensure program, in accordance with State law.

(c) *HCFA validation inspection results.* HCFA may disclose the results of all validation inspections conducted by HCFA or its agent.

§ 493.573 Continuing Federal oversight of private nonprofit accreditation organizations and approved State licensure programs.

(a) *Comparability review.* In addition to the initial review for determining equivalency of specified organization or State requirements to the comparable condition-level requirements, HCFA reviews the equivalency of requirements in the following cases:

(1) When HCFA promulgates new condition-level requirements.

(2) When HCFA identifies an accreditation organization or a State licensure program whose requirements are no longer equal to, or more stringent than, condition-level requirements.

(3) When an accreditation organization or State licensure program adopts new requirements.

(4) When an accreditation organization or State licensure program adopts changes to its inspection process, as required by § 493.575(b)(1), as applicable.

(5) Every 6 years, or sooner if HCFA determines an earlier review is required.

(b) *Validation review.* Following the end of a validation review period, HCFA evaluates the validation inspection results for each approved accreditation organization and State licensure program.

(c) *Reapplication procedures.* (1) Every 6 years, or sooner, as determined by HCFA, an approved accreditation organization must reapply for continued approval of deeming authority and a State licensure program must reapply for continued approval of a CLIA exemption. HCFA provides notice of the materials that must be submitted as part of the reapplication procedure.

(2) An accreditation organization or State licensure program that does not meet the requirements of this subpart, as determined through a comparability or

validation review, must furnish HCFA, upon request, with the reapplication materials HCFA requests. HCFA establishes a deadline by which the materials must be submitted.

(d) *Notice.* (1) HCFA provides written notice, as appropriate, to the following:

(i) An accreditation organization indicating that its approval may be in jeopardy if a comparability or validation review reveals that it is not meeting the requirements of this subpart and HCFA is initiating a review of the accreditation organization's deeming authority.

(ii) A State licensure program indicating that its CLIA exemption may be in jeopardy if a comparability or validation review reveals that it is not meeting the requirements of this subpart and that a review is being initiated of the CLIA exemption of the State's laboratories.

(2) The notice contains the following information:

(i) A statement of the discrepancies that were found as well as other related documentation.

(ii) An explanation of HCFA's review process on which the final determination is based and a description of the possible actions, as specified in § 493.575, that HCFA may impose based on the findings from the comparability or validation review.

(iii) A description of the procedures available if the accreditation organization or State licensure program, as applicable, desires an opportunity to explain or justify the findings made during the comparability or validation review.

(iv) The reapplication materials that the accreditation organization or State licensure program must submit and the deadline for that submission.

§ 493.575 Removal of deeming authority or CLIA exemption and final determination review.

(a) *HCFA review.* HCFA conducts a review of the following:

(1) A deeming authority review of an accreditation organization's program if the comparability or validation review produces findings, as described at § 493.573. HCFA reviews, as appropriate, the criteria described in §§ 493.555 and 493.557(a) to reevaluate whether the accreditation organization continues to meet all these criteria.

(2) An exemption review of a State's licensure program if the comparability or validation review produces findings, as described at § 493.573. HCFA reviews, as appropriate, the criteria described in §§ 493.555 and 493.557(b) to reevaluate whether the licensure program continues to meet all these criteria.

(3) A review of an accreditation organization or State licensure program, at HCFA's discretion, if validation review findings, irrespective of the rate of disparity, indicate widespread or systematic problems in the organization's accreditation or State's licensure process that provide evidence that the requirements, taken as a whole, are no longer equivalent to CLIA requirements, taken as a whole.

(4) A review of the accreditation organization or State licensure program whenever validation inspection results indicate a rate of disparity of 20 percent or more between the findings of the organization or State and those of HCFA or a HCFA agent for the following periods:

(i) One year for accreditation organizations.

(ii) Two years for State licensure programs.

(b) *HCFA action after review.* Following the review, HCFA may take the following action:

(1) If HCFA determines that the accreditation organization or State has failed to adopt requirements equal to, or more stringent than, CLIA requirements, HCFA may give a conditional approval for a probationary period of its deeming authority to an organization 30 days following the date of HCFA's determination, or exempt status to a State within 30 days of HCFA's determination, both not to exceed 1 year, to afford the organization or State an opportunity to adopt equal or more stringent requirements.

(2) If HCFA determines that there are widespread or systematic problems in the organization's or State's inspection process, HCFA may give conditional approval during a probationary period, not to exceed 1 year, effective 30 days following the date of the determination.

(c) *Final determination.* HCFA makes a final determination as to whether the organization or State continues to meet the criteria described in this subpart and issues a notice that includes the reasons for the determination to the organization or State within 60 days after the end of any probationary period. This determination is based on an evaluation of any of the following:

(1) The most recent validation inspection and review findings. To continue to be approved, the organization or State must meet the criteria of this subpart.

(2) Facility-specific data, as well as other related information.

(3) The organization's or State's inspection procedures, surveyors' qualifications, ongoing education, training, and composition of inspection teams.

(4) The organization's accreditation requirements, or the State's licensure or approval requirements.

(d) *Date of withdrawal of approval.* HCFA may withdraw its approval of the accreditation organization or State licensure program, effective 30 days from the date of written notice to the organization or State of this proposed action, if improvements acceptable to HCFA have not been made during the probationary period.

(e) *Continuation of validation inspections.* The existence of any validation review, probationary status, or any other action, such as a deeming authority review, by HCFA does not affect or limit the conduct of any validation inspection.

(f) *Federal Register notice.* HCFA publishes a notice in the **Federal Register** containing a justification for removing the deeming authority from an accreditation organization, or the CLIA-exempt status of a State licensure program.

(g) *Withdrawal of approval-effect on laboratory status*—(1) *Accredited laboratory.* After HCFA withdraws approval of an accreditation organization's deeming authority, the certificate of accreditation of each affected laboratory continues in effect for 60 days after it receives notification of the withdrawal of approval.

(2) *CLIA-exempt laboratory.* After HCFA withdraws approval of a State licensure program, the exempt status of each licensed or approved laboratory in the State continues in effect for 60 days after a laboratory receives notification from the State of the withdrawal of HCFA's approval of the program.

(3) *Extension.* After HCFA withdraws approval of an accreditation organization or State licensure program, HCFA may extend the period for an additional 60 days for a laboratory if it determines that the laboratory submitted an application for accreditation to an approved accreditation organization or an application for the appropriate certificate to HCFA or a HCFA agent before the initial 60-day period ends.

(h) *Immediate jeopardy to patients.* (1) If at any time HCFA determines that the continued approval of deeming authority of any accreditation organization poses immediate jeopardy to the patients of the laboratories accredited by the organization, or continued approval otherwise constitutes a significant hazard to the public health, HCFA may immediately withdraw the approval of deeming authority for that accreditation organization.

(2) If at any time HCFA determines that the continued approval of a State licensure program poses immediate jeopardy to the patients of the laboratories in that State, or continued approval otherwise constitutes a significant hazard to the public health, HCFA may immediately withdraw the approval of that State licensure program.

(i) *Failure to pay fees.* HCFA withdraws the approval of a State licensure program if the State fails to pay the applicable fees, as specified in §§ 493.645(a) and 493.646(b).

(j) *State refusal to take enforcement action.* (1) HCFA may withdraw approval of a State licensure program if the State refuses to take enforcement action against a laboratory in that State when HCFA determines it to be necessary.

(2) A laboratory that is in a State in which HCFA has withdrawn program approval is subject to the same requirements and survey and enforcement processes that are applied to a laboratory that is not exempt from CLIA requirements.

(k) *Request for reconsideration.* Any accreditation organization or State that is dissatisfied with a determination to withdraw approval of its deeming authority or remove approval of its State licensure program, as applicable, may request that HCFA reconsider the determination, in accordance with subpart D of part 488.

Subpart H—Participation in Proficiency Testing for Laboratories Performing Tests of Moderate Complexity (Including the Subcategory), High Complexity, or Any Combination of These Tests

5. In § 493.803, paragraph (b) is revised and a new paragraph (c) is added to read as follows:

§ 493.803 Condition: Successful participation.

* * * * *

(b) Except as specified in paragraph (c) of this section, if a laboratory fails to participate successfully in proficiency testing for a given specialty, subspecialty, analyte or test, as defined in this section, or fails to take remedial action when an individual fails gynecologic cytology, HCFA imposes sanctions, as specified in subpart R of this part.

(c) If a laboratory fails to perform successfully in a HCFA-approved proficiency testing program, for the initial unsuccessful performance, HCFA may direct the laboratory to undertake training of its personnel or to obtain technical assistance, or both, rather than imposing alternative or principle sanctions except when one or more of the following conditions exists:

(1) There is immediate jeopardy to patient health and safety.

(2) The laboratory fails to provide HCFA or a HCFA agent with satisfactory evidence that it has taken steps to correct the problem identified by the unsuccessful proficiency testing performance.

(3) The laboratory has a poor compliance history.

Subpart Q—Inspection

6. In subpart Q, new §§ 493.1771 and 493.1773 are added to read as follows:

§ 493.1771 Condition: Inspection requirements applicable to all CLIA-certified and CLIA-exempt laboratories.

(a) Each laboratory issued a CLIA certificate must meet the requirements in § 493.1773 and the specific requirements for its certificate type, as specified in §§ 493.1775 through 493.1780.

(b) All CLIA-exempt laboratories must comply with the inspection requirements in §§ 493.1773 and 493.1780, when applicable.

§ 493.1773 Standard: Basic inspection requirements for all laboratories issued a CLIA certificate and CLIA-exempt laboratories.

(a) A laboratory issued a certificate must permit HCFA or a HCFA agent to conduct an inspection to assess the laboratory's compliance with the requirements of this part. A CLIA-exempt laboratory and a laboratory that requests, or is issued a certificate of accreditation, must permit HCFA or a HCFA agent to conduct validation and complaint inspections.

(b) General requirements: As part of the inspection process, HCFA or a HCFA agent may require the laboratory to do the following:

(1) Test samples, including proficiency testing samples, or perform procedures.

(2) Permit interviews of all personnel concerning the laboratory's compliance with the applicable requirements of this part.

(3) Permit laboratory personnel to be observed performing all phases of the total testing process (preanalytic, analytic, and postanalytic).

(4) Permit HCFA or a HCFA agent access to all areas encompassed under the certificate including, but not limited to, the following:

(i) Specimen procurement and processing areas.

(ii) Storage facilities for specimens, reagents, supplies, records, and reports.

(iii) Testing and reporting areas.

(5) Provide HCFA or a HCFA agent with copies or exact duplicates of all records and data it requires.

(c) Accessible records and data: A laboratory must have all records and data accessible and retrievable within a reasonable time frame during the course of the inspection.

(d) Requirement to provide information and data: A laboratory must provide, upon request, all information and data needed by HCFA or a HCFA agent to make a determination of the laboratory's compliance with the applicable requirements of this part.

(e) Reinspection: HCFA or a HCFA agent may reinspect a laboratory at any time to evaluate the ability of the laboratory to provide accurate and reliable test results.

(f) Complaint inspection: HCFA or a HCFA agent may conduct an inspection when there are complaints alleging noncompliance with any of the requirements of this part.

(g) Failure to permit an inspection or reinspection: Failure to permit HCFA or a HCFA agent to conduct an inspection or reinspection results in the suspension or cancellation of the laboratory's participation in Medicare and Medicaid for payment, and suspension or limitation of, or action to revoke the laboratory's CLIA certificate, in accordance with subpart R of this part.

7. Section 493.1775 is revised to read as follows:

§ 493.1775 Standard: Inspection of laboratories issued a certificate of waiver or a certificate for provider-performed microscopy procedures.

(a) A laboratory that has been issued a certificate of waiver or a certificate for provider-performed microscopy procedures is not subject to biennial inspections.

(b) If necessary, HCFA or a HCFA agent may conduct an inspection of a laboratory issued a certificate of waiver or a certificate for provider-performed microscopy procedures at any time during the laboratory's hours of operation to do the following:

(1) Determine if the laboratory is operated and testing is performed in a manner that does not constitute an imminent and serious risk to public health.

(2) Evaluate a complaint from the public.

(3) Determine whether the laboratory is performing tests beyond the scope of the certificate held by the laboratory.

(4) Collect information regarding the appropriateness of tests specified as waived tests or provider-performed microscopy procedures.

(c) The laboratory must comply with the basic inspection requirements of § 493.1773.

§ 493.1776 [Removed]

8. Section 493.1776 is removed.

9. Section 493.1777 is revised to read as follows:

§ 493.1777 Standard: Inspection of laboratories that have requested or have been issued a certificate of compliance.

(a) *Initial inspection.* (1) A laboratory issued a registration certificate must permit an initial inspection to assess the laboratory's compliance with the requirements of this part before HCFA issues a certificate of compliance.

(2) The inspection may occur at any time during the laboratory's hours of operation.

(b) *Subsequent inspections.* (1) HCFA or a HCFA agent may conduct subsequent inspections on a biennial basis or with such other frequency as HCFA determines to be necessary to ensure compliance with the requirements of this part.

(2) HCFA bases the nature of subsequent inspections on the laboratory's compliance history.

(c) *Provider-performed microscopy procedures.* The inspection sample for review may include testing in the subcategory of provider-performed microscopy procedures.

(d) *Compliance with basic inspection requirements.* The laboratory must comply with the basic inspection requirements of § 493.1773.

10. Section 493.1780 is revised to read as follows:

§ 493.1780 Standard: Inspection of CLIA-exempt laboratories or laboratories requesting or issued a certificate of accreditation.

(a) *Validation inspection.* HCFA or a HCFA agent may conduct a validation inspection of any accredited or CLIA-exempt laboratory at any time during its hours of operation.

(b) *Complaint inspection.* HCFA or a HCFA agent may conduct a complaint inspection of a CLIA-exempt laboratory or a laboratory requesting or issued a certificate of accreditation at any time during its hours of operation upon receiving a complaint applicable to the requirements of this part.

(c) *Noncompliance determination.* If a validation or complaint inspection results in a finding that the laboratory is not in compliance with one or more condition-level requirements, the following actions occur:

(1) A laboratory issued a certificate of accreditation is subject to a full review by HCFA, in accordance with subpart E of this part and § 488.11 of this chapter.

(2) A CLIA-exempt laboratory is subject to appropriate enforcement actions under the approved State licensure program.

(d) *Compliance with basic inspection requirements.* CLIA-exempt laboratories and laboratories requesting or issued a certificate of accreditation must comply with the basic inspection requirements in § 493.1773.

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

Dated: October 13, 1997.

Nancy-Ann Min DeParle,

Deputy Administrator, Health Care Financing Administration.

Dated: September 18, 1997.

David Satcher,

Director, Centers for Disease Control and Prevention.

Approved: February 2, 1998.

Donna E. Shalala,

Secretary.

[FR Doc. 98–12752 Filed 5–13–98; 8:45 am]

BILLING CODE 4120–01–P

DEPARTMENT OF JUSTICE

48 CFR Part 2802 and 2846

[Justice Acquisition Circular 98–1]

Amendment to the Justice Acquisition Regulations (JAR Regarding: Definitions

AGENCY: Justice Management Division, Justice.

ACTION: Final rule, correction.

SUMMARY: This document contains corrections to the final regulations (Justice Acquisition Regulations) that were published Thursday, April 2, 1998 (63 FR 16118–16136). The regulations related to the reissuance of the JAR to implement regulatory changes resulting from the Federal Acquisition Reform Act, the Federal Acquisition Streamlining Act and the recommendations of the National Performance Review.

EFFECTIVE DATE: May 14, 1998.

FOR FURTHER INFORMATION CONTACT: Janis Sposato, Procurement Executive, Justice Management Division (202) 514–3103.

SUPPLEMENTARY INFORMATION:

A. Background

The final regulations that are the subject of these corrections superseded the 1985 version of the JAR and all amendments (Justice Acquisition Circulars 85–1 through 97–1) issued prior to the date of publication of that final rule.

B. Regulatory Flexibility Act

The Department of Justice certifies that this final rule will not have a significant economic impact on a substantial number of small entities within the meaning of the Regulatory Flexibility Act, 5 U.S.C. 601 *et seq.*, because the amendment sets forth only corrections to internal departmental procedures.

C. Paperwork Reduction Act

The final rule imposes no new information collection requirements that require approval by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1980 (Pub. L. 96–511). All information collection requirements have been submitted to OMB. In those cases where an OMB control number has been assigned, the control number is included in the regulation.

List of Subjects in 48 CFR Parts 2802 and 2846

Government procurement.

Stephen R. Colgate,

Assistant Attorney General for Administration.

Accordingly, 48 CFR parts 2802 and 2846 are corrected by making the following correcting amendments.

1. The authority citation for 48 CFR Parts 2802 and 2846 continues to read as follows:

Authority: 28 U.S.C. 510; 40 U.S.C. 486(c); 28 CFR 0.75(j) and 28 CFR 0.76(j).

PART 2802—DEFINITIONS OF WORDS AND TERMS—[CORRECTED]

2. On page 16121, in the middle of the first column, the citation set forth as Subpart 2.1—Definitions in the table of contents of part 2802 and in the accompanying text which immediately follows, is corrected to read as follows:

Subpart 2802.1—Definitions

PART 2802—QUALITY ASSURANCE—[CORRECTED]

3. On page 16134, in the lower third of the third column, under Part 2846, a paragraph number and title (2846.610, General) are added as set forth below, to the table of contents and the text that appears directly under Subpart 2846.6—Material Inspection and Receiving reports.

PART 2846—QUALITY ASSURANCE

Subpart 2846.6—Material Inspection and Receiving Reports

2846.601 General.

Subpart 2846.7—Warranties

2846.704 Authority for use of warranties.

Subpart 2846.6—Material Inspection and Receiving reports

§ 2846.601 General.

Bureaus shall prescribe procedures and instructions for the use, preparation, and distribution of material inspection and receiving reports and commercial shipping document/packing lists to evidence Government inspection.

[FR Doc. 98–12791 Filed 5–13–98; 8:45 am]

BILLING CODE 4410–AR–M

DEPARTMENT OF THE INTERIOR

Fish and Wildlife Service

50 CFR Part 23

RIN 1018–AE94

Amendment to Appendix III Listing of Bigleaf Mahogany Under the Convention on International Trade in Endangered Species of Wild Fauna and Flora

AGENCY: Fish and Wildlife Service, Interior.

ACTION: Final rule.

SUMMARY: This rule announces an amendment to the Appendix III listing of bigleaf mahogany (*Swietenia macrophylla*) under the Convention on International Trade in Endangered Species of Wild Fauna and Flora (CITES or Convention). The species in the Americas and its logs, sawn wood, and veneer sheets have been included in Appendix III since November 1995, based on an action by the Government of Costa Rica. The Government of Bolivia has recently supplied information to the CITES Secretariat to independently include its population in Appendix III to support its national legislation for the species and the need for cooperation of other CITES countries in controlling the international trade. The Service will consider any comments received on whether to enter a reservation on the Republic of Bolivia's action for its population.

DATES: The change to the Appendix III listing for the Bolivian population of the species as set forth in this rule entered into force on March 19, 1998, under the terms of the Convention. This rule is effective on May 14, 1998.

ADDRESSES: Please send correspondence concerning the amendment announced in this rule to Chief, Office of Scientific Authority, ARLSQ 750; U.S. Fish and Wildlife Service; Washington, DC 20240; fax number 703–358–2276. Express and messenger deliveries should be addressed to Chief, Office of Scientific Authority, Room 750; U.S. Fish and Wildlife Service; 4401 North Fairfax Drive; Arlington, Virginia 22203.

The text of the Appendix III notification from the Convention's Secretariat is available on request, and related materials are available for public inspection by appointment from 8:00 a.m. to 4:00 p.m. Monday through Friday, at the above address in Arlington, Virginia.

Please send certificate/permit questions or any applications concerning this regulation to Chief, Office of Management Authority; U.S. Fish and Wildlife Service; 4401 North Fairfax Drive, Room 700; Arlington, Virginia 22203; fax number 703–358–2281. Express and messenger deliveries should be addressed to Chief, Office of Management Authority, at that Arlington address.

FOR FURTHER INFORMATION CONTACT: Dr. Susan Lieberman, Chief, Office of Scientific Authority, phone 703–358–1708, fax 703–358–2276, e-mail susan__lieberman@mail.fws.gov; or the Office of Management Authority, telephone 800–358–2104, e-mail r9oma__cites@mail.fws.gov

SUPPLEMENTARY INFORMATION:

Background

The Convention on International Trade in Endangered Species of Wild Fauna and Flora (TIAS 8249) regulates international trade in certain animal and plant species. The species for which trade in particular specimens is controlled are listed in Appendices I, II, and III to the Convention. Appendix III comprises the list of species subject to regulation within any CITES Party country that has requested the cooperation of the other Parties in regulating international trade in the specified specimens of the species.

This rule revises the list of CITES species that is reproduced in the U.S. Code of Federal Regulations (CFR) at 50 CFR 23.23(f). The current information following COP10 (see below) was published in the **Federal Register** of August 22, 1997 (62 FR 44627). As advanced by the Government of Bolivia pursuant to Article XVI paragraph 1 of the Convention, the present rule acknowledges that now both Bolivia and Costa Rica have added *Swietenia macrophylla* (bigleaf mahogany [called mara or caoba]) to Appendix III in support of their domestic conservation measures and need for cooperation of other Parties.

The species continues to be included in Appendix III in the Americas (i.e., South America, Central America, the Caribbean, and North America), including only its logs, sawn wood, and veneer sheets as the parts or derivatives covered by the provisions of the Convention. Thus, products such as finished furniture are excluded. Moreover, export of specimens from plantations located outside the Americas is not regulated. (At COP10 in June 1997, the categories saw-logs, sawn wood, and veneers were revised slightly to the above for several such listings; cf. 62 FR 44627.)

The CITES Secretariat notified all Party countries on December 19, 1997 (in Notification No. 1011), of this addition to Appendix III by Bolivia of their population of this species. In accordance with Article XVI paragraph 2, such an amendment becomes effective 90 days after notification, in this case on March 19, 1998. All the shipments of bigleaf mahogany originating from Bolivia that are exported on or after that date must be accompanied by the appropriate documentation as required by CITES (usually an export permit), which is to be presented upon import to the Party countries.

International trade in Appendix III species and their parts and derivatives that are specified as being included requires the issuance of either an export permit, a certificate of origin, a re-export certificate, or a pre-Convention certificate, by the exporting or the re-exporting Party. An export permit, which signifies that the specimens were not obtained in contravention of the laws of that country for conservation, is required if the shipment originates from the Party that added the species to Appendix III, in this case Bolivia, as well as Costa Rica, which had earlier added the species to Appendix III, effective November 16, 1995 (see **Federal Register** of February 22, 1996, 61 FR 6793–6795).

Export from the other countries in the Americas requires the issuance of either a certificate from the country of origin, a certificate from the country of re-export, or a pre-Convention certificate (from the country of export). (The species is native from Bolivia and Brazil to Mexico.) These documents legally verify either: (1) that the specimens originated in a non-listing country; (2) that they are being re-exported after a

legal importation in accordance with CITES; or (3) that they were acquired before the provisions of the Convention applied to them. All the countries of South America, Central America, and North America and some countries in the Caribbean are Parties to the Convention. Article X of CITES and Resolution Conf. 9.5 specify the requirements for comparable documentation from countries not party to the treaty. The pre-Convention date for *Swietenia macrophylla* (bigleaf mahogany) remains November 16, 1995.

The Convention's Secretariat and U.S. Office of Management Authority in 1995 (and sometimes since) have inquired regarding certificates of origin or permits that exporting range countries issue for shipments of the specimens of this species (i.e., logs, sawn wood, and veneer sheets). Responses have been received from Mexico, Guatemala, Belize, Honduras, Nicaragua, Venezuela, Peru, and Brazil (*cf.* Secretariat's December 19, 1997, Notification No. 1004). Costa Rica and Bolivia, as Parties listing the species in Appendix III, use their regular documents (e.g., permits). Importation or exportation of CITES-regulated plant specimens must be through particular designated U.S. Department of Agriculture ports (50 CFR 24.12), which includes additional ports designated for logs and lumber. For information on the types of documents required for such mahogany importation into the United States, as well as requests for any documents needed for such re-export or export from the United States, contact the Service's Office of Management Authority (address and phone number above).

Any Party at any time may enter a reservation on a species (or pertinent population) added to Appendix III. A Party that has entered a reservation is treated as a country that is not party to the Convention with respect to the trade in the species concerned (until such time as that Party withdraws its reservation). The limited effects of a reservation in alleviating importers and exporters from documentation requirements with the other CITES Parties were thoroughly discussed in a **Federal Register** notice on November 17, 1987 (52 FR 43924). In a subsequent **Federal Register** notice of March 28, 1988 (53 FR 9945; see also 53 FR 12497, April 14, 1988), the Service made a procedural change in requesting comments about such reservations for species added to Appendix III. Because the effects of such a reservation are limited, and there is also no time limit for reserving on a species or a population added to Appendix III, a proposed rule is not published at the time the list in § 23.23 is amended. Regardless of any U.S. decision to enter a reservation, this particular amendment to Appendix III entered into force on March 19, 1998, under terms of the Convention. Publishing this rule informs the public of this international action while still affording those interested the opportunity and time to assess the merits of entering a reservation. Therefore, good cause exists to omit a proposed-rule notice and public-comment process, since it is unnecessary and contrary to the public interest [5 U.S.C. 553(b)]. Because bigleaf mahogany in the Americas was added to Appendix III of the Convention effective on November 16, 1995, and because of the other reasons stated herein, the Service finds that good cause exists for making this rule effective upon its date of publication [5 U.S.C. 553(d)]. Accordingly, 50 CFR 23.23(f) is amended at the conclusion of this document.

At the tenth meeting of the Conference of the Parties to the Convention (COP10) in June 1997, the United States was among 67 of 112 Parties that voted to include this species in Appendix II; this 60 percent of the Parties in favor, however, fell short of the two-thirds majority needed for adoption of the proposal (see the **Federal Register** notice of August 22, 1997 [62 FR 44627]). After the vote, Bolivia in plenary stated its intention to include its population of the species in Appendix III [cf. Resolution Conf. 9.25 (Rev.)]. The Service has not recommended entering a reservation on this enhanced status for the Bolivian population of the species in Appendix III. Consideration for doing so would be given if valid and compelling reasons are shown that implementation of this listing would be contrary to the interests or laws of the United States. The Service now solicits comments on whether to enter a reservation, and particularly seeks any new information that becomes available. The Service will consider all comments received, and if appropriate, will consider recommending that the United States submit a reservation to the depositary government (which is Switzerland).

Other Procedural Requirements

The Department has determined that changes to the Convention Appendices, which result from actions of the Parties to the treaty, do not require preparation of Environmental Assessments as defined under authority of the National Environmental Policy Act (42 U.S.C. 4321–4347). This rule recognizes the Republic of Bolivia's decision to include one of their native species in CITES Appendix III and serves public notice of their decision. As such, this rulemaking does not constitute an agency action under the Administrative Procedure Act.

This document was prepared by Dr. Bruce MacBryde and Dr. Susan Lieberman, Office of Scientific Authority, under the authority of the Endangered Species Act of 1973, as amended (16 U.S.C. 1531 *et seq.*, 87 Stat. 884, as amended).

List of Subjects in 50 CFR Part 23

Endangered and threatened species, Exports, Imports, and Treaties.

Regulation Promulgation

PART 23—ENDANGERED SPECIES CONVENTION

Accordingly, for the reasons set out above in this document, Part 23, Subpart C of Title 50 (Chapter I, Subchapter B) of the Code of Federal Regulations is amended as set forth below:

1. The authority citation for Part 23 continues to read as follows:

Authority: Convention on International Trade in Endangered Species of Wild Fauna and Flora, 27 U.S.T. 1087; and Endangered Species Act of 1973, as amended (16 U.S.C. 1531 *et seq.*).

2. Section 23.23(f) is amended by revising the entry of Swietenia macrophylla under the plant family Meliaceae to read as follows:

§ 23.23 Species listed in Appendices I, II, and III.

* * * * *

(f) * * *

Species	Common name	Appendix	First listing date (month/day/year)
* * *	* * *	* * *	
Plant Kingdom:	PLANTS:		
* * *	* * *	* * *	
Family Meliaceae:	Mahogany family:		
* * *	* * *	* * *	
Swietenia macrophylla populations in the Americas (including logs, sawn wood, and veneer sheets, but no other parts or derivatives, e.g., products).	Bigleaf mahogany	III (Bolivia, Costa Rica)	11/16/95
* * *	* * *	* * *	

Dated: May 5, 1998.

Donald Barry,

Acting Assistant Secretary for Fish and Wildlife and Parks.

[FR Doc. 98–12803 Filed 5–13–98; 8:45 am]

BILLING CODE 4310–55–P

Proposed Rules

Federal Register
Vol. 63, No. 93
Thursday, May 14, 1998

This section of the FEDERAL REGISTER contains notices to the public of the proposed issuance of rules and regulations. The purpose of these notices is to give interested persons an opportunity to participate in the rule making prior to the adoption of the final rules.

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 39

[Docket No. 98–NM–132–AD]

RIN 2120–AA64

Airworthiness Directives; Airbus Model A300, A310, and A300–600 Series Airplanes

AGENCY: Federal Aviation Administration, DOT.

ACTION: Notice of proposed rulemaking (NPRM).

SUMMARY: This document proposes the adoption of a new airworthiness directive (AD) that is applicable to certain Airbus Model A300, A310, and A300–600 series airplanes. This proposal would require a one-time operational test and repetitive functional tests of the free fall control mechanism of the landing gear, to ensure proper release of the main landing gear (MLG), and corrective action, if necessary. This proposal also would require eventual modification of the free fall control mechanism of landing gear, which constitutes terminating action for the repetitive functional tests. This proposal is prompted by issuance of mandatory continuing airworthiness information by a foreign civil airworthiness authority. The actions specified by the proposed AD are intended to prevent malfunction of the free fall control mechanism of the landing gear, which could result in the inability to extend the MLG in the event of failure of the hydraulic extension system.

DATES: Comments must be received by June 15, 1998.

ADDRESSES: Submit comments in triplicate to the Federal Aviation Administration (FAA), Transport Airplane Directorate, ANM–114, Attention: Rules Docket No. 98–NM–132–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 Airbus Industrie, 1 Rond Point Maurice Bellonte, 31707 Blagnac Cedex, France. This information may be examined at the FAA, Transport Airplane Directorate, 1601 Lind Avenue, SW., Renton, Washington.

FOR FURTHER INFORMATION CONTACT: Norman B. Martenson, Manager, International Branch, ANM–116, FAA, Transport Airplane Directorate, 1601 Lind Avenue, SW., Renton, Washington 98055–4056; telephone (425) 227–2110; fax (425) 227–1149.

SUPPLEMENTARY INFORMATION:

Comments Invited

Interested persons are invited to participate in the making of the proposed rule by submitting such written data, views, or arguments as they may desire. Communications shall identify the Rules Docket number and be submitted in triplicate to the address specified above. All communications received on or before the closing date for comments, specified above, will be considered before taking action on the proposed rule. The proposals contained in this notice may be changed in light of the comments received.

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

Commenters wishing the FAA to acknowledge receipt of their comments submitted in response to this notice must submit a self-addressed, stamped postcard on which the following statement is made: ‘‘Comments to Docket Number 98–NM–13–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–114, Attention: Rules Docket No. 98–NM–132–AD, 1601 Lind Avenue, SW., Renton, Washington 98055–4056.

Discussion

The Direction Générale de l’Aviation Civile (DGAC), which is the airworthiness authority for France, recently notified the FAA that an unsafe condition may exist on certain Airbus Model A300, A310, and A300–600 series airplanes. The DGAC advises that during training flights on two Airbus Model A300 series airplanes, the flight crew reported difficulty in extending the main landing gear (MLG) by means of the free fall control mechanism of the landing gear. The free fall control mechanism allows the flight crew to extend the landing gear in the event of failure of the hydraulic system that normally is used to extend the landing gear. A functional test of the free fall control mechanism on both airplanes revealed that this mechanism was rigged incorrectly, which caused the cockpit control handle of the free fall control mechanism to reach its mechanical stop before the MLG was released for extension by free fall. Malfunction of the free fall control mechanism, if not corrected, could result in the inability to extend the MLG in the event of failure of the hydraulic extension system.

Explanation of Relevant Service Information

The manufacturer has issued Airbus Industrie All operator Telex (AOT) 32–14, dated February 3, 1997, and Revision 01, dated March 13, 1997, which describe procedures or a one-time operational test and repetitive functional tests of the free fall control mechanism of the landing gear, and corrective action, if necessary. Procedures for the one-time operational test of the free fall control mechanism include inspecting the free fall control mechanism of the MLG with the landing gear extended and the weight of the airplane on the landing gear. Procedures for the repetitive functional test of the free fall control mechanism of the landing gear while the airplane is on jacks. Corrective actions, if necessary, including readjusting the telescopic rods of the MLG uplock of the free fall control mechanism, or completely rerigging the free fall control mechanism by adjusting specified components of the mechanism. The AOT also recommends that operators of airplanes

on which installation of Airbus Modification 04443 is pending need not accomplish the scheduled operational test of the free fall control mechanism of he landing gear.

The manufacturer also has issued Airbus Industrie Service Bulletins A300–32–0425, Revision 01; A310–32–2111, Revision 01; and A300–32–6072, Revision 01; all dated October 10, 1997. These service bulletins describe procedures for modification of the free fall control mechanism of the landing gear on Airbus Model A300, A310, and A300–600 series airplanes. The Modification includes removing telescope rods and cranks or crank assemblies from the MLG part of the free fall control mechanism of the landing gear, replacing the telescopic rods with new parts, and replacing the cranks or crank assemblies with improved parts. Accomplishment of the modification eliminates the need for the repetitive inspections described previsously.

Accomplishment of the actions specified in the AOT's and service bulletins described previously is intended to adequately address the identified unsafe condition. The DGAC classified the AOT's and service bulletins as mandatory and issued French airworthiness directive 97–113–322(B)R1, dated December 3, 1997, in order to assure the continued airworthiness of these airplanes in France.

FAA's Conclusions

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

Explanation of Requirements of Proposed Rule

Since an unsafe condition has been identified that is likely to exist or develop on other airplanes of the same type design registered in the United States, the proposed AD would require accomplishment of the actions specified in the AOT's and the service bulletins described previously.

Cost Impact

The FAA estimates that 24 Model A300 series airplanes, 41 Model, A310 series airplanes, and 61 Model A300–600 series airplanes of U.S. registry would be affected by this proposed AD.

It would take approximately 3 work hours per airplane to accomplish the proposed operational test, at an average labor rate of $60 per work hour. Based on these figures, the cost impact of the proposed operational test on U.S. operators is estimated to be $22,680, or $180 per airplane.

It would take approximately 2 work hours per airplane to accomplish the proposed functional test, at an average labor rate of $60 per work hour. Based on these figures, the cost impact of the proposed functional test on U.S. operators is estimated to be $15,120, or $120 per airplane, per test cycle.

It would take approximately 26 work hours per airplane to accomplish the proposed modification on the Model A300 and A300–600 series airplanes, at an average labor rate of $60 per work hour. Required parts would cost approximately $2,630 per airplane. Based on these figures, the cost impact of the proposed modification on U.S. operators of Model A300 or A300–600 series airplanes is estimated to be $356,150, or $4,190 per airplane.

It would take approximately 28 work hours per airplane to accomplish the proposed modification on the Model A310 series airplanes, at an average labor rate of $60 per work hour. Required parts would cost approximately $3,710 per airplane. Based on these figures, the cost impact of the proposed modification on U.S. operators of Model A310 series airplanes is estimated to be $220,990, or $5,390 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.

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:

Airbus Industrie: Docket 98–NM–132–AD.

Applicability: Model A300, A310, and A300–600 series airplanes; on which Airbus Industrie Modification 02781 has been accomplished, and on which Airbus Industrie Modification 03433 or 04443 has not been accomplished; certificated in any category.

Note: 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 malfunction of the free fall control mechanism of the landing gear, which could result in the inability to extend the main landing gear (MLG) in the event of

failure of the hydraulic extension system, accomplish the following:

(a) Within 600 flight hours after the effective date of this AD, perform a one-time operational test of the free fall control mechanism of the landing gear to ensure proper release of the MLG for extension by free fall, in accordance with Airbus Industrie All Operator Telex (AOT) 32–14, dated February 3, 1997, or Revision 01, dated March 13, 1997. If any discrepancy is detected in the functioning of the free fall control mechanism of the landing gear, prior to further flight, readjust the mechanism, and repeat the operational test in accordance with the AOT. If any discrepancy is detected in the second operational test, prior to further flight, rerig the free fall control mechanism in accordance with the AOT, and accomplish the actions required by paragraph (b) of this AD.

(b) Within 10 months after the effective date of this AD, perform a functional test of the free fall control mechanism of the landing gear to ensure proper release of the MLG for extension by free fall, in accordance with AOT 32–14, dated February 3, 1997, or Revision 01, dated March 13, 1997. Thereafter, repeat the functional test of the free fall control mechanism of the landing gear at intervals not to exceed 12 months, until the modification required by paragraph (c) of the AD has been accomplished. During any test performed in accordance with paragraph (b) of this AD, if the free fall control mechanism of the landing gear fails to fully extend the MLG, prior to further flight, readjust or rerig the mechanism in accordance with the AOT.

(c) Within 66 months after the effective date of this AD, modify the free fall control mechanism of the landing gear in accordance with Airbus Industrie Service bulletin A300–32–0425, Revision 01 (for Model A300 series airplanes); A310–32–2111, Revision 01 (for Model A310 series airplanes): or A300–32–6072, Revision 01 (for Model A300–600 series airplanes); all dated October 10, 1997; as applicable. Accomplishment of the modification constitutes terminating action for the repetitive functional tests required by paragraph (b) of 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, International Branch, ANM–116, 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, International Branch, ANM–116.

Note 2: Information concerning the existence of approved alternative methods of compliance with this AD, if any, may be obtained from the International Branch, ANM–116.

(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.

Note 3: The subject of this AD is addressed in French airworthiness directive 97–113–221(B)R1, dated December 3, 1997.

Issued in Renton, Washington, on May 7, 1998.

John J. Hickey,

Acting Manager, Transport Airplane Directorate, Aircraft Certification Service.

[FR Doc. 98–12807 Filed 5–13–98; 8:45 am]

BILLING CODE 4910–13–U

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Parts 207, 807, and 1271

[Docket No. 97N–484R]

RIN 0910–AB05

Establishment Registration and Listing for Manufacturers of Human Cellular and Tissue-Based Products

AGENCY: Food and Drug Administration, HHS.

ACTION: Proposed rule.

SUMMARY: The Food and Drug Administration (FDA) is proposing to require manufacturers of certain human cellular and tissue-based products to register with the agency and list their products. In addition, the agency is proposing to amend the registration and listing regulations that currently apply to human cellular and tissue-based products regulated as drugs, devices, and/or biological products. This action is being taken to establish a unified registration and listing program for human cellular and tissue-based products.

DATES: Submit written comments on the proposed rule by August 12, 1998. Submit written comments on the information collection provisions by June 15, 1998.

ADDRESSES: Submit written comments to the Dockets Management Branch (HFA–305), Food and Drug Administration, 12420 Parklawn Dr., rm. 1–23, Rockville, MD 20857. Submit written comments on the information collection provisions to the Office of Information and Regulatory Affairs, OMB, New Executive Office Bldg., 725 17th St. NW., Washington, DC 20503, Attn: Desk Officer for FDA.

FOR FURTHER INFORMATION CONTACT: Dano B. Murphy or Paula S. McKeever, Center for Biologics Evaluation and Research (HFM–17), Food and Drug Administration, 1401 Rockville Pike, suite 200N, Rockville, MD 20852–1448, 301–827–6210.

SUPPLEMENTARY INFORMATION:

I. Introduction

FDA is putting in place a comprehensive new system of regulation for human cellular and tissue-based products. As a first step toward accomplishing this goal, the agency is proposing regulations that will require establishments that manufacture those products to register and list their products with the agency.

A. Background

The term ''human cellular and tissue-based products'' encompasses an array of medical products derived from the human body and used for replacement, reproductive, or therapeutic purposes. Skin, tendons, bone, heart valves, and corneas have long been used as replacements for damaged or diseased tissues. Semen, ova, and embryos are transferred for reproductive purposes. Currently, some human cellular and tissue-based products are being developed for new therapeutic uses. For example, scientists are studying the use of manipulated human cells to treat viral infections, Parkinson's disease, and diabetes, among other diseases.

Human cellular and tissue-based products serve a crucial role in medicine, and they have the potential for providing important new therapies. Yet they also raise public health concerns. With the development of new products, and new uses for existing products, come questions about safety and effectiveness that need to be answered through clinical investigation. Furthermore, all human cellular and tissue-based products, because they contain components of the human body, pose some risk of carrying pathogens that could cause disease in health-care personnel, other handlers of tissue, recipients, and family members or other close contacts of recipients.

FDA has never had a single regulatory program for human cellular and tissue-based products. Instead, it has regulated these products on a case-by-case basis responding as it determined appropriate to the particular characteristics of and concerns raised by each type of product. Some tissues have been regulated as medical devices under section 201 of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 321 *et seq.*). Corneal lenticules, dura mater, heart valve allografts, and umbilical cord vein grafts fall into this category. Other products have been considered biological products under section 351 of the Public Health Service Act (the PHS Act) (42 U.S.C. 262) and drugs under the act (hereinafter referred to as biological drugs). Somatic cell therapy products and some gene therapy products fall

into this category. (See 58 FR 53248, October 14, 1993.)

FDA has also relied on section 361 of the PHS Act (42 U.S.C. 264), which provides the authority to issue regulations to prevent the spread of communicable diseases, to regulate tissues that it has chosen not to regulate as devices or biological drugs. In 1993, in response to concerns about the safety of human tissue intended for transplantation, FDA used this authority to require testing and screening of tissue donors for hepatitis and human immunodeficiency viruses. (See 58 FR 65514, December 14,1993.) Until it issued those regulations (''Human Tissues Intended for Transplantation,'' codified in title 21 of the Code of Federal Regulations (CFR) part 1270), FDA exerted little or no regulatory control over certain types of human cellular and tissue-based products. Instead, human tissue for transplantation was subject to some State regulation and to voluntary accreditation systems. Even today, FDA's human tissue regulations do not address the infectious disease risk of donating, processing, and storing reproductive cells and tissue.

FDA has evaluated its approach to regulating human cellular and tissue-based products and has determined that changes are needed. In light of the development of new products, coupled with a growing awareness of infectious-disease concerns, the agency believes that the current patchwork of regulatory policies is no longer adequate and plans to create a comprehensive regulatory program that will cover a broad range of human cellular and tissue-based products. The agency has considered the relevant provisions of the act and the PHS Act and has concluded that these two statutes provide sufficiently broad authority for the proposed regulatory program.

The agency announced its plans for reform in two documents released in February 1997: ''Reinventing the Regulation of Human Tissue,'' and ''A Proposed Approach to the Regulation of Cellular and Tissue-Based Products'' (hereinafter ''Proposed Approach document''). The agency requested written comments on its proposed approach and, on March 17, 1997, held a public meeting to solicit information and views from the interested public. (See 62 FR 9721, March 4, 1997) (Docket No.: 97N–0068). FDA has considered the comments submitted at the public meeting and to the docket in drafting this proposed rule. FDA welcomes comments on the proposed rule from all interested parties.

B. The Proposed Approach

FDA seeks to achieve several goals with its new approach to regulating human cellular and tissue-based products. Primary among them is the improved protection of the public health without the imposition of unnecessary restrictions on research, development, or the availability of new products. Under the new program, the degree of scrutiny afforded different types of products will be commensurate with the risks presented, enabling the agency to use its resources more effectively. Consolidating the regulation of human cellular and tissue-based products into one regulatory program is expected to lead to increased consistency and greater efficiency. Together, these planned improvements should increase the safety of human cellular and tissue-based products, and public confidence in that safety, while encouraging the development of new products.

In developing its proposed approach, FDA examined five issues that it considered fundamental to the proper regulation of the various types of human cellular and tissue-based products. First, the agency asked how the transmission of communicable disease by these products occurs and could be prevented. Second, the agency looked at the types of handling, processing, and manufacturing controls that are necessary to prevent contamination and to preserve the integrity and function of these products. Third, the agency examined concerns about the products' clinical safety and effectiveness. Fourth, FDA considered the type of labeling necessary for proper use of the products and the kind of promotion that would be permissible. Finally, the agency asked how it could best monitor and communicate with the cell and tissue industry.

Through examination of these five public-health and regulatory concerns, FDA was able to develop a proposed comprehensive regulatory scheme tailored to the relevant characteristics of human cellular and tissue-based products. In order to devise an umbrella approach, the agency first focused on the products' common attributes. Then, to ensure appropriate levels of regulation, the agency differentiated between the various types of products based on the public health risks associated with them. For example, the risks posed by cells that are extensively manipulated in a laboratory and then implanted for their systemic effect on a patient are different from those of an unmanipulated tissue that is transplanted into a patient to replace an injured structural tissue.

Taking into account these differences, the agency designed a risk-based tiered approach intended to regulate human cellular and tissue-based products only to the extent necessary to protect public health. Some products will be subject to little or no regulation. For example, no regulatory requirements will be imposed on tissues transplanted into the same patient during the same surgical procedure.

As the potential risk posed by a product increases, so will the level of oversight afforded that product. Thus, minimally processed tissues transplanted from one person to another for their normal structural functions would be subject to infectious disease screening and testing and to requirements for good handling procedures, but would not need FDA premarket review or marketing approval. In contrast, premarket approval would generally be required for cells and tissues that are processed extensively, are combined with noncellular or nontissue components, are labeled or promoted for purposes other than their normal functions, or have a systemic effect. In addition, these products would be subject to requirements for good tissue practices and infectious disease screening and testing, as well as to the good manufacturing practice requirements applicable to drugs and devices.

Although FDA's proposed regulatory approach is far more comprehensive in scope than its present system, some products will not be covered. Among the products not included under the approach are vascularized organs and minimally manipulated bone marrow, both of which fall under the purview of the Health Resources Services Administration. FDA already comprehensively regulates transfusable blood products (e.g., whole blood, red blood cells, platelets, and plasma) under a different regulatory scheme and will not at this time regulate those products as human cellular and tissue-based products. Xenograft transplantation (transplantation using tissues derived from animals) raises different public health issues from transplantation with human tissue, and so will not be subject to the new regulatory program. The new program will also exclude from coverage ancillary products used in cell or tissue propagation, storage, or processing, as well as products that are secreted by or extracted from cells or tissues (e.g., human milk, collagen, urokinase, cytokines, and growth factors), because these products often raise different manufacturing, safety, and effectiveness

issues, and generally are covered by other rules, regulations, or standards.

II. Registration of Human Cellular and Tissue-Based Products

FDA is now proposing to extend registration and listing requirements to manufacturers of human cellular and tissue-based products not currently subject to such requirements.

A. Need for Registration and Listing

In order to implement its new approach to the regulation of human cellular and tissue-based products, FDA needs to be able to assess the state of the cell and tissue industry. Although some human cellular and tissue-based products are currently regulated by the agency as devices or biological drugs—and thus are covered by registration and listing requirements—others have not been subject to such regulation. As a result, FDA does not know the full size and scope of the cell and tissue industry and its products.

Through the current proposal to extend the requirements of registration and product listing to members of the tissue and cell industry not presently under such obligations, FDA seeks to accrue the basic knowledge about the industry that is necessary for its effective regulation. Without reliable data on the tissue and cell industry (e.g., names and addresses of manufacturers and types of products) FDA cannot apply appropriate oversight to a rapidly changing industry. FDA must keep informed of the state of the industry, including developments such as the introduction of new products, in order to understand and respond to all relevant public health issues. Because FDA intends to calibrate its level of regulation to the risks posed by various types of cellular and tissue-based products, it is crucial for the agency to have accurate information about those products.

The proposed registration requirement will facilitate communication between the agency and industry. Once FDA has a complete list of the cell and tissue industry and its products, the agency will be able to reach members of the industry with educational materials and information regarding FDA policies, guidances, and requirements. Important information (e.g., about a newly identified public health risk) can also be quickly disseminated to the industry. Moreover, information obtained through the new registration and listing regulation will permit the agency to monitor the industry more effectively. For example, FDA will be able to identify quickly which establishments should be inspected for compliance with applicable laws and regulations, including those to be issued as part of the new tissue regulation program. Required updating of industry registrations and product lists will ensure that FDA's information about the industry remains current.

B. How Registration Will Be Achieved

In proposing these new registration regulations, FDA seeks to improve the way it collects and manages information about the cell and tissue industry and its products. The agency plans to create a single, comprehensive data base with information about human cellular and tissue-based products, maintained by the Center for Biologics Evaluation and Research (CBER). By requiring registration and product listing from manufacturers not presently subject to such requirements, and by consolidating that new information with data currently being collected, FDA will be able to develop a less fragmented and more efficient oversight program. Meanwhile, manufacturers already under a registration obligation will benefit from the availability of new, electronic procedures.

The main set of regulations being proposed, new part 1271 of title 21 of the CFR, will apply to those human cellular and tissue-based products that the agency will regulate under section 361 of the PHS Act. Proposed part 1271 will cover those products, including products consisting of reproductive cells or tissue, that: (1) Are minimally manipulated; (2) are not promoted or labeled for any use other than a homologous use; (3) have not been combined with or modified by the addition of any noncellular or nontissue component that is a drug or device; and (4) do not have a systemic effect, except in cases of autologous use, transplantation into a first-degree blood relative, or reproductive use. For convenience these products will be referred to as ''products regulated under section 361'' or ''361 products.'' (However, the use of these terms does not indicate that other products will not be regulated under section 361 of the PHS Act. In fact, FDA intends to rely in part on section 361 of the PHS Act when imposing requirements on human cellular and tissue-based products regulated as biological drugs or devices under the act and/or section 351 of the PHS Act.) Examples of products to be regulated under section 361 of the PHS Act include bone, tendons, skin, corneas, and sclera. If all other criteria are met, products with a systemic effect that could come under section 361 of the PHS Act include peripheral and cord blood stem cells used autologously or in first degree blood relatives and sperm, oocytes, and embryos for reproductive use.

Establishments that manufacture human cellular or tissue-based products that meet the criteria set out above would be required to register and list those products under proposed part 1271. However, certain exceptions would apply. For example, although the agency's proposed definition of ''manufacture'' includes distribution, commercial carriers would not need to register. Also, certain scientific, educational, or other uses of cellular or tissue-based products would not be covered by part 1271. These and other exceptions are discussed in greater detail in section III of this document.

In order to unify its registration system, FDA also proposes to amend parts 207 and 807 (21 CFR parts 207 and 807) so that information on human cellular and tissue-based products regulated as biological drugs or devices will be submitted to the same data base used for 361 products. Parts 207 and 807 contain the registration and listing requirements for drugs and devices. Under the proposed amendments, manufacturers of human cellular and tissue-based products regulated as biological drugs or devices will be required to comply with the registration and listing requirements in part 207 or 807, as applicable, by following the procedures set out in proposed part 1271.

Human cellular and tissue-based products subject to regulation as biological drugs or devices are those that do not meet the criteria set out above for regulation under section 361 of the PHS Act. That is, they are: (1) More than minimally manipulated; (2) are promoted or labeled for a nonhomologous use; (3) have been combined with or modified by the addition of a noncellular or nontissue component that is a drug or device; or (4) have a systemic effect (except in cases of autologous use, transplantation into a first degree blood relative, or reproductive use). Examples include: Hematopoietic stem cells intended for use in recipients who are not close blood relatives of the cell donor or for uses other than to reconstitute the cellular components of the blood; more than minimally manipulated bone marrow; hematopoietic stem cells that have been expanded or modified as part of gene therapy; cloned and/or activated lymphocyte therapies for cancer or infectious diseases; bone combined with collagen or growth factors; and manipulated cells for autologous structural use (MAS cells), such as

expanded chondrocytes to repair damaged knee cartilage.

Under the proposed regulatory system, some products that are currently regulated as medical devices might be regulated as section 361 products instead. One such product under consideration is dura mater, the collagenous connective tissue that covers the human brain and spinal cord. Dura mater is excised from cadavers shortly after death, washed, cut into smaller pieces, sterilized, preserved, and reconstituted before use in neurosurgical, gynecological, oral, otolaryngological, and general surgical procedures. This manner of processing does not change the tissue's original characteristics relating to its ability to carry out reconstruction, repair, or replacement and, therefore, would be considered minimal manipulation as defined in proposed part 1271. Moreover, dura mater does not have a systemic effect. Thus, dura mater that is not combined with or modified by the addition of any nontissue or noncellular component that is a drug or device, and that is not promoted or labeled for any use other than a homologous use, appears to meet the proposed criteria in part 1271 for regulation under section 361 of the PHS Act.

Recent reports linking the transmission of Creutzfeldt-Jakob Disease (CJD) to several recipients of human cadaveric dura mater have raised questions as to the controls needed to regulate dura mater. Following discussion of data and information relating to dura mater, on October 6 and 7, 1997, FDA's Transmissible Spongiform Encephalopathy Advisory Committee recommended that FDA adopt measures intended to decrease the risk of CJD transmission via dura mater. These recommendations include specific handling procedures to reduce or eliminate CJD infectious agents in cadaveric dura mater and histological examinations of brain biopsies taken from donor cadavers. In light of these recent developments and the committee's recommendations, FDA is requesting comments on whether FDA's proposal to regulate dura mater under the authority of section 361 of the PHS Act will provide adequate controls, or, conversely, whether tissues with certain risk and disease factors should be subject to premarket submission requirements found in the act and in section 351 of the PHS Act. The agency invites comments regarding the appropriate controls for dura mater and like products, and whether such controls may be appropriately addressed in ''good tissue practice'' requirements specific to these products issued under the authority of section 361 of the PHS Act. In the meantime, FDA will continue to regulate dura mater as a device.

The agency intends to regulate as 361 products human heart valve allografts that meet the criteria of proposed § 1271.10, which are now subject to regulation as medical devices. In the past, these products were considered by FDA to be class III medical devices. In 1994, in a stipulated order of dismissal in *Northwest Tissue Center* v. *Shalala*, No. 91–C–6515 (N.D. Ill., October 7, 1994), FDA stipulated that it would not enforce the class III requirement of premarket approval for human heart valve allografts. In 1995, the American Red Cross (ARC) requested that FDA regulate human heart valve allografts as human tissues for transplantation, rather than as medical devices. ARC's request for jurisdictional change for the regulation of human heart allografts was supported by the Northwest Tissue Center.

The agency now proposes to regulate, as section 361 products, heart valve allografts that are minimally manipulated, do not a have a systemic effect, and are not promoted for a nonhomologous use or combined with a nontissue or noncellular component that is a drug or a device.

C. Legal Authority

FDA is proposing to issue new regulations in part 1271 solely under the authority of section 361 of the PHS Act. Under that section, FDA may make and enforce regulations necessary to prevent the introduction, transmission, or spread of communicable diseases between the States or from foreign countries into the States. (See sec. 1, Reorg. Plan No. 3 of 1966 at 42 U.S.C. 202 for delegation of section 361 authority from the Surgeon General to the Secretary, Health and Human Services; see 21 CFR 5.10(a)(4) for delegation from the Secretary to the Food and Drug Administration.) Intrastate transactions may also be regulated under section 361 of the PHS Act. (See *Louisiana* v. *Mathews*, 427 F. Supp. 174, 176 (E.D. La. 1977).

Because of their nature as derivatives of the human body, all human cellular and tissue-based products pose a potential risk of transmitting diseases. FDA has determined that it may appropriately and effectively regulate certain of these products (described in section II.B of this document) by controlling the infectious disease risks they present rather than by requiring premarket approval or licensing under the act or the PHS Act.

In order to prevent the spread of infectious disease, FDA must obtain the type of basic information about the industry and its products that these proposed regulations will require be provided to the agency. This information will enable the agency to react swiftly to newly discovered or understood risks by alerting members of the industry of its concerns and, when appropriate, by conducting establishment inspections.

Moreover, the registration regulations now being proposed lay the foundation for a regulatory program that will further the goal of preventing the transmission of communicable disease. FDA intends to propose regulations to be issued at a later date that would require such measures as the maintenance of ''good tissue practices'' and various tests for communicable diseases. Without the information that the agency will collect through establishment registration and product listing, FDA cannot effectively monitor compliance with these future regulations—and, thus, prevent the transmission of communicable disease.

Authority for the enforcement of section 361 of the PHS Act is provided by section 368 of the PHS Act (42 U.S.C. 271). Under section 368(a), any person who violates a regulation prescribed under section 361 of the PHS Act may be punished by imprisonment for up to 1 year, a fine of not more than $1,000, or both (42 U.S.C. 271(a)). In addition, Federal District Courts have jurisdiction to enjoin individuals and organizations from violating regulations implementing section 361 of the PHS Act. The agency intends, in a future rulemaking, to issue regulations including requirements for testing, good tissue practices, and enforcement under the authority of section 361 of the PHS Act.

Human cellular and tissue-based products that do not meet FDA's criteria set forth in part 1271 for regulation solely under section 361 of the PHS Act are subject to regulation as biological drugs or devices, and their manufacturers are required to register with the agency under section 510 of the act. Regulations implementing section 510 are found under parts 207 and 807, among other parts. As discussed earlier, in order to consolidate its data base on the cell and tissue industry and thus to improve its oversight functions, FDA proposes to amend parts 207 and 807 to require registering establishments to follow the procedures set out in part 1271. Section 510 of the act remains the authority for the substantive registration requirement for products subject to parts 207 and 807. Because harmonizing the registration and listing procedures

applicable to the various human cellular and tissue-based products is intended to further the goal of preventing the spread of communicable disease, the agency is also relying on the additional authority of section 361 of the PHS Act for the proposed amendments to parts 207 and 807.

III. Summary of the Proposed Regulations

A. Purpose, Coverage, and Exceptions of Part 1271

1. Purpose

The purpose of part 1271, as set out in § 1271.1, is to establish a unified registration and product listing system for establishments that manufacture human cellular and tissue-based products.

2. Coverage

Section 1271.1 states that manufacturers of human cellular and tissue-based products regulated under section 361 of the PHS Act are required by part 1271 to register and list their products with CBER. These products are further described in § 1271.10, which states who must register and submit a list. The products are those that: (1) Are minimally manipulated; (2) are not promoted for any use other than homologous use; (3) are not combined with or modified by the addition of any nontissue or noncellular component that is a drug or device; and (4) do not have a systemic effect, except in cases of autologous or family-related allogeneic systemic use or reproductive use. Many of these terms are defined in the definition section of the regulation, § 1271.3.

In addition, § 1271.1 notes that manufacturers of products regulated under section 351 of the PHS Act and/or the act are required to register and list their products following the procedures in subpart B of part 1271.

3. Exceptions

Section 1271.20 sets out exceptions to the provisions of part 1271. These exceptions are for activities that do not raise issues the agency currently believes warrant regulation.

a. The use of human cellular or tissue-based products solely for nonclinical scientific or educational purposes does not trigger the registration or listing requirements. Any use for implantation, transplantation, infusion, or transfer into humans is considered clinical use and would be subject to part 1271.

b. An establishment or person that removes human cellular or tissue-based products from an individual and then implants, transplants, infuses, or transfers those cells or tissues into the same individual is not required to register or list with the agency, so long as the human cellular or tissue-based product is quarantined pending completion of the surgery. For example, a surgeon might remove a saphenous vein from a patient for use in a later coronary bypass in the same patient. Registration and listing would not be required unless the saphenous vein was stored with other cellular or tissue-based products. Storage in the same location as other human cellular or tissue-based products gives rise to concerns about the spread of infectious disease and would be considered beyond the bounds of the exception.

c. Carriers that accept, receive, carry, hold, or deliver human cellular or tissue-based products in the usual course of business are not required to register or list.

d. Establishments that receive human cellular or tissue-based products solely for implantation, transplantation, infusion, or transfer within the same facility do not come under the terms of part 1271. This exception is intended only for end-user establishments, that is, establishments that do not procure, distribute, or otherwise manufacture human cellular or tissue-based products.

B. Definitions

Section 1271.3 contains definitions of many of the terms used in part 1271. Some of the definitions relate to the types of product covered by part 1271, e.g., § 1271.3(d) defines ''homologous use.'' Other definitions are intended to clarify the sorts of activities that will trigger the requirements of part 1271, e.g., § 1271.3(f) defines ''manufacture.''

1. Human Cellular or Tissue-Based Product

A *human cellular or tissue-based product* is defined in § 1271.3(e) as a product containing human cells or tissues, or any cell or tissue-based component of such a product.

The following products are excluded from this definition: Vascularized human organs for transplantation; products that are secreted or extracted from humans, such as milk, collagen, and cell factors; minimally manipulated bone marrow; ancillary products used in the propagation of cells or tissues, and cells, tissues, or organs derived from animals.

Whole blood, blood components, or blood derivative products subject to listing under 21 CFR part 607 are also excluded. Such products include, among others, whole blood, red blood cells, cryoprecipitated AHF, platelets, leukocytes/granulocytes, plasma, blood products for diagnostic use, and blood bank reagents. In contrast, peripheral and cord blood stem cells are not subject to the exception for whole blood, blood components and blood derivative products and therefore are subject to part 1271.

2. Minimal Manipulation

One of the criteria for regulation of a human cellular or tissue-based product under section 361 of the PHS Act and part 1271 is that it be minimally manipulated. *Minimal manipulation* is defined in § 1271.3(g). For structural tissue, minimal manipulation is defined as processing that does not alter the original relevant characteristics of the tissue that relate to the tissue's utility for reconstruction, repair, or replacement. For example, separation of structural tissue into components whose relevant characteristics relating to reconstruction or repair are not altered would be considered minimal manipulation, as would extraction or separation of cells from structural tissue in which the remaining structural tissue's relevant characteristics relating to reconstruction and repair remain unchanged. Other examples of procedures that would be considered minimal manipulation include: Cutting, grinding, and shaping; soaking in antibiotic solution; sterilization by ethylene oxide treatment or irradiation; cell separation; lyophilization; cryopreservation; and freezing.

For cells (structural and nonstructural) and nonstructural tissues, minimal manipulation is defined as processing that does not alter the relevant biological characteristics and, thus potentially, the function or integrity of the cells or tissues. For example, FDA considers cell selection (e.g., selection of stem cells from amongst lymphocytes and mature cells of other lineages) to be minimal manipulation.

FDA considers the processing of cells and tissue to be ''more than minimal'' if information does not exist to show that the process meets the definition of minimal manipulation. Examples of manipulation not considered minimal, based on current scientific knowledge, include cell expansion, encapsulation, activation, and genetic modification. FDA recognizes that the subsequent accumulation of clinical data and experience about a particular process may demonstrate that it does not alter the original relevant characteristics of the cells or tissue, and the agency will consider this information in determining whether a procedure should be considered minimal as opposed to more-than-minimal

manipulation. For example , FDA previously considered demineralized bone products (DMB) to be more than minimally manipulated. However, at the March 17, 1997, public meeting, and during a July 11, 1997, meeting between the American Association of Tissue Banks and FDA, the agency was urged to reconsider its position regarding the regulatory status of DMB. After reviewing information provided, the agency believes that the relevant characteristics that relate to DMB's utility for replacement, reconstruction and repair are not altered by processing bone specimens into DMB. Therefore, FDA proposes to regulate DMB under section 361 of the PHS Act provided it is used for homologous function and is not combined with a noncellular or nontissue component that is a drug or device because FDA believes DMB falls within the minimal manipulation definition.

3. Homologous Use

The second criterion for regulation under part 1271 is that a human cellular or tissue-based product not be promoted or labeled for any use other than homologous use. *Homologous use* is defined in § 1271.3(d) as the use of a cellular or tissue-based product for replacement or supplementation of a recipient's cells or tissues. Homologous use of a structural tissue-based product occurs when the tissue is used for the same basic structural function that it fulfills in its native state, in a location where such structural function normally occurs. Basic function of a structural tissue is what the tissue does from a biological/physiological point of view, or is capable of doing when in its native state. For example, the agency considers structural tissue to be used for a homologous function when it is used to replace an analogous structural tissue that has been damaged or otherwise does not function adequately. Conversely, the agency would consider structural tissue to be performing a nonhomologous function when it is fulfilling a function that is different from the basic function it fulfills in its native state.

Examples of homologous use claims for structural tissues that would fall within the scope of part 1271 include bone allograft obtained from a long bone but labeled for use in a vertebra; skin allograft obtained from the arm but labeled for use as a skin graft on the face; pericardium, a structural membranous covering of the heart, labeled for use as a structural membranous covering for the brain; and heart valves labeled for use as heart valves. An example of a nonhomologous use claim for structural tissue is cartilage labeled for placement under the submucosal layer of the urinary bladder to change the angle of the ureter and thereby prevent backflow of urine from the bladder into the ureter. The cartilage would be performing a structural function (adding volume to change the angle of the ureter) which is different from the function in its native state (to afford flexibility and provide musculoskeletal support).

According to the definition, homologous use of nonstructural cellular or tissue-based products occurs when the cells or tissues are used to perform the function(s) that they performed in the donor. An example of a homologous use claim would be hematopoietic stem cells labeled for use for hematopoietic reconstitution. An example of a nonhomologous use claim for the same cellular product would be a claim for treatment of adrenal leukodystrophies (congenital metabolic deficiencies).

In determining whether a product comes under part 1271 or is instead required to comply with premarketing requirements, FDA has tentatively decided to focus on whether a cellular or tissue-based product is promoted or labeled by its manufacturer for a nonhomologous use, rather than on the intent of the practitioner who uses the product. Accordingly, the actual use of a cellular or tissue-based product for a nonhomologous function would not trigger premarket review requirements if the product was not labeled or promoted for nonhomologous use. This change from the Proposed Approach document comes in response to industry concerns and is expected to lead to the more efficient use of the agency's resources. The agency specifically requests comments on this new language.

4. Nontissue or Noncellular Component

Products combined with or modified by the addition of any *nontissue or noncellular component that is a drug or device* will not be regulated under part 1271. Because ''nontissue or noncellular component' is self-explanatory, FDA does not consider it necessary to define the term. However, the agency has modified the phrase ''nontissue or noncellular component'' with the words ''that is a drug or device'' in order to clarify that water and buffers would not ordinarily be considered nontissue or noncellular components. In contrast, a product composed of human cells or tissue in combination with a mechanical or synthetic component, such as epithelial cells on a biomatrix to cover burns, would not come under part 1271 and would be regulated under section 351 of the PHS Act and/or the act.

5. Systemic Effect

The final requirement for a product to be regulated under part 1271 is that the product not have a systemic effect. Given that ''systemic'' is a commonly used medical term, FDA is not proposing a regulatory definition of the word. The agency would consider the insertion of pancreatic islet cells, pituitary cells, or stem cells into an individual to have a mainly systemic effect. In contrast, the insertion of replacement bone would not have a mainly systemic effect; the effect would be limited to the immediate area around the insertion. FDA recognizes that some products may have both systemic and structural effects but intends that a product's primary effect be determinative.

Earlier discussions of FDA's regulatory plans, including the Proposed Approach document, used the term ''metabolic function.'' After considering concerns raised by comments on the proposed approach, FDA has decided that ''systemic effect'' more accurately reflects the agency's intended meaning.

6. Autologous, Allogeneic, Family-Related Allogeneic, and Reproductive Uses

Under § 1271.10(d), there are several exceptions to the requirement that a human cellular or tissue-based product not have a systemic effect to be regulated under part 1271. These exceptions are for cases of autologous or family-related allogeneic systemic use and for reproductive use. Thus, products with a systemic effect that are utilized for autologous, family-related allogeneic, or reproductive use and that meet the other criteria set out in § 1271.10 will be regulated under part 1271.

Autologous use is defined in § 1271.3(a) as the implantation, transplantation, infusion, or transfer of a cellular or tissue-based product back into the individual from whom the cells or tissue comprising such product were removed. Several comments on the Proposed Approach document pointed out that the agency had used ''Autologous'' in a confusing manner. With the previous definition, the agency intends to clarify the meaning of the word. In contrast with autologous use, allogeneic use (not defined in this regulation) is the transplantation of cells or tissue obtained from a different individual.

FDA is using the phrase ''family-related'' for situations where the

recipient of cells or tissue is a biological parent, child, or sibling of the donor. Thus, *family-related allogeneic use* is defined in § 1271.3(c) as the implantation, transplantation, infusion, or transfer of a human cellular or tissue-based product into a first-degree blood relative of the individual from whom cells or tissue comprising such product were removed. Some comments on the Proposed Approach document have disagreed with FDA's definition of ''family-related,'' arguing that its scope should be made broader to include such relatives as cousins and grandparents. Other comments have argued against an exception for family related allogeneic use, asserting that the family-related allogeneic use of products with a systemic effect should be treated no differently from any other allogeneic use. The agency specifically requests further comment on this issue.

The third situation in which a product with a systemic effect will be regulated under part 1271 is when the product contains human reproductive cells or tissue and is for *reproductive use*. In contrast to other tissues with a systemic effect, transfer of reproductive tissues such as semen and ova pose less risk to the health of the recipient from rejection, graft-versus-host disease, and compatibility. In addition, the failure of a reproductive-tissue product will generally cause lesser health risks to the individual than the failure of other systemic products. FDA has decided that it is not necessary to define ''reproductive use'' in the regulation, because the term is well understood.

7. Transfer

Some of the definitions in § 1271.3 contain the terms implantation, transplantation, and infusion, which FDA believes are generally understood. However, FDA is proposing to define, for the purpose of this part, *transfer*, which may not be as well understood, to mean ''the placement of human reproductive cells or tissues into a human recipient.'' This definition, in § 1271.3(k), reflects the way the term ''transfer'' is used within the reproductive tissue industry.

8. Establishment and Manufacture

Other terms defined in § 1271.3 relate to the manufacturing of human cellular and tissue-based products. An *establishment* is defined as a place of business under one management, at one general physical location that engages in the manufacture of human cellular or tissue-based products. The term includes facilities that engage in contract manufacturing services for a manufacturer. The term also includes any individual, partnership, corporation, association, or other legal entity engaged in the manufacture of human cellular or tissue-based products.

Under § 1271.3(f), the term manufacture includes all steps in the recovery, screening, testing, processing, storage, labeling, packaging, or distribution of any human cellular or tissue-based product. The agency interprets certain terms used in the definition of ''manufacture'' in the following ways. By ''recovery'' FDA means obtaining cells or tissues from a donor that are intended for use in human transplantation, infusion, implantation, or transfer. ''Storage'' would include holding human cells or tissue for future distribution or use. ''Processing'' means any activity, other than recovery, performed on a human cellular or tissue-based product, including preventing contamination and preserving the function and integrity of the product. Processing includes preparation, preservation for storage, removal from storage, and any steps to inactivate and remove adventitious agents. ''Distribution'' includes any conveyance or shipment of human cellular or tissue-based product (including importation and exportation), whether or not such conveyance or shipment is entirely intrastate and whether or not possession of the human cellular or tissue-based product is taken.

Many entities and individuals that would be considered manufacturers under part 1271 because they recover human cells or tissues expressed concerns that they would be subject to registration requirements. FDA anticipates that individuals engaged solely in the procurement or recovery of cells or tissues and under contract to organizations that coordinate procurement or recovery of human cells or tissues will not have to independently register under part 1271. Registration will be the responsibility of the employer or contracting organization, which will also be required under future rulemaking to ensure that its employees, agents, and contractors that engage in the recovery of cells or tissues comply with applicable regulations or procedures regarding the collection, safe handling, and proper shipment of human cells or tissues.

C. Procedures for Registration and Listing

The procedures for complying with proposed part 1271, found in subpart B, are designed to impose only a minimal burden on manufacturers while providing FDA with the basic information needed to underpin its regulatory program. Under § 1271.21(a), registration and listing are required within 5 days after the initiation of an establishment's operations. Registration updates are required annually, by December 31, under § 1271.21(b). Section 1271.21(c) governs the semi-annual updating of product lists. Product lists must be updated with the following information: (1) Each human cellular or tissue-based product introduced by the registrant for distribution that has not been included in any list previously submitted; (2) each human cellular or tissue-based product formerly listed for which distribution has been discontinued; (3) each human cellular or tissue-based product for which a notice of discontinuance was submitted and for which distribution has been resumed; and (4) any material change in any information previously submitted. Product list updates must be submitted each June and December; alternatively, they may be submitted at the time the change occurs. When no changes have occurred since the previously submitted product list, no update is required.

Section 1271.22 requires registration, listing, and annual updates to be submitted on Form FDA 3356. That section also tells how to obtain the form and where to submit it, including information on obtaining the form electronically. The agency anticipates that some firms may prefer the ease of obtaining the registration and listing form electronically. For this reason, an electronic version of this form is currently being developed. It will be available by the time the final regulations go into effect.

Section 1271.25 sets out the information required for registration and listing, including the name and address of the establishment. Information required for product listings includes the established and proprietary names of each product, as well as a statement of whether the product meets the criteria set out in § 1271.10. (Any change in whether a product meets these criteria will be considered a ''material change'' subject to reporting under § 1271.21(c)(iv).)

Under § 1271.26, changes in an establishment's ownership or location are to be submitted as an amendment to registration within 5 days of such changes. Section 1271.27 states that the agency will provide the registrant with a permanent registration number. Section 1271.37 sets out the registration and product listing information that will be made available to the public.

At this time, the agency is not proposing to charge a fee for registration

or product listing. FDA is evaluating its authority to assess a fee and the impacts of such a fee. If it determines that a fee it is appropriate, the agency will make such a proposal in a future rulemaking.

D. Amendments to Parts 207 and 807

FDA proposes to add new paragraph (f) to § 207.20 and new paragraph (e) to § 807.20. These additions will state that owners and operators of establishments that recover, screen, test, process, store, label, package, or distribute human cellular or tissue-based products, as defined in § 1271.3(f), shall register and list those products with CBER on Form FDA 3356, following the procedures found in subpart B of part 1271. Thus, instead of following the procedures in subpart C of part 207 (e.g., procedures contained in §§ 207.21, 207.22, 207.25, 207.26, and 207.30), establishments that manufacture human cellular or tissue-based products regulated as biological drugs under the act and the PHS Act would follow the procedures set out in part 1271, subpart B. Regulations that do not pertain to the procedural requirements for registration and listing (e.g., § 207.39, on misbranding) would still apply. In addition, new § 207.20(f) will specifically state that the procedures for submitting additional information, in § 207.31, remain applicable.

With respect to human cellular or tissue-based products regulated as devices under the act, manufacturers would follow the registration and listing procedures of part 1271, subpart B, instead of those found in part 807, subpart B (e.g., procedures in §§ 807.21, 807.22, 807.25, 807.26, and 807.30). As would be the case for devices, the requirements for additional listing information in § 807.31 will remain in place and regulations that do not pertain to registration and listing (e.g., § 807.39) would still be applicable.

IV. Analysis of Economic Impacts

FDA has examined the impacts of the proposed rule under Executive Order 12866, under the Regulatory Flexibility Act (5 U.S.C. 601–612), and under the Unfunded Mandates Reform Act (Pub. L. 104–4). Executive Order 12866 directs agencies to assess all costs and benefits of available regulatory alternatives and, when regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety, and other advantages; distributive impacts; and equity).

The Regulatory Flexibility Act requires agencies to analyze whether a rule may have a significant impact on a substantial number of small entities and, if it does, to analyze regulatory options that would minimize the impact. The Unfunded Mandates Reform Act requires that agencies prepare an assessment of anticipated costs and benefits before proposing any rule that may result in an expenditure by State, local, and tribal governments, in the aggregate, or by the private sector, of $100,000,000 (adjusted annually for inflation) in any 1 year. The agency has determined that the proposed rule is a significant rule as described in the Executive Order, but not a significant action as defined in the Unfunded Mandates Reform Act. Aggregate impacts of the rule, and aggregate expenditures caused by the rule, will not approach $100 million for either the public or the private sector.

An analysis of available information suggests that costs to the entities most affected by this rule, including small entities, are not expected be significant, as described in the analysis below. Therefore, the agency certifies that this rule will not have a significant impact on a substantial number of small entities.

A. Objective and Basis of the Proposed Action.

FDA is proposing this action as a first step in the regulation of the rapidly evolving industry of human cellular and tissue-based products. This industry has not been previously subject to a comprehensive regulatory program by FDA or other public health authorities. Lack of a single regulatory approach or registration system has prevented the agency from acquiring information regarding the full size of the cell and tissue industry and the scope of its products. The proposed rule will require all manufacturers of human cellular and tissue-based products to register with the agency and to submit to the agency a list of their products. Through registration and listing, FDA will be able to identify industry participants and the products manufactured. This will enable the agency to more efficiently monitor the industry, distribute new information such as guidances, policies, or requirements, and identify entities that may be subject to inspection by FDA. This action is taken solely under the authority of section 361 of the PHS Act. Section 361 is also used as authority to amend parts 207 and 807 so that the registration data bases developed for drugs and devices may be consolidated with the data base of the proposed human cell and tissue registration program. Section 510 of the act remains the substantive registration requirement for products subject to parts 207 and 807. FDA has reviewed related Federal rules and has not identified any rules that duplicate, overlap, or conflict with the proposed rule.

B. Small Entities Affected

This proposal affects both entities that currently register with FDA and submit product lists to the agency under applicable sections of the act (parts 207 and 807), and those entities that are not presently required to register or list with the agency. FDA has structured registration and listing to have a minimal impact on affected entities. However, the agency anticipates that the impact will be greater for those entities that do not currently register or list.

The number of entities that will be required to begin registration and listing under part 1271 is difficult to ascertain. Because the agency has not previously regulated certain human cellular and tissue-based products, the agency can only approximate the number of entities that may fall under the requirements of the proposed rule. This lack of accessible, accurate information is, in fact, a major reason behind the agency's registration and listing initiative. In calculating the burden, the agency has used information obtained from various trade organizations related to the human cellular and tissue-based industry. Several organizations also provided estimates of what portion of the industry their membership represented, and the agency included in its analysis the 65 manufacturers of human cellular and tissue-based device products that are registered with the agency under part 807. The Musculoskeletal Transplant Foundation lists approximately 25 tissue and organ recovery members, which it estimates to be about one-third of the tissue and organ procurement organizations in the United States. The National Bone Marrow Donor Program, which includes establishments that recover peripheral blood stem cells, lists approximately 101 donor centers and 114 collection centers in the United States. The American Association of Tissue Banks (AATB) lists approximately 60 tissue banks. The Eye Bank Association of America represents about 112 eye banks, which it estimates is about 95 percent of the U.S. eye banks. The American Society for Reproductive Medicine has a membership of approximately 7,200 physicians, researchers, and other health care professionals, of which perhaps only 120 are fertility doctors who would be subject to the registration and listing requirements. In addition, it is estimated that there are about 90 semen

depositories in commercial operation. Any of the entities described above that engage in manufacture (including, but not limited to, recovery, screening, testing, processing, storage, labeling, packaging, or distribution) of human cellular or tissue-based products would be affected by the proposed rule. A great majority of these approximately 680 entities would be considered ''small'' under criteria established by the Small Business Administration. FDA invites comments on this analysis of the number of entities that may be affected by the proposed registration and listing rule.

C. Nature of the Impact

The main cost involved in implementing the proposed rule would be the time required to obtain the form, read the instructions, and complete and submit the form. FDA has no precise estimate of the initial registration and listing procedure but estimates that it should require an average of 1 hour of staff time per registrant. This estimate is supported by the estimates prepared for the completion of the blood product registration on FDA Form 2830, which is similar in length, type of information requested, and complexity to the proposed Form FDA 3356 (62 FR 11898, March 13, 1997). In addition, the proposed rule will require an update of the product list which is estimated to require about 0.5 hour of staff time. Thus, registration and listing is anticipated to require about 1.5 hours of staff time per annum. At an estimated $38.00/hour value of staff time, most registrants are expected to incur an annual cost of approximately $57.00 to comply with the requirements of the proposed rule. There are no specific educational or technical skills required to complete and submit the registration and listing form. Similar activities are generally completed by trained and qualified employees of an establishment who are intimately involved with the operations of the entity.

The proposed rule is the first step in creating a tiered, risk-based regulatory scheme that will tailor the degree of scrutiny afforded to different products to the risks associated with each product. Through registration and listing, FDA will acquire the information needed to characterize the nature and extent of the human cellular and tissue-based industry. This information will enable FDA to efficiently and effectively respond to emerging public health concerns related to human cellular or tissue-based products. Lists of industry members and their products will also help FDA disseminate educational materials and other important information regarding FDA policies, guidances, and requirements.

D. Minimizing the Impact on Small Entities

FDA recognizes that a large number of the establishments that would be required to register and list under the proposed rule will be small entities with limited resources. In recognition of this, the agency is proposing that the information to be provided during registration and listing be only that which is necessary to achieve the agency's goals of industry characterization and identification of its participants. To alleviate the impact on entities, especially small entities, FDA proposes that Form FDA 3356 be electronically retrievable. Future development of registration and listing will consider the use of electronic submissions (e-mail or Internet) and electronic signatures.

V. Proposed Effective Date

The agency proposes that any final rule that may issue based on this proposed rule become effective 180 days after its date of publication in the **Federal Register**.

VI. Environmental Impact

The agency has determined under 21 CFR 25.30(h) that this action is of a type that is categorically excluded from the preparation of an environmental assessment because these actions, as a class, will not result in the production or distribution of any substance and therefore will not result in the production of any substance into the environment.

VII. The Paperwork Reduction Act of 1995

This proposed rule contains information collection requirements that are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3520). The title, description, and respondent description of the information collection requirements are shown below with an estimate of the annual reporting burden. Included in the estimate is the time for reviewing the instructions, gathering necessary information, and completing and reviewing the report.

With respect to the following collection of information, FDA 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 proposed collection of information, including the validity of the methodology and assumptions used; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques, when appropriate, and other forms of information technology.

Title: Establishment Registration and Product Listing for Manufacturers of Human Cellular and Tissue-based Products.

Description: FDA is proposing to require establishments that recover, screen, test, process, store, label, package, or distribute any human cellular or tissue-based product to register with FDA and submit lists of the manufactured products to be updated twice a year. FDA proposes to define certain terms relevant to registration and listing, define which manufactures will be subject to the provisions of the proposed rule, and provide a form (Form FDA 3356) to be used for the entry of an entity's name and location information and its product list. FDA is proposing this action in response to the agency's public health concerns regarding products comprised of human cells or tissues, or that incorporate such cells or tissues. Through this initiative the agency will improve its ability to protect the public health by controlling the spread of communicable diseases.

Description of Respondents: Manufacturers of human cellular and tissue-based products.

TABLE 1.—ESTIMATED ANNUAL REPORTING BURDEN[1]

21 CFR	Form No.	No. of Respondents	Annual Frequency per Response	Total Annual Responses	Hours per Response (average)	Total Hours
1271	FDA 3356	680	2	1,360	0.75	1,020
207.20	FDA 3356	1	2	2	0.75	1.5

TABLE 1.—ESTIMATED ANNUAL REPORTING BURDEN[1]—Continued

21 CFR	Form No.	No. of Respondents	Annual Frequency per Response	Total Annual Responses	Hours per Response (average)	Total Hours
807.20	FDA 3356	65	2	130	0.75	97.5
TOTAL		746	2	1,492	0.75	1,119

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.

Because many manufacturers of products using human cells or tissues have not been required to register or list with FDA, the agency's ability to predict how many entities would be affected by the proposed rule is limited. The estimates for number of respondents are based on the number of entities currently registered with FDA as manufacturers of human cellular or tissue-based devices, membership information obtained from trade organizations related to the manufacturing of products utilizing human cells or tissues, and an estimate of entities that are not presently registered with FDA or members of trade organizations but that would be subject to registration under the proposed rule. The annual frequency of responses is based on the requirement in the proposed rule for the submission of an annual registration and a biannual product list updating. In practice, it is expected that the annual registration, or annual confirmation of registration for entities that have already registered once, and the first product list update of the biannual requirement will be completed simultaneously on the same form. The hours for response was obtained by averaging the estimates of 1 hour of staff time for the initial, or confirmatory registration and 0.5 hour of staff time for the update of the product list. The ''Total Hours'' column provides the estimated total number of hours for registration and listing by manufacturers of human cellular and tissue-based products under proposed part 1271, existing §§ 207.20 and 807.20 as they would be amended by the proposal, and a cumulative total for registration and listing by manufacturers of such products under all three sections.

In compliance with section 3507(d) of the Paperwork Reduction Act of 1995 (44 U.S.C. 3507(d)), the agency has submitted a copy of this proposed rule to OMB for review of the information collection provisions. Interested persons are requested to submit written comments regarding information collection by June 15, 1998, to the Office of Information and Regulatory Affairs, OMB (address above), Attention: Desk Officer for FDA.

VIII. Request for Comments

Interested person may, on or before August 12, 1998, submit to the Dockets Management Branch (address above) written comments regarding this proposal, except that comments regarding information collection provisions should be submitted in accordance with the instructions in section VII of this document. Two copies of any comments on issues other than information collection are to be submitted, except that individuals may submit one copy. Comments are to be identified with the docket number found in brackets in the heading of this document. Received comments may be seen in the office above between 9 a.m. and 4 p.m., Monday through Friday.

List of Subjects

21 CFR Part 207

Drugs, Reporting and recordkeeping requirements.

21 CFR Part 807

Confidential business information, Imports, Medical devices, Reporting and recordkeeping requirements.

21 CFR Part 1271

Human cellular and tissue-based products, Reporting and recordkeeping requirements.

Therefore, under the Federal Food, Drug, and Cosmetic Act and the Public Health Service Act, and under authority delegated to the Commissioner of Food and Drugs, it is proposed that chapter I of title 21 of the Code of Federal Regulations be amended as follows:

PART 207—REGISTRATION OF PRODUCERS OF DRUGS AND LISTING OF DRUGS IN COMMERCIAL DISTRIBUTION

1. The authority citation for 21 CFR part 207 is revised to read as follows:

Authority: 21 U.S.C. 331, 351, 352, 355, 356, 357, 360, 360b, 371, 374; 42 U.S.C. 262, 264, 271.

2. Section 207.20 is amended by adding new paragraph (f) to read as follows:

§ 207.20 Who must register and submit a drug list.

* * * * *

(f) Owners and operators of establishments or persons engaged in the recovery, screening, testing, processing, storage, or distribution of human cellular or tissue-based products, as defined in § 1271.3(e) of this chapter, that are regulated under section 351 of the Public Health Service Act and/or the Federal Food, Drug, and Cosmetic Act shall register and list those products with the Center for Biologics Evaluation and Research on Form FDA 3356 following the procedures set out in subpart B of part 1271 of this chapter, except that the additional listing information requirements in § 207.31 remain applicable.

PART 807—ESTABLISHMENT REGISTRATION AND DEVICE LISTING FOR MANUFACTURERS AND DISTRIBUTORS OF DEVICES

3. The authority citation for 21 CFR part 807 is revised to read as follows:

Authority: 21 U.S.C. 331, 351, 352, 360, 360c, 360e, 360i, 360j, 371, 374; 42 U.S.C. 264, 271.

4. Section 807.20 is amended by adding new paragraph (e) to read as follows:

§ 807.20 Who must register and submit a device list.

* * * * *

(e) Owners and operators of establishments or persons engaged in the recovery, screening, testing, processing, storage, or distribution of human cellular or tissue-based products, as defined in § 1271.3(e) of this chapter, that are regulated under section 351 of the Public Health Service Act and/or the Federal Food, Drug, and Cosmetic Act shall register and list those products with the Center for Biologics Evaluation and Research on Form FDA 3356 following the procedures set out in subpart B of part 1271 of this chapter, except that the additional listing information requirements in § 807.31 remain applicable.

5. New part 1271 is added to read as follows:

PART 1271—ESTABLISHMENT REGISTRATION AND PRODUCT LISTING FOR MANUFACTURERS OF HUMAN CELLULAR AND TISSUE-BASED PRODUCTS

Subpart A—General Provisions

Sec.
1271.1 Purpose.
1271.3 Definitions.
1271.10 Who must register and submit a list.
1271.20 Establishments not required to register or list under this part.

Subpart B—Procedures for Registration and Listing

1271.21 When to register and list.
1271.22 How and where to register and list.
1271.25 Information required for registration and listing.
1271.26 Amendments to registration.
1271.27 Assignment of a registration number.
1271.37 Inspection of establishment registration and product lists.

Authority: 42 U.S.C. 216, 243, 264, 271.

Subpart A—General Provisions

§ 1271.1 Purpose.

The purpose of this part is to create a unified registration and product listing system for establishments that manufacture human cellular and tissue-based products. Manufacturers of human cellular and tissue-based products regulated under the authority of section 361 of the Public Health Service Act are required by this part to register and list their products with the Food and Drug Administration, Center for Biologics Evaluation and Research. Under §§ 207.20(f) and 807.20(e) of this chapter, manufacturers of human cellular and tissue-based products regulated under section 351 of the Public Health Service Act and/or the Federal Food, Drug, and Cosmetic Act are required to register and list their products following the procedures in subpart B of this part.

§ 1271.3 Definitions.

The following definitions apply only to this part:

(a) *Autologous* use means the implantation, transplantation, infusion, or transfer of a human cellular or tissue-based product back into the individual from whom the cells or tissue comprising such product were removed.

(b) *Establishment* means a place of business under one management, at one general physical location, that engages in the manufacture of human cellular or tissue-based products. The term includes, among others, facilities that engage in contract manufacturing services for a manufacturer of human cellular or tissue-based products. The term also includes any individual, partnership, corporation, association, or other legal entity engaged in the manufacture of human cellular or tissue-based products, except that an individual engaged solely in the procurement or recovery of cells or tissues or under contract to a registered establishment is not required to independently register.

(c) *Family-related allogeneic use* means the implantation, transplantation, infusion, or transfer of a human cellular or tissue-based product into a first-degree blood relative of the individual from whom cells or tissue comprising such product were removed.

(d) *Homologous use* means the use of a cellular or tissue-based product for replacement or supplementation and:

(1) For structural tissue-based products, occurs when the tissue is used for the same basic function that it fulfills in its native state, in a location where such structural function normally occurs; or

(2) For cellular and nonstructural tissue-based products, occurs when the cells or tissue is used to perform the function(s) that they perform in the donor.

(e) *Human cellular or tissue-based product* means a product containing human cells or tissues or any cell or tissue-based component of such a product. The following products are not considered human cellular or tissue-based products and establishments that manufacture only one or more of the following would not be subject to the registration or listing provisions of this part:

(1) Vascularized human organs for transplantation;

(2) Whole blood or blood components or blood derivative products subject to listing under part 607 of this chapter;

(3) Secreted or extracted human products, such as milk, collagen, and cell factors;

(4) Minimally manipulated bone marrow;

(5) Ancillary products used in the propagation of cells or tissues; or

(6) Cells, tissues or organs derived from animals.

(f) *Manufacture* means, but is not limited to, any or all steps in the recovery, screening, testing, processing, storage, labeling, packaging, or distribution of any human cellular or tissue-based product.

(g) *Minimal manipulation* means:

(1) For structural tissue, processing that does not alter the original relevant characteristics of the tissue relating to the tissue's utility for reconstruction, repair, or replacement; and

(2) For cells and nonstructural tissues, processing that does not alter the relevant biological characteristics of cells or tissues.

(h) *Transfer* means the placement of human reproductive cells or tissues into a human recipient.

§ 1271.10 Who must register and submit a list.

All owners and operators of establishments, both foreign and domestic, that manufacture human cellular and tissue-based products, whether or not the product enters into interstate commerce, are required under this part to register with the Food and Drug Administration and submit to the agency a list of each human cellular or tissue-based product manufactured, if such product is:

(a) Minimally manipulated;

(b) Not promoted or labeled for any use other than a homologous use;

(c) Not combined with or modified by the addition of any nontissue or noncellular component that is a drug or a device; and

(d) Does not have a systemic effect; except that a human cellular or tissue-based product that meets the requirements in paragraphs (a), (b), and (c) of this section may have a systemic effect if the product is for:

(1) Autologous use;

(2) Family-related allogeneic use; or

(3) Reproductive use and contains human reproductive cells or tissue.

§ 1271.20 Establishments not required to register or list under this part.

The following establishments are not required to register or submit product listings under this part:

(a) Establishments that use human cellular or tissue-based products solely for nonclinical scientific or educational purposes;

(b) Establishments that remove human cellular or tissue-based products from an individual and implant such cells or tissues into the same individual during the same surgical procedure;

(c) Carriers who accept, receive, carry, hold, or deliver human cellular or tissue-based products in the usual course of business as carriers; and

(d) Establishments that only receive or store human cellular or tissue-based products solely for pending scheduled implantation, transplantation, infusion, or transfer within the same facility.

Subpart B—Procedures for Registration and Listing

§ 1271.21 When to register and list.

(a) Owners and operators of establishments required to register and list under § 1271.10 or required under other provisions of this chapter to follow the procedures in subpart B of this part shall register within 5 days after beginning operations and shall submit a list of every product that is manufactured.

(b) Owners and operators of establishments shall update their registration annually by December 31, except as required by § 1271.26. Annual registration may be accomplished in conjunction with the updating of product lists under paragraph (c) of this section.

(c)(1) Owners and operators of establishments shall update their product lists during each June and December or, at their discretion, at the time the change occurs, with the following information:

(i) A list of each human cellular or tissue-based product introduced by the registrant for distribution that has not been included in any list previously submitted. The registrant shall provide all of the information required by § 1271.25(b) for each such product.

(ii) A list of each human cellular or tissue-based product formerly listed in accordance with paragraph (a) of this section and for which distribution has been discontinued, including for each product so listed, the identity by established name and proprietary name, and the date of discontinuance. It is requested but not required that the reason for discontinuance of distribution be included with this information.

(iii) A list of each human cellular or tissue-based product for which a notice of discontinuance was submitted under paragraph (c)(1)(ii) of this section and for which distribution has been resumed, including the identity by established name and proprietary name, the date of resumption, and any other information required by § 1271.25(b) not previously submitted.

(iv) Any material change in any information previously submitted. Material changes include any change in whether the product meets the criteria set out in § 1271.10.

(2) When no changes have occurred since the previously submitted list, no report is required.

§ 1271.22 How and where to register and list.

(a) Establishment registration, product listing, and updates of registration and listing shall be submitted on Form FDA 3356 to the Center for Biologics Evaluation and Research (HFM–370), Food and Drug Administration, 1401 Rockville Pike, Rockville, MD 20852–1448, Attention: Tissue Establishment Registration Coordinator, or electronically in accordance with instructions provided with Form FDA 3356.

(b) Copies of Form FDA 3356 can be obtained from the Center for Biologics Evaluation and Research (HFM–370), Food and Drug Administration, 1401 Rockville Pike, Rockville, MD 20852–1448, Attention: Tissue Establishment Registration Coordinator (from any Food and Drug Administration district office); by calling the CBER Voice Information System at 1–800–835–4709 or 301–827–1800, or by calling the Fax Information System at 1–888–CBER–FAX or 301–827–3844. Persons with access to the Internet may obtain the document using the World Wide Web (WWW) by connecting to: CBER at ''http//www.fda.gov/cber/publication.htm''.

§ 1271.25 Information required for registration and listing.

(a) Registration shall include:

(1) The legal name(s) of the establishment;

(2) Each location, including the street address of the establishment and the postal service zip code;

(3) The name, address, and title of the reporting official; and

(4) A signed and dated statement by the reporting official affirming that all information contained in the registration and listing form is true and accurate.

(b) Listing information shall include all human cellular or tissue-based products (including the established name and the proprietary name) that are recovered, screened, tested, processed, stored, labeled, packaged, and distributed. Listing information shall also include a statement of whether each product meets the criteria set out in § 1271.10.

(c) Copies of all contract service agreements shall be available at the time of inspection of the establishment.

§ 1271.26 Amendments to registration.

Changes in the ownership or location of an establishment shall be submitted as an amendment to registration within 5 days of such changes.

§ 1271.27 Assignment of a registration number.

(a) A permanent registration number will be assigned to each location.

(b) FDA acceptance of establishment registration and listing forms for human cellular and tissue-based products does not constitute a determination that an establishment is in compliance with applicable rules and regulations.

§ 1271.37 Inspection of establishment registration and product lists.

(a) A copy of the Form FDA 3356 filed by each establishment will be available for inspection at the Office of Communication, Training, and Manufacturers Assistance (HFM–48), Center for Biologics Evaluation and Research, Food and Drug Administration, 1401 Rockville Pike, suite 200N, Rockville, MD 20852–1448. In addition, there will be available for inspection at each of the Food and Drug Administration district offices the same information for firms within the geographical area of such district office. Upon request and receipt of a self-addressed stamped envelope, verification of a registration number or the location of a registered establishment will be provided. The following information submitted under the human cellular and tissue-based product requirements is illustrative of the type of information that will be available for public disclosure when it is compiled:

(1) A list of all human cellular and tissue-based products;

(2) A list of all human cellular and tissue-based products manufactured by each establishment;

(3) A list of all human cellular and tissue-based products discontinued; and

(4) All data or information that has already become a matter of public record.

(b) Requests for information regarding human cellular and tissue-based product establishment registrations and product listings should be directed to the Office of Communication, Training and Manufacturers Assistance (HFM–48), Center for Biologics Evaluation and Research, Food and Drug Administration, 1401 Rockville Pike, suite 200N, Rockville, MD 20852–1448.

Dated: March 10, 1998.

Michael A. Friedman,

Lead Deputy Commissioner for the Food and Drug Administration.

Donna E. Shalala,

Secretary of Health and Human Services.

[FR Doc. 98–12751 Filed 5–13–98; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF LABOR

Mine Safety and Health Administration

30 CFR Parts 56, 57, 62, 70 and 71

RIN 1219–AB05

Occupational Noise Exposure; Correction

AGENCY: Mine Safety and Health Administration, Labor.

ACTION: Proposed rule; correction.

SUMMARY: This document corrects the RIN number to the rule for health standards for occupational noise exposure published in the **Federal Register** on December 31, 1997.

FOR FURTHER INFORMATION CONTACT: Patricia W. Silvey, Director, Office of Standards, Regulations, and Variances, MSHA, (703) 235–1910.

Correction

On December 31, 1997, (62 FR 68468) MSHA published a supplemental proposed rule on health standards for occupational noise exposure. This document corrects an error that appears on the front page of the notice. The RIN number 1219–AA53 is corrected to read 1219–AB05.

Dated: May 7, 1998.

Patricia W. Silvey,

Director, Office of Standards, Regulations, and Variances.

[FR Doc. 98–12757 Filed 5–13–98; 8:45 am]

BILLING CODE 4510–43–P

DEPARTMENT OF TRANSPORTATION

Coast Guard

33 CFR Ch. I

46 CFR Ch. I

[USCG–1997–3198]

Alternate Convention Tonnage

AGENCY: Coast Guard, DOT.

ACTION: Notice; request for comments; extension of comment period.

SUMMARY: The Coast Guard is extending the comment period on its notice requesting comments on the potential implementation of alternate convention tonnage thresholds to October 15, 1998, to allow additional time for public comment.

DATES: Comments must be received on or before October 15, 1998.

ADDRESSES: You may mail comments to the Docket Management Facility, [USCG–1997–3198], U.S. Department of Transportation, room PL–401, 400 Seventh Street SW., Washington DC 20590–0001, or deliver them to room PL–401, located on the Plaza Level of the Nassif Building at the same address between 10 a.m. and 5 p.m., Monday through Friday, except Federal holidays. The telephone number is 202–366–9329.

The Docket Management Facility maintains the public docket for this rulemaking. Comments will become part of this docket and will be available for inspection or copying at room PL–401, located on the Plaza Level of the Nassif Building at the same address between 10 a.m. and 5 p.m., Monday through Friday, except Federal holidays. You may also access this docket on the Internet at http://dms.dot.gov.

FOR FURTHER INFORMATION CONTACT: For questions about the notice, call Lieutenant John G. White, Office of Standards Evaluation and Development (G–MSR–2), Coast Guard, telephone 202–267–6885. For information on the public docket, call Carol Kelley, Coast Guard Dockets Team Leader, or Paulette Twine, Chief, Documentary Services Division, Department of Transportation, telephone 202–366–9329.

SUPPLEMENTARY INFORMATION:

Request for Comments

The Coast Guard encourages you to participate in this request by submitting written data, views, or arguments. If you submit comments, you should include your name and address, identify this notice (USCG–1997–3198) and the specific section or question in this document to which your comments apply, and give the reason for each comment. Please submit all comments and attachments in an unbound format, no larger than 8½ by 11 inches, suitable for copying and electronic filing to the DOT Docket Management Facility at the address under **ADDRESSES**. If you want acknowledgment of receipt of your comments, you should enclose a stamped, self-addressed postcard or envelope.

The Coast Guard will consider all comments received during the comment period.

The Coast Guard may schedule a public meeting depending on input received in response to this notice. You may request a public meeting by submitting a request to the address under **ADDRESSES**. The request should include the reasons why a meeting would be beneficial. If the Coast Guard determines that a public meeting should be held, it will hold the meeting at a time and place announced by a later notice in the **Federal Register**.

Background and Purpose

On February 4, 1998, the Coast Guard published a notice requesting comments in the **Federal Register** (63 FR 5767) to announce it was considering development of alternate tonnage thresholds for certain vessels based on the measurement system established under the International Convention on Tonnage Measurement of Ships, 1969. Existing tonnage thresholds in domestic laws and regulations are based on the U.S. regulatory measurement system. Establishing alternate convention tonnages as an option for the application of domestic regulations may result in the building of safer, more efficient vessels and may enable designers and operators of U.S. vessels to be more competitive in the international market. The Coast Guard asked for comments on the issues and questions listed in the notice. Due to the special need for public comment on this issue and requests for a comment period extension from the public, the Coast Guard is extending the comment period to October 15, 1998.

Dated: May 8, 1998.

Joseph J. Angelo,

Acting Assistant Commandant for Marine Safety and Environment Protection.

[FR Doc. 98–12847 Filed 5–13–98; 8:45 am]

BILLING CODE 4910–15–M

LIBRARY OF CONGRESS

Copyright Office

37 CFR Parts 201 and 256

[Docket No. RM 98–4]

Cable Compulsory Licenses: Application of the 3.75% Rate

AGENCY: Copyright Office, Library of Congress.

ACTION: Proposed amendments and policy statement.

SUMMARY: On April 30, 1997, the Copyright Office published an amendment to its rules to allow a cable system to calculate its copyright liability for carriage of distant signals on a partially permitted/partially non-permitted basis where applicable. Under the new rule, a cable system will apply the current base rates and the syndicated exclusivity surcharge, where applicable, to those subscribers in communities where the signal would have been permitted on or before June 24, 1981, and the 3.75% rate to those subscribers in communities where the signal would not have been permitted before that date. Both the base rate fee

and the 3.75% fee shall be applied toward the required minimum fee. These changes, however, are not reflected clearly in the current regulations. Therefore, the Copyright Office is proposing amendments which would harmonize the existing regulations with the new methodology for calculating the royalty fees for carriage of partially permitted/partially non-permitted distant signals.

DATES: Comments on the proposed technical amendments are due June 15, 1998.

FOR FURTHER INFORMATION CONTACT: David O. Carson, General Counsel, or Tanya M. Sandros, Attorney Advisor, Copyright GC/I&R, P.O. Box 70400, Southwest Station, Washington, D.C. 20024. Telephone (202) 707–8380 or Telefax (202) 707–8366.

SUPPLEMENTARY INFORMATION: Section 111 of the Copyright Act, 17 U.S.C., establishes a compulsory license which authorizes a cable system to make secondary transmissions of copyrighted works embodied in broadcast signals provided that it pays a royalty fee according to the fee structure set out in section 111 and meets all other conditions of the statutory license. The license also provides for an opportunity to adjust the statutory royalty rates once every five years, see 17 U.S.C. 803(a)(2), or whenever the Federal Communications Commission (FCC) amends its rules to allow a cable system to carry additional signals beyond the local service area of the primary transmitter, or its rules governing syndicated program and sports exclusivity. See 17 U.S.C. 801(b)(2)(B)–(C).

The FCC's distant signal and syndicated program exclusivity rules were promulgated in 1972. Cable Television Report and Order, 36 F.C.C. 2d 143 (1972). In 1976 after Congress created the cable compulsory license, the FCC conducted an inquiry to reexamine the need for these rules and determined ultimately that there was no longer a need for maintaining the distant signal and syndicated program exclusivity rules. Report and Order in Docket Nos. 20988 and 21284, 79 FCC2d 663 (1980).

In response to the FCC's order repealing its distant signal carriage and program syndication exclusivity restrictions on cable retransmissions, see Report and Order in Docket Nos. 20988 and 21284, 79 F.C.C. 2d 663 (1980), [1] the National Cable Television Association (NCTA) filed a petition with the former Copyright Royalty Tribunal (CRT) to initiate a cable rate adjustment proceeding in 1981. [2] In that proceeding, the CRT set two new rate structures, apart from those specified in the statute, to compensate the copyright owners for the loss of the surrogate copyright protection afforded them under the FCC rules: a 3.75% rate for the secondary transmission of formerly non-permitted distant signals, and a syndicated exclusivity surcharge for the secondary transmission of permitted signals that had been subject to the FCC's former syndicated program exclusivity regulations. 47 FR 52146 (November 19, 1982).

In 1984, the Copyright Office adopted final regulations to implement the new rate decision of the CRT, but when questions concerning the proper application of the rules concerning the 3.75% rate arose, the Office decided to take no position on this issue. See 49 FR 26722, 26726 (June 29, 1984). Instead, the Office allowed each cable system to decide whether to report a distant signal as entirely permitted, entirely non-permitted, or in some instances as partially permitted and partially non-permitted, and calculate its copyright liability accordingly.

This practice comes to an end under a regulation promulgated last year which directs cable systems to calculate the 3.75% rate fee for distant signals on a ''partially permitted/partially non-permitted'' basis. 62 FR 23360 (April 30, 1997). Under the new rule, a cable system shall calculate its royalty fees for a partially permitted/partially non-permitted signal on the basis of gross receipts from subscribers within the relevant communities, without regard to whether the subscriber actually receives the signal. If the distant signal is considered permitted with respect to particular communities under the Federal Communication Commission's former distant carriage rules in effect on June 24, 1981 (or in the case of those systems that commenced operation after June 24, 1981, would have been considered permitted subject to these regulations), then the cable system shall apply the base rate to the signal in those communities. Alternatively, if the FCC rules would not have allowed carriage of the signal with respect to specific communities, then the cable system must apply the 3.75% rate to the signal. 62 FR 23360 (April 30, 1997). In an effort to clarify how to file a statement of account in those instances where the cable system carries partially permitted/partially non-permitted signals, the Office proposes additional regulatory language describing how to create discrete subscriber groups for calculating the appropriate 3.75% fee, the base fee, and any applicable syndicated exclusivity surcharge. Similarly, for the accounting period beginning January 1, 1998, we have begun revision of the statement of account form to include some specific changes and special instructions to guide cable systems in making these computations.

The Office also proposes amending 37 CFR 256.2 by specifying ''paragraphs (a)(2) through (4)'' when the reference is to the base fee in place of the more general reference to ''paragraph (a).'' The Office makes this proposal because paragraph (a)(1) explains how to calculate the minimum fee whereas paragraphs (a)(2) through (4) explain the methodology for calculating the base fee. The Office also suggests adding amendatory language to § 256.2(a)(1) which makes it clear that both the base fee and the 3.75% fee shall be applied toward the cable system's obligation to pay a statutory minimum.[3] 17 U.S.C. 111(d)(1)(B)(i). These suggested changes do not effect the substance of the current regulations in any material way.

List of Subjects

37 CFR Part 201

Cable television, Copyright, Jukeboxes, Literary works, Satellites.

37 CFR Part 256

Cable television, Copyright.

In consideration of the foregoing, parts 201 and 256 are proposed to be amended as follows:

PART 201—GENERAL PROVISIONS

1. The authority citation for part 201 continues to read as follows:

Authority: 17 U.S.C. 702.

2. Section 201.17(h)(2)(iv) is amended by adding the phrase ''and the

[1] The U.S. Court of Appeals for the Second Circuit stayed the FCC order pending an appeal of its decision. On June 16, 1981, the court upheld the FCC order, see Malrite T.V. of New York, Inc. v. F.C.C., 652 F.2d 1140 (2d Cir. 1981), cert. denied, 454 U.S. 1143 (1982), and vacated the stay on June 25, 1981.

[2] The American Society of Composers, Authors, and Publishers (ASCAP), and the Motion Picture Association of America (MPAA) also filed separate petitions requesting an adjustment of the cable rates with the CRT in 1981.

[3] In a policy statement issued in 1986, the Office considered whether a cable system could apply both the base fee and the 3.75% fee toward the minimum fee imposed by law, see 17 U.S.C. 111(d)(1)(B)(i), and determined that the minimum fee would not be added to the base fee in those instances where the 3.75% fee exceeded the minimum fee. 51 FR 599 (January 7, 1986). In making this decision, the Office relied upon statements in the House report accompanying the Copyright Act of 1976, which indicated that any fee for a distant signal should be applied against the minimum. H.R. Rep. No. 94–1476, at 96 (1976).

syndicated exclusivity surcharge, where applicable,'' after the phrase ''the current base rate''.

3. Section 201.17(h)(2)(iv) is amended by adding three sentences to the end of the paragraph to read as follows:

§ 201.17 Statements of Account covering compulsory licenses for secondary transmissions by cable systems.

* * * * *

(h) * * *

(2) * * *

(iv) * * * The calculations shall be based upon the gross receipts from subscribers within the relevant communities. No cable system shall make its calculations based solely on the number of subscribers receiving a particular signal. For partially-distant stations, gross receipts shall be the total gross receipts from subscribers outside the local service area.''

* * * * *

PART 256—ADJUSTMENT OF ROYALTY FEE FOR CABLE COMPULSORY LICENSE

4. The authority citation for part 256 continues to read as follows:

Authority: 17 U.S.C. 801–803.

5. Section 256.2(a)(1) is amended by removing the word ''fee'' and adding the word ''fees'' before the phrase '', if any,''.

6. Section 256.2(a)(1) is amended by adding the phrase ''and (c)'' after ''(4)''.

7. Section 256.2(c) is amended by adding the phrase ''(2) through (4)'' after the ''(a)'' in the phrase which reads ''the royalty rate shall be in lieu of the royalty rates specified in paragraphs (a) and (d) of this section,''.

Dated: May 7, 1998.

Marybeth Peters,

Register of Copyrights.

[FR Doc. 98–12652 Filed 5–13–98; 8:45 am]

BILLING CODE 1410–31–P

FEDERAL COMMUNICATIONS COMMISSION

47 CFR Parts 0, 1, 13, 22, 24, 26, 27, 80, 87, 90, 97, and 101

[WT Docket No. 98–20; DA 98–827]

Facilitate the Development and Use of the Universal Licensing System

AGENCY: Federal Communications Commission.

ACTION: Notice of proposed rulemaking; extension of comment period.

SUMMARY: The Commission has released an order which extends the filing deadlines for comments on its *Notice of Proposed Rulemaking* (FCC 98–25) regarding the Universal Licensing System. We also waive the rules that require the paper filing of comments and replies. Consequently, the electric filing of comments and replies will be permitted. These steps have been taken to permit more thorough, detailed comments and replies on the proposed rulemaking to be filed with the Commission. The effect will be to improve the quality of the Commission's final determinations in this rulemaking.

DATES: Comments are due on or before May 22, 1998; reply comments are due on or before June 8, 1998.

ADDRESSES: Federal Communications Commission, Room 222, 1919 M Street, NW., Washington, DC 20554.

FOR FURTHER INFORMATION CONTACT: Wilbert Nixon or Chris Gacek of the Policy & Rules Branch, Commercial Wireless Division, Wireless Telecommunications Bureau, (202) 418–7240.

SUPPLEMENTARY INFORMATION: The following documents relate to the aforementioned rulemaking *Notice of Proposed Rulemaking*, WT Docket No. 98–20, FCC 98–25, 63 FR 16938, April 7, 1998, (*ULS NPRM*); Electronic Filing of Documents in Rulemaking Proceedings, *Report and Order*, GC Docket No. 97–113, FCC 98–56, 63 FR 24121, May 1, 1998; Implementation of Section 255 of the Telecommunications Act of 1996, *Notice of Proposed Rulemaking*, WT Docket No. 96–198, FCC 98–55 (adopted April 2, 1998; released April 20, 1998), paragraph 185.

The order may be found on the internet at: <http://www.fcc.gov/Bureaus/Wireless/Orders/1998/da980827.txt>.

Federal Communications Commission.

Ramona E. Melson,

Chief, Policy & Rules Branch, Commercial Wireless Division, Wireless Telecommunications Bureau.

[FR Doc. 98–12835 Filed 5–13–98; 8:45 am]

BILLING CODE 6712–01–M

FEDERAL COMMUNICATIONS COMMISSION

47 CFR Chapter 1

[MM Docket No. 98–35; DA: 98–854]

Broadcast Services; Radio Stations, Television Stations

AGENCY: Federal Communications Commission.

ACTION: Proposed rule; extension of comment period.

SUMMARY: Pursuant to the request of the National Association of Broadcasters, the Chief, Mass Media Bureau, acting under delegated authority, extends the comment and reply comment deadlines, on whether any or all of its broadcast ownership rules are no longer in the public interest as a result of competition, for sixty days. The new deadlines will be July 21, 1998, for comments and August 21, 1998, for reply comments.

DATES: Comments are now due by July 21, 1998, and reply comments are due by August 21, 1998.

ADDRESSES: Federal Communications Commission, 1919 M Street, N.W., Washington, D.C. 20554

FOR FURTHER INFORMATION CONTACT: Roger Holberg, Mass Media Bureau, Policy and Rules Division, (202) 418–2134, or Dan Bring, Mass Media Bureau, Policy and Rules Division, (202) 418–2170.

SUPPLEMENTARY INFORMATION: This is a synopsis of the Commission's *Order* in MM Docket No. 98–35, DA–854, adopted and released May 7, 1998. The complete text of this *Order* is available for inspection and copying during normal business hours in the FCC Reference Center (Room 239), 1919 M Street, N.W., Washington, D.C., and may also be purchased from the Commission's copy contractor, International Transcription Service, (202) 857–3800, 1231 20th Street, N.W., Washington, D.C. 20036. The *Order* is also available on the Internet at the Commission's web site: http://www.fcc.gov.:

1. On March 12, 1998, the Commission, pursuant to Section 202(h) of the Telecommunications Act of 1996 (''Telecom Act''),[1] adopted a Notice of Inquiry (''Notice''), 63 FR 15353, March 31, 1998, in this proceeding soliciting comment on all of the Commission's broadcast ownership rules except for those already being examined in pending proceedings. The deadline for filing comments was set at May 22, 1998, and for reply comments June 22, 1998.

2. On April 20, 1998, the National Association of Broadcasters (''NAB'') filed a ''Motion for Extension of Time of Comment and Reply Comment Deadlines'' seeking a sixty-day extension of the comment and reply comment deadlines. NAB states that it has identified several areas pertinent to the biennial review in which it plans to complete research and analysis. It believes that the results of these studies, and additional studies currently being

[1] Pub. L. No. 104–104, 110 Stat. 56 (1996).

discussed among NAB's staff and other parties, will be helpful to the Commission's inquiry. Furthermore, NAB asserts, the issues raised by the Notice, and the NAB's position on them, will be major subjects of its Joint Board of Directors meeting scheduled June 27–30, 1998.

3. We will grant the requested extension. Although the Commission has a policy of not routinely granting extensions of time for filing comments in rulemaking proceedings [2] this proceeding raises a number of complex issues concerning the nature, dimension, and competitiveness of the several markets in which the subject rules operate. A well-documented record will best conduce to an informed decision as to which of the Commission's broadcast ownership rules are no longer necessary in the public interest as a result of competition. Additionally: (1) The National Association of Broadcasters represents many of the parties that will most directly be affected by any actions we take in this proceeding; (2) it has shown good cause why a sixty-day extension will enable it to provide more well-informed comments; and (3) no party will be prejudiced by this extension. Rather, all may make good use of this added time to prepare and present well-supported comments on these important issues.

4. This action is taken pursuant to the authority found in Sections 4(i) and 303(r) of the Communications Act of 1934, as amended, 47 U.S.C. 154(i) and 303(r), and sections 204(b), 0.283, and 1.45 of the Commission's Rules.

Federal Communications Commission.

Roy J. Stewart,

Chief, Mass Media Bureau.

[FR Doc. 98–12668 Filed 5–13–98; 8:45 am]

BILLING CODE 6712–01–P

[2] 47 CFR 1.46.

DEPARTMENT OF TRANSPORTATION

Federal Highway Administration

49 CFR Part 393

[FHWA Docket No. FHWA–97–3201]

RIN 2125–AE15

Parts and Accessories Necessary for Safe Operation; Rear Impact Guards and Rear Impact Protection

AGENCY: Federal Highway Administration (FHWA), DOT.

ACTION: Notice of proposed rulemaking (NPRM); request for comments.

SUMMARY: The FHWA is proposing to amend the Federal Motor Carrier Safety Regulations (FMCSRs) to require that certain trailers and semitrailers with a gross vehicle weight rating (GVWR) of 4,536 kilograms (kg) (10,000 pounds) or more, and manufactured on or after January 26, 1998, be equipped with rear impact guards that meet the requirements of Federal Motor Vehicle Safety Standard (FMVSS) No. 223. The rear impact guards would be installed to ensure that the trailer or semitrailer meets the rear impact protection requirements of FMVSS No. 224. This rulemaking is intended to ensure that the rear impact protection requirements of the FMCSRs are consistent with the FMVSSs and to improve the safety of operation of commercial motor vehicles (CMVs) by reducing the incidence of passenger compartment intrusion during underride accidents in which the passenger vehicle strikes the rear of the trailer. With regard to trailers manufactured before January 26, 1998, the FHWA is not proposing that motor carriers be required to retrofit a rear impact guard that conforms to FMVSS No. 223. However, motor carriers operating these trailers would be required to continue complying with the FHWA's current requirements for rear impact guards and rear impact protection.

DATES: Comments must be received on or before July 13, 1998.

ADDRESSES: Submit written, signed comments to the docket number that appears in the heading of this document to the Docket Clerk, U.S. DOT Dockets, Room PL–401, 400 Seventh Street, SW., Washington, DC 20590–0001. All comments received will be available for examination at the above address from 10 a.m. to 5 p.m., et., Monday through Friday, except Federal holidays. Those desiring notification of receipt of comments must include a self-addressed, stamped envelope or postcard.

FOR FURTHER INFORMATION CONTACT: Mr. Larry W. Minor, Office of Motor Carrier Research and Standards, (202) 366–4009, or Mr. Charles Medalen, Office of the Chief Counsel, (202) 366–1354, Federal Highway Administration, Department of Transportation, 400 Seventh Street, SW., Washington, D.C. 20590. Office hours are from 7:45 a.m. to 4:15 p.m., e.t., Monday through Friday, except Federal holidays.

SUPPLEMENTARY INFORMATION:

Electronic Access

Internet users can access all comments received by the U.S. DOT Dockets, Room PL–401, by using the universal resource locator (URL): http://dms.dot.gov. It is available 24 hours each day, 365 days each year. Please follow the instructions online for more information and help.

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Background

On January 24, 1996 (61 FR 2003), the National Highway Traffic Safety Administration (NHTSA) published a final rule creating Federal Motor Vehicle Safety Standards (FMVSSs) Nos. 223, Rear Impact Guards, and 224, Rear Impact Protection. The requirements apply to trailers manufactured on or after January 26, 1997.

The first standard, FMVSS No. 223 (49 CFR 571.223), specifies performance requirements that rear impact guards must meet before they can be installed on new trailers and semitrailers. It specifies strength requirements for the impact guards as well as test procedures that manufacturers and the NHTSA will use to determine compliance with the standard. The standard also requires the guard manufacturer to permanently label the impact guard to certify that the device meets the requirements and to provide instructions on the proper installation of the guard.

The second standard, FMVSS No. 224 (49 CFR 571.224), requires that most new trailers and semitrailers with a gross vehicle weight rating (GVWR) of 4,536 kg (10,000 pounds) or more be equipped with a rear impact guard meeting FMVSS No. 223. Requirements for the location of the guard relative to the rear end and sides of the trailer are also specified in the vehicle standard. In addition, the vehicle standard requires that the guard be mounted on the trailer or semitrailer in accordance with the instructions of the guard manufacturer.

History of Current FHWA Requirements

The first Federal requirements concerning heavy vehicle rear underride protection were issued in 1952 by the Bureau of Motor Carriers of the Interstate Commerce Commission (ICC) (presently the Office of Motor Carriers of the Federal Highway Administration). The regulation, which is still in effect (49 CFR 393.86), requires heavy trucks, trailers, and semitrailers to be equipped with a rear-end protection device

designed to help prevent underride. The rule requires that the ground clearance of the underride guard be no more than 760 mm (30 inches) when the vehicle is empty. The rule also requires that the underride guard be located no more than 610 mm (24 inches) forward of the rear of the vehicle and that it extend laterally to within 460 mm (18 inches) of each side. The underride device is required to be ''substantially constructed and firmly attached.''

The language that the ICC adopted was based upon the recommendations of the Bumper Heights Committee of the Society of Automotive Engineers (SAE). On January 2, 1947, the Director of the Bureau of Motor Carriers sent a letter to the SAE requesting that the Bumper Heights Committee consider expanding its work on passenger car bumpers to include recommendations for rear bumpers on heavy vehicles. The SAE provided a report entitled ''Recommendations Covering Rear Bumpers on Trucks and Trailers,'' in September 1947. A copy of the report is included in the docket file.

NHTSA and FHWA Efforts To Develop Improved Underride Regulations

Efforts to improve the Federal requirements for rear underride protection started in the late 1960's. On October 14, 1967, the FHWA's National Highway Safety Bureau (NHSB, the predecessor of the NHTSA) issued an advance notice of proposed rulemaking (ANPRM) requesting comments on possible amendments to the Federal Motor Vehicle Safety Standards (32 FR 14278).

On March 19, 1969, the NHSB issued a notice of proposed rulemaking on rear underride protection devices (34 FR 5383). The proposal would have applied to all new trucks and trailers (except pole trailers) with a GVWR greater than 4,536 kgs (10,000 pounds). The maximum ground clearance for the underride protection would have been 457 mm (18 inches). The proposal also included a static strength test that would have required that the device deflect no more than 381 mm (15 inches) forward of the rearmost part of the vehicle when a force of 333,600 Newtons (75,000 pounds) was applied.

In 1970, the NHSB (acting as a regulatory agency within the Department of Transportation but independent of the FHWA) issued a supplemental notice of proposed rulemaking (SNPRM) in response to comments to the 1969 NPRM (35 FR 12956, August 14, 1970). The commenters had expressed concern about operational problems that would be created if the ground clearance for the rear underride guard could not exceed 457 mm (18 inches). Commenters also expressed concerns about the test procedures. Although the NHSB did not increase the ground clearance for the underride guard, the agency proposed reducing the test force requirements from 333,600 Newtons (75,000 pounds) to 222,400 Newtons (50,000 pounds).

The NHTSA (successor to the NHSB pursuant to the Highway Safety Act of 1970) terminated the rulemaking on rear underride on June 18, 1971 (36 FR 11750). The NHTSA stated that ''[b]ased upon the information received in response to the notices and evaluations of cost and accident data, the Administration has concluded that, at the present time, the safety benefits achievable in terms of lives and injuries saved would not be commensurate with the cost of implementing the proposed requirements.''

In response to a petition for rulemaking from the Insurance Institute for Highway Safety (IIHS) and a March 16, 1977, hearing before the Senate Committee on Commerce, Science, and Transportation on auto-truck crash safety, the NHTSA and the FHWA jointly issued an ANPRM requesting information on possible revisions to 49 CFR 571 and 49 CFR 393.86 (42 FR 43414, August 29, 1977). The notice stated:

> [I]t is the conclusion of the Department of Transportation that the present requirements should be reexamined because the problem of rear underride accidents remains, and it is likely to become more severe as automobiles become smaller and are used in greater numbers. Improved rear end protection devices on heavy motor vehicles that may contribute substantially to saving lives and preventing injuries may be possible without incurring either unacceptable costs or unacceptable restrictions on operations.

The notice also indicated that the FHWA was starting a research program to ''establish the level of rear underride protection needed to reduce injuries and fatalities in a variety of realistic accident situations.'' The goals of the research program were described:

> This will be an attempt to develop a number of rear underride designs to determine the desired level of performance, giving due consideration to cost, weight, and operational problems. Results of this contract effort will be used in determining what form any amendments to FMCSR Section 393.86 and FMVSS Part 571 should take.

The FHWA and the NHTSA worked together in developing a rear underride research program and initiated two separate studies. The FHWA contracted with the Texas Transportation Institute (TTI) of Texas A&M University to develop low-cost underride guards that would be practical and effective in preventing underride. The NHTSA contracted with Dynamic Sciences, Inc. (DSI) to develop compliance test procedures for the guards. These joint contract efforts were intended to generate sufficient data to support a rule applicable to vehicles with a GVWR greater than 4,536 kg (10,000 pounds).

The research contracts focused on preventing excessive underride primarily through the use of a rigid guard having a low ground clearance. This approach was similar to that followed by IIHS in a test program conducted in 1976. The tests performed by TTI and DSI demonstrated what the IIHS program had shown earlier: Excessive underride could be prevented with rigid guards. However, the tests also indicated that rigid guards increase the deceleration forces experienced by passenger car occupants during a crash and therefore increase the risk of injury due to hazards other than underride.

Restrained anthropomorphic test devices (commonly referred to as test dummies) placed in passenger cars that were crashed into the rigid guards at speeds of 56.3 km/hr (35 mph) or more experienced injury responses (forces detected by sensors in the test dummies) that were outside of the ranges allowed under FMVSS No. 208, Occupant Crash Protection. This was significant because the accident statistics available at that time indicated that most accidents in which a passenger car collided with a heavy vehicle rear end were survivable. The data further indicated that a majority of the fatalities that occurred took place in accidents that did not involve excessive underride.

Dynamic Sciences, Inc. also tested production underride devices that were typical of the guards in use at the time. The guards were not able to prevent small cars from excessively underriding test trailers at collision speeds above 48.3 km/hr (30 mph). In these tests, the dummies experienced injury responses that were above the limits of FMVSS No. 208. When small cars were crashed into the guards, the guards did not fail (i.e., did not permanently deform). In tests of large cars at collision speeds of 48.3 km/hr (30 mph), underride was excessive in offset collisions but not when the collision was centric. Occupant injury responses were within the allowable limits of FMVSS No. 208 and none of the guards failed. Occupant injury responses were also within the permissible limits of FMVSS No. 208 when the large cars were crashed into the guard at 64.4 km/hr (40 mph). However, the underride was excessive

and the guards were permanently deformed.

In addition, the TTI program tested a hydraulic energy-absorbing guard manufactured by Quinton-Hazell Automotive Ltd. (Quinton-Hazell). The Quinton-Hazell device was very effective at preventing excessive underride, reducing occupant injury responses, and reducing damage to the colliding vehicle.

The TTI also conducted two tests in which passenger vehicles were crashed into a van-type trailer that had no guard but whose adjustable rear wheels were set in the rearmost position. The purpose of these tests was to determine the effectiveness of rear tandems as a means for preventing underride. The tests demonstrated that the rear wheels, when placed at the extreme rear of the truck or trailer, prevent excessive underride at approximately 56.3 km/hr (35 mph). Further, the restrained dummies used in these tests experienced injury responses that were within the allowable limits of FMVSS No. 208.

The NHTSA issued an NPRM on January 8, 1981 (46 FR 2136). The proposed standard would have required large trucks and trailers to be equipped with an underride guard that met specified strength requirements and prescribed requirements concerning the configuration of the impact guard. The proposed standard differed from the FHWA's regulation in three ways. First, the NHTSA's proposal included objective strength requirements for the guard. Second, the proposed configuration requirements would have resulted in the guard having a lower ground clearance and being closer to the rear of the vehicle. Third, the NHTSA's proposed impact guard would have been wider (i.e., closer to the sides of the vehicle).

Based upon comments received in response to the 1981 NPRM and the results of the TTI and DSI studies, the NHTSA published a supplemental notice of proposed rulemaking (SNPRM) (57 FR 252, January 3, 1992). Instead of a vehicle-based safety standard as proposed in 1981, the NHTSA proposed separate standards for the impact guard as an item of motor vehicle equipment and for the vehicle. The equipment standard would specify the strength requirements that the guard would have to meet when attached to a rigid test fixture rather than the vehicle. The vehicle standard would require vehicle manufacturers to install a guard meeting the equipment standard, and to certify that the trailer has an impact guard installed at the required location.

The NHTSA's Vehicle Research and Test Center (VRTC) initiated a program to develop and evaluate the effectiveness of a rear impact guard design that would meet the proposed requirements. The VRTC developed a static test fixture and fabricated an impact guard design that met, but did not exceed, the minimum requirements. A number of additional guards were fabricated and tested to evaluate the repeatability of the design.

In addition, a rigid simulated trailer was developed to mount the guard for dynamic testing. Two sub-compact and two compact vehicle models were selected for crash testing to evaluate the effectiveness of the guard design in preventing rear underride injuries. Tests were conducted using the simulated trailer and an actual tractor trailer. A crash test was also performed with a rigid guard configuration for comparison with the results of the design. The researchers concluded that:

1. The currently proposed maximum guard height of 22 inches appeared to adequately engage the structures of all 4 vehicles tested [Honda Civic, Ford Tempo, General Motors Saturn, and Chevrolet Corsica]. The test vehicles were all high sales volume sub-compact and compact models with a low frontal profile.

a. The guards contacted each vehicle just above the bumper, engaging hood and fenders, engine, and upper suspension support structures.

b. The air bag restraints of all 4 vehicles deployed early enough to provide protection for the unbelted driver dummy.

2. For the test conducted, the 22 inch guard height prevented occupant compartment intrusion as long as the attachment at the guard/trailer interface was sufficiently strong. In one test (the first Saturn test), the guard attachment hardware failed. In the first test with the production trailer, the trailer sub-frame rails to which the guard was attached also failed. In each case, the mounting hardware was changed and all subsequent tests produced no interface failure or occupant compartment intrusion by the rear end of the trailer.

3. There is a trade-off between energy absorption, which reduces occupant accelerations by allowing the guard to give, and limiting underride, which reduces the possibility of passenger compartment intrusion. It is possible to significantly increase the strength of the guard, without exceeding the NHTSA's Occupant Crash Protection criteria [FMVSS No. 208 (49 CFR 571.208) Occupant Crash Protection].

The Corsica test with the ''minimally compliant'' guard design resulted in a clearance of 0.2 inches between the rear of the trailer and the forward-most part of the windshield after the collision, and low test dummy injury responses. A rigid guard test for the same vehicle resulted in 32.2 inches of clearance to the windshield. Dummy injury responses increased with one chest response just over 60 g's [60 times gravitational acceleration, 9.825 m/sec^2 (32.2 feet/sec^2)], but in general response levels were similar to that seen in [FMVSS No. 208 compliance] tests.

A copy of the NHTSA's report, ''Heavy Truck Rear Underride Protection,'' DOT HS 808–081, June 1993, has been placed in the docket file.

On January 24, 1996, the NHTSA issued a final rule establishing new safety standards for rear impact guards and rear impact protection (61 FR 2004). The rule applies to certain trailers manufactured on or after January 26, 1998. One of the major differences between the final rule and the SNPRM is the addition of a requirement for energy absorption. The SNPRM would have permitted fairly rigid guards because it did not require the guard to yield in response to force. The preamble to the final rule indicated that rigid guards may stop the passenger vehicles too quickly, causing occupant deaths and injuries.

The NHTSA also changed some of the impact guard configuration requirements to allow rounded guard ends. To account for high rear overhang on trailers such as automobile transporters, the NHTSA changed the definition of the vertical zone to be considered when determining the trailer's rear extremity. The location of the guard is based upon the location of the rear extremity.

On January 26, 1998, the NHTSA issued a final rule responding to petitions for reconsideration of the 1996 final rule, and making technical amendments to the rear impact guard requirements (63 FR 3654). The 1998 final rule clarified the applicability of the energy-absorption requirements with regard to cargo tank motor vehicles, as defined in 49 CFR 171.8, excluded pulpwood trailers from the rear impact protection requirements (a definition of pulpwood trailer was added to § 571.224), and revised the definition of special purpose vehicle.

Discussion of the FHWA Proposal

To ensure that the safety benefits intended by the NHTSA rulemaking are achieved, the FHWA is proposing to amend § 393.86 to establish a requirement that certain trailers manufactured on or after January 26, 1998, and operated in interstate commerce, be equipped to comply with FMVSS Nos. 223 and 224. This action is necessary because the FMVSSs are applicable only to vehicle and vehicle component manufacturers. In the absence of an amendment to the FMCSRs, there would be no Federal

requirement that motor carriers maintain their trailers to conform to the rear impact protection requirements of FMVSS No. 224, or repair damaged rear impact guards. Motor carriers could also replace rear impact guards with devices that failed to comply with the NHTSA requirements.

Paragraph (a) of § 393.86 would provide a general statement of the applicability of the new rear impact guard requirements and cross reference FMVSS Nos. 223 and 224. Paragraph (a) would also identify the types of trailers (which would be defined in § 393.5) that are exempted from the new rear impact guard requirements. Paragraphs (b) through (e) would specify the following requirements, respectively: The minimum width for the impact guard; the maximum ground clearance; the maximum distance from the rear of the vehicle to the rear surface of the impact guard; and the cross-sectional vertical height of the horizontal member of the guard. Paragraph (f) would specify the certification and labeling requirements. The agency is proposing to include detailed requirements in § 393.86(b) through (f) to help motor carriers quickly determine if the underride device on a newly manufactured trailer meets the NHTSA's requirements, and to assist State agencies responsible for enforcing motor carrier safety regulations.

The existing requirements (for all commercial motor vehicles manufactured after December 31, 1952, except trailers or semitrailers manufactured on or after January 26, 1998) would be covered under paragraphs (g) through (i). Paragraph (g) would specify the minimum dimensions for the rear impact guard as installed on the motor vehicle. Paragraph (h) would specify that the impact guard must be substantially constructed and attached by bolts, welding, or other comparable means. Paragraph (h) differs from the current attachment requirements in that the phrase ''firmly attached'' would be replaced with ''attached by means of bolts, welding, or other comparable means'' to make the regulations easier to understand and enforce.

The current language contained in paragraph (e) would be revised and included in a new paragraph (i). The FHWA would specify that low chassis vehicles, special purpose vehicles, and wheels-back vehicles which are constructed and maintained so that the body, chassis, or other parts of the vehicle provide rear end protection comparable to an impact guard(s) conforming to the requirements of paragraph (g) of § 393.86 shall be considered in compliance with the requirements.

Retrofitting

The FHWA is not proposing a retrofitting requirement for improved rear impact protection on trailers and semitrailers manufactured before January 26, 1998. There is insufficient accident, cost, and research data to support such a proposal at this time. The types of data required to justify a retrofitting requirement would be much more detailed than the information analyzed by the NHTSA.

Section 393.86(g) does not specify minimum strength requirements, or energy absorption capabilities, nor does it prohibit the use of impact guards that have a ground clearance less than 762 mm (30 inches), and impact guards that are closer than 61 cm (24 inches) to the rear and 45.7 cm (18 inches) to the sides of the vehicle. In addition, the existing standard allows impact guards to be constructed of more than one section provided the distance between the sections does not exceed 610 mm (24 inches). As a result, manufacturers have used a number of rear impact guard designs to satisfy the FHWA's requirements.

To develop a sound technical basis for a retrofitting proposal, the FHWA would have to establish criteria for determining which of the older impact guard designs should be considered acceptable, and which ones should be replaced. The FHWA would then have to estimate the total number of guards that would have to be replaced or modified, the total cost for replacing or modifying those guards (including lost revenues while the trailer was being retrofitted), and the benefits in lives saved and injuries prevented if a certain number of vehicles were retrofitted. This is particularly difficult because some rear impact guards currently in use may meet or exceed the NHTSA's strength requirements but fail to meet dimensional or energy absorption requirements. Others may meet the dimensional requirements but fall short of the minimum strength requirements.

The FHWA does not have test data or engineering analyses concerning the performance capabilities of any of the rear impact guard designs currently in use. The ICC did not have authority to regulate vehicle and component manufacturers when it issued the first rear underride protection requirements in 1952 and, consequently, had no authority to compel manufacturers to provide technical data on their products. Also, the initial FMVSSs issued by the FHWA did not include rear impact protection requirements. Therefore, the agency did not have access to this information during the relatively short period of time (between 1966 and 1970, when the NHTSA was established) in which vehicle and component manufacturers were regulated by the FHWA. Because of the lack of technical data concerning the performance capabilities of underride devices currently in use, the agency cannot prepare an accurate estimate of the costs and benefits associated with a retrofitting requirement.

The FHWA specifically requests comments from any interested party with data relevant to the costs and benefits of retrofitting.

Applicability to Canadian and Mexican Vehicles

The FHWA is not proposing an exemption for CMVs operated in the United States by Canada- and Mexico-based motor carriers. Although the Federal governments of Canada and Mexico have not indicated whether they intend to require rear impact guards (which meet the NHTSA standard) on newly manufactured trailers operating in their countries, the FHWA believes that it is appropriate to require such guards on foreign-based trailers manufactured on or after the effective date of the NHTSA requirements if those vehicles are operated within the United States.

Vehicles operated in the United States by Canada- and Mexico-based motor carriers are required to comply with the existing rear underride device requirements. The proposed revision of § 393.86 would require that trailers and semitrailers manufactured on or after January 26, 1998, and operated by foreign-based motor carriers meet the NHTSA standards. The FHWA specifically requests comments from Canada- and Mexico-based motor carriers and original equipment manufacturers that sell trailers and semitrailers for the Canadian and Mexican markets.

Rulemaking Analyses and Notices

All comments received before the close of business on the comment closing date indicated above will be considered and will be available for examination in the docket at the above address. Comments received after the comment closing date will be filed in the public docket and will be considered to the extent practicable, but the FHWA may adopt a final rule at any time after the close of the comment period. In addition to late comments, the FHWA will also continue to file, in the public docket, relevant information that becomes available after the

comment closing date. Interested persons should continue to examine the public docket for new material.

Executive Order 12866 (Regulatory Planning and Review) and DOT Regulatory Policies and Procedures

The FHWA has determined that this action is not a significant regulatory action within the meaning of Executive Order 12866. This rule would, if adopted, require that certain trailers and semitrailers manufactured on or after January 26, 1998, be equipped with rear impact protection devices meeting the requirements of FMVSS No. 223 and installed on trailers in accordance with FMVSS 224. Motor carriers would be responsible for maintaining the underride protection devices on these trailers. It is anticipated that the economic impact of this proposed requirement would be minimal because the NHTSA requires trailer manufacturers to equip new trailers and semitrailers with rear impact guards and the FHWA's rulemaking would only require motor carriers to maintain the improved underride protection devices. It is expected that the costs of repairing damaged underride devices would be the only economic burden placed upon motor carriers and that this burden generally would not exceed the costs of properly repairing underride devices on trailers manufactured prior to the effective date of the NHTSA's requirements. Accordingly, a full regulatory evaluation is not required. For the purposes of the Department of Transportation's regulatory policies and procedures, however, the proposed rule would be significant because of the substantial public interest in the prevention of rear-underride accidents involving commercial motor vehicles.

Regulatory Flexibility Act

In compliance with the Regulatory Flexibility Act (5 U.S.C. 601–612), the FHWA has evaluated the effects of this proposed rule on small entities. This rule would modify the rear impact protection standards for trailers in the Federal Motor Carrier Safety Regulations (FMCSRs) to make them consistent with the manufacturing standards in the FMVSS No. 224, which requires the installation of rear impact protection devices conforming to FMVSS No. 223 on certain newly-manufactured semitrailers and trailers. The FHWA believes that maintenance costs of the rear impact protection devices required under the new FMVSSs will be minimal. Therefore, the FHWA hereby certifies that this action would not have a significant economic impact on a substantial number of small entities.

Executive Order 12612 (Federalism Assessment)

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

Executive Order 12372 (Intergovernmental Review)

Catalog of Domestic Assistance Program Number 20.217, Motor Carrier Safety. The regulations implementing Executive Order 12372 regarding intergovernmental consultation on Federal programs and activities do not apply to this program.

Unfunded Mandates Reform Act

This proposal would not impose an unfunded Federal mandate, as defined by the Unfunded Mandates Reform Act of 1995 (2 U.S.C. 1532 *et seq.*), that will result in the expenditure by State, local, and tribal governments, in the aggregate, or by the private sector, or $100 million or more in any one year.

Paperwork Reduction Act

This document does not contain information collection requirements for the purposes of the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 *et seq*).

National Environmental Policy Act

The agency has analyzed this rulemaking for the purpose of the National Environmental Policy Act of 1969 (42 U.S.C. 4321 *et seq.*) and has determined that this action would not have any effect on the quality of the environment.

Regulation Identification Number

A regulation identification number (RIN) is assigned to each regulatory action listed in the Unified Agenda of Federal Regulations. The Regulatory Information Service Center publishes the Unified Agenda in April and October of each year. The RIN contained in the heading of this document can be used to cross-reference this action with the Unified Agenda.

List of Subjects in 49 CFR Part 393

Highways and roads, Motor carriers, Motor vehicle equipment, Motor vehicle safety.

Issued on: April 28, 1998.

Kenneth R. Wykle,

Administrator, Federal Highway Administration.

In consideration of the foregoing, the FHWA proposes to amend title 49, Code of Federal Regulations, subchapter B, chapter III, as follows:

PART 393—[AMENDED]

1. The authority citation for part 393 continues to read as follows:

Authority: Section 1041(b) of Pub. L. 102–240, 105 Stat. 1914, 1993 (1991); 49 U.S.C. 31136 and 31502; 49 CFR 1.48.

2. Section 393.5 is amended by adding the definitions of ''low chassis vehicle,'' ''special purpose vehicle,'' and ''wheels back vehicle,'' and by revising the definitions of ''pulpwood trailer,'' ''rear extremity,'' and ''side extremities'' (now ''side extremity'') to read as follows:

§ 393.5 Definitions.

* * * * *

Low chassis vehicle. A trailer or semitrailer having a chassis which extends behind the rearmost point of the rearmost tires and a lower rear surface that meets the guard width, height, and rear surface requirements of § 571.224. For vehicles not subject to the requirements of § 571.224 on the date of manufacture, the configuration requirements of § 393.86(g) may be used.

* * * * *

Pulpwood trailer. A trailer or semitrailer that is designed exclusively for harvesting logs or pulpwood and constructed with a skeletal frame with no means for attachment of a solid bed, body, or container.

Rear extremity. The rearmost point on a vehicle that falls above a horizontal plane located 560 mm (22 inches) above the ground and below a horizontal plane located 1,900 mm (75 inches) above the ground when the vehicle is stopped on level ground; unloaded; its fuel tanks are full; the tires (and air suspension, if so equipped) are inflated in accordance with the manufacturer's recommendations; and the vehicle's cargo doors, tailgate, or other permanent structures are positioned as they normally are when the vehicle is in motion. Nonstructural protrusions such as taillamps, rubber bumpers, hinges and latches are excluded from the determination of the rearmost point.

* * * * *

Side extremity. The outermost point on a side of the vehicle that is above a horizontal plane located 560 mm (22 inches) above the ground, below a

horizontal plane located 1,900 mm (75 inches) above the ground, and between a transverse vertical plane tangent to the rear extremity of the vehicle and a transverse vertical plane located 305 mm (12 inches) forward of that plane when the vehicle is unloaded; its fuel tanks are full; and the tires (and air suspension, if so equipped) are inflated in accordance with the manufacturer's recommendations. Non-structural protrusions such as taillights, hinges and latches are excluded from the determination of the outermost point.

* * * * *

Special purpose vehicle. A trailer or semitrailer having work-performing equipment that, while the vehicle is in transit, resides in or moves through the area that could be occupied by the horizontal member of the rear impact guard, as defined by the guard width, height and rear surface requirements of § 571.224 (paragraphs S5.1.1 through S5.1.3).

* * * * *

Wheels back vehicle. A trailer or semitrailer whose rearmost axle is permanently fixed and is located such that the rearmost surface of the tires (of the size recommended by the vehicle manufacturer for the rear axle) is not more than 305 mm (12 inches) forward of the transverse vertical plane tangent to the rear extremity of the vehicle.

3. Section 393.86 is revised to read as follows:

§ 393.86 Rear impact guards and rear end protection.

(a) *General requirements for trailers and semitrailers manufactured on or after January 26, 1998.* Each trailer and semitrailer with a gross vehicle weight rating of 4,536 kg (10,000 pounds) or more, and manufactured on or after January 26, 1998, must be equipped with a rear impact guard that meets the requirements of Federal Motor Vehicle Safety Standard No. 223 (49 CFR 571.223) in effect at the time the vehicle was manufactured. When the rear impact guard is installed on the trailer or semitrailer, the vehicle must, at a minimum, meet the requirements of FMVSS No. 224 (49 CFR 571.224) in effect at the time the vehicle was manufactured. Trailers and semitrailers subject to this paragraph must meet the requirements of paragraphs (b) through (f) of this section. The requirements of paragraphs (a) through (f) do not apply to pole trailers (as defined in § 390.5); pulpwood trailers, low chassis trailers, special purpose trailers, wheels back trailers (as defined in § 393.5); and trailers towed in driveaway-towaway operations (as defined in § 390.5).

(b) *Impact guard width.* The outermost surfaces of the horizontal member of the guard must extend to within 100 mm (4 inches) of the side extremities of the vehicle. The outermost surface of the horizontal member shall not extend beyond the side extremity of the vehicle.

(c) *Guard height.* The vertical distance between the bottom edge of the horizontal member of the guard and the ground shall not exceed 560 mm (22 inches) at any point across the full width of the member. Guards with rounded corners may curve upward within 255 mm (10 inches) of the longitudinal vertical planes that are tangent to the side extremities of the vehicle.

(d) *Guard rear surface.* At any height 560 mm (22 inches) or more above the ground, the rearmost surface of the horizontal member of the guard must be within 305 mm (12 inches) of the rear extremity of the vehicle. This paragraph shall not be construed to prohibit the rear surface of the guard from extending beyond the rear extremity of the vehicle. Guards with rounded corners may curve forward within 255 mm (10 inches) of the side extremity.

(e) *Cross-sectional vertical height.* The horizontal member of each guard must have a cross sectional vertical height of at least 100 mm (3.94 inches) at any point across the guard width.

(f) *Certification and labeling requirements for rear impact protection guards.* Each rear impact guard used to satisfy the requirements of paragraph (a) of this section must be permanently marked or labeled as required by FMVSS No. 223 (49 CFR 571.223, S5.3). The label must be on the forward-facing surface of the horizontal member of the guard, 305 mm (12 inches) inboard of the right end of the guard. The certification label must contain the following information:

(1) The impact guard manufacturer's name and address;

(2) The statement ''Manufactured in _____'' (inserting the month and year that the guard was manufactured); and,

(3) The letters ''DOT'', constituting a certification by the guard manufacturer that the guard conforms to all requirements of FMVSS No. 223.

(g) *Requirements for motor vehicles manufactured after December 31, 1952 (except trailers or semitrailers manufactured on or after January 26, 1998).* Each motor vehicle manufactured after December 31, 1952, (except of truck tractors, pole trailers, or vehicles in driveaway-towaway operations) in which the vertical distance between the rear bottom edge of the body (or the chassis assembly if the chassis is the rearmost part of the vehicle) and the ground is greater than 76.2 cm (30 inches) when the motor vehicle is empty, shall be equipped with a rear impact guard(s). The rear impact guard(s) must be installed and maintained in such a manner that:

(1) The vertical distance between the bottom of the guard(s) and the ground does not exceed 76.2 cm (30 inches) when the motor vehicle is empty;

(2) The maximum distance between the closest points between guards, if more than one is used, does not exceed 61 cm (24 inches);

(3) The outermost surfaces of the horizontal member of the guard are no more than 45.7 cm (18 inches) from each side extremity of the motor vehicle;

(4) The impact guard(s) are no more than 61 cm (24 inches) forward of the rear extremity of the motor vehicle.

(h) *Construction and attachment.* The rear impact guard(s) must be substantially constructed and attached by means of bolts, welding, or other comparable means.

(i) *Vehicle components and structures that may be used to satisfy the requirements of paragraph (g) of this section.* Low chassis vehicles, special purpose vehicles, or wheels back vehicles constructed and maintained so that the body, chassis, or other parts of the vehicle provide the rear end protection comparable to impact guard(s) conforming to the requirements of paragraph (g) of this section shall be considered to be in compliance with those requirements.

[FR Doc. 98–12753 Filed 5–13–98; 8:45 am]

BILLING CODE 4910–22–P

DEPARTMENT OF THE INTERIOR

Fish and Wildlife Service

50 CFR Part 17

RIN 1018–AE86

Endangered and Threatened Wildlife and Plants; Notice of Public Hearing on Proposed Endangered Status for Devils River Minnow (Dionda diaboli)

AGENCY: Fish and Wildlife Service, Interior.

ACTION: Proposed rule; notice of public hearing.

SUMMARY: The U.S. Fish and Wildlife Service (Service) gives notice that a public hearing will be held on the proposed determination of endangered status for the Devils River minnow (*Dionda diaboli*). This fish is found in

Val Verde and Kinney counties, Texas, and Coahuila, Mexico. All interested parties are invited to submit comments on this proposal.

DATES: The public hearing will be held from 5:30 p.m. to 8 p.m. on May 28, 1998, in Del Rio, Texas. The comment period closes July 27, 1998.

ADDRESSES: The public hearing will be held at the Freshmen School Cafeteria of the San Felipe-Del Rio Independent School District, located at 90 Memorial Drive in Del Rio, Texas. Written comments and materials concerning the proposal should be sent to the Field Supervisor, Austin Ecological Services Field Office, U.S. Fish and Wildlife Service, 10711 Burnet Road, Suite 200, Austin, Texas, 78758. Comments and materials received will be available for public inspection, by appointment, during normal business hours at the above address.

FOR FURTHER INFORMATION CONTACT: Nathan Allan, Fish and Wildlife Biologist (see **ADDRESSES** section) (telephone 512/490–0057; facsimile 512/490–0974).

SUPPLEMENTARY INFORMATION:

Background

The current range of the Devils River minnow is limited to three stream systems in Val Verde and Kinney counties, Texas, and one drainage in Coahuila, Mexico. The species' range has been significantly contracted and fragmented. In addition, the numbers of Devils River minnows collected during fish surveys has declined dramatically over the past 25 years; the species has declined from one of the most abundant fish to one of the least abundant. Based on the current information, the decline of the species in both distribution and abundance may be attributed in large part to the effects of habitat loss and modification and the introduction of nonnative fish into habitats of the Devils River minnow.

On March 27, 1998, the Service published a proposed rule to list the Devils River minnow as endangered under the Endangered Species Act (Act) of 1973, as amended. Section 4(b)(5)(E) of the Act requires that a public hearing be held if requested within 45 days of the proposal's publication in the **Federal Register**. Because of the past public interest in the listing of this species, the Service opened the public comment period for 120 days and planned the public hearing in advance of a request.

The Service has scheduled this hearing for 5:30 p.m. to 8 p.m. on May 28, 1998, at the Freshmen School Cafeteria of the San Felipe-Del Rio Independent School District, located at 90 Memorial Drive in Del Rio, Texas. Anyone wishing to make an oral statement for the record is encouraged to provide a written copy of their statement to be presented to the Service at the start of the hearing. In the event there is a large attendance, the time allotted for oral statements may have to be limited. Oral and written statements receive equal consideration. There are no limits on the length of written comments presented at this hearing or mailed to the Service. Legal notices announcing the date, time and location of the hearing are being published in newspapers concurrently with this **Federal Register** notice.

The comment period on the proposal will remain open until July 27, 1998. Written comments may be submitted until that date to the Service office in the **ADDRESSES** section.

Author

The primary author of this notice is Nathan Allan (see **ADDRESSES** section) (telephone 512/490–0057; facsimile 512/490–0974).

Authority

The authority for this action is the Endangered Species Act of 1973 (16 U.S.C. 1531 *et seq.*).

Dated: May 7, 1998.

Nancy M. Kaufman,

Regional Director, Fish and Wildlife Service.

[FR Doc. 98–12839 Filed 5–13–98; 8:45 am]

BILLING CODE 4310–55–P

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

50 CFR Part 654

[Docket No. 980501114–8114–01; I.D. 041698G]

RIN 0648–AK48

Stone Crab Fishery of the Gulf of Mexico; Amendment 6

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

ACTION: Proposed rule; request for comments.

SUMMARY: NMFS issues this proposed rule to implement Amendment 6 to the Fishery Management Plan for the Stone Crab Fishery of the Gulf of Mexico (FMP). Amendment 6 would extend, for up to 4 years, the existing temporary moratorium on the Federal registration of stone crab vessels. The intended effect is to provide additional time for the industry and Florida to develop and implement a limited access system for the fishery.

DATES: Written comments will be considered if received on or before June 29, 1998.

ADDRESSES: Send comments on the proposed rule to the Southeast Regional Office, NMFS, 9721 Executive Center Drive N., St. Petersburg, FL 33702. Requests for copies of Amendment 6, which includes a regulatory impact review and an environmental assessment, should be sent to the Gulf of Mexico Fishery Management Council, 3018 U.S. Highway 301 North, Suite 1000, Tampa, FL 33619–2266; Phone: 813–228–2815; Fax: 813-225–7015.

FOR FURTHER INFORMATION CONTACT: Michael E. Justen, 813–570–5305.

SUPPLEMENTARY INFORMATION: The FMP was prepared by the Gulf of Mexico Fishery Management Council (Council) and is implemented under the authority of the Magnuson-Stevens Fishery Conservation and Management Act (Magnuson-Stevens Act) by regulations at 50 CFR part 654.

Background

Final regulations implemented the FMP on September 30, 1979 (44 FR 53519), and apply only to the exclusive economic zone (EEZ) off Florida's west coast (including Monroe County), the primary location of the directed stone crab fishery.

The original FMP required vessels to be registered by the appropriate state or Federal agency and assigned an identification number and color code for the vessel and gear. Federal regulations allowed fishermen to obtain a Federal identification number and color code from the NMFS Southeast Regional Office, if the applicant could not obtain an identification number and color code from Florida. However, the NMFS Southeast Regional Office has never issued an identification number and color code to anyone to participate in the stone crab fishery because fishermen could obtain them from Florida.

Amendment 5, implemented on April 14, 1995 (60 FR 13918), placed a 3-year moratorium (April 15, 1995 - June 30, 1998) on the Federal registration of stone crab vessels. The Council recommended, and NMFS approved and implemented, the Federal moratorium because the Florida Legislature passed a moratorium on the issuance of state permits, effective July 1, 1995, while the Florida Marine Fisheries Commission (FMFC), in cooperation with the stone crab industry, considered development

of a limited access system. Without the Federal moratorium, fishermen could have circumvented the state moratorium.

The Council recommended Amendment 6 to extend the Federal moratorium on vessel registration for up to 4 years (i.e., through June 30, 2002) because it is concerned that legislative action by Florida to create a limited access system may be delayed beyond June 30, 1998.

If the Federal moratorium expires on June 30, 1998, anyone could apply to NMFS for vessel registration. Substantial entry into the stone crab fishery would adversely affect current participants in the fishery by reducing their respective shares of the harvest. The fishery is already overcapitalized both in gear deployed, with approximately 798,000 traps deployed in 1995–96, and in the number of permitted vessels. As of July 1, 1995, there were 6,501 commercial permits issued. Only 1,556 permit holders, however, had stone crab landings, and 70 percent of them, or 1,102 permittees, had annual landings of 500 lb (225 kg) or less. Landings have not increased significantly since 1982–83, when approximately 350,000 traps were deployed. Catch-per-unit-of-effort has declined significantly since then.

In cooperation with the stone crab industry, the FMFC has proposed to the Florida Legislature a limited access program that contains provisions for a license limitation system that would exclude permit holders with no record of landings during recent years. The Florida Legislature is expected to pass this limited access program in 1999 with the state law to become effective July 1, 1999. The Council will then submit a regulatory amendment to extend the license limitation program to Federal waters off Florida's Gulf coast, including Monroe County.

Management Measures in Amendment 6

Amendment 6 would continue, for up to 4 years, the FMP's temporary moratorium on the Federal registration of stone crab vessels. This Federal moratorium would end no later than June 30, 2002.

Control Date

At the Council's request, NMFS published a control date of July 24, 1995, for the commercial fishery (60 FR 37868, July 24, 1995). That action notified fishermen entering the commercial stone crab fishery that after that date they may not be allowed to participate in the fishery if that date is used in a limited access program to limit entry.

Availability of and Comments on Amendment 6

Additional background and rationale for the measures discussed above are contained in Amendment 6, the availability of which was announced in the **Federal Register** on April 23, 1998 (63 FR 20163). Written comments on Amendment 6 must be received on or before June 22, 1998. Comments that are received by NMFS on or before June 22, 1998, whether specifically directed to Amendment 6 or the proposed rule, will be considered by NMFS in its decision to approve, disapprove, or partially approve Amendment 6. Comments received after that date will not be considered by NMFS in this decision. All comments received on Amendment 6 or on this proposed rule during their respective comment periods will be addressed in the preamble to the final rule.

Classification

At this time, NMFS has not made a final determination that the provisions of Amendment 6 are consistent with the national standards, other provisions of the Magnuson-Stevens Act, and other applicable laws. In making that final determination, NMFS will take into account the data, views, and comments received during the comment period.

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

The Assistant General Council for Legislation and Regulation of the Department of Commerce, based on the Council's Regulatory Impact Review (RIR) that assesses the economic impact of maangement measures proposed in this rule on fishery participants, certified to the Chief Counsel for Advocacy of the Small Business Administration that this proposed rule, if adopted, would not have a significant economic impact on a substantial number of small entities as follows:

The regulations are not likely to change annual gross revenues by more than 5 percent. Instead, the Federal moratorium would simply maintain current rules, and vessels would not be subjected to a regulatory-induced reduction in gross revenue.

Annual compliance costs are not likely to increase total costs of production for small entities by more than 5 percent. It has been estimated that there would be no additional costs associated with compliance with the provisions of this amendment, as no additional permits, gear modifications, or other changes are required.

Compliance costs as a percent of sales for small entities are not likely to be at least 10 percent higher than compliance costs as a percent of sales for large entities. All the firms expected to be impacted by the rule are small entities and hence there is no differential impact.

Capital costs of compliance are not likely to represent a significant portion of capital available to small entities, considering internal cash flow and external financing capabilities. Significant effects of this type are not expected to occur from any of the alternatives that would extend the moratorium.

The requirements of the regulations are not likely to force a number of the small entities to cease operations. The action to extend the moratorium would not force any vessels out of the fishery.

As a result, a regulatory flexibility analysis was not prepared. A copy of the RIR is available from the Council (see **ADDRESSES**).

List of Subjects in 50 CFR Part 654

Fisheries, Fishing.

Dated: May 8, 1998.

David L. Evans,

Deputy Assistant Administrator for Fisheries, National Marine Fisheries Service.

For the reasons set out in the preamble, 50 CFR part 654 is proposed to be amended as follows:

PART 654—STONE CRAB FISHERY OF THE GULF OF MEXICO

1. The authority citation for part 654 continues to read as follows:

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

2. In § 654.3, paragraph (d) is revised to read as follows.

§ 654.3 Relation to other laws.

* * * * *

(d) Under Amendment 6 to the Fishery Management Plan for the Stone Crab Fishery of the Gulf of Mexico, there is a temporary moratorium on the issuance by the Regional Director of Federal identification numbers and color codes for vessels and gear in the stone crab fishery in the management area. The moratorium will end not later than June 30, 2002. During the moratorium, fishermen must obtain identification numbers and color codes for these vessels and gear from Florida. (See § 654.6(a).)

[FR Doc. 98–12843 Filed 5–13–98; 8:45 am]

BILLING CODE 3510–22–F

Notices

Federal Register
Vol. 63, No. 93
Thursday, May 14, 1998

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

National Appeals Division

Notice of Request for Approval of an Information Collection

AGENCY: National Appeals Division, USDA.

ACTION: Proposed collection.

SUMMARY: Notice. In accordance with the Paperwork Reduction Act of 1995 (44 U.S.C. Chapter 35), this notice announces the intention of the National Appeals Division (NAD) to request approval of an information collection for the purpose of setting customer service standards.

DATES: Comments on this notice must be received by July 13, 1998.

FOR FURTHER INFORMATION CONTACT: Robert Day, Jr., USDA/NAD Suite 1020, 3101 Park Center Drive, Alexandria, VA 22302, (703–305–2538).

SUPPLEMENTARY INFORMATION: Title: National Appeals Division Customer Service Survey

OMB Number. Not yet designated.

Type of Request: Approval of new information collection.

Abstract: Executive Order 12862 requires Federal agencies to identify the customers who are, or should be served by the Agency and survey those customers to determine the kind and quality of services they want and their level of satisfaction with existing services. Agencies will then use the results of the survey to establish customer service standards.

The National Appeals Division (NAD) of the U.S. Department of Agriculture was established by the Secretary of Agriculture on October 20, 1994, by Secretary's Memorandum 1010–1, pursuant to the Federal Crop Insurance Reform and Department of Agriculture Reorganization Act of 1994 (Pub. L. 103–354, section 271 et seq. (October 13, 1994). The Act consolidated the appellate functions and staffs of several USDA agencies to provide for independent hearings and reviews of adverse agency decisions. NAD is responsible for all administrative appeals arising from program activities of assigned Agencies, as well as such other administrative appeals arising from decisions of agencies and offices of USDA as may be assigned by the Secretary. NAD appeals involve program decisions of the Farm Service Agency, Risk Management Agency, Natural Resources Conservation Service, Rural Business-Cooperative Service, Rural Housing Service, and Rural Utilities Service.

Need for the Information: The information collection in this request is essential for NAD to comply with the requirement of Executive Order 12862 to set customer service standards. The information collected is used only by authorized representatives of the USDA.

Estimate of Burden: Public reporting burden for this collection of information is estimated to average 0.25 hours per response.

Respondents: The primary respondents will be individuals and/or households who are participants in Farm Service Agency and Rural Housing Service programs. A small percentage of respondents may be businesses, institutions or state and local governments.

Estimated Number of Respondents: 210.

Estimated Number of Responses per Respondent: 1.00.

Estimated Total Annual Burden on Respondents: 52.5.

Copies of this information collection can be obtained from Robert J. Day, Jr., National Appeals Division at (703) 305–2538.

Send comments regarding, but not limited to the following: (a) whether the collection of the information is necessary for the proper performance of the functions of NAD, including whether the information will have a practical utility; (b) the accuracy of NAD's estimate of the burden including the validity of the methodology and assumptions used; (c) ways to enhance the quality, utility, and clarity of the information to be collected; and (d) 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. Comments should be addressed to Robert J. Day, Jr., Deputy Director for Planning, Training and Quality Control, USDA/NAD, Suite 1020, 3101 Park Center Drive, Alexandria, VA 22302. 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: May 7, 1998.

Norman G. Cooper,

Director, National Appeals Division.

[FR Doc. 98–12797 Filed 5–13–98; 8:45 am]

BILLING CODE 3410–WY–M

DEPARTMENT OF AGRICULTURE

Animal and Plant Health Inspection Service

[Docket No. 98–041–1]

Secretary's Advisory Committee on Foreign Animal and Poultry Diseases; Notice of Solicitation for Membership

AGENCY: Animal and Plant Health Inspection Service, USDA.

ACTION: Notice of solicitation for membership.

SUMMARY: We are giving notice that we anticipate renewing the Secretary's Advisory Committee on Foreign Animal and Poultry Diseases for a 2-year period. The Secretary is soliciting nominations for membership for this Committee.

DATES: Consideration will be given to nominations received on or before June 29, 1998.

ADDRESSES: Nominations should be addressed to the person listed under **FOR FURTHER INFORMATION CONTACT.**

FOR FURTHER INFORMATION CONTACT: Dr. Joe Annelli, Chief Staff Veterinarian, Emergency Programs, VS, APHIS, 4700 River Road Unit 41, Riverdale, MD 20737–1231, (301) 734–8073.

SUPPLEMENTARY INFORMATION: The Secretary's Advisory Committee on Foreign Animal and Poultry Diseases (the Committee) advises the Secretary of Agriculture on actions necessary to keep foreign diseases of livestock and poultry from being introduced into the United States. In addition, the Committee advises on contingency planning and on maintaining a state of preparedness to deal with these diseases, if introduced.

The Committee Chairperson and Vice Chairperson shall be elected by the Committee from among its members.

Terms will expire for the current members of the Committee in June 1998. We are soliciting nominations from interested organizations and individuals to replace members on the Committee. An organization may nominate individuals from within or outside its membership. The Secretary will select members to obtain the broadest possible representation on the Committee, in accordance with the Federal Advisory Committee Act (Pub. L. 92–463) and U.S. Department of Agriculture (USDA) Regulation 1041–1. Equal opportunity practices, in line with the USDA policies, will be followed in all appointments to the Committee. To ensure that the recommendations of the Committee have taken into account the needs of the diverse groups served by the Department, membership should include, to the extent practicable, individuals with demonstrated ability to represent minorities, women, and persons with disabilities.

Done in Washington, DC, this 8th day of May 1998.

Charles P. Schwalbe,

Acting Administrator, Animal and Plant Health Inspection Service.

[FR Doc. 98–12845 Filed 5–13–98; 8:45 am]

BILLING CODE 3410–34–P

COMMISSION ON CIVIL RIGHTS

Agenda and Notice of Public Meeting of the Connecticut Advisory Committee

Notice is hereby given, pursuant to the provisions of the rules and regulations of the U.S. Commission on Civil Rights, that a meeting of the Connecticut Advisory Committee to the Commission will convene at 10:30 a.m. and adjourn at 3:30 p.m. on June 2, 1998, at the Catholic Charities/Catholic Families Services, Inc., Conference Room, 467 Bloomfield Avenue, Bloomfield, Connecticut 06002. The purpose of the meeting is: (1) follow up discussion of the Civil Rights Leadership Conference and its report and (2) program planning of future activities.

Persons desiring additional information, or planning a presentation to the Committee, should contact Committee Chairperson Neil Macy, 860–242–7287, or Ki-Taek Chun, Director of the Eastern Regional Office, 202–376–7533 (TDD 202–376–8116). Hearing-impaired persons who will attend the meeting and require the services of a sign language interpreter should contact the Regional Office at least ten (10) working days before the scheduled date of the meeting.

The meeting will be conducted pursuant to the provisions of the rules and regulations of the Commission.

Dated at Washington, DC, May 7, 1998.

Carol-Lee Hurley,

Chief, Regional Programs Coordination Unit.

[FR Doc. 98–12872 Filed 5–13–98; 8:45 am]

BILLING CODE 6335–01–P

COMMISSION ON CIVIL RIGHTS

Agenda and Notice of Public Meeting of the Oregon Advisory Committee

Notice is hereby given, pursuant to the provisions of the rules and regulations of the U.S. Commission on Civil Rights, that a meeting of the Oregon Advisory Committee to the Commission will convene at 1:00 p.m. and adjourn at 5:00 p.m. on June 19, 1998, at the Red Lion Hotel, Columbia River, 1401 North Hayden Island Drive, Portland, Oregon 97217. The purpose of the meeting is to ascertain the status of civil rights in Oregon and plan future activities.

Persons desiring additional information, or planning a presentation to the Committee, should contact Philip Montez, Director of the Western Regional Office, 213–894–3437 (TDD 213–894–3435). Hearing-impaired persons who will attend the meeting and require the services of a sign language interpreter should contact the Regional Office at least ten (10) working days before the scheduled date of the meeting.

The meeting will be conducted pursuant to the provisions of the rules and regulations of the Commission.

Dated at Washington, DC, May 7, 1998.

Carol-Lee Hurley,

Chief, Regional Programs Coordination Unit.

[FR Doc. 98–12873 Filed 5–13–98; 8:45 am]

BILLING CODE 6335–01–P

DEPARTMENT OF COMMERCE

Bureau of Economic Analysis

Annual Survey of Construction, Engineering, Architectural, and Mining Services Provided by U.S. Firms to Unaffiliated Foreign Persons

ACTION: Proposed collection; comment request.

SUMMARY: The Department of Commerce, as part of its continuing effort to reduce paperwork and respondent burden, invites the general public and other Federal agencies to comment on proposed and/or continuing information collections, as required by the Paperwork Reduction Act of 1995, Public Law 104–13 (44 U.S.C. 3506(c)(2)(A)).

DATES: Written comments must be submitted on or before July 13, 1998.

ADDRESSES: Direct all written comments to Linda Engelmeier, Departmental Forms Clearance Officer, Department of Commerce, Room 5327, 14th and Constitution Avenue, NW, Washington, DC 20230.

FOR FURTHER INFORMATION CONTACT: Requests for additional information or copies of the information collection instrument and instructions should be directed to: R. David Belli, U.S. Department of Commerce, Bureau of Economic Analysis, BE–50(OC), Washington, DC 20230 (Telephone: 202–606–9800).

SUPPLEMENTARY INFORMATION:

I. Abstract

The BE–47 Annual Survey of Construction, Engineering, Architectural, and Mining Services Provided by U.S. Firms to Unaffiliated Foreign Persons will obtain data on U.S. sales to unaffiliated foreign persons of construction, engineering, architectural, and mining services. The information gathered is needed, among other purposes, to support U.S. trade policy initiatives and to compile the U.S. international transactions, input-output, and national income and product accounts. BEA is proposing to drop the requirement to report data on Form BE–47 by individual project and instead require reporting only by country. This proposed change will bring the format and design of the survey generally more into line with those of other surveys of international services transactions that BEA conducts. In addition, BEA is proposing a change in the way transactions are coded by type of service. Currently, eight codes are used to classify the data reported on Form BE-47 by type of service. These codes are based on the 1987 U.S. Standard Industrial Classification (SIC) system. BEA proposes to collapse these eight codes into three broad groupings, which will be based on the new North American Industry Classification System that is replacing the SIC. These proposed changes will result in a small reduction in the estimated time per response.

II. Method of Collection

The survey will be sent each year to potential respondents in January and responses are due by March 31. A U.S.

person providing construction, engineering, architectural, or mining services to unaffiliated foreign persons is required to report if the gross value of new contracts received or the gross operating revenues from all existing contracts is $1 million or more during the covered year. A U.S. person that receives a form but is not required to report data must file an exemption claim.

III. Data

OMB Number: 0608–0015.

Form Number: BE–47.

Type of Review: Regular submission.

Affected Public: U.S. business or other for-profit institutions providing construction, engineering, architectural, and mining services to unaffiliated foreign persons.

Estimated Number of Responses: 155.

Estimated Time Per Response: 4.5 hours.

Estimated Total Annual Burden Hours: 700.

Estimated Total Annual Cost: $21,000 (based on an estimated reporting burden of 700 hours and an estimated hourly cost of $30).

IV. Request for Comments

Comments are invited on: (a) Whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information has practical utility; (b) the accuracy of the agency's estimate of the burden (including hours and cost) of the proposed collection of information; (c) ways to enhance the quality, utility, and clarity of the information to be collected; and (d) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or other forms of information technology.

Comments submitted in response to this notice will be summarized and/or included in the request for OMB approval of this information collection; they also will become a matter of public record.

Dated: May 8, 1998.

Linda Engelmeier,

Departmental Forms Clearance Officer, Office of Management and Organization.

[FR Doc. 98–12820 Filed 5–13–98; 8:45 am]

BILLING CODE 3510–06–P

DEPARTMENT OF COMMERCE

International Trade Administration

Commercial News USA

ACTION: Proposed collection; comment request.

SUMMARY: The Department of Commerce, as part of its continuing effort to reduce paperwork and respondent burdens, invites the general public and other Federal agencies to take this opportunity to comment on the continuing information collections, as required by the Paperwork Reduction Act of 1995, Public Law 104–13 (44 U.S.C. 3506(c)(2)(A)).

DATES: Written comments must be submitted on or before July 13, 1998.

ADDRESSES: Direct all written comments to Linda Engelmeier, Departmental Forms Clearance Officer, Department of Commerce, Room 5327, 14th and Constitution Avenue, NW., Washington, DC 20230. Phone number: (202) 482–3272.

FOR FURTHER INFORMATION CONTACT: Request for additional information or copies of the information collection instrument and instructions should be directed to: Jana Nelhybel, U.S. & Foreign Commercial Service, Export Promotion Service, Room 2202, 14th and Constitution Avenue, NW., Washington, DC 20230. Phone number: (202) 482–5367, and fax number (202) 482–5362.

SUPPLEMENTARY INFORMATION:

I. Abstract

Commercial News USA (CNUSA), published twelve times a year by a private sector firm, is the U.S. Department of Commerce's export catalog-magazine. The product information in CNUSA reaches more than 145,000 distributors, government officials, and potential buyers overseas through direct distribution from U.S. embassies and consulates. Firms use the form to request that their product information be published in CNUSA, a service for which the firms pay a minimum fee of $445.

This information collection item allows the U.S. Department of Commerce to promote U.S. products and services available for export as part of the USDOC's trade promotion activities. CNUSA is a unique export promotion service for U.S. manufacturers, service firms, and publishers of trade and technical literature; nothing similar is available to them through the private sector. The product promotions in CNUSA differ from paid advertisements in that they must meet program criteria. Because U.S. embassies and consulates handle distribution, the product information reaches a vast, screened readership not only through direct dissemination but also via counseling by commercial officers and through walk-in visits to commercial libraries where CNUSA is displayed. Further, American Chambers of Commerce, local business editors, and other trade entities that reprint information from CNUSA or display or disseminate the entire magazine provide a multiplier effect.

II. Method of Data Collection

The requests are sent to the private sector publisher.

III. Data

OMB Number: 0625–0061.

Form Number: ITA–4063P.

Type of Review: Renewal; regular submission.

Affected Public: Companies interested in placing their product information available for export in Commercial News USA.

Estimated Number of Respondents: 2,200.

Estimated Time Per Response: 20 minutes.

Estimated Total Annual Burden Hours: 917.

Estimated Total Annual Costs: $32,095.

IV. Request for Comments

Comments are invited on (a) whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; (b) the accuracy of the agency's estimate of the burden (including hours and costs) of the proposed collection of information; (c) ways to enhance the quality, utility, and clarity of the information to be collected; and (d) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or forms of information technology.

Comments submitted in response to this notice will be summarized and/or included in the request for OMB approval of this information collection; they also will become a matter of public record.

Dated: May 8, 1998.

Linda Engelmeier,

Departmental Forms Clearance Officer, Office of Management and Organization.

[FR Doc. 98–12821 Filed 5–13–98; 8:45 am]

BILLING CODE 3510–FP–P

DEPARTMENT OF COMMERCE

Bureau of Economic Analysis

Annual Survey of Financial Services Transactions Between U.S. Financial Services Providers and Unaffiliated Foreign Persons

ACTION: Proposed collection; comment request.

SUMMARY: The Department of Commerce, as part of its continuing effort to reduce paperwork and respondent burden, invites the general public and other Federal agencies to comment on proposed and/or continuing information collections, as required by the Paperwork Reduction Act of 1995, Public Law 104–13 (44 U.S.C. 3506(c)(2)(A)).

DATES: Written comments must be submitted on or before July 13, 1998.

ADDRESSES: Direct all written comments to Linda Engelmeier, Departmental Forms Clearance Officer, Department of Commerce, Room 5327, 14th and Constitution Avenue, NW, Washington, DC 20230.

FOR FURTHER INFORMATION CONTACT: Requests for additional information or copies of the information collection instrument and instructions should be directed to: R. David Belli, U.S. Department of Commerce, Bureau of Economic Analysis, BE–50 (OC), Washington, DC 20230 (Telephone: 202–606–9800).

SUPPLEMENTARY INFORMATION:

I. Abstract

The BE–82 Annual Survey of Financial Services Transactions between U.S. Financial Services Providers and Unaffiliated Foreign Persons will obtain data on financial services transactions between U.S. financial services providers and unaffiliated foreign persons and covers all transactions above a size-exemption level. The data from the survey will update the data collected in the quinquennial BE–80 benchmark survey of such services. The information gathered is needed, among other purposes, to support U.S. trade policy initiatives and to compile the U.S. international transactions, input-output, and national income and product accounts. BEA is requesting only an extension of a currently approved collection and is not proposing any changes in either language or data collected.

II. Method of Collection

The survey will be sent each year to potential respondents in January and responses are due by March 31. A U.S. person that is a financial services provider is required to report if its total receipts from, or total payments to, unaffiliated foreign persons for financial services exceeded $5 million during the covered year. A U.S. person that receives a form but is not required to report data must file an exemption claim.

III. Data

OMB Number: 0608–0063.

Form Number: BE–82.

Type of Review: Regular submission.

Affected Public: U.S. businesses or other for-profit institutions engaging in international financial services transactions.

Estimated Number of Responses: 425.

Estimated Time Per Response: 7.5 hours.

Estimated Total Annual Burden Hours: 3,200.

Estimated Total Annual Cost: $96,000 (based on an estimated reporting burden of 3,200 hours and an estimated hourly cost of $30).

IV. Request for Comments

Comments are invited on: (a) Whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information has practical utility; (b) the accuracy of the agency's estimate of the burden (including hours and cost) of the proposed collection of information; (c) ways to enhance the quality, utility, and clarity of the information to be collected; and (d) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or other forms of information technology.

Comments submitted in response to this notice will be summarized and/or included in the request for OMB approval of this information collection; they also will become a matter of public record.

Dated: May 8, 1998.

Linda Engelmeier,

Departmental Forms Clearance Officer, Office of Management and Organization.

[FR Doc. 98–12822 Filed 5–13–98; 8:45 am]

BILLING CODE 3510–06–P

DEPARTMENT OF COMMERCE

Bureau of the Census

Survey of Income and Program Participation Wave 9 of the 1996 Panel

ACTION: Proposed collection; comment request.

SUMMARY: The Department of Commerce, as part of its continuing effort to reduce paperwork and respondent burden, invites the general public and other Federal agencies to take this opportunity to comment on proposed and/or continuing information collections, as required by the Paperwork Reduction Act of 1995, Public Law 104–13 (44 U.S.C. 3506(c)(2)(A)).

DATES: Written comments must be submitted on or before July 13, 1998.

ADDRESSES: Direct all written comments to Linda Engelmeier, Departmental Forms Clearance Officer, Department of Commerce, Room 5327, 14th and Constitution Avenue, NW., Washington, DC 20230.

FOR FURTHER INFORMATION CONTACT: Requests for additional information or copies of the information collection instrument(s) and instructions should be directed to Michael McMahon, Bureau of the Census, FOB 3, Room 3319, Washington, DC 20233–0001, (301) 457–3819.

SUPPLEMENTARY INFORMATION:

I. Abstract

The Census Bureau conducts the Survey of Income and Program Participation (SIPP) which is a household-based survey designed as a continuous series of national panels, each lasting four years. Respondents are interviewed once every four months, in monthly rotations. Approximately 37,000 households are in the current panel.

The SIPP represents a source of information for a wide variety of topics and allows information for separate topics to be integrated to form a single, unified data base so that the interaction between tax, transfer, and other government and private policies can be examined. Government domestic policy formulators depend heavily upon SIPP information concerning the distribution of income received directly as money or indirectly as in-kind benefits, and the effect of tax and transfer programs on this distribution. They also need improved and expanded data on the income and general economic and financial situation of the U.S. population. The SIPP has provided these kinds of data on a continuing basis since 1983, permitting levels of economic well-being and changes in these levels to be measured over time.

The survey is molded around a central ''core'' of labor force and income questions that will remain fixed throughout the life of a panel. The core is supplemented with questions designed to answer specific needs, such

as obtaining information about the terms of child support agreements and whether they are being fulfilled by the absent parent, examining the program participation status of persons with specific health and disability statuses, and obtaining detailed information needed to understand the current status of the employment-based health care system and changes that have occurred. These supplemental questions are included with the core and are referred to as ''topical modules.''

The topical modules for the 1996 Panel Wave 9 collect information about:

(1) Assets, Liabilities, and Eligibility,

(2) Medical Expenses/Utilization of Health Care Services,

(3) Work Related Expenses and Child Support Paid.

Wave 9 interviews will be conducted from December 1998 through March 1999.

II. Method of Collection

The SIPP is designed as a continuing series of national panels of interviewed households that are introduced every 4 years, with each panel having a duration of 4 years in the survey. All household members 15 years old or over are interviewed using regular proxy-respondent rules. They are interviewed a total of 12 times (12 waves) at 4-month intervals, making the SIPP a longitudinal survey. Sample persons (all household members present at the time of the first interview) who move within the country and reasonably close to a SIPP Primary Sampling Unit will be followed and interviewed at their new address. Persons 15 years old or over who enter the household after Wave 1 will be interviewed; however, if these persons move, they are not followed unless they happen to move along with a Wave 1 sample person.

III. Data

OMB Number: 0607–0813.

Form Number: SIPP/CAPI Automated Instrument.

Type of Review: Regular.

Affected Public: Individuals or Households.

Estimated Number of Respondents: 77,700.

Estimated Time Per Response: 30 minutes per person.

Estimated Total Annual Burden Hours: 117,800.

Estimated Total Annual Cost: $31,269,000.

Respondent's Obligation: Voluntary.

Legal Authority: Title 13 U.S.C., Section 182.

IV. Request for Comments

Comments are invited on: (a) Whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; (b) the accuracy of the agency's estimate of the burden (including hours and cost) of the proposed collection of information; (c) ways to enhance the quality, utility, and clarity of the information to be collected; and (d) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or other forms of information technology.

Comments submitted in response to this notice will be summarized and/or included in the request for OMB approval of this information collection; they also will become a matter of public record.

Dated: May 8, 1998.

Linda Engelmeier,

Departmental Forms Clearance Officer, Office of Management and Organization.

[FR Doc. 98–12823 Filed 5–13–98; 8:45 am]

BILLING CODE 3510–07–P

DEPARTMENT OF COMMERCE

Office of the Secretary

Revision to the Commerce Acquisition Regulation (CAR) Clause at 1352.219–109 Entitled ''Insurance Requirements''

ACTION: Proposed collection; comment request.

SUMMARY: The Department of Commerce, as part of its continuing effort to reduce paperwork and respondent burden, invites the general public and other Federal agencies to take this opportunity to comment on proposed and/or continuing information collections, as required by the Paperwork Reduction Act of 1995, Public Law 104–13 (44 U.S.C. 3506(c)(2)(A)).

DATES: Written comments must be submitted on or before July 13, 1998.

ADDRESSES: Direct all written comments to Linda Engelmeier, Departmental Clearance Officer, Department of Commerce, Room 5327, 14th and Constitution Avenue, NW, Washington, DC 20230.

FOR FURTHER INFORMATION CONTACT: Requests for additional information or copies of the information collection instrument(s) and instructions should be directed to Ms. Deborah O'Neill, Department of Commerce, 14th and Constitution Avenue, NW, Room 6422, Washington, DC, 20230. Her telephone number is (202) 482–0202.

SUPPLEMENTARY INFORMATION:

I. Abstract

The Department of Commerce requires the contractor to procure and maintain certain kinds of insurance, in contracts for construction, alteration and repair of ships as specified in the Commerce Acquisition Regulation (CAR) clause 1352.217–109, ''Insurance Requirements.'' This insurance is necessary to protect the multi-million dollar ships and the interests of the U.S. taxpayers. Prior to the commencement of work, the contractor is required to present proof of this insurance to the Government. As evidence that it has obtained insurance specified, the Contractor must furnish the Contracting Officer with a certificate of certificates executed by an agent of the insurer authorized to execute such certificates. The requirement to present proof of insurance is contract specific. Therefore, there is no duplication of effort from contract to contract. There is no outside source of information that can be used to obtain the required information. The Department has minimized the burden by requiring the proof of insurance only once. The levels of insurance that the Department requires its contractor to maintain are based upon industry standards and is consistent with the levels of insurance required by the U.S. Navy and U.S. Coast Guard. Commerce collects only the minimum amount of information needed to ensure that the ships are protected and that the terms of its contracts are complied with.

II. Method of Collection

Written submission.

III. Data

OMB Number: 0690–0010.

Form Number: N/A.

Type of Review: Regular submission for extension of a currently approved collection.

Affected Public: Businesses or other for-profit and not-for-profit institutions.

Estimated Number of Respondents: 30.

Estimated Time per Response: 1.

Estimated Total Annual Burden Hours: 30.

Estimated Total Annual Cost: $0 (no capital expenditures are required).

IV. Request for Comments

Comments are invited on: (a) Whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; (b) the accuracy of the agency's estimate of the burden (including hours and cost) of the proposed collection of information; (c) ways to enhance the quality, utility, and

clarity of the information to be collected; and (d) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or other forms of information technology. Comments submitted in response to this notice will be summarized and/or included in the request for OMB approval of this information collection; they will also become a matter of public record.

Dated: May 7, 1998.

Linda Engelmeier,

Departmental Forms Clearance Officer, Office of Management and Organization.

[FR Doc. 98–12890 Filed 5–13–98; 8:45 am]

BILLING CODE 3510–EC–P

DEPARTMENT OF COMMERCE

Office of the Secretary

Department of Commerce Partners in Quality Contracts (PQC) Program

ACTION: Proposed collection; comment request.

SUMMARY: The Department of Commerce, as part of its continuing effort to reduce paperwork and respondent burden, invites the general public and other Federal agencies to take this opportunity to comment on proposed and/or continuing information collections, as required by the Paperwork Reduction Act of 1995, Public Law 104–13 (44 U.S.C. 3506(c)(2)(A)).

DATES: Written comments must be submitted on or before July 13, 1998.

ADDRESSES: Direct all written comments to Linda Engelmeier, Departmental Clearance Officer, Department of Commerce, Room 5327, 14th and Constitution Avenue, NW, Washington, DC 20230.

FOR FURTHER INFORMATION CONTACT: Requests for additional information or copies of the information collection instrument(s) and instructions should be directed to Ms. Deborah O'Neill, Department of Commerce, 14th and Constitution Avenue, NW, Room 6422, Washington, DC, 20230. Her telephone number is (202) 482–0202.

SUPPLEMENTARY INFORMATION:

I. Abstract

The National Performance Review (NPR) conducted by Vice President Gore outlined several objectives, including improving the Federal acquisition process. Along with the NPR objectives are associated Administration initiatives, such as greater emphasis on contractor's past performance; expanding the use of alternative disputes' resolution procedures; and improving communications overall between industry and government. The Department of Commerce (DOC) has developed a program that is philosophically consistent with NPR, known as the Partners in Quality Contracting (PQC) Program. PQC is a creative nonmonetary recognition program that showcases the importance of quality in the government acquisition process. It is intended as an effective yet inexpensive means of recognizing quality performance from both DOC contractors and acquisition personnel. The information collected is used to determine qualifications of applicants by DOC for purposes of recognizing DOC contractors and acquisition personnel who have promoted excellence in contracting through quality performance. The DOC PQC Evaluation Committee will be an independent committee, comprised of DOC employees from key functional areas. The universe of applicants includes all DOC contractors that have performed a DOC contract valued during the previous fiscal year at or above $100,000, if a large business, $50,000 or above, if a small one. A small business is defined as ''a business, including an affiliate, that is independently owned and operated, is not dominant in producing or performing the supplies or services being purchased, and has no more than 500 employees.'' Eligible contractors would ''self nominate'' through the submission of a company profile than an application that would be independently evaluated against pre-established criteria. Finalists would be site visited, as appropriate, by a government team before the final selections are made. Award recipients will be selected by consensus of the Committee. Award recipients will be invited to send representatives to attend an award reception.

II. Method of Collection

Written submission.

III. Data

OMB Number: 0690–0012.

Form Number: N/A.

Type of Review: Regular submission for extension of a currently approved collection.

Affected Public: Businesses or other for-profit organizations.

Estimated Number of Respondents: 50.

Estimated Time per Response: 38.

Estimated Total Annual Burden Hours: 1,900.

Estimated Total Annual Cost: $0 (no capital expenditures are required).

IV. Request for Comments

Comments are invited on: (a) Whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; (b) the accuracy of the agency's estimate of the burden (including hours and cost) of the proposed collection of information; (c) ways to enhance the quality, utility, and clarity of the information to be collected; and (d) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or other forms of information technology. Comments submitted in response to this notice will be summarized and/or included in the request for OMB approval of this information collection; they will also become a matter of public record.

Dated: May 7, 1998.

Linda Engelmeier,

Departmental Forms Clearance Officer, Office of Management and Organization.

[FR Doc. 98–12891 Filed 5–13–98; 8:45 am]

BILLING CODE 3510–EC–P

DEPARTMENT OF COMMERCE

Office of the Secretary

Women-Owned Small Business Sources

ACTION: Proposed collection; comment request.

SUMMARY: The Department of Commerce, as part of its continuing effort to reduce a paperwork and respondent burden, invites the general public and other Federal agencies to take this opportunity to comment on proposed and/or continuing information collections, as required by the Paperwork Reduction Act of 1995, Public Law 104–13 (44 U.S.C. 3506 (c)(2) (A)).

DATES: Written comments must be submitted on or before July 13, 1998.

ADDRESSES: Direct all written comments to Linda Engelmeier, Departmental Clearance Officer, Department of Commerce, Room 5327, 14th and Constitution Avenue, NW, Washington, DC 20230.

FOR FURTHER INFORMATION CONTACT: Requests for additional information or copies of the information collection instrument(s) and instructions should be directed to Ms. Deborah O'Neill, Department of Commerce, 14th and Constitution Avenue, NW, Room 6422,

Washington, DC 20230. Her telephone number is (202) 482–0202.

SUPPLEMENTARY INFORMATION:

I. Abstract

This information is collected in order to respond to the Executive Order 12138 to promote women-owned business enterprises. Additionally, it is the intent of Congress to promote federal contracting opportunities for women-owned businesses as expressed in the proposed legislation in H.R. 3517, ''The Women's Business Procurement Assistance Act.'' The Department of Commerce through its use of the clause entitled ''Women-Owned Small Business Sources'' in certain Commerce contracts, implements this policy and encourages the use of women-owned small businesses in its acquisition programs. The Department currently provides opportunities to women-owned businesses on their mailing lists to receive solicitations for contracts. By allowing these firms to compete for, and receive, a fair proportion of the Department's contracts, it reduces a significant economic impact on a substantial number of small entities. This clause is used by the Federal Acquisition Regulation (FAR) Clause 52.219–9, entitled ''Small, Small Disadvantaged and Women-Owned Small Business Subcontracting Plan'' for all negotiated contracts with large businesses which exceed $500,000. The FAR clause requires the successful offeror to negotiate a small business and small disadvantaged subcontracting plan which provides subcontracting goals for utilization of both small businesses and small disadvantaged concerns. The Department of Commerce clause adds the requirement to include subcontracting goals for women-owned businesses in these subcontracting plans. The clause also requires the contractors to maintain lists of qualified potential women-owned firms. The Commerce Office of Small and Disadvantaged Business Utilization (OSDBU) provides assistance to the contractors in complying with the required list of potential subcontractors. They also submit the Department's proposal goals for award of contracts and subcontracts for women-owned businesses to the Small Business Administration (SBA).

II. Method of Collection

Written submission.

III. Data

OMB Number: 0605–0019.

Form Number: N/A.

Type of Review: Regular submission for extension of a currently approved collection.

Affected Public: Businesses or other for-profit and not-for-profit institutions.

Estimated Number of Respondents: 20.

Estimated Time per Response: 12.

Estimated Total Annual Burden Hours: 240.

Estimated Total Annual Cost: $0 (no capital expenditures are required).

IV. Request for Comments

Comments are invited on: (a) Whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; (b) the accuracy of the agency's estimate of the burden (including hours and cost) of the proposed collection of information; (c) ways to enhance the quality, utility, and clarity of the information to be collected; and (d) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or other forms of information technology. Comments submitted in response to this notice will be summarized and/or included in the request for OMB approval of this information collection; they will also become a matter of public record.

Dated: May 7, 1998.

Linda Engelmeier,

Departmental Forms Clearance Officer, Office of Management and Organization.

[FR Doc. 98–12892 Filed 5–13–98; 8:45 am]

BILLING CODE 3510–EC–U

DEPARTMENT OF COMMERCE

Office of the Secretary

Department of Commerce Solicitations: Requests for Proposals (RFPs) or Invitations for Bids (IFBs)

ACTION: Proposed collection; comment request.

SUMMARY: The Department of Commerce, as part of its continuing effort to reduce paperwork and respondent burden, invites the general public and other Federal agencies to take this opportunity to comment on proposed and/or continuing information collections, as required by the Paperwork Reduction Act of 1995, Public Law 104–13 (44 U.S.C. 3506 (c)(2)(A)).

DATES: Written comments must be submitted on or before July 13, 1998.

ADDRESSES: Direct all written comments to Linda Engelmeier, Departmental Clearance Officer, Department of Commerce, Room 5327, 14th and Constitution Avenue, NW, Washington, DC 20230.

FOR FURTHER INFORMATION CONTACT: Requests for additional information or copies of the information collection instrument(s) and instructions should be directed to Ms. Deborah O'Neill, Department of Commerce, 14th and Constitution Avenue, NW, Room 6422, Washington, DC, 20230. Her telephone number is (202) 482–0202.

SUPPLEMENTARY INFORMATION:

I. Abstract

The Department of Commerce (DOC) is required by the Competition in Contracting Act (Pub. L. 98–369) to seek maximum competition when issuing contracts for supplies and services. The Federal Acquisition Regulations (FAR) require each Federal agency to obtained needed supplies and services by soliciting proposals from prospective contractors prior to entering into contracts necessary to accomplished the missions of the agency. The Department is required to issue solicitations which require prospective contractors to prepare and submit technical and cost proposals as part of the Federal acquisition process for awarding these contracts. In soliciting proposals, the agency collects, from each competing contractor, the information necessary to evaluate the proposals and make a decision as to which proposal offers the most benefit to the Government. In its solicitations, the Commerce Department uses Standard Forms and uniform solicitation format which are prescribed by the FAR. Each competing contractor is required to submit a proposal comprising various parts (technical, business, and cost). Instructions for the preparation of the proposal is tailored to the statement of work, the amount of information to be submitted in the proposal will vary with the complexity and size of the work. The proposal will be evaluated by the Government using criteria which must be stated in the solicitation. The results of the evaluation are used to make a decision as to which firm shall be selected for the contract. Commerce collects no information other than that needed to evaluate and select contractors to meet the unique requirements of the Department, and to meet the requirement of the Federal procurement system.

II. Method of Collection

Written submission.

III. Data

OMB Number: 0690–0008.

Form Number: N/A.

Type of Review: Regular submission for extension of a currently approved collection.

Affected Public: Businesses or other for-profit and not-for-profit institutions.

Estimated Number of Respondents: 250.

Estimated Time per Response: 20.

Estimated Total Annual Burden Hours: 5,000.

Estimated Total Annual Cost: $0 (no capital expenditures are required).

IV. Request for Comments

Comments are invited on: (a) Whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; (b) the accuracy of the agency's estimate of the burden (including hours and cost) of the proposed collection of information; (c) ways to enhance the quality, utility, and clarity of the information to be collected; and (d) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or other forms of information technology. Comments submitted in response to this notice will be summarized and/or included in the request for OMB approval of this information collection; they will also become a matter of public record.

Dated: May 7, 1998.

Linda Engelmeier,

Departmental Forms Clearance Officer, Office of Management and Organization.

[FR Doc. 98–12893 Filed 5–13–98; 8:45 am]

BILLING CODE 3510–EC–P

DEPARTMENT OF COMMERCE

Economics and Statistics Administration

Census Advisory Committees

AGENCY: Economics and Statistics Administration, Department of Commerce.

ACTION: Notice of public meeting.

SUMMARY: Pursuant to the Federal Advisory Committee Act (Pub. L. 92–463, as amended by Pub. L. 94–409, P.L. 96–523, and Pub. L. 97–375), we are giving notice of a joint meeting of the Commerce Secretary's 2000 Census Advisory Committee (CAC), the CAC of Professional Associations, the CAC on the African American Population, the CAC on the American Indian and Alaska Native Populations, the CAC on the Asian and Pacific Islander Populations, and the CAC on the Hispanic Population. The meeting will convene on June 3, 1998, at the Holiday Inn Hotel and Suites, 625 First Street, Alexandria, VA 22314. The agenda will be limited to discussion on issues involved in the tabulation and presentation of data on race from Census 2000 within the framework of the decision on standards for maintaining, collecting, and presenting Federal data on race and ethnicity issued by the Office of Management and Budget (OMB) in October 1997. This discussion will also assist the Census Bureau in providing input into the OMB process of developing final guidelines on the tabulation of data on race for use across the Federal system.

DATES: On Wednesday, June 3, 1998, the meeting will begin at 9 a.m. and adjourn for the day at 4:30 p.m.

ADDRESSES: The meeting will take place at the Holiday Inn Hotel and Suites, 625 First Street, Alexandria, VA 22314.

FOR FURTHER INFORMATION CONTACT: Anyone wishing additional information about this meeting, or who wishes to submit written statements or questions, may contact Maxine Anderson-Brown, Committee Liaison Officer, Department of Commerce, Bureau of the Census, Room 3039, Federal Building 3, Washington, DC 20233, telephone: 301–457–2308.

SUPPLEMENTARY INFORMATION: The Commerce Secretary's 2000 Census Advisory Committee is composed of a Chair, Vice-Chair, and up to 35 member organizations, all appointed by the Secretary of Commerce. The Advisory Committee considers the goals of Census 2000 and user needs for information provided by that census and provides a perspective from the standpoint of the outside user community about how operational planning and implementation methods proposed for Census 2000 will realize those goals and satisfy those needs. The Advisory Committee considers all aspects of the conduct of the 2000 Census of Population and Housing and makes recommendations to the Secretary of Commerce for improving that census.

The CAC of Professional Associations is composed of 36 members appointed by the Presidents of the American Economic Association, the American Statistical Association, the Population Association of America, and the Chairman of the Board of the American Marketing Association. The Committee advises the Director, Bureau of the Census, on the full range of Census Bureau programs and activities in relation to its areas of expertise.

The CACs on the African American, American Indian and Alaska Native, Asian and Pacific Islander, and Hispanic Populations are composed of nine members each appointed by the Secretary of Commerce. The Committees provide an organized and continuing channel of communications between the communities they represent and the Bureau of the Census on its efforts to reduce the differential in the count for Census 2000 and on ways that census data can be disseminated to maximum usefulness to their communities and other users.

A brief period will be set aside for public comment and questions. However, individuals with extensive questions or statements for the record must submit them in writing to the Commerce Department official named above at least three working days prior to the meeting.

The meeting is physically accessible to people with disabilities. Requests for sign language interpretation or other auxiliary aids should be directed to the Census Bureau Committee Liaison Officer on 301–457–2308, TDD 301–457–2540.

Dated: May 6, 1998.

Lee Price,

Acting Under Secretary for Economic Affairs, Economics and Statistics Administration.

[FR Doc. 98–12764 Filed 5–13–98; 8:45 am]

BILLING CODE 3510–07–M

DEPARTMENT OF COMMERCE

Bureau of Export Administration

Action Affecting Export Privileges; David Irwin Portnoy; Order Denying Permission To Apply for or Use Export Licenses

In the matter of: David Irwin Portnoy, 2315 W. 5th Street, Irving, Texas 75060.

On August 1, 1997, David Irwin Portnoy (Portnoy) was convicted in the United States District Court for the Northern District of Texas, Dallas Division, on three counts of violating the International Emergency Economic Powers Act (50 U.S.C.A. §§ 1701–1706 (1991 & Supp. 1998)) (IEEPA). Specifically, Portnoy was convicted of knowingly and willfully exporting and causing to be exported from the United States to Switzerland, for trans-shipment to Libya, shipments of electronic components and telecommunications equipment.

Section 11(h) of the Export Administration Act of 1979, as amended (currently codified at 50 U.S.C.A. app.

§§ 2401–2420 (1991 & Supp. 1998)) (the Act),[1] provides that, at the discretion of the Secretary of Commerce,[2] no person convicted of violating the IEEPA, or certain other provisions of the United States Code, shall be eligible to apply for or use any license, including any License Exception, issued pursuant to, or provided by, the Act or the Export Administration Regulations (currently codified at 15 CFR Parts 730–774 (1997)) (the Regulations), for a period of up to 10 years from the date of the conviction. In addition, any license issued pursuant to the Act in which such a person had any interest at the time of conviction may be revoked.

Pursuant to §§ 766.25 and 750.8(a) of the Regulations, upon notification that a person has been convicted of violating the IEEPA, the Director, Office of Exporter Services, in consultation with the Director, Office of Export Enforcement, shall determine whether to deny that person permission to apply for or use any license, including any License Exception, issued pursuant to, or provided by, the Act or the Regulations, and shall also determine whether to revoke any license previously issued to such a person.

Having received notice of Portnoy's conviction for violating the IEEPA, and following consultations with the Acting Director, Office of Export Enforcement, I have decided to deny Portnoy permission to apply for or use any license, including any License Exception, issued pursuant to, or provided by, the Act and the Regulations, for a period of 10 years from the date of his conviction. The 10-year period ends on August 1, 2007. I have also decided to revoke all licenses issued pursuant to the Act in which Portnoy had an interest at the time of his conviction.

Accordingly, *it is hereby Ordered*.

I. Until August 1, 2007, David Irwin Portnoy, 2315 W. 5th Street, Irving, Texas 75060, may not, directly or indirectly, participate in any way, in any transaction involving any commodity, software or technology (hereinafter collectively referred to as ''item'') exported or to be exported from the United States, that is subject to the Regulations, or in any other activity subject to the Regulations, including, but not limited to:

A. Applying for, obtaining, or using any license, License Exception, or export control document;

B. Carrying on negotiations concerning, or ordering, buying, receiving, using, selling, delivering, storing, disposing of, forwarding, transporting, financing, or otherwise servicing in any way, any transaction involving any item exported or to be exported from the United States that is subject to the Regulations, or in any other activity subject to the Regulations; or

C. Benefiting in any way from any transaction involving any item exported or to be exported from the United States that is subject to the Regulations, or in any other activity subject to the Regulations.

II. No person may do, directly or indirectly, any of the following:

A. Export or reexport to or on behalf of the denied person any item subject to the Regulations;

B. Take any action that facilitates the acquisition or attempted acquisition by the denied person of the ownership, possession, or control of any item subject to the Regulations that has been or will be exported from the United States, including financing or other support activities related to a transaction whereby the denied person acquires or attempts to acquire such ownership, possession or control;

C. Take any action to acquire from or to facilitate the acquisition or attempted acquisition from the denied person of any item subject to the Regulations that has been exported from the United States;

D. Obtain from the denied person in the United States any item subject to the Regulations with knowledge or reason to know that the item will be, or is intended to be, exported from the United States; or

E. Engage in any transaction to service any item subject to the Regulations that has been or will be exported from the United States and which is owned, possessed or controlled by the denied person, or service any item, of whatever origin, that is owned, possessed or controlled by the denied person if such service involves the use of any item subject to the Regulations that has been or will be exported from the United States. For purposes of this paragraph, servicing means installation, maintenance, repair, modification or testing.

III. After notice and opportunity for comment as provided in Section 766.23 of the Regulations, any person, firm, corporation, or business organization related to Portnoy by affiliation, ownership, control, or position of responsibility in the conduct of trade or related services may also be subject to the provisions of this Order.

IV. This Order does not prohibit any export, reexport, or other transaction subject to the Regulations where the only items involved that are subject to the Regulations are the foreign-produced direct product of U.S.-origin technology.

V. This Order is effective immediately and shall remain in effect until August 1, 2007.

VI. A copy of this Order shall be delivered to Portnoy. This Order shall be published in the **Federal Register.**

Dated: May 5, 1998.

Eileen M. Albanese,

Director, Office of Exporter Services.

[FR Doc. 98–12786 Filed 5–13–98; 8:45 am]

BILLING CODE 3510–DT–M

[1] The Act expired on August 20, 1994. Executive Order 12924 (3 CFR, 1994 Comp. 917 (1995)), extended by Presidential Notices of August 15, 1995 (3 CFR , 1995 Comp. 501 (1996)), August 14, 1996 (3 CFR 1996 Comp. 298 (1997)), and August 13, 1997 (62 FR 43629, August 15, 1997), continued the Export Administration Regulations in effect under the IEEPA.

[2] Pursuant to appropriate delegations of authority, the Director, Office of Exporter Services, in consultation with the Director, Office of Export Enforcement, exercises the authority granted to the Secretary by Section 11(h) of the Act.

DEPARTMENT OF COMMERCE

Bureau of Export Administration

Acting Affecting Export Privileges; Wayne P. Smith; Order Denying Permission To Apply for or Use Export Licenses

In the Matter of: Wayne P. Smith currently incarcerated at: Federal Correction Institute, USM No. 09046–035, Federal Detention Center, 5010 Whatley Road, Oakdale, Louisiana 71463 and with an address at: 2333 Big Woods Edgerly Road, Rt. 1, Box 845c, Vinton, Louisiana 70668.

On July 3, 1996, Wayne P. Smith (Smith) was convicted in the United States District Court for the Western District of Louisiana, Lake Charles Division, on one count of violating Section 38 of the Arms Export Control Act (currently codified at 22 U.S.C.A. 2778 (1990 & Supp. 1998)) (the AECA). Specifically, Smith was convicted of knowingly and willfully exporting and causing to be exported to England 80 plain self-aligning ball bearings designed for and used on the McDonald Douglas F–4 Phantom II military jet, without obtaining the required export license from the Department of State.

Section 11(h) of the Export Administration Act of 1979, as amended currently codified at 50 U.S.C.A. app. §§ 2401–2420 (1991 & Supp. 1998)) (the Act),[1] provides that, at the discretion of

[1] The Act expired on August 20, 1994. Executive Order 12924 (3 CFR, 1994 Comp. 917 (1995)), extended by Presidential Notices of August 15, 1995 (3 CFR, 1995 Comp. 501 (1996)), August 14, 1996 (3 CFR, 1996 Comp. 298 (1997)), and August 13, 1997 (62 FR 43629, August 15, 1997), continued the

Continued

the Secretary of Commerce,[2] no person convicted of violating the AECA, or certain other provisions of the United States Code, shall be eligible to apply for or use any license, including any License Exception, issued pursuant to, or provided by, the Act or the Export Administration Regulations (currently codified at 15 CFR Parts 730–774 (1997)) (the Regulations), for a period of up to 10 years from the date of the conviction. In addition, any license issued pursuant to the Act in which such a person had any interest at the time of conviction may be revoked.

Pursuant to Sections 766.25 and 750.8(a) of the Regulations, upon notifications that a person has been convicted of violating the AECA, the Director, Office of Exporter Services, in consultation with the Director, Office of Export Enforcement, shall determine whether to deny that permission to apply for or use any license, including any License Exception, issued pursuant to, or provided by, the Act or the Regulations, and shall also determine whether to revoke any license previously issued to such a person.

Having received notice of Smith's conviction for violating the AECA, and following consultations with the Acting Director, Office of Export Enforcement, I have decided to deny Smith permission to apply for or use any license, including any License Exception, issued pursuant to, or provided by, the Act and the Regulations, for a period of 10 years from the date of his conviction. The 10-year period ends on July 3, 2006. I have also decided to revoke all licenses issued pursuant to the Act in which Smith had an interest at the time of his conviction.

Accordingly, *it is hereby ordered*.

I. Until July 3, 2006, Wayne P. Smith, currently incarcerated at the Federal Correction Institute, USM No. 09046–035, Federal Detention Center, 5010 Whatley Road, Oakdale, Louisiana 71463, and with an address at 2333 Big Woods Edgerly Road, Rt. 1, Box 845c, Vinton, Louisiana 70668, may not, directly or indirectly, participate in any way, in any transaction involving any commodity, software or technology (hereinafter collectively referred to as ''item'') exported or to be exported from the United States, that is subject to the Regulations, or in any other activity subject to the Regulations, including, but not limited to:

A. Applying for, obtaining, or using any license, License Exception, or export control document;

B. Carrying on negotiations concerning, or ordering, buying, receiving, using, selling, delivering, storing, disposing of, forwarding, transporting, financing, or otherwise servicing in any way, any transaction involving any item exported or to be exported from the United States that is subject to the Regulations, or in any other activity subject to the Regulations; or

C. Benefiting in any way from any transaction involving any item exported or to be exported from the United States that is subject to the Regulations, or in any other activity subject to the Regulations.

II. No person may do, directly or indirectly, any of the following:

A. Export or reexport to or on behalf of the denied person any item subject to the Regulations;

B. Take any action that facilitates the acquisition or attempted acquisition by the denied person of the ownership, possession, or control of any item subject to the Regulations that has been or will be exported from the Untied States, including financing or other support activities related to a transaction whereby the denied person acquires or attempts to acquire such ownership, possession or control;

C. Take any action to acquire from or to facilitate the acquisition or attempted acquisition from the denied person of any item subject to the Regulations that has been exported from the United States;

D. Obtain from the denied person in the United States any item subject to the Regulations with knowledge or reason to know that the item will be, or is intended to be, exported from the United States; or

E. Engage in any transaction to service any item subject to the Regulations that has been or will be exported from the United States and which is owned, possessed or controlled by the denied person, or service any item, of whatever origin, that is owned, possessed or controlled by the denied person if such service involves the use of any item subject to the Regulations that has been or will be exported from the United States. For purposes of this paragraph, servicing means installation, maintenance, repair, modification or testing.

III. After notice and opportunity for comment as provided in Section 766.23 of the Regulations, any person, firm, corporation, or business organization related to Smith by affiliation, ownership, control, or position of responsibility in the conduct or trade or related services may also be subject to the provisions of this Order.

IV. This Order does not prohibit any export, reexport, or other transaction subject to the Regulations where the only items involved that are subject to the Regulations are the foreign-produced direct product of U.S.-origin technology.

V. This Order is effective immediately and shall remain in effect until July 3, 2006.

VI. A copy of this Order shall be delivered to Smith. This Order shall be published in the **Federal Register.**

Dated: May 5, 1998.

Eileen M. Albanese,

Director, Office of Exporter Services.

[FR Doc. 98–12769 Filed 5–13–98; 8:45 am]

BILLING CODE 3510–DT–M

Export Administration Regulations in effect under the International Emergency Economic Powers Act (50 U.S.C.A. Secs. 1701–1706 (1991 & Supp. 1998)).

[2] Pursuant to appropriate delegations of authority, the Director, Office of Exporter Services, in consultation with the Director, Office of Export Enforcement, exercises the authority granted to the Secretary by Section 11(h) of the Act.

DEPARTMENT OF COMMERCE

Foreign-Trade Zones Board

[Docket 24–98]

Foreign-Trade Zone 169—Manatee County, Florida Application For Foreign-Trade Subzone Status Aso Corporation (Adhesive Bandages) Sarasota County, Florida

An application has been submitted to the Foreign-Trade Zones Board (the Board) by the Manatee County Port Authority, grantee of FTZ 169, requesting special-purpose subzone status for the first aid dressings manufacturing facility (adhesive bandages, sterile pads, waterproof adhesive tapes) of Aso Corporation (Aso), located in Sarasota County, Florida. The application was submitted pursuant to the Foreign-Trade Zones Act, as amended (19 U.S.C. 81a–81u), and the regulations of the Board (15 CFR part 400). It was formally filed on May 5, 1998.

The Aso facility (65,000 sq. ft. on 38 acres) is located at 300 Sarasota Center Blvd., within the International Trade Industrial Park, east of Sarasota (Sarasota County), Florida. The facility (148 employees) is used for the manufacture of first aid dressings, including adhesive bandages, sterile pads, and waterproof adhesive tapes. However, the applicant is only requesting to use FTZ procedures for the production of adhesive bandages (HTSUS 3005.10.50) using foreign-sourced adhesive tape (HTSUS 3919.90.50).

Zone procedures would enable Aso to choose the lower duty rate that applies

to the finished products (duty-free) instead of the duty rate that would otherwise apply to foreign adhesive tape (duty rate—5.8%). The application indicates that the savings from zone procedures would help improve the plant's competitiveness and increase exports.

In accordance with the Board's regulations, a member of the FTZ Staff has been designated examiner to investigate the application and report to the Board.

Public comment on the application is invited from interested parties. Submissions (original and three copies) shall be addressed to the Board's Executive Secretary at the address below. The closing period for their receipt is July 13, 1998. Rebuttal comments in response to material submitted during the foregoing period may be submitted during the subsequent 15-day period to July 28, 1998. A copy of the application and the accompanying exhibits will be available for public inspection at each of the following locations:

Office of the Executive Secretary, Foreign-Trade Zones Board, U.S. Department of Commerce, Room 3716, 14th and Pennsylvania Avenue, N.W., Washington, D.C. 20230.

U.S. Department of Commerce Export Assistance Center, 1130 Cleveland St., Clearwater, Florida 34615.

Dated: May 7, 1998.

Dennis Puccinelli,

Acting Executive Secretary.

[FR Doc. 98–12883 Filed 5–13–98; 8:45 am]

BILLING CODE 3510–DS–P

DEPARTMENT OF COMMERCE

International Trade Administration

Policies Regarding the Conduct of Five-Year (''Sunset'') Reviews of Antidumping and Countervailing Duty Orders; Policy Bulletin

AGENCY: Import Administration, International Trade Administration, Department of Commerce.

ACTION: Extension of deadline for submitting comments.

SUMMARY: On April 16, 1998, the Department of Commerce (''the Department'') published in the **Federal Register** a notice of Policy Bulletin; request for comments (63 FR 18871). In response to requests for extension of the deadlines contained in that notice, the Department has granted an extension until May 18, 1998 for the submission of written comments and until June 8, 1998, for the submission of rebuttal comments.

FOR FURTHER INFORMATION CONTACT: Melissa G. Skinner, Office of Policy, Import Administration, International Trade Administration, U.S. Department of Commerce, at (202) 482–1560 or Mark A. Barnett, Office of Chief Counsel for Import Administration, U.S. Department of Commerce, at (202) 482–2866.

SUPPLEMENTARY INFORMATION: The policy bulletin proposes policies regarding the conduct of five-year (''sunset'') reviews of antidumping and countervailing duty orders and suspended investigations pursuant to the provisions of sections 751(c) and 752 of the Tariff Act of 1930, as amended, and the Department's regulations. In the request for comment, the Department stated that to be assured of consideration, written comments must be received not later than May 12, 1998, and rebuttal comments must be received not later than June 2, 1998. In response to requests from several parties, we have granted an extension of these deadlines. Therefore, in order to be assured of consideration, written comments must be received not later than May 18, 1998. Rebuttal comments must be received not later than June 8, 1998. The filing requirements contained in the notice of April 16, continue to apply.

Dated: May 8, 1998.

Robert S. LaRussa,

Assistant Secretary for Import Administration.

[FR Doc. 98–12886 Filed 5–13–98; 8:45 am]

BILLING CODE 3510–DS–P

DEPARTMENT OF COMMERCE

International Trade Administration

[A–588–804]

Antifriction Bearings (Other Than Tapered Roller Bearings) and Parts Thereof From Japan; Amended Final Results of Antidumping Duty Administrative Reviews

AGENCY: Import Administration, International Trade Administration, Department of Commerce.

ACTION: Notice of final court decision and amended final results of administrative reviews.

SUMMARY: On March 27, 1998, the United States Court of International Trade affirmed the Department of Commerce's final remand results affecting final assessment rates for the second administrative reviews of the antidumping duty orders on antifriction bearings (other than tapered roller bearings) and parts thereof from Japan with respect to NSK. The classes or kinds of merchandise covered by these reviews are ball bearings and parts thereof, cylindrical roller bearings and parts thereof, and spherical plain bearings and parts thereof. As there is now a final and conclusive court decision in these actions, we are amending our final results of reviews and we will subsequently instruct the U.S. Customs Service to liquidate entries subject to these reviews.

EFFECTIVE DATE: May 14, 1998.

FOR FURTHER INFORMATION CONTACT: Lisa Tomlinson or Richard Rimlinger, Import Administration, International Trade Administration, U.S. Department of Commerce, 14th Street and Constitution Avenue, N.W., Washington, D.C. 20230; telephone (202) 482–4733.

Applicable Statute

Unless otherwise indicated, all citations to the Tariff Act of 1930, as amended (the Tariff Act), are references to the provisions in effect as of December 31, 1994. In addition, unless otherwise indicated, all citations to the Department of Commerce's (the Department's) regulations are to the regulations as codified at 19 CFR Part 353 (April 1, 1997).

SUPPLEMENTARY INFORMATION:

Background

On June 24, 1992, the Department published its final results of administrative reviews of the antidumping duty orders on antifriction bearings (other than tapered roller bearings) and parts thereof, from Japan *et al.* covering the period May 1, 1990 through April 30, 1991. *See Antifriction Bearings (Other Than Tapered Roller Bearings) and Parts Thereof From France, et al.; Final Results of Antidumping Duty Administrative Reviews,* 57 FR 28360 (June 24, 1992). These final results were amended on July 24, 1992, and December 14, 1992, to correct clerical errors. *See Antifriction Bearings (Other Than Tapered Roller Bearings) and Parts Thereof From France, et al., Amendment to Final Results of Antidumping Duty Administrative Reviews,* 57 FR 32969, and *Antifriction Bearings (Other Than Tapered Roller Bearings) and Parts Thereof From France, et al., Amendment to Final Results of Antidumping Duty Administrative Reviews,* 57 FR 59080, respectively. The classes or kinds of merchandise covered by these reviews are ball bearings and parts thereof (BBs), cylindrical roller bearings and parts thereof (CRBs), and spherical plain

bearings and parts thereof (SPBs). Subsequently, two domestic producers, the Torrington Company and Federal-Mogul, and a number of other interested parties, filed lawsuits with the U.S. Court of International Trade (CIT) challenging the final results. These lawsuits were litigated at the CIT and the United States Court of Appeals for the Federal Circuit (CAFC). On February 23, 1998, as a result of a final court decision, we issued amended final results for all firms whose dumping margins had changed as a result of litigation except for NSK. *See Antifriction Bearings (Other Than Tapered Roller Bearings) and Parts Thereof From France, et al.; Amended Final Results of Antidumping Duty Administrative Reviews* (63 FR 8908). At that time our determination of NSK's dumping margins was still subject to outstanding litigation.

On March 27, 1998, the CIT affirmed the Department's remand results for *Final Results of Redetermination Pursuant to Court Remand, NSK Ltd. And NSK Corporation* v. *United States,* Slip Op. 97–122 (CIT August 28, 1997), and dismissed this case. *NSK Ltd. and NSK Corp.* v. *United States,* Slip Op. 98–37 (CIT March 27, 1998). As a result of this and other litigation cited in our February 23, 1998, amended final results notice, the CIT (in some cases based on decisions by the CAFC) ordered the Department to make methodological changes and to recalculate the dumping margins for NSK. Specifically, the CIT ordered the Department, *inter alia:* (1) To change its methodology to account for value-added taxes with respect to the comparison of U.S. and home market prices; (2) not to deduct pre-sale inland freight incurred in the home market if the Department determined that there was no statutory authority to make such a deduction; (3) to develop a methodology which removes post-sale price adjustments and rebates paid on out-of-scope merchandise from any adjustment made to foreign market value or to deny such an adjustment if a viable method could not be found; (4) remove zero-priced United States sample sales from our antidumping calculations; and (5) to correct certain clerical errors.

As there is now a final and conclusive court decision with respect to NSK, we are amending our final results of review for this firm and we will subsequently instruct the U.S. Customs Service to liquidate NSK's entries subject to these reviews.

Amendment to Final Results

Pursuant to section 516A(e) of the Tariff Act, we are now amending the final results of administrative reviews of the antidumping duty orders on antifriction bearings (other than tapered roller bearings) and parts thereof from Japan for the period May 1, 1990, through April 30, 1991, with respect to NSK. The revised weighted-average percentage margins are as follows:

Company	BBs	CRBs	SPBs
NSK	4.63	12.47	([1])

[1] AA(1) No U.S. sales during the review period.

Accordingly, the Department will determine and the U.S. Customs Service will assess appropriate antidumping duties on entries of the subject merchandise made by NSK. Individual differences between United States price and foreign market value may vary from the percentages listed above. The Department will issue appraisement instructions to the U.S. Customs Service after publication of these amended final results of reviews.

This notice is published pursuant to section 751(a) of the Tariff Act.

Dated: May 7, 1998.

Robert S. LaRussa,

Assistant Secretary for Import Administration.

[FR Doc. 98–12884 Filed 5–13–98; 8:45 am]

BILLING CODE 3510–DS–P

DEPARTMENT OF COMMERCE

International Trade Administration

[A–549–813]

Notice of Preliminary Results and Partial Rescission of Antidumping Duty Administrative Review: Canned Pineapple Fruit From Thailand; Correction

AGENCY: Import Administration, International Trade Administration, Department of Commerce.

ACTION: Correction.

SUPPLEMENTARY INFORMATION: This notice corrects the case number previously published in the **Federal Register** on April 9, 1998 (Notice of Preliminary Results and Partial Rescission of Antidumping Duty Administrative Review, 63 FR 17357). On page 17357, we used the incorrect case number to reference this case. The correct case number is ''A–549–813.''

Dated: May 7, 1998.

Richard W. Moreland,

Deputy Assistant Secretary for Import Administration.

[FR Doc. 98–12760 Filed 5–13–98; 8:45 am]

BILLING CODE 3510–DS–P

DEPARTMENT OF COMMERCE

International Trade Administration

[A–201–601]

Certain Fresh Cut Flowers From Mexico; Notice of Final Results of Antidumping Duty Administrative Review, and Revocation of Antidumping Duty Order in Part

AGENCY: Import Administration, International Trade Administration, Department of Commerce.

ACTION: Notice of Final Results of Antidumping Duty Administrative Review, and Revocation of Antidumping Duty Order in Part.

SUMMARY: On January 9, 1998, the Department of Commerce (the Department) published the preliminary results of its administrative review of the antidumping duty order on certain fresh cut flowers from Mexico and intent to revoke in part with respect to respondent Rancho del Pacifico (Pacifico). This review covers one producer/exporter, Pacifico, and the period April 1, 1996 through March 31, 1997.

We gave interested parties an opportunity to comment on our preliminary results; however, we received no comments from interested parties. We have not changed the results from those presented in the preliminary results of review. We have also determined to revoke the order in part, with respect to Pacifico.

EFFECTIVE DATE: May 14, 1998.

FOR FURTHER INFORMATION CONTACT: Elfi Blum or Maureen Flannery, Import Administration, International Trade Administration, U.S. Department of Commerce, 14th Street and Constitution Avenue, N.W., Washington D.C. 20230; telephone: (202) 482–0197 or (202) 482–3020, respectively.

Applicable Statute

Unless otherwise indicated, all citations to the statute are references to the provisions effective January 1, 1995, the effective date of the amendments made to the Tariff Act of 1930 (the Act) by the Uruguay Round Agreements Act. In addition, unless otherwise indicated, all citations to the Department's regulations are to the regulations as codified at 19 CFR Part 353 (1996).

SUPPLEMENTARY INFORMATION:

Background

On January 9, 1998, the Department published in the **Federal Register** (63 FR 1428) the preliminary results of the administrative review of the

antidumping duty order on certain fresh cut flowers from Mexico, 52 FR 13491 (April 23, 1987), wherein we gave notice of our intent to revoke the order with respect to Pacifico's sales of the subject merchandise. We did not receive any comments from interested parties.

Scope of the Review

The products covered by this review are certain fresh cut flowers, defined as standard carnations, standard chrysanthemums, and pompon chrysanthemums (pompons). During the period of review (POR), such merchandise was classifiable under the Harmonized Tariff Schedule of the United States (HTSUS) items 0603.10.7010 (pompons), 0603.10.7020 (standard chrysanthemums), and 0603.10.7030 (standard carnations). The HTSUS item numbers are provided for convenience and Customs purposes only. The written description remains dispositive as to the scope of the order.

This review covers one manufacturer/exporter of fresh cut flowers from Mexico, Pacifico, and the period April 1, 1996 through March 31, 1997.

Final Results of Review and Revocation of the Order in Part

We determine that the following weighted-average dumping margin exists:

Manufacturer/exporter	Time period	Margin (percent)
Rancho del Pacifico	04/01/96–03/31/97	0.00

The Department shall determine, and the U.S. Customs Service shall assess, antidumping duties on all appropriate entries. The Department will issue appraisement instructions directly to the U.S. Customs Service.

We further determine that Pacifico sold fresh cut flowers at not less than NV for three consecutive review periods, including this review period, and it is not likely that Pacifico will in the future sell subject merchandise at less than NV. Additionally, Pacifico has submitted the required certifications, and has agreed to its immediate reinstatement in the antidumping duty order, as long as any firm is subject to the order, if the Department concludes under 19 CFR 353.22(f) that, subsequent to revocation, it sold the subject merchandise at less than NV. Furthermore, we received no comments from any interested party contesting the revocation. For these reasons, we are revoking the order on certain fresh cut flowers from Mexico with respect to Pacifico in accordance with section 751(d) of the Act and 19 CFR 353.25(a)(2).

This revocation applies to all entries of the subject merchandise from Pacifico entered, or withdrawn from warehouse, for consumption on or after April 1, 1997. The Department will order the suspension of liquidation ended for all such entries and will instruct the Customs Service to release any cash deposit or bonds. The Department will further instruct the Customs Service to refund with interest any cash deposits on entries made on or after April 1, 1997.

The following deposit rates will be effective upon publication of these final results of administrative review for all shipments of certain fresh cut flowers from Mexico entered, or withdrawn from warehouse, for consumption on or after the publication date, as provided for by section 751 (a)(2)(C) of the Act: (1) for previously reviewed or investigated companies not listed above, the cash deposit rate will continue to be the company-specific rate published for the most recent period; (2) if the exporter is not a firm covered in this review, a prior review, or the original less-than-fair-value investigation, but the manufacturer is, the cash deposit rate will be the rate established for the most recent period for the manufacturer of the merchandise; and (3) for all other producers and/or exporters of this merchandise, the cash deposit rate shall be the rate established in the investigation of sales at less than fair value, which is 18.20 percent. *See* 52 FR 6361 (March 3, 1987). These deposit requirements shall remain in effect until publication of the final results of the next administrative review.

This notice serves as a final reminder to importers of their responsibility under 19 CFR 353.25(b) to file a certificate regarding the reimbursement of antidumping duties prior to liquidation of the relevant entries during this review period. Failure to comply with this requirement could result in the Secretary's presumption that reimbursement of antidumping duties occurred and the subsequent assessment of double antidumping duties.

This notice also serves as a reminder to parties subject to administrative protective order (APO) of their responsibility concerning the disposition of proprietary information disclosed under APO in accordance with 19 CFR 353.34(d)(1). Timely written notification of return/destruction of APO materials or conversion to judicial protective order is hereby requested. Failure to comply with the regulations and the terms of an APO is a sanctionable violation.

This administrative review, revocation in part, and notice are in accordance with section 751(a)(1) of the Act (19 U.S.C. 1675(a)(1)) and 19 CFR 353.22 and 353.25.

Dated: May 5, 1998.

Robert S. LaRussa,

Assistant Secretary for Import Administration.

[FR Doc. 98–12885 Filed 5–13–98; 8:45 am]

BILLING CODE 3510–DS–P

DEPARTMENT OF COMMERCE

International Trade Administration

Transition Orders; Final Schedule and Grouping of Five-Year Reviews

AGENCY: Import Administration, International Trade Administration, Department of Commerce

ACTION: Notice of final schedule and grouping of five-year reviews of transition orders.

SUMMARY: The Department of Commerce (''the Department'') hereby publishes its final schedule for the conduct of the initial five-year reviews of transition orders and the International Trade Commission's (''the Commission'') final grouping of reviews.

FOR FURTHER INFORMATION CONTACT: Melissa G. Skinner, Office of Policy, Import Administration, International Trade Administration, U.S. Department of Commerce, at (202) 482–1560, or Vera Libeau, Office of Investigations, U.S. International Trade Commission, at (202) 205–3176.

SUPPLEMENTARY INFORMATION:

Background

On October 9, 1997, the Department published its proposed schedule for the conduct of the initial five-year reviews of transition orders and the Commission's proposal for grouping reviews (Transition Orders; Schedule and Grouping of Five-year Reviews, 62 FR 52686), as amended on November

17, 1997 (Transition Orders; Schedule and Grouping of Five-year Reviews, 62 FR 61294). We invited comments from interested parties on the proposed schedule and grouping of reviews. On December 8, 1997, the Department and the Commission received comments. On January 6, 1998, the Department and the Commission received rebuttal comments.

Comments on Schedule

We received comments from 22 parties, 11 of which addressed the proposed schedule. Five commenters requested that the proposed schedule be amended. After consideration of these comments, and following consultations with the Commission, the Department has decided to continue to apply the methodology described in the notice of proposed schedule and leave the schedule intact, with the exceptions caused by changes to specific groupings and revocations that have taken place since the publication of the proposed schedule. In addition, because of the embargo on imports from Iran, the Department has not scheduled the sunset review of the antidumping duty order on pistachios from Iran at this time.

Counsel for petitioners with respect to the antidumping duty order on stainless steel plate from Sweden requested that initiation of the sunset review of that order be rescheduled at a later time. Counsel suggests that an affirmative duty absorption determination is possible in the administrative review that the Department may initiate in July 1998. Counsel stated that the 1998 review offers the first opportunity to examine the issue of duty absorption because there was a zero margin on imports from respondent Avesta Sheffield AB (''Avesta'') at the time of the administrative review initiated in 1996 and, thus, there was no duty absorption to be found. Counsel for Avesta objected to any delay stating that an affirmative duty absorption determination is highly speculative and the Commission is not required to consider a duty absorption determination unless one exists.

The Department is not delaying the sunset review of stainless steel plate from Sweden. If we were to adopt the position of petitioners, we would need to delay the initiation of the sunset review of any order for which there is a theoretical potential for an affirmative duty absorption determination in the fourth review. Such a step would not be practical in light of the deadlines imposed by the statute and the need to begin sunset reviews of transition order in July 1998. In addition, we note that a duty absorption finding was possible in the second review (because dumping margins were found); however, petitioners did not request that the Department examine this issue.

Counsel for Roquette Frères requested that the initiation of the sunset review of the order on sorbitol from France be accelerated from October 1998 to July 1998. Among the reasons cited in support, counsel noted that: imports should have ceased altogether; there is no likelihood of resumption of imports; no interested party is expected to request that the order remain in effect; given Roquette Frères' investment in U.S. production facilities, no comment suggesting continuation of the order is expected from interested parties other than competing producers; and given the order is not grouped with any others, it is administratively convenient and will contribute to an expeditious sunsetting of the order. The Department is not accelerating the schedule for review of the order on sorbitol from France. Consideration of case specific facts such as the level of imports, their likelihood of resumption, and the willingness of domestic producers to participate in a sunset review is more appropriately done in the course of the sunset review itself. It is inappropriate for us to consider many of these substantive issues which may be relevant to the sunset determination itself in the context of scheduling the sunset reviews. The Department, instead, has elected to stay with its objective criteria described in its October 9, 1997 notice.

Counsel for domestic producers of circular welded non-alloy steel pipe, light-walled rectangular pipe and tube, and oil country tubular goods requested that these products be considered as three separate groupings and that a staggered schedule of March, May, and July be established for initiation of sunset reviews on these three groups because simultaneous initiation would impose a burden on counsel and the domestic producers it represents. Similarly, counsel for interested parties in cases covering industrial belts, V belts, drafting machines, small business telephone systems, and mechanical transfer presses requested separation of initiations of sunset reviews on these orders by at least a few months in order to allow adequate representation of clients in each of these cases that the proposed schedule would make almost impossible. While we are sympathetic to the administrative burden imposed on counsel, we do not consider that this schedule denies adequate representation to any parties desiring to participate in sunset reviews. Additionally, we do not find these reasons sufficient to depart from the methodology used to develop the proposed schedule. Therefore, we have not adopted these suggested changes to the schedule.

Counsel for Norsk Hydro Canada Inc., a producer and exporter from Canada of pure magnesium and alloy magnesium objected to the proposed schedule for initiation of reviews on the antidumping order on pure magnesium and the countervailing duty orders on pure and alloy magnesium. Counsel stated that the proposed schedule results in the Department, prior to initiating sunset reviews on the magnesium orders, initiating sunset reviews of fifteen orders issued subsequent to the issuance of the magnesium orders. In support of its request, counsel stated that: the SAA requires that, to the maximum extent practical, older orders be reviewed first; the Department provided no reason for reviewing the newer orders out of chronological sequence; the Department did not identify any special problem that would justify the out-of-sequence review; the proposed groupings by the Commission, which group orders covering products that are not identical, do not support the out-of-sequence review for the majority of the fifteen orders; given that subsequent reviews are to follow the same time frame as initial reviews, companies following non-sequential reviews are penalized forever; and the proposed schedule for review of the fifteen orders favors trade with other countries over trade with Canada. For these reasons, counsel requested that the Department and Commission reconsider the proposed schedule and groupings.

We continue to believe that the methodology used to develop the proposed schedule results in the creation of a schedule that permits the Department and the Commission to conduct sunset reviews of over 300 transition orders consistent with the provisions of the statute and, at the same time, provides the most rational and equitable schedule for interested parties. As explained in the Methodology section of the notice of proposed schedule and groupings (62 FR at 52686), the groups were created by combining orders involving the same domestic product or related like products. The schedule placed the groups in chronological sequence based on the average date of the group. Each of the fifteen orders cited by counsel was grouped with older orders such that the average date of the group pre-dated the orders on pure and alloy magnesium. This is the type of ''special problem'' that may arise where reviews of transition orders are grouped and

which has been addressed through the use of the average date of the orders in the group. We continue to believe that the proposed groupings are appropriate and have not revised the schedule.

Comments on Grouping

Commenters objected to five specific groupings proposed in the notice.[1] The Commission has decided to modify one of these groups and leave the remaining three intact.

The Ad Hoc Committee of Domestic Nitrogen Producers and Mississippi Potash Corp. objected to the proposed grouping of 17 antidumping orders concerning solid urea with a suspension agreement concerning an antidumping investigation relating to potassium chloride (potash) from Canada. The Commission has concluded that consolidating reviews of urea and potash would not enhance administrative efficiency because urea and potash are chemically distinct, do not serve as practical or functional substitutes, and the only two U.S. producers that produce both urea and potash do so through distinct production facilities and entities. Accordingly, the Commission has not included the suspension agreement concerning potash from Canada within the group of urea orders.

The Cookware Manufacturers Association and counsel for three U.S. cookware manufacturers, objected to the proposed grouping of four antidumping and countervailing duty orders concerning porcelain-on-steel cookware, on the one hand, with four antidumping and countervailing duty orders on top-of-the-stove stainless steel cookware, on the other. Although these commenters are correct in asserting that the Commission has not previously determined that porcelain-on-steel and stainless steel cookware are within the same domestic like product, the legislative history of the Uruguay Round Agreements Act does not limit the Commission's ability to group reviews to those reviews involving identical like products. Instead, the legislative history indicates that the Commission may group reviews involving related products when such consolidation will promote administrative efficiency in conducting the review. Although the Commission is not defining domestic like products at this time, it has concluded that porcelain-on-steel and stainless steel cookware are sufficiently similar that consolidating reviews of all orders concerning these products into a single group will promote administrative efficiency.

Counsel for eight U.S. producers of circular welded non-alloy steel pipe, six U.S. producers of light-walled rectangular pipe and tube, and four U.S. producers of oil country tubular goods, objected to the grouping of 18 antidumping and countervailing duty orders involving various types of carbon steel pipe and tube products. The Commission has concluded that there is sufficient similarity among the products and overlap among the producers that a grouped review of these orders would promote administrative efficiency. The Commission has consequently decided not to modify this group.

The Japan Bearing Industrial Association objected to the proposed ''bearings'' group encompassing 22 antidumping and countervailing duty orders. It requested that the Commission group orders involving tapered roller bearings separately from orders involving other antifriction bearings. By contrast, Timken Co. and Torrington Co., respectively the petitioners in the original tapered roller bearings and antifriction bearings investigations, stated in comments that they did not object to the proposed ''bearings'' grouping. Because of the overall similarity of the products and the existence of some overlap among producers, the Commission has concluded that including all bearings in a single group will promote administrative efficiency. Accordingly, it has not modified the ''bearings'' group.

Final Schedule and Grouping

After considering the comments received, the Department and the Commission have developed, in consultation, the final schedule and grouping provided in the Appendix to this notice.

Dated: May 8, 1998.

Robert S. LaRussa,

Assistant Secretary for Import Administration.

FINAL SCHEDULE AND GROUPING

Initiation month/year	Group average date month/year	Effective date (mm.dd.yy)	DOC Case No.	ITC Case No.	Country	Product
July 98	9. 66	09. 13. 66	A–122–006	AA–49	Canada	Steel Jacks.
	6. 72	06. 9. 72	A–588–029	AA–85	Japan	Fish Netting of Manmade Fiber.
	6. 72	06. 14. 72	A–427–030	AA–86	France	Large Power Transformers.
	6. 72	06. 14. 72	A–475–031	AA–87	Italy	Large Power Transformers.
	6. 72	06. 14. 72	A–588–032	AA–88	Japan	Large Power Transformers.
	9. 72	08. 28. 68	A–843–803	AA–51	Kazakstan	Titanium Sponge.
	9. 72	08. 28. 68	A–821–803	AA–51	Russia	Titanium Sponge.
	9. 72	08. 28. 68	A–823–803	AA–51	Ukraine	Titanium Sponge.
	9. 72	11. 30. 84	A–588–020	A–161	Japan	Titanium Sponge.
	11. 72	11. 22. 72	A–588–038	AA–98	Japan	Bicycle Speedometers.
	3. 73	03. 23. 73	A–602–039	AA–110	Australia	Canned Bartlett Pears.
	4. 73	04. 12. 73	A–588–028	AA–111	Japan	Roller Chain.
Aug. 98	6. 73	06. 08. 73	A–401–040	AA–114	Sweden	Stainless Steel Plate.
	7. 73	07. 10. 73	A–588–041	AA–115	Japan	Synthetic Methionine.
	12. 73	12. 06. 73	A–588–046	AA–129	Japan	Polychloroprene Rubber.
	12. 73	12. 17. 73	A–122–047	AA–127	Canada	Elemental Sulphur.
	2. 74	02. 27. 74	A–122–050	AA–137	Canada	Racing Plates.
	8. 76	08. 30. 76	A–588–055	AA–154	Japan	Acrylic Sheet.
	2. 77	02. 02. 77	A–588–056	AA–162	Japan	Melamine.
Sep. 98	3. 77	03. 15. 77	C–351–037	C4–21	Brazil	Cotton Yarn.
	10. 77	10. 21. 77	A–475–059	AA–167	Italy	Pressure Sensitive Tape.

[1] U.S. producers of gray portland cement calcium aluminate flux objected to the proposed cement/flux grouping. The Commission agreed that these products should not be grouped. However, on April 7, 1998, the Department revoked the antidumping duty order on flux; therefore this issue is moot.

FINAL SCHEDULE AND GROUPING—Continued

Initiation month/year	Group average date month/year	Effective date (mm.dd.yy)	DOC Case No.	ITC Case No.	Country	Product
	12. 77	12. 22. 77	A–428–062	AA–172	Germany	Animal Glue.
	2. 78	02. 17. 78	A–433–064	AA–173	Austria	Railway Track Equipment.
	5. 78	05. 25. 78	A–588–066	AA–176	Japan	Impression Fabric.
	12. 78	12. 08. 78	A–588–068	AA–188	Japan	Steel Wire Strand.
	4. 79	03. 21. 79	A–405–071	AA–191	Finland	Rayon Staple Fiber.
	4. 79	05. 15. 79	C–401–056	C4–13	Sweden	Rayon Staple Fiber.
Oct. 98	6. 79	07. 31. 78	C–408–046	C4–7	EC	Sugar.
	6. 79	06. 13. 79	A–423–077	AA–198	Belgium	Sugar.
	6. 79	06. 13. 79	A–427–078	AA–199	France	Sugar.
	6. 79	06. 13. 79	A–428–082	AA–200	Germany	Sugar.
	6. 79	04. 09. 80	A–122–085	A–3	Canada	Sugar and Syrups.
	12. 79	03. 10. 71	A–588–015	AA–66	Japan	Television Receivers.
	12. 79	04. 30. 84	A–580–008	A–134	Korea (South)	Color Television Receivers.
	12. 79	04. 30. 84	A–583–009	A–135	Taiwan	Color Television Receivers.
	11. 80	11. 06. 80	A–588–090	A–7	Japan	Small Electric Motors (SA).
	1. 81	01. 07. 81	A–427–098	A–25	France	Anhydrous Sodium Metasilicate.
	4. 82	04. 09. 82	A–427–001	A–44	France	Sorbitol.
	7. 82	07. 20. 82	A–588–005	A–48	Japan	High Power Microwave Amplifiers.
	2. 83	06. 25. 81	A–428–061	A–31	Germany	Barium Carbonate.
	2. 83	10. 17. 84	A–570–007	A–149	China, PR	Barium Chloride.
Nov. 98	9. 83	09. 16. 83	A–570–101	A–101	China, PR	Griege Polyester Cotton Print Cloth.
	10. 83	09. 27. 82	C–357–004	C-None	Argentina	Carbon Steel Wire Rod (SA).
	10. 83	11. 23. 84	A–357–007	A–157	Argentina	Carbon Steel Wire Rod.
	11. 83	11. 07. 83	C–559–001	C-None	Singapore	Refrigeration Compressors (SA).
	1. 84	01. 19. 84	A–469–007	A–126	Spain	Potassium Permanganate.
	1. 84	01. 31. 84	A–570–001	A–125	China, PR	Potassium Permanganate.
	3. 84	03. 22. 84	A–570–002	A–130	China, PR	Chloropicrin.
	3. 85	10. 16. 80	C–533–063	C3–13	India	Iron Metal Castings.
	3. 85	03. 05. 86	A–122–503	A–263	Canada	Iron Construction Castings.
	3. 85	05. 09. 86	A–351–503	A–262	Brazil	Iron Construction Castings.
	3. 85	05. 09. 86	A–570–502	A–265	China, PR	Iron Construction Castings.
	3. 85	05. 15. 86	C–351–504	C–249	Brazil	Heavy Iron Construction Castings.
	3. 85	03. 01. 85	A–475–401	A–165	Italy	Brass Fire Protection Equipment.
Dec. 98	3. 85	3. 12. 85	C–301–401	C-None	Colombia	Textiles & Textile Products (SA).
	3. 85	3. 12. 85	C–549–401	C-None	Thailand	Certain Textile Mill Products (SA).
	4. 85	03. 02. 83	C–351–005	C–184	Brazil	Frozen Concentrated Orange Juice (SA).
	4. 85	05. 05. 87	A–351–605	A–326	Brazil	Frozen Concentrated Orange Juice.
	4. 85	04. 18. 85	A–588–401	A–189	Japan	Calcium Hypochlorite.
	5. 85	03. 16. 76	C–351–029	C4–20	Brazil	Castor Oil.
	5. 85	07. 14. 94	A–570–825	A–653	China, PR	Sebacic Acid.
	6. 85	06. 24. 85	A–122–401	A–196	Canada	Red Raspberries.
	8. 85	08. 15. 85	C–122–404	C–224	Canada	Live Swine.
	10. 85	10. 22. 85	C–351–406	C–223	Brazil	Tillage Tools.
	11. 85	11. 13. 85	A–357–405	A–208	Argentina	Barbed Wire.
Jan. 99	12. 85	12. 04. 85	A–614–502	A–246	New Zealand	Brazing Copper Wire & Rod.
	12. 85	01. 29. 86	A–791–502	A–247	South Africa	Brazing Copper Wire & Rod.
	12. 85	12. 19. 85	A–588–405	A–207	Japan	Cellular Mobile Phones.
	2. 86	02. 14. 86	A–570–501	A–244	China, PR	Paint Brushes.
	3. 86	10. 04. 83	A–570–003	A–103	China, PR	Shop Towels
	3. 86	03. 09. 84	C–535–001	C–202	Pakistan	Shop Towels.
	3. 86	09. 12. 84	C–333–401	C-None	Peru	Cotton Shop Towels (SA).
	3. 86	03. 20. 92	A–538–802	A–514	Bangladesh	Shop Towels.
	8. 86	08. 28. 86	A–570–504	A–282	China, PR	Candles.
	9. 86	10. 15. 73	A–588–045	AA–124	Japan	Steel Wire Rope.
	9. 86	03. 25. 93	A–201–806	A–547	Mexico	Steel Wire Rope.
	9. 86	03. 26. 93	A–580–811	A–546	Korea (South)	Steel Wire Rope.

FINAL SCHEDULE AND GROUPING—Continued

Initiation month/year	Group average date month/year	Effective date (mm.dd.yy)	DOC Case No.	ITC Case No.	Country	Product
	11. 86	05. 21. 86	A–351–505	A–278	Brazil	Malleable Cast Iron Pipe Fittings.
	11. 86	05. 23. 86	A–580–507	A–279	Korea (South)	Malleable Cast Iron Pipe Fittings.
	11. 86	05. 23. 86	A–583–507	A–280	Taiwan	Malleable Cast Iron Pipe Fittings.
	11. 86	07. 06. 87	A–588–605	A–347	Japan	Malleable Cast Iron Pipe Fittings.
	11. 86	08. 20. 87	A–549–601	A–348	Thailand	Malleable Cast Iron Pipe Fittings.
Feb. 99	1. 87	12. 02. 86	A–570–506	A–298	China, PR	Porcelain-on-Steel Cooking Ware.
	1. 87	12. 02. 86	A–201–504	A–297	Mexico	Porcelain-on-Steel Cooking Ware.
	1. 87	12. 02. 86	A–583–508	A–299	Taiwan	Porcelain-on-Steel Cooking Ware.
	1. 87	12. 12. 86	C–201–505	C–265	Mexico	Porcelain-on-Steel Cooking Ware.
	1. 87	01. 20. 87	A–580–601	A–304	Korea (South)	Top-of-the-Stove Stainless Steel Cooking Ware.
	1. 87	01. 20. 87	C–580–602	C–267	Korea (South)	Top-of-the-Stove Stainless Steel Cooking Ware.
	1. 87	01. 20. 87	C–583–604	C–268	Taiwan	Top-of-the-Stove Stainless Steel Cooking Ware.
	1.87	01. 20. 87	A–583–603	A–305	Taiwan	Top-of-the-Stove Stainless Steel Cooking Ware.
	3. 87	03. 12. 87	C–421–601	C–278	Netherlands	Standard Chrysanthemums.
	3. 87	03. 18. 87	A–301–602	A–329	Colombia	Fresh Cut Flowers.
	3. 87	03. 18. 87	A–331–602	A–331	Ecuador	Fresh Cut Flowers.
	3. 87	03. 19. 87	C–337–601	C–276	Chile	Standard Carnations.
	3. 87	03. 20. 87	A–337–602	A–328	Chile	Standard Carnations.
	3. 87	04. 23. 87	A–779–602	A–332	Kenya	Standard Carnations.
	3. 87	04. 23. 87	A–201–601	A–333	Mexico	Fresh Cut Flowers.
	3. 87	04. 23. 87	C–333–601	C3–18	Peru	Pompon Chrysanthemums.
	5. 87	01. 08. 87	C–351–604	C–269	Brazil	Brass Sheet & Strip.
	5. 87	01. 12. 87	A–351–603	A–311	Brazil	Brass Sheet & Strip.
	5. 87	01. 12. 87	A–122–601	A–312	Canada	Brass Sheet & Strip.
	5. 87	01. 12. 87	A–580–603	A–315	Korea (South)	Brass Sheet & Strip.
	5. 87	03. 06. 87	C–427–603	C–270	France	Brass Sheet & Strip.
	5. 87	03. 06. 87	A–427–602	A–313	France	Brass Sheet & Strip.
	5. 87	03. 06. 87	A–428–602	A–317	Germany	Brass Sheet & Strip.
	5. 87	03. 06. 87	A–475–601	A–314	Italy	Brass Sheet & Strip.
	5. 87	03. 06. 87	A–401–601	A–316	Sweden	Brass Sheet & Strip.
	5. 87	08. 12. 88	A–588–704	A–379	Japan	Brass Sheet & Strip.
	5. 87	08. 12. 88	A–421–701	A–380	Netherlands	Brass Sheet & Strip.
Mar. 99	7. 87	07. 14. 87	A–831–801	A–340	Armenia	Solid Urea.
	7. 87	07. 14. 87	A–832–801	A–340	Azerbaijan	Solid Urea.
	7. 87	07. 14. 87	A–822–801	A–340	Belarus	Solid Urea.
	7. 87	07. 14. 87	A–447–801	A–340	Estonia	Solid Urea.
	7. 87	07. 14. 87	A–833–801	A–340	Georgia	Solid Urea.
	7. 87	07. 14. 87	A–843–801	A–340	Kazakstan	Solid Urea.
	7. 87	07. 14. 87	A–835–801	A–340	Kyrgyzstan	Solid Urea.
	7. 87	07. 14. 87	A–449–801	A–340	Latvia	Solid Urea.
	7. 87	07. 14. 87	A–451–801	A–340	Lithuania	Solid Urea.
	7. 87	07. 14. 87	A–841–801	A–340	Moldova	Solid Urea.
	7. 87	07. 14. 87	A–485–601	A–339	Romania	Solid Urea.
	7. 87	07. 14. 87	A–821–801	A–340	Russia	Solid Urea.
	7. 87	07. 14. 87	A–842–801	A–340	Tajikistan	Solid Urea.
	7. 87	07. 14. 87	A–843–801	A–340	Turkmenistan	Solid Urea.
	7. 87	07. 14. 87	A–823–801	A–340	Ukraine	Solid Urea.
	7. 87	07. 14. 87	A–844–801	A–340	Uzbekistan	Solid Urea.
	8. 87	08. 19. 87	C–508–605	C–286	Israel	Industrial Phosphoric Acid.
	8. 87	08. 19. 87	A–508–604	A–366	Israel	Industrial Phosphoric Acid.
	8. 87	08. 20. 87	A–423–602	A–365	Belgium	Industrial Phosphoric Acid.
	8. 87	08. 25. 87	A–489–602	A–364	Turkey	Aspirin.
	1. 88	01. 07. 88	A–122–605	A–367	Canada	Color Picture Tubes.
	1. 88	01. 07. 88	A–588–609	A–368	Japan	Color Picture Tubes.
	1. 88	01. 07. 88	A–580–605	A–369	Korea (South)	Color Picture Tubes.
	1. 88	01. 07. 88	A–559–601	A–370	Singapore	Color Picture Tubes.

FINAL SCHEDULE AND GROUPING—Continued

Initiation month/year	Group average date month/year	Effective date (mm.dd.yy)	DOC Case No.	ITC Case No.	Country	Product
Apr. 99	1. 88	01. 19. 88	A–122–701	A–374	Canada	Potassium Chloride (Potash) (SA).
	6. 88	08. 08. 76	A–588–054	AA–143	Japan	Tapered Roller Bearings, 4 Inches and Under.
	6. 88	06. 15. 87	A–570–601	A–344	China, PR	Tapered Roller Bearings.
	6. 88	06. 19. 87	A–437–601	A–341	Hungary	Tapered Roller Bearings.
	6. 88	06. 19. 87	A–485–602	A–345	Romania	Tapered Roller Bearings.
	6. 88	10. 06. 87	A–588–604	A–343	Japan	Tapered Roller Bearings, Over 4 Inches.
	6. 88	05. 15. 89	A–427–801	A–392	France	Cylindrical Roller Bearings.
	6. 88	05. 15. 89	A–427–801	A–392	France	Ball Bearings.
	6. 88	05. 15. 89	A–427–801	A–392	France	Spherical Plain Bearings.
	6. 88	05. 15. 89	A–428–801	A–391	Germany	Spherical Plain Bearings.
	6. 88	05. 15. 89	A–428–801	A–391	Germany	Cylindrical Roller Bearings.
	6. 88	05. 15. 89	A–428–801	A–391	Germany	Ball Bearings.
	6. 88	05. 15. 89	A–475–801	A–393	Italy	Ball Bearings.
	6. 88	05. 15. 89	A–475–801	A–393	Italy	Cylindrical Roller Bearings.
	6. 88	05. 15. 89	A–588–804	A–394	Japan	Cylindrical Roller Bearings.
	6. 88	05. 15. 89	A–588–804	A–394	Japan	Spherical Plain Bearings.
	6. 88	05. 15. 89	A–588–804	A–394	Japan	Ball Bearings.
	6. 88	05. 15. 89	A–485–801	A–395	Romania	Ball Bearings.
	6. 88	05. 15. 89	A–559–801	A–396	Singapore	Ball Bearings.
	6. 88	05. 15. 89	A–401–801	A–397	Sweden	Ball Bearings.
	6. 88	05. 15. 89	A–401–801	A–397	Sweden	Cylindrical Roller Bearings.
	6. 88	05. 15. 89	A–412–801	A–399	United Kingdom	Cylindrical Roller Bearings.
	6. 88	05. 15. 89	A–412–801	A–399	United Kingdom	Ball Bearings.
	6. 88	06. 07. 88	A–588–703	A–377	Japan	Forklift Trucks.
	6. 88	06. 16. 88	A–588–706	A–384	Japan	Nitrile Rubber.
May 99	8. 88	05. 07. 84	A–583–008	A–132	Taiwan	Small Diameter Carbon Steel Pipe and Tube.
	8. 88	03. 07. 86	C–489–502	C–253	Turkey	Welded Carbon Steel Pipes and Tubes.
	8. 88	03. 07. 86	C–489–502	C–253	Turkey	Welded Carbon Steel Line Pipe.
	8. 88	03. 11. 86	A–549–502	A–252	Thailand	Welded Carbon Steel Pipes and Tubes.
	8. 88	05. 12. 86	A–533–502	A–271	India	Welded Carbon Steel Pipes and Tubes.
	8. 88	05. 15. 86	A–489–501	A–273	Turkey	Welded Carbon Steel Pipes and Tubes.
	8. 88	06. 16. 86	A–122–506	A–276	Canada	Oil Country Tubular Goods.
	8. 88	06. 18. 86	A–583–505	A–277	Taiwan	Oil Country Tubular Goods.
	8. 88	11. 13. 86	A–559–502	A–296	Singapore	Small Diameter Standard & Rectangular Pipe & Tube.
	8. 88	03. 06. 87	A–508–602	A–318	Israel	Oil Country Tubular Goods.
	8. 88	03. 06. 87	C–508–601	C–271	Israel	Oil Country Tubular Goods.
	8. 88	03. 27. 89	A–583–803	A–410	Taiwan	Light Walled Rectangular Tubing.
	8. 88	05. 26. 89	A–357–802	A–409	Argentina	Light Walled Rectangular Tubing.
	8. 88	11. 02. 92	A–351–809	A–532	Brazil	Circular-Welded Non-Alloy Steel Pipe.
	8. 88	11. 02. 92	A–580–809	A–533	Korea (South)	Circular-Welded Non-Alloy Steel Pipe.
	8. 88	11. 02. 92	A–201–805	A–534	Mexico	Circular-Welded Non-Alloy Steel Pipe.
	8. 88	11. 02. 92	A–583–814	A–536	Taiwan	Circular-Welded Non-Alloy Steel Pipe.
	8. 88	11. 02. 92	A–307–805	A–537	Venezuela	Circular-Welded Non-Alloy Steel Pipe.
	8. 88	08. 24. 88	A–588–707	A–386	Japan	Granular Polytetrafluoroetheylene Resin.
	8. 88	08. 30. 88	A–475–703	A–385	Italy	Granular Polytetraflouroetheylene Resin.
	3. 89	12. 17. 86	A–351–602	A–308	Brazil	Carbon Steel Butt-Weld Pipe Fittings.

FINAL SCHEDULE AND GROUPING—Continued

Initiation month/year	Group average date month/year	Effective date (mm.dd.yy)	DOC Case No.	ITC Case No.	Country	Product
	3. 89	12. 17. 86	A–583–605	A–310	Taiwan	Carbon Steel Butt-Weld Pipe Fittings.
	3. 89	02. 10. 87	A–588–602	A–309	Japan	Carbon Steel Butt-Weld Pipe Fittings.
	3. 89	07. 06. 92	A–570–814	A–520	China, PR	Carbon Steel Butt-Weld Pipe Fittings.
	3. 89	07. 06. 92	A–549–807	A–521	Thailand	Carbon Steel Butt-Weld Pipe Fittings.
	4. 89	04. 03. 89	A–588–802	A–389	Japan	Micro Disks.
	4. 89	04. 17. 89	A–484–801	A–406	Greece	Electrolytic Manganese Dioxide.
	4. 89	04. 17. 89	A–588–806	A–408	Japan	Electrolytic Manganese Dioxide.
Jun. 99	6. 89	06. 14. 89	A–428–802	A–419	Germany	Industrial Belts Except Synchronous & V Belts.
	6. 89	06. 14. 89	A–475–802	A–413	Italy	Synchronous and V-Belts.
	6. 89	06. 14. 89	A–588–807	A–414	Japan	Industrial Belts.
	6. 89	06. 14. 89	A–559–802	A–415	Singapore	V-Belts.
	9. 89	08. 10. 83	A–427–009	A–96	France	Industrial Nitrocellulose.
	9. 89	07. 10. 90	A–351–804	A–439	Brazil	Industrial Nitrocellulose.
	9. 89	07. 10. 90	A–570–802	A–441	China, PR	Industrial Nitrocellulose.
	9. 89	07. 10. 90	A–428–803	A–444	Germany	Industrial Nitrocellulose.
	9. 89	07. 10. 90	A–588–812	A–440	Japan	Industrial Nitrocellulose.
	9. 89	07. 10. 90	A–580–805	A–442	Korea (South)	Industrial Nitrocellulose.
	9. 89	07. 10. 90	A–412–803	A–443	United Kingdom	Industrial Nitrocellulose.
	9. 89	10. 16. 90	A–479–801	A–445	Yugoslavia	Industrial Nitrocellulose.
	9. 89	09. 15. 89	A–122–804	A–422	Canada	Steel Rail.
	9. 89	09. 22. 89	C–122–805	C–297	Canada	Steel Rail.
	12. 89	12. 29. 89	A–588–811	A–432	Japan	Drafting Machines.
	1. 90	12. 11. 89	A–588–809	A–426	Japan	Small Business Telephone Systems.
	1. 90	12. 11. 89	A–583–806	A–428	Taiwan	Small Business Telephone Systems.
	1. 90	02. 07. 90	A–580–803	A–427	Korea (South)	Small Business Telephone Systems.
	2. 90	02. 16. 90	A–588–810	A–429	Japan	Mechanical Transfer Presses.
	11. 90	11. 19. 90	A–588–813	A–455	Japan	Multiangle Laser Light Scattering Instruments.
	2. 91	02. 13. 91	A–588–816	A–462	Japan	Benzyl Paraben.
Jul. 99	2. 91	02. 19. 91	A–570–803	A–457	China, PR	Bars, Wedges.
	2. 91	02. 19. 91	A–570–803	A–457	China, PR	Axes, Adzes.
	2. 91	02. 19. 91	A–570–803	A–457	China, PR	Picks, Mattocks.
	2. 91	02. 19. 91	A–570–803	A–457	China, PR	Hammers, Sledges.
	2. 91	02. 19. 91	A–570–805	A–466	China, PR	Sulfur Chemicals (Sodium Thiosulfate).
	2. 91	02. 19. 91	A–428–807	A–465	Germany	Sulfur Chemicals (Sodium Thiosulfate).
	2. 91	02. 19. 91	A–412–805	A–468	United Kingdom	Sulfur Chemicals (Sodium Thiosulfate).
	4. 91	01. 03. 83	C–469–004	C–178	Spain	Stainless Steel Wire Rods.
	4. 91	12. 01. 93	A–533–808	A–638	India	Stainless Steel Wire Rods.
	4. 91	01. 28. 94	A–351–819	A–636	Brazil	Stainless Steel Wire Rods.
	4. 91	01. 28. 94	A–427–811	A–637	France	Stainless Steel Wire Rods.
	4. 91	12. 03. 87	A–401–603	A–354	Sweden	Seamless Stainless Steel Hollow Products.
	4. 91	12. 30. 92	A–580–810	A–540	Korea (South)	Welded Stainless Steel Pipes.
	4. 91	12. 30. 92	A–583–815	A–541	Taiwan	Welded Stainless Steel Pipes.
	4. 91	04. 12. 91	A–403–801	A–454	Norway	Fresh & Chilled Atlantic Salmon.
	4. 91	04. 12. 91	C–403–802	C–302	Norway	Fresh & Chilled Atlantic Salmon.
	6. 91	06. 05. 91	A–580–807	A–459	Korea (South)	Polyethylene Terephthalate Film.
	6. 91	06. 18. 91	A–570–804	A–464	China, PR	Sparklers.
	8. 91	03. 25. 88	A–588–702	A–376	Japan	Stainless Steel Butt-Weld Pipe Fittings.

FINAL SCHEDULE AND GROUPING—Continued

Initiation month/year	Group average date month/year	Effective date (mm.dd.yy)	DOC Case No.	ITC Case No.	Country	Product
	8. 91	02. 23. 93	A–580–813	A–563	Korea (South)	Stainless Steel Butt-Weld Pipe Fittings.
	8. 91	06. 16. 93	A–583–816	A–564	Taiwan	Stainless Steel Butt-Weld Pipe Fittings.
Aug. 99	8. 91	08. 30. 90	A–201–802	A–451	Mexico	Grey Portland Cement and Cement Clinker.
	8. 91	05. 10. 91	A–588–815	A–461	Japan	Grey Portland Cement and Cement Clinker.
	8. 91	02. 27. 92	A–307–803	A–519	Venezuela	Grey Portland Cement and Cement Clinker (SA).
	8. 91	03. 17. 92	C–307–804	C3–21	Venezuela	Grey Portland Cement and Cement Clinker (SA).
	9. 91	09. 04. 91	A–588–817	A–469	Japan	Flat Panel Displays (Electroluminescent).
	9. 91	09. 20. 91	A–570–808	A–474	China, PR	Chrome-Plated Lug Nuts.
	9. 91	09. 20. 91	A–583–810	A–475	Taiwan	Chrome-Plated Lug Nuts.
	11.91	11.21.91	A–570–811	A–497	China, PR	Tungsten Ore Concentrates.
	6.92	06.02.92	A–614–801	A–516	New Zealand	Kiwifruit.
	8.92	08.31.92	C–122–815	C–309	Canada	Pure Magnesium.
	8.92	08.31.92	C–122–815	C–309	Canada	Alloy Magnesium.
	8.92	08.31.92	A–122–814	A–528	Canada	Pure Magnesium.
	10.92	10.07.92	A–557–805	A–527	Malaysia	Extruded Rubber Thread.
	12.92	10.16.92	A–843–802	A–539	Kazakstan	Uranium (SA).
	12.92	10.16.92	A–835–802	A–539	Kyrgyzstan	Uranium (SA).
	12.92	10.16.92	A–821–802	A–539	Russia	Uranium (SA).
	12.92	10.16.92	A–844–802	A–539	Uzbekistan	Uranium (SA).
	12.92	08.30.93	A–823–802	A–539	Ukraine	Uranium.
Sep. 99	1.93	06.13.79	A–583–080	AA–197	Taiwan	Carbon Steel Plate.
	1.93	10.11.85	C–401–401	C–231	Sweden	Carbon Steel Products.
	1.93	08.17.93	C–423–806	C–319	Belgium	Cut-to-Length Carbon Steel Plate.
	1.93	08.17.93	C–351–818	C–320	Brazil	Cut-to-Length Carbon Steel Plate.
	1.93	08.17.93	C–427–810	C–348	France	Corrosion-Resistant Carbon Steel Flat Products.
	1.93	08.17.93	C–428–817	C–322	Germany	Cut-to-Length Carbon Steel Plate.
	1.93	08.17.93	C–428–817	C–349	Germany	Corrosion-Resistant Carbon Steel Flat Products.
	1.93	08.17.93	C–428–817	C–340	Germany	Cold-Rolled Carbon Steel Flat Products.
	1.93	08.17.93	C–580–818	C–342	Korea (South)	Cold-Rolled Carbon Steel Flat Products.
	1.93	08.17.93	C–580–818	C–350	Korea (South)	Corrosion-Resistant Carbon Steel Flat Products.
	1.93	08.17.93	C–201–810	C–325	Mexico	Cut-to-Length Carbon Steel Plate.
	1.93	08.17.93	C–469–804	C–326	Spain	Cut-to-Length Carbon Steel Plate.
	1.93	08.17.93	C–401–804	C–327	Sweden	Cut-to-Length Carbon Steel Plate.
	1.93	08.17.93	C–412–815	C–328	United Kingdom	Cut-to-Length Carbon Steel Plate.
	1.93	08.19.93	A–602–803	A–612	Australia	Corrosion-Resistant Carbon Steel Flat Products.
	1.93	08.19.93	A–423–805	A–573	Belgium	Cut-to-Length Carbon Steel Plate.
	1.93	08.19.93	A–351–817	A–574	Brazil	Cut-to-Length Carbon Steel Plate.
	1.93	08.19.93	A–122–822	A–614	Canada	Corrosion-Resistant Carbon Steel Flat Products.
	1.93	08.19.93	A–122–823	A–575	Canada	Cut-to-Length Carbon Steel Plate.
	1.93	08.19.93	A–405–802	A–576	Finland	Cut-to-Length Carbon Steel Plate.
	1.93	08.19.93	A–427–808	A–615	France	Corrosion-Resistant Carbon Steel Flat Products.
	1.93	08.19.93	A–428–815	A–616	Germany	Corrosion-Resistant Carbon Steel Flat Products.

FINAL SCHEDULE AND GROUPING—Continued

Initiation month/year	Group average date month/year	Effective date (mm.dd.yy)	DOC Case No.	ITC Case No.	Country	Product
	1.93	08.19.93	A–428–814	A–604	Germany	Cold-Rolled Carbon Steel Flat Products.
	1.93	08.19.93	A–428–816	A–578	Germany	Cut-to-Length Carbon Steel Plate.
	1.93	08.19.93	A–588–826	A–617	Japan	Corrosion-Resistant Carbon Steel Flat Products.
	1.93	08.19.93	A–580–816	A–618	Korea (South)	Corrosion-Resistant Carbon Steel Flat Products.
	1.93	08.19.93	A–580–815	A–607	Korea (South)	Cold-Rolled Carbon Steel Flat Products.
	1.93	08.19.93	A–201–809	A–582	Mexico	Cut-to-Length Carbon Steel Plate.
	1.93	08.19.93	A–421–804	A–608	Netherlands	Cold-Rolled Carbon Steel Flat Products.
	1.93	08.19.93	A–455–802	A–583	Poland	Cut-to-Length Carbon Steel Plate.
	1.93	08.19.93	A–485–803	A–584	Romania	Cut-to-Length Carbon Steel Plate.
	1.93	08.19.93	A–469–803	A–585	Spain	Cut-to-Length Carbon Steel Plate.
	1.93	08.19.93	A–401–805	A–586	Sweden	Cut-to-Length Carbon Steel Plate.
	1.93	08.19.93	A–412–814	A–587	United Kingdom	Cut-to-Length Carbon Steel Plate.
Oct. 99	1. 93	08. 19. 92	A–570–815	A–538	China, PR	Sulfanilic Acid.
	1. 93	03. 02. 93	C–533–807	C–318	India	Sulfanilic Acid.
	1. 93	03. 02. 93	A–533–806	A–561	India	Sulfanilic Acid.
	3. 93	03. 22. 93	C–351–812	C–314	Brazil	Hot-Rolled Lead & Bismuth Carbon Steel Products.
	3. 93	03. 22. 93	A–351–811	A–552	Brazil	Hot-Rolled Lead & Bismuth Carbon Steel Products.
	3. 93	03. 22. 93	A–427–804	A–553	France	Hot-Rolled Lead & Bismuth Carbon Steel Products.
	3. 93	03. 22. 93	C–427–805	C–315	France	Hot-Rolled Lead & Bismuth Carbon Steel Products.
	3. 93	03. 22. 93	C–428–812	C–316	Germany	Hot-Rolled Lead & Bismuth Carbon Steel Products.
	3. 93	03. 22. 93	A–428–811	A–554	Germany	Hot-Rolled Lead & Bismuth Carbon Steel Products.
	3. 93	03. 22. 93	C–412–811	C–317	United Kingdom	Hot-Rolled Lead & Bismuth Carbon Steel Products.
	3. 93	03. 22. 93	A–412–810	A–555	United Kingdom	Hot-Rolled Lead & Bismuth Carbon Steel Products.
Nov. 99	5. 93	06. 10. 91	A–570–806	A–472	China, PR	Silicon Metal.
	5. 93	07. 31. 91	A–351–806	A–471	Brazil	Silicon Metal.
	5. 93	09. 26. 91	A–357–804	A–470	Argentina	Silicon Metal.
	5. 93	03. 11. 93	A–570–819	A–567	China, PR	Ferrosilicon.
	5. 93	04. 07. 93	A–843–804	A–566	Kazakstan	Ferrosilicon.
	5. 93	04. 07. 93	A–823–804	A–569	Ukraine	Ferrosilicon.
	5. 93	05. 10. 93	C–307–808	C3–23	Venezuela	Ferrosilicon.
	5. 93	06. 24. 93	A–821–804	A–568	Russia	Ferrosilicon.
	5. 93	06. 24. 93	A–307–807	A–570	Venezuela	Ferrosilicon.
	5. 93	03. 14. 94	A–351–820	A–641	Brazil	Ferrosilicon.
	5. 93	10. 31. 94	A–823–805	A–673	Ukraine	Silicomanganese (SA).
	5. 93	12. 22. 94	A–351–824	A–671	Brazil	Silicomanganese.
	5. 93	12. 22. 94	A–570–828	A–672	China, PR	Silicomanganese.
	5. 93	05. 10. 93	A–580–812	A–556	Korea (South)	DRAMS of 1 Megabit and Above.
	7. 93	07. 12. 93	A–588–823	A–571	Japan	Electric Cutting Tools.
	8. 93	06. 28. 93	A–583–820	A–625	Taiwan	Helical Spring Lock Washers.
	8. 93	10. 19. 93	A–570–822	A–624	China, PR	Helical Spring Lock Washers.
	9. 93	09. 07. 93	A–570–820	A–621	China, PR	Compact Ductile Iron Waterworks Fittings and Glands.
Dec. 99	2. 94	02. 09. 94	A–533–809	A–639	India	Forged Stainless Steel Flanges.
	2. 94	02. 09. 94	A–583–821	A–640	Taiwan	Forged Stainless Steel Flanges.

FINAL SCHEDULE AND GROUPING—Continued

Initiation month/year	Group average date month/year	Effective date (mm.dd.yy)	DOC Case No.	ITC Case No.	Country	Product
	3. 94	03. 02. 94	A–588–829	A–643	Japan	Defrost Timers.
	6. 94	06. 24. 94	A–421–805	A–652	Netherlands	Aramid Fiber.
	7. 94	06. 07. 94	C–475–812	C–355	Italy	Grain-Oriented Electrical Steel.
	7. 94	06. 10. 94	A–588–831	A–660	Japan	Grain-Oriented Electrical Steel.
	7. 94	08. 12. 94	A–475–811	A–659	Italy	Grain-Oriented Electrical Steel.
	8. 94	08. 12. 94	A–588–832	A–661	Japan	Color Negative Photo Paper & Chemical Components (SA).
	8. 94	08. 12. 94	A–421–806	A–662	Netherlands	Color Negative Photo Paper & Chemical Components (SA).
	11. 94	11. 16. 94	A–570–831	A–683	China, PR	Garlic.
	11. 94	11. 25. 94	A–570–826	A–663	China, PR	Paper Clips.
	12. 94	12. 28. 94	A–570–827	A–669	China, PR	Cased Pencils.

[FR Doc 98–2887 Filed 5–13–98; 8:45 am]

BILLING CODE 3510 DS–P

COMMISSION OF FINE ARTS

Notice of Meeting

The Commission of Fine Arts will review revised designs for the World War II Memorial at its meeting on May 21, 1998. Please note the special time and location: 10:30 AM in the lecture hall of the West Building, National Gallery of Art at 6th Street and Constitution Avenue, NW. The building can be entered from the Constitution Avenue entrance after 10:00 AM, and is fully accessible. For those persons wishing to attend this meeting, please contact the Commission offices at 202–504–2200 to register. For those wishing to testify, statements should be brief, no more than five minutes.

Prior to the meeting, the Commission will view a partial mock-up of the Memorial on its site next to 17th Street, NW. at the Rainbow Pool on the Mall. Individuals wishing to view this mock-up are welcome and need not register in advance.

The remaining items on the agenda will be considered at the Commission's offices at the National Building Museum, 441 F Street, NW., Suite 312 following the World War II Memorial review.

Dated in Washington, DC, May 8, 1998.

Charles H. Atherton,

Secretary.

[FR Doc. 98–12861 Filed 5–13–98; 8:45 am]

BILLING CODE 6330–01–M

COMMITTEE FOR THE IMPLEMENTATION OF TEXTILE AGREEMENTS

Adjustment of Import Limits for Certain Cotton, Wool and Man-Made Fiber Textiles and Textile Products Produced or Manufactured in Korea

May 8, 1998.

AGENCY: Committee for the Implementation of Textile Agreements (CITA).

ACTION: Issuing a directive to the Commissioner of Customs reducing limits.

EFFECTIVE DATE: May 20, 1998.

FOR FURTHER INFORMATION CONTACT: Ross Arnold, International Trade Specialist, Office of Textiles and Apparel, U.S. Department of Commerce, (202) 482–4212. For information on the quota status of these limits, refer to the Quota Status Reports posted on the bulletin boards of each Customs port or call (202) 927–5850. For information on embargoes and quota re-openings, call (202) 482–3715.

SUPPLEMENTARY INFORMATION:

Authority: Section 204 of the Agricultural Act of 1956, as amended (7 U.S.C. 1854); Executive Order 11651 of March 3, 1972, as amended.

The current limits for certain categories are being reduced for carryforward used.

A description of the textile and apparel categories in terms of HTS numbers is available in the CORRELATION: Textile and Apparel Categories with the Harmonized Tariff Schedule of the United States (see **Federal Register** notice 62 FR 66057, published on December 17, 1997). Also see 62 FR 67833, published on December 30, 1997.

D. Michael Hutchinson,

Acting Chairman, Committee for the Implementation of Textile Agreements.

Committee for the Implementation of Textile Agreements

May 8, 1998.

Commissioner of Customs,
Department of the Treasury, Washington, DC 20229.

Dear Commissioner: This directive amends, but does not cancel, the directive issued to you on December 22, 1997, by the Chairman, Committee for the Implementation of Textile Agreements. That directive concerns imports of certain cotton, wool, man-made fiber, silk blend and other vegetable fiber textiles and textile products, produced or manufactured in Korea and exported during the period January 1, 1998 through December 31, 1998.

Effective on May 20, 1998, you are directed to reduce the limits for the following categories, as provided for under the Uruguay Round Agreement on Textiles and Clothing:

Category	Adjusted limit [1]
Group I 200–223, 224–V [2], 224–O [3], 225, 226, 227, 300–326, 360–363, 369pt. [4], 400–414, 464, 469pt. [5], 600–629, 666, 669–P [6], 669pt. [7], and 670–O [8], as a group.	382,507,864 square meters equivalent.
Sublevel within Group I 619/620	94,397,452 square meters.
Sevlevels within Group II 338/339	1,228,179 dozen.

Category	Adjusted limit [1]
340	648,052 dozen of which not more than 329,995 dozen shall be in Category 340–D [9].

[1] The limits have not been adjusted to account for any imports exported after December 31, 1997.

[2] Category 224–V: only HTS numbers 5801.21.0000, 5801.23.0000, 5801.24.0000, 5801.25.0010, 5801.25.0020, 5801.26.0010, 5801.26.0020, 5801.31.0000, 5801.33.0000, 5801.34.0000, 5801.35.0010, 5801.35.0020, 5801.36.0010 and 5801.36.0020.

[3] Category 224–O: all remaining HTS numbers in Category 224.

[4] Category 369pt.: all HTS numbers except 4202.12.4000, 4202.12.8020, 4202.12.8060, 4202.92.1500, 4202.92.3016, 4202.92.6091, 6307.90.9905, (Category 369–L); 5601.10.1000, 5601.21.0090, 5701.90.1020, 5701.90.2020, 5702.10.9020, 5702.39.2010, 5702.49.1020, 5702.49.1080, 5702.59.1000, 5702.99.1010, 5702.99.1090, 5705.00.2020 and 6406.10.7700.

[5] Category 469pt.: all HTS numbers except 5601.29.0020, 5603.94.1010 and 6406.10.9020.

[6] Category 669–P: only HTS numbers 6305.32.0010, 6305.32.0020, 6305.33.0010, 6305.33.0020 and 6305.39.0000.

[7] Category 669pt.: all HTS numbers except 6305.32.0010, 6305.32.0020, 6305.33.0010, 6305.33.0020, 6305.39.0000 (Category 669–P); 5601.10.2000, 5601.22.0090, 5607.49.3000, 5607.50.4000 and 6406.10.9040.

[8] Category 670–O: all HTS numbers except 4202.12.8030, 4202.12.8070, 4202.92.3020, 4202.92.3031, 4202.92.9026 and 6307.90.9907 (Category 670–L).

[9] Category 340–D: only HTS numbers 6205.20.2015, 6205.20.2020, 6205.20.2025 and 6205.20.2030.

The Committee for the Implementation of Textile Agreements has determined that these actions fall within the foreign affairs exception of the rulemaking provisions of 5 U.S.C. 553(a)(1).

Sincerely,

D. Michael Hutchinson,

Acting Chairman, Committee for the Implementation of Textile Agreements.

[FR Doc. 98–12888 Filed 5–13–98; 8:45 am]

BILLING CODE 3510–DR–F

COMMITTEE FOR THE IMPLEMENTATION OF TEXTILE AGREEMENTS

Adjustment of Import Limits for Certain Cotton, Man-Made Fiber, Silk Blend and Other Vegetable Fiber Textiles and Textile Products Produced or Manufactured in Sri Lanka

May 8, 1998.

AGENCY: Committee for the Implementation of Textile Agreements (CITA).

ACTION: Issuing a directive to the Commissioner of Customs increasing limits.

EFFECTIVE DATE: May 20, 1998.

FOR FURTHER INFORMATION CONTACT: Helen L. LeGrande, International Trade Specialist, Office of Textiles and Apparel, U.S. Department of Commerce, (202) 482–4212. For information on the quota status of these limits, refer to the Quota Status Reports posted on the bulletin boards of each Customs port or call (202) 927–5850. For information on embargoes and quota re-openings, call (202) 482–3715.

SUPPLEMENTARY INFORMATION:

Authority: Section 204 of the Agricultural Act of 1956, as amended (7 U.S.C. 1854); Executive Order 11651 of March 3, 1972, as amended.

The current limits for certain categories are being increased by recrediting unused carryforward and special carryforward applied to the 1997 limits.

A description of the textile and apparel categories in terms of HTS numbers is available in the CORRELATION: Textile and Apparel Categories with the Harmonized Tariff Schedule of the United States (see **Federal Register** notice 62 FR 66057, published on December 17, 1997). Also see 62 FR 67837, published on December 30, 1997.

D. Michael Hutchinson,

Acting Chairman, Committee for the Implementation of Textile Agreements.

Committee for the Implementation of Textile Agreements

May 8, 1998.

Commissioner of Customs,

Department of the Treasury, Washington, DC 20229.

Dear Commissioner: This directive amends, but does not cancel, the directive issued to you on December 22, 1997, by the Chairman, Committee for the Implementation of Textile Agreements. That directive concerns imports of certain cotton, wool, man-made fiber, silk blend and other vegetable fiber textiles and textile products, produced or manufactured in Sri Lanka and exported during the period January 1, 1998 through December 31, 1998.

Effective on May 20, 1998, you are directed to increase the limits for the following categories, as provided for under the Uruguay Round Agreement on Textiles and Clothing:

Category	Adjusted limit [1]
331/631	3,210,404 dozen pairs.
335/835	311,324 dozen.
336/636/836	434,683 dozen.
340/640	1,276,084 dozen.
341/641	2,100,508 dozen of which not more than 1,400,339 dozen shall be in Category 341 and not more than 1,400,339 dozen shall be in Category 641.
342/642/842	735,857 dozen.
347/348/847	1,103,659 dozen.
363	13,679,396 numbers.
369–S [2]	855,842 kilograms.
840	330,239 dozen.

[1] The limits have not been adjusted to account for any imports exported after December 31, 1997.

[2] Category 369–S: only HTS number 6307.10.2005.

The Committee for the Implementation of Textile Agreements has determined that these actions fall within the foreign affairs exception of the rulemaking provisions of 5 U.S.C. 553(a)(1).

Sincerely,

D. Michael Hutchinson,

Acting Chairman, Committee for the Implementation of Textile Agreements.

[FR Doc. 98–12889 Filed 5–13–98; 8:45 am]

BILLING CODE 3510–DR–F

DEPARTMENT OF DEFENSE

Office of the Secretary

Submission for OMB Review; Comment Request

ACTION: Notice.

SUMMARY: 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, Associated Form, And OMB Number; Export-Controlled DoD Technical Data Agreement; DD Form 2345; OMB Number 0704–0207.

Type of Request: Extension.

Number of Respondents: 6,000.

Responses Per Respondent: 1.

Annual Responses: 6,000.

Average Burden Per Response: 20 minutes.

Annual Burden Hours: 2,000.

Needs and Uses: The Information collection requirement is necessary as a basis for certifying individuals or businesses to have access to DoD export-controlled militarily critical technical data subject to the provisions of 32 CFR 250. Individuals and enterprises who need access to unclassified DoD-controlled militarily critical technical data must certify on DD Form 2345, Militarily Critical Technical Data Agreement, that data will be used only in ways that will inhibit unauthorized access and maintain the protection afforded by U.S. export control laws.

The information collected is disclosed only to the extent consistent with prudent business practices, current regulations, and statutory requirements

and is so indicated on the Privacy Act statement of DD Form 2345. Use of DD Form 2345 permits U.S. and Canada defense contractors to certify their eligibility to obtain certain unclassified technical data with military and space applications. Nonavailability of the form prevents defense contractors from accessing certain restricted databases and obstructs conference attendance where restricted data will be discussed.

Affected Public: Business or Other For-Profit; Not-For-Profit Institutions.

Frequency: on occasion

Respondent's Obligation: Required to obtain or retain benefits.

OMB Desk Officer: Mr. Peter N.Weiss.

Written comments and recommendations on the proposed information collection should be sent to Mr. Weiss at the Office of Management and Budget, Desk Officer for DoD, Room 10236, New Executive Office Building, Washington, DC 20503.

DOD Clearance Officer: Mr. Robert Cushing.

Written requests for copies of the information collection proposal should be sent to Mr. Cushing, WHS/DIOR, 1215 Jefferson Davis Highway, Suite 1204, Arlington, VA 22202–4302.

Dated: May 8, 1998.

Patricia L. Toppings,

Alternate OSD Federal Register Liaison Officer, Department of Defense.

[FR Doc. 98–12763 Filed 5–13–98; 8:45 am]

BILLING CODE 5000–04–M

DEPARTMENT OF DEFENSE

Department of the Air Force

HQ USAF Scientific Advisory Board Meeting

The ''Going to Space'' Space Control Panel Meeting in support of the HQ USAF Scientific Advisory Board will meet at Los Angeles Air Force Base, CA on May 26–28, 1998 from 8:00 a.m. to 5:00 p.m.

The purpose of the meeting is to gather information and receive briefings for the Going to Space 1998 Summer Study.

The meeting will be closed to the public in accordance with Section 552b of Title 5, United States Code, specifically subparagraphs (1) and (4) thereof.

For further information, contact the HQ USAF Scientific Advisory Board Secretariat at (703) 697–8404.

Barbara A. Carmichael,

Alternate Air Force Federal Register Liaison Officer.

[FR Doc. 98–12894 Filed 5–13–98; 8:45 am]

BILLING CODE 3910–01–P

DEPARTMENT OF DEFENSE

Department of the Air Force

HQ USAF Scientific Advisory Board Meeting

The ''Going to Space'' Space Control Panel Meeting in support of the HQ USAF Scientific Advisory Board will meet in Chantilly, VA and Rosslyn, VA on June 2, 1998 from 8:00 a.m. to 5:00 p.m.

The purpose of the meeting is to gather information and receive briefings for Going to Space 1998 Summer Study.

The meeting will be closed to the public in accordance with Section 552b of Title 5, United States Code, specifically subparagraphs (1) and (4) thereof.

For further information, contact the HQ USAF Scientific Advisory Board Secretariat at (703) 697–8404.

Barbara A. Carmichael,

Alternate Air Force Federal Register Liaison Officer.

[FR Doc. 98–12895 Filed 5–13–98; 8:45 am]

BILLING CODE 3910–01–P

DEPARTMENT OF DEFENSE

Department of the Air Force

HQ USAF Scientific Advisory Board Meeting

The 1998 Summer Study General Board Meeting in support of the HQ USAF Scientific Advisory Board will meet at the Arnold and Mabel Beckman Center, National Academies of Engineering & Sciences, Irvine, CA on June 15–26, 1998 from 8:00 a.m. to 5:00 p.m.

The purpose of the meeting is to gather information and receive briefings for the 1998 Summer Study topic on Going to Space.

The meeting will be closed to the public in accordance with Section 552b of Title 5, United States Code, specifically subparagraphs (1) and (4) thereof.

For further information, contact the HQ USAF Scientific Advisory Board Secretariat at (703) 697–8404.

Barbara A. Carmichael,

Alternate Air Force Federal Register Liaison Officer.

[FR Doc. 98–12896 Filed 5–13–98; 8:45 am]

BILLING CODE 3910–01–P

DEPARTMENT OF DEFENSE

Department of the Army

Army Science Board; Notice of Partially Closed Meeting

In accordance with Section 10(a)(2) of the Federal Advisory Committee Act (Pub. L. 92–463), announcement is made of the following Committee Meeting:

Name of Committee: Army Science Board (ASB).

Date of Meeting: 12–13 May 1998.

Time of Meeting: 0800–1700, 12 May 1998, 0900–1600, 13 May 1998.

Place: Arlington, VA.

Agenda: The Army Science Board's (ASB) Issue Group Study Panel on ''Impacts of Precision Guided Munitions on Future Tank and Howitzer Capabilities'' will meet for briefings and discussions on the study subject. The open portions of these meetings are open to the public. Any person may attend, appear before or file statements with the committee. The closed portions of these meetings will be closed to the public in accordance with Section 522b(c) of title 5, U.S.C., specifically subparagraph (1) thereof, and Title 5, U.S.C., Appendix 2, subsection 10(d). For further information, please contact our office at (703) 604–7490.

Wayne Joyner,

Program Support Specialist, Army Science Board.

[FR Doc. 98–12798 Filed 5–13–98; 8:45 am]

BILLING CODE 3710–08–M

DEPARTMENT OF DEFENSE

Department of the Army

Army Science Board; Notice of Closed Meeting

In accordance with Section 10(a)(2) of the Federal Advisory Committee Act (Pub. L. 92–463), announcement is made of the following Committee Meeting:

Name of Committee: Army Science Board (ASB).

Date of Meeting: 20 May 1998.

Time of Meeting: 1230–1630.

Place: Ft. Monmouth, NJ.

Agenda: The Army Science Board's (ASB) Issue Group Panel on ''Schedule Realism'' will meet for briefings and discussions on the Ground Based Common Sensor its past technical and programmatic problems. This meeting will be closed to the public in accordance with Section 552b(c) of Title 5, U.S.C., specifically subparagraphs (1) and (4) thereof, and Title 5, U.S.C., Appendix 2, subsection 10(d). The classified and unclassified matters to be discussed are so inextricably intertwined so as to preclude opening any portion of this meeting. For

further information, please contact our office at (703) 604–7490.

Wayne Joyner,

Program Support Specialist, Army Science Board.

[FR Doc. 98–12799 Filed 5–13–98; 8:45 am]

BILLING CODE 3710–08–M

DEPARTMENT OF DEFENSE

Department of the Army

Army Science Board. Notice of Closed Meeting

In accordance with Section 10(a)(2) of the Federal Advisory Committee Act (Pub. L. 92–463), announcement is made of the following Committee Meeting:

Name of Committee: Army Science Board (ASB).

Date of Meeting: 22–23 May 1998.

Time of Meeting: 0830–1630.

Place: Owega, New York.

Agenda: The Army Science Board's (ASB) Issue Group Panel on ''Schedule Realism'' will meet for briefings and discussions on the Ground Based Common Sensor its past technical and programmatic problems. These meetings will be closed to the public in accordance with Section 552b(c) of Title 5, U.S.C. specifically subparagraphs (1) and (4) thereof, and Title 5, U.S.C., Appendix 2, subsection 10(d). The classified and unclassified matters to be discussed are so inextricably intertwined so as to preclude opening any portions of these meetings. For further information, please contact our office at (703) 604–7490.

Wayne Joyner,

Program Support Specialist, Army Science Board.

[FR Doc. 98–12800 Filed 5–13–98; 8:45 am]

BILLING CODE 3710–08–M

DEPARTMENT OF DEFENSE

Department of the Army

Army Science Board; Notice of Closed Meeting

In accordance with Section 10(a)(2) of the Federal Advisory Committee Act (Pub. L. 92–463), announcement is made of the following Committee Meeting:

Name of committee: Army Science Board (ASB).

Date of meeting: 21 May 1998.

Time of meeting: 0830–1200.

Place: Ft. Monmouth, NJ.

Agenda: The Army Science Board's (ASB) Issue Group Panel on ''Schedule Realism'' will meet for briefings and discussions on the Ground Based Common Sensor its past technical and programmatic problems. This meeting will be closed to the public in accordance with Section 552b(c) of Title 5, U.S.C., specifically subparagraphs (1) and (4) thereof, and title 5, U.S.C., Appendix 2, subsection 10(d). The classified and unclassified matters to be discussed are so inextricably intertwined so as to preclude opening any portion of this meeting. For further information, please contact our office at (703) 604–7490.

Wayne Joyner,

Program Support Specialist Army Science Board.

[FR Doc. 98–12801 Filed 5–13–98; 8:45 am]

BILLING CODE 3710–08–M

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Docket No. RP98–196–001]

Algonquin Gas Transmission Company; Notice of Supplemental Filing

May 8, 1998.

Take notice that on May 5, 1998, Algonquin Gas Transmission Company (Algonquin) tendered for filing as part of its FERC Gas Tariff, Fourth Revised Volume No. 1, the corrected ''hard copy'' of the following tariff sheet to become effective May 31, 1998: Thirty First Revised Sheet No. 20A.

Algonquin states that the filing is submitted in supplement of its April 29, 1998 filing in Docket No. RP98–196–000 providing for the recovery of upstream transition costs of $5,519.88 billed to Algonquin by Texas Eastern Transmission Corporation. Algonquin states that the sole purpose of this supplemental filing is to correct the pagination on the hard copy of Tariff Sheet No. 20A, and that the electronic version of such tariff sheet filed on April 29, 1998 needs no correction, since it was correct in the April 29, 1998 filing.

Algonquin states that copies of the filing were mailed to all affected customers and interested state commissions.

Any person desiring to protest this filing should file a protest with the Federal Energy Regulatory Commission, 888 First Street, NE, Washington, DC 20426, in accordance with § 385.211 of the Commission's Rules and Regulations. All such protests must be filed as provided in § 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. Copies of this filing are on file with the Commission and are available for public inspection in the Public Reference Room.

Linwood A. Watson, Jr.,

Acting Secretary.

[FR Doc. 98–12783 Filed 5–13–98; 8:45 am]

BILLING CODE 6717–01–M

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

American Electric Power Service Corporation, Central and South West Services, Inc.; Notice of Extension of Time

May 8, 1998.

On May 4, 1998, the Commission issued a notice of filing in the above-docketed proceedings, respectively. The due date for comments and protests was set for May 20, 1998. By this notice, the date for the filing of interventions and protests is hereby extended to and including June 30, 1998.

Linwood A. Watson, Jr.,

Acting Secretary.

[FR Doc. 98–12838 Filed 5–13–98; 8:45 am]

BILLING CODE 6717–01–M

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Docket Nos. CP72–50–001 and CP72–274–001]

Georgia-Pacific Corporation; Notice of Amendment

May 8, 1998

Take notice that on April 8, 1998, Georgia-Pacific Corporation (Georgia-Pacific), 233 Peachtree Street N.E., Atlanta, Georgia 30303, filed in Docket Nos. CP72–50–001 and CP72–274–001, an application as supplemented on May 6, 1998, pursuant to Section 7(c) of the Natural Gas Act (NGA) and Part 157 of the Federal Energy Regulatory Commission's (Commission) regulations, to amend the certificate of public convenience and necessity issued in Docket Nos. CP72–50–000 and CP72–274–000 to authorize Georgia-Pacific to increase the maximum certificated capacity of its 8-inch diameter pipeline, all as more fully set forth in the application which is on file with the Commission and open to public inspection.

Georgia-Pacific proposes to increase the maximum certificated capacity of its 19.5 mile, 8-inch diameter pipeline (the Crossett Pipeline) located in Morehouse Parish, Louisiana and Ashley County,

Arkansas from 23,460 Mcf per day to 56,000 Mcf per day by increasing the maximum operating pressure of the Crossett Pipeline from 460 psig to 960 psig which is within the maximum allowable operating pressure (MAOP) for the pipeline. Georgia-Pacific states that the increased capacity is required to accommodate increased quantities of gas to be purchased by Georgia-Pacific and transported on the Crossett Pipeline for consumption by Georgia-Pacific in its pulp, paper, and chemical plant (the Crossett Plant). Georgia-Pacific further states that it has never utilized any of its pipeline facilities to provide transportation services for another party.

Any person desiring to be heard or making any protest with reference to said application should on or before May 29, 1998, 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 385.214 or 385.211) and the Regulations under the Natural Gas Act (18 CFR 157.10). All protests filed with the Commission will be considered by it in determining the appropriate action to be taken but will not serve to make the protestants parties to the proceeding. The Commission's rules require that protestors provide copies of their protests to the party or person to whom the protests are directed. Any person wishing to become a party to a proceeding or to participate as a party in any hearing therein must file a motion to intervene in accordance with the Commission's Rules.

A person obtaining intervenor status will be placed on the service list maintained by the Secretary of the Commission and will receive copies of all documents issued by the Commission, filed by the applicant, or filed by all other intervenors. An intervenor can file for rehearing of any Commission order and can petition for court review of any such order. However, an intervenor must serve copies of comments or any other filing it makes with the Commission to every other intervenor in the proceeding, as well as filing an original and 14 copies with the Commission.

A person does not have to intervene, however, in order to have comments considered. A person, instead, may submit two copies of such comments to the Secretary of the Commission. Commenters will be placed on the Commission's environmental mailing list, will receive copies of environmental documents, and will be able to participate in meetings associated with the Commission's environmental review process. Commenters will not be required to serve copies of filed documents on all other parties. However, commenters will not receive copies of all documents filed by other parties or issued by the Commission, and will not have the right to seek rehearing or appeal the Commission's final order to a Federal court.

The Commission will consider all comments and concerns equally, whether filed by commenters or those requesting intervenor status.

Take further notice that, pursuant to the authority contained in and subject to the jurisdiction conferred upon the Federal Energy Regulatory Commission by Sections 7 and 15 of the NGA and the Commission's Rules of Practice and Procedure, a hearing will be held without further notice before the Commission or its designee on these applications 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 Georgia-Pacific to appear or be represented at the hearing.

Linwood A. Watson, Jr.,

Acting Secretary.

[FR Doc. 98–12780 Filed 5–13–98; 8:45 am]

BILLING CODE 6717–01–M

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Docket No. RP97–142–009]

K N Interstate Gas Transmission Co.; Notice of Tariff Filing

May 8, 1998.

Take notice that on May 5, 1998, K N Interstate Gas Transmission Co. (KNI), tendered for filing as part of its FERC Gas Tariff, of the following actual tariff sheets, to be effective November 1, 1997:

Third Revised Volume No. 1–B
1st Rev Original Sheet No. 24
First Revised Volume No. 1–D
1st Rev Original Sheet No. 21
1st Rev First Revised Sheet No. 4

KNI states that the above referenced actual tariff sheets are being filed in compliance with the Commission's May 1, 1998 letter order, to be effective November 1, 1997. On April 28, 1998, KNI filed actual tariff sheets, which included those referenced above, as a result of the July 2, 1997 order approving ProForma sheets KNI filed on May 1, 1997.

KNI states the three tariff sheets referenced in this filing were submitted inadvertently with incorrect pagination. Therefore, KNI is submitting for acceptance and approval these corrected tariff sheets, to be effective November 1, 1997.

KNI states that copies of the filing were served upon KNI's jurisdictional customers, interested public bodies and all parties to the proceeding.

Any person desiring to protest this 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 proceedings. Copies of this filing are on file with the Commission and are available for public inspection in the Public Reference Room.

Linwood A. Watson, Jr.,

Acting Secretary.

[FR Doc. 98–12782 Filed 5–13–98; 8:45 am]

BILLING CODE 6717–01–M

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Docket No. ER98–2284–000]

MEG Marketing, LLC; Notice of Issuance of Order

May 8, 1998.

MEG Marketing, LLC (MEG) submitted for filing a rate schedule under which MEG will engage in wholesale electronic power and energy transactions as a marketer. MEG also requested waiver of various Commission regulations. In particular, MEG requested that the Commission grant blanket approval under 18 CFR Part 34 of all future issuances of securities and assumptions of liability by MEG.

On May 4, 1998, 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 MEG should file a motion to intervene or protest with the Federal Energy Regulatory Commission, 888 First Street, NE, Washington, DC 20426, in accordance with Rules 211 and 214 of the Commission's Rules of Practice and Procedure (18 CFR 385.211 and 385.214).

Absent a request for hearing within this period, MEG 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 MEG'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 June 3, 1998. 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.

Linwood A. Watson, Jr.,

Acting Secretary.

[FR Doc. 98–12785 Filed 5–13–98; 8:45 am]

BILLING CODE 6717–01–M

DEPARTMENT OF ENERGY

United States of America Federal Energy Regulatory Commission

[Docket No. RP98–214–000]

Transwestern Pipeline Company; Notice of Proposed Changes in FERC Gas Tariff

May 8, 1998.

Take notice that on May 5, 1998, Transwestern Pipeline Company (Transwestern), tendered for filing to become part of Transwestern's FERC Gas Tariff, Second Revised Volume No. 1, the following tariff sheets:

Ninth Revised Sheet No. 1
Sixth Revised Sheet No. 5B.02
Third Revised Sheet No. 5B.03
Fifth Revised Sheet No. 72
Second Revised Sheet No. 91B

Transwestern states that the purpose of this filing is to notify the Commission and submit the appropriate tariff sheet changes with respect to the assignment of firm capacity between Transwestern and Santa Fe Energy Resources, Inc. to Texaco Natural Gas Inc.; update the Table of Contents of Transwestern's Tariff to reference the Park 'N' Ride Rate Schedule; to eliminate the reference to the FTS-2 Rate Schedule under Form D of the Form of Service Agreement and to update Transwestern's General Terms and Conditions section of the tariff to reflect Transwestern's revised Internet address.

Transwestern states that copies of the filing were served upon Transwestern's customers and interested State Commissions.

Any person desiring to be heard or to protest this filing should file a motion to intervene or a 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 proceedings. 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.

Linwood A. Watson, Jr.,

Acting Secretary.

[FR Doc. 98–12784 Filed 5–13–98; 8:45 am]

BILLING CODE 6717–01–M

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Project No. 11591 Alaska]

City of Wrangell (Sunrise Lake Water Supply and Hydroelectric Project); Notice of Intent to Conduct Environmental Scoping Meetings and a Site Visit

May 8, 1998.

The Energy Policy Act of 1992 allows applicants to prepare their own Environmental Assessment (EA) for hydropower projects and file it with the Federal Energy Regulatory Commission (Commission) along with their license application as part of the applicant-prepared EA (APEA) process. The City of Wrangell (City) intends to prepare an EA to file with the Commission for the proposed Sunrise Lake Water Supply and Hydroelectric Project (Sunrise Lake Project), No. 11591. The City will hold two scoping meetings, pursuant to the National Environmental Policy Act (NEPA) of 1969, to identify the scope of environmental issues that should be analyzed in the EA.

Scoping Meetings

The times and locations of the two scoping meetings are:

	Agency meeting	Public meeting
Date:	Wednesday, May 27, 1998.	Wednesday, May 27, 1998
Place:	City Hall, Wrangell, Alaska.	City Hall, Wrangell, Alaska
Time:	2:00 P.M.	7:00 P.M.

At the scoping meetings, the City will: (1) summarize the environmental issues tentatively identified for analysis in the EA; (2) outline any resources they believe would not require a detailed analysis; (3) identify reasonable alternatives to be addressed in the EA; (4) solicit from the meeting participants all available information, especially quantitative data, on the resources at issue; and (5) encourage statements from experts and the public on issues that should be analyzed in the EA.

All interested individuals, organizations, and agencies are invited and encouraged to attend either or both meetings to assist in identifying and clarifying the scope of environmental issues that should be analyzed in the EA.

To help focus discussions at the meetings, the City prepared and distributed an Initial Stage Consultation Document (ISCD) in January 1998, and a Scoping Document on May 7, 1998. Copies of the ISCD and the Scoping Document can be obtained by calling Mr. Stephen M. Hart of R.W. Beck, Inc., the City's agent, at (206) 695–4720. Copies of both documents will also be available at both scoping meetings.

Site Visit

For those who intend to participate in scoping, the City will also conduct a site visit to the proposed Sunrise Lake Project on Thursday, May 28, 1998. Those attending the site visit should meet at Wrangell airport at 10:00 A.M. We will promptly leave for the project site, via helicopter. Those being shuttled by helicopter to the project site may need to sign a waiver of liability regarding helicopter use. Because of the remoteness and difficulty of ground access at the project site, those attending the site visit should be physically fit and must wear appropriate clothing and

footgear. Participants must provide their own sack lunches.

To plan on helicopter use in advance of the visit, the City must identify the number of individuals interested in the site visit. Therefore, if you intend on visiting the proposed project site, you must register with Ms. Christy Jamieson at (907) 874–2381, no later than May 20, 1998. If inclement weather prevents a site visit on May 28, the alternative date will be May 29 at the same time and location.

Meeting Procedures

The meetings will be conducted according to the procedures used at Commission scoping meetings. Because this meeting will be a NEPA scoping meeting under the APEA process, the Commission will not conduct a NEPA scoping meeting after the application and draft EA are filed with the Commission.

Both scoping meetings will be recorded by a stenographer or tape recorder, and will become part of the formal record of the proceedings for this project.

Those who choose not to speak during the scoping meetings may instead submit written comments on the project. Written comments must be submitted by June 26, 1998, and should be mailed to: Mr. Stephen M. Hart, P.E., R.W. Beck, Inc., 1001 Fourth Avenue, Suite 2500, Seattle, Washington 98154–1004. All correspondence should show the following caption on the first page:

Scoping Comments, Sunrise Lake Water Supply and Hydroelectric Project, Project No. 11591, Alaska.

For further information please contact Stephen M. Hart at (206) 695–4720, or Nick Jayjack of the Commission at (202) 219–2825.

Linwood A. Watson, Jr.,

Acting Secretary.

[FR Doc. 98–12781 Filed 5–13–98; 8:45 am]

BILLING CODE 6717–01–M

ENVIRONMENTAL PROTECTION AGENCY

[OPPTS–00239; FRL–5785–3]

Toxic Substances; Generic Collection of Economic and Program Support Data; Agency Information Collection Activities; Proposed Renewal and Request for Comment

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice.

SUMMARY: In compliance with the Paperwork Reduction Act (44 U.S.C. 3501 *et seq.*), this notice announces that EPA is planning to submit the following continuing Information Collection Request (ICR) to the Office of Management and Budget (OMB) pursuant to the procedures described in 5 CFR 1320.12. Before submitting the following ICR to OMB for review and reapproval, EPA is soliciting comments on specific aspects of the information collection, which is briefly described under Unit I. and Unit II. of this document. The ICR is a continuing ICR entitled ''Collection of Economic and Program Support Data; Request for Generic Clearance,'' EPA ICR No. 1170.06, OMB No. 2070–0034. This ICR covers the reporting of economic or other data that EPA may use in developing regulatory or voluntary actions. An Agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number. The OMB control numbers for EPA's regulations are listed in 40 CFR part 9.

DATES: Written comments must be submitted on or before July 18, 1998.

ADDRESSES: Each comment must bear the docket control number ''OPPTS–00239'' and administrative record number 196. All comments should be sent in triplicate to: OPPT Document Control Officer (7407), Office of Pollution Prevention and Toxics, Environmental Protection Agency, 401 M St., SW., Rm. G–099, East Tower, Washington, DC 20460.

Comments and data may also be submitted electronically to: oppt.ncic@epamail.epa.gov. Follow the instructions under Unit III. of this document. No TSCA Confidential Business Information (CBI) should be submitted through e-mail.

All comments that contain information claimed as CBI must be clearly marked as such. Three sanitized copies of any comments containing information claimed as CBI must also be submitted and will be placed in the public record for this document. Persons submitting information on any portion of which they believe is entitled to treatment as CBI by EPA must assert a business confidentiality claim in accordance with 40 CFR 2.203(b) for each such portion. This claim must be made at the time that the information is submitted to EPA. If a submitter does not assert a confidentiality claim at the time of submission, EPA will consider this as a waiver of any confidentiality claim and the information may be made available to the public by EPA without further notice to the submitter.

FOR FURTHER INFORMATION CONTACT: For general information contact: Susan B. Hazen, Director, Environmental Assistance Division (7408), Office of Pollution Prevention and Toxics, Environmental Protection Agency, 401 M St., SW., Washington, DC 20460, Telephone: (202) 554–1404, TDD: (202) 554–0551, e-mail: TSCA-Hotline@epamail.epa.gov. For technical information contact: Robert Lenahan, Economics, Exposure, and Technology Division (7406), Office of Pollution Prevention and Toxics, Environmental Protection Agency, 401 M St., SW., Washington, DC 20460, Telephone: (202) 260–1672; Fax: (202) 260–0981; e-mail: lenahan.robert@epamail.epa.gov.

SUPPLEMENTARY INFORMATION:

Electronic Availability:

Internet

Electronic copies of the ICR are available from the EPA Home Page at the **Federal Register** - Environmental Documents entry for this document under ''Laws and Regulations'' (http://www.epa.gov/fedrgstr/).

Fax-on-Demand

Using a faxphone call (202) 401–0527 and select item 4061 for a copy of the ICR.

I. Background

Affected entities: Entities potentially affected by this action are persons in the United States who manufacture, distribute, process, import, use or dispose of chemical substances or mixtures.

For the collection of information addressed in this notice, EPA would like to 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 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.

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.

II. Information Collection

EPA is seeking comments on the following ICR, as well as the Agency's intention to renew the corresponding OMB approval, which is currently scheduled to expire on August 31, 1998.

Title: Collection of Economic and Program Support Data; Request for Generic Clearance.

ICR numbers: EPA ICR No. 1170.06, OMB No. 2070–0032.

Abstract: Staff of EPA's Office of Pollution Prevention and Toxics (OPPT) are obliged to provide a wide array of analyses in support of Agency activities. These analyses allow OPPT staff to provide statistically valid information to assist in the development of regulations and voluntary activities that minimize costs and maximize net societal benefits. While some questions can be answered satisfactorily through information that EPA has in its possession or through existing secondary sources of data, there are others for which no relevant sources exist. Moreover, much of the work OPPT does requires information in a timely manner. Because of various pressures, the Agency often has to make decisions quickly. The ability for OPPT to collect information in relatively short periods to support such decisions is essential in ensuring that EPA makes sound decisions.

OPPT is required, through statute, to consider the economic impacts of actions taken to control the manufacture, distribution, processing, use, or disposal of chemical substances or mixtures that present unreasonable risks of injury to human health or the environment. OPPT uses cost-benefit analyses to determine that a proposed regulatory action maximizes the net benefits to society when compared to the alternatives. Given the record regarding the lack of publicly available information on many chemicals, and other situations that arise during the course of determining regulatory options, an information collection activity often is required to collect the needed data. OPPT and other EPA staff then use these data to evaluate the regulatory options available, to determine the impact of a specific program, or to develop non-regulatory, voluntary options.

Responses to this collection of information are voluntary.

Burden statement: The burden to respondents for complying with this ICR is estimated to total 6,000 hours per year with an annual cost of $490,000. These totals are based on an average burden of 1.5 hour per response for an estimated 4,000 respondents making one or more responses annually. These estimates include the time needed to determine applicability; review instructions; develop, acquire, install and utilize technology and systems for the purposes of collecting, validating and verifying information, processing and maintaining information, and disclosing and providing information; adjust the existing ways to comply with any previously applicable instructions and requirements; train personnel to be able to respond to a collection of information; search data sources; complete and review the collection of information; and transmit or otherwise disclose the information.

III. Public Record and Electronic Submissions

The official record for this document, as well as the public version, has been established for this document under docket control number ''OPPTS–00239'' (including comments and data submitted electronically as described below). A public version of this record, including printed, paper versions of electronic comments, which does not include any information claimed as CBI, is available for inspection from 12 noon to 4 p.m., Monday through Friday, excluding legal holidays. The official rulemaking record is located in the TSCA Nonconfidential Information Center, Rm. NE–B607, 401 M St., SW., Washington, DC.

Electronic comments can be sent directly to EPA at:

oppt.ncic@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 5.1/6.1 or ASCII file format. All comments and data in electronic form must be identified by the docket control number ''OPPTS–00239'' and administrative record number 196. Electronic comments on this document may be filed online at many Federal Depository Libraries.

List of Subjects

Environmental protection, Information collection requests, Reporting and recordkeeping.

Dated: May 6, 1998.

Lynn R. Goldman,

Assistant Administrator for Prevention, Pesticides and Toxic Substances.

[FR Doc. 98–12854 Filed 5–13–98; 8:45 am]

BILLING CODE 6560–50–F

ENVIRONMENTAL PROTECTION AGENCY

[FRL–6013–7]

Retrofit/Rebuild Requirements for 1993 and Earlier Model Year Urban Buses; Public Review of a Notification of Intent To Certify Equipment

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice of Agency receipt of a notification of intent to certify equipment and initiation of 45-day public review and comment period.

SUMMARY: Johnson Matthey Incorporated (JM) has submitted to EPA a notification of intent to certify urban bus retrofit/rebuild equipment pursuant to 40 CFR Part 85, Subpart O. The equipment, referred to by JM as the Cam Converter Technology (CCT™) upgrade kit, consists of proprietary cam shafts, a CEM II™ catalytic exhaust muffler containing an oxidation catalyst, specified engine rebuild parts, and a set of instructions. The candidate kit is applicable to all Detroit Diesel Corporation (DDC) 6V92TA DDEC two-cycle urban bus diesel engines from model years 1985 to 1993 with power ratings of 253 and 277 horsepower (hp).

JM intends this equipment to be certified to the particulate matter standard of 0.10 grams per brake-horsepower-hour (g/bhp-hr). JM has not submitted life cycle cost information and does not intend that certification of the equipment trigger (initiate) any new program requirements for urban bus operators.

Pursuant to § 85.1407(a)(7), today's **Federal Register** notice summarizes the notification, announces that the notification is available for public review and comment, and initiates a 45-day period during which comments can be submitted. EPA will review this notification of intent to certify, as well as any comments it receives, to determine whether the equipment described in the notification of intent to certify should be certified. If certified, the equipment can be used by urban bus operators to reduce the particulate matter of urban bus engines.

The notification of intent to certify, as well as other materials specifically relevant to it, are contained in Category XXI–A of Public Docket A–93–42, entitled ''Certification of Urban Bus Retrofit/Rebuild Equipment''. This docket is located at the address listed below.

Today's notice initiates a 45-day period during which EPA will accept written comments relevant to whether or not the equipment included in this

notification of intent to certify should be certified. Comments should be provided in writing to the addresses below.

DATES: Comments must be submitted on or before June 29, 1998.

ADDRESSES: Submit separate copies of comments to each of the two following addresses:

1. U.S. Environmental Protection Agency, Public Air Docket A–93–42 (Category XXI–A), Room M–1500, 401 M Street S.W., Washington, DC 20460.

2. William Rutledge, Engine Compliance Programs Group, Engine Programs and Compliance Division (6403J), U.S. Environmental Protection Agency, 401 ''M'' Street S.W., Washington, DC 20460.

The JM notification of intent to certify, as well as other materials specifically relevant to it, are contained in the public docket indicated above. Docket items may be inspected from 8:00 a.m. until 5:30 p.m., Monday through Friday. As provided in 40 CFR Part 2, a reasonable fee may be charged by EPA for copying docket materials.

FOR FURTHER INFORMATION CONTACT: William Rutledge, Engine Programs and Compliance Division (6403J), U.S. Environmental Protection Agency, 401 M St. SW, Washington, D.C. 20460. Telephone: (202) 564–9297.

SUPPLEMENTARY INFORMATION:

I. Program Background

On April 21, 1993, EPA published final Retrofit/Rebuild Requirements for 1993 and Earlier Model Year Urban Buses (58 FR 21359). The retrofit/rebuild program is intended to reduce the ambient levels of particulate matter (PM) in urban areas and is limited to 1993 and earlier model year (MY) urban buses operating in metropolitan areas with 1980 populations of 750,000 or more, whose engines are rebuilt or replaced after January 1, 1995. Operators of the affected buses are required to choose between two compliance options: Option 1 establishes particulate matter emissions requirements for each urban bus engine in an operator's fleet which is rebuilt or replaced; Option 2 is a fleet averaging program that establishes a specific annual target level for average PM emissions from urban buses in an operator's fleet.

A key aspect of the program is certification of retrofit/rebuild equipment, which begins when an equipment manufacturer submits an application for certification (referred to in the rule as a notification of intent to certify). To meet either of the two compliance options, operators of the affected buses must use equipment that has been certified by EPA. Emissions requirements under either of the two options depend on the availability of retrofit/rebuild equipment certified for each engine model. To be used for Option 1, equipment must be certified as meeting a 0.10 g/bhp-hr PM standard or as achieving a 25 percent reduction in PM. Equipment used for Option 2 must be certified as providing some level of PM reduction that would in turn be claimed by urban bus operators when calculating their average fleet PM levels attained under the program.

Under Option 1, additional information regarding cost must be submitted in the notification, in order for certification of that equipment to initiate (or trigger) program requirements for a particular engine model. In order for the equipment to serve as a trigger, the certifier must guarantee that the equipment will be offered to affected operators for $7,940 or less at the 0.10 g/bhp-hr PM level, or for $2,000 or less for the 25 percent or greater reduction in PM. Both of the above amounts are based on 1992 dollars and include life cycle costs incremental to the cost of a standard rebuild.

II. Notification of Intent To Certify

In a notification of intent to certify equipment signed March 6, 1998, Johnson Matthey (JM) applied for certification of equipment under the Environmental Protection Agency's (EPA) Urban Bus Retrofit/Rebuild Program. The candidate kit is applicable to 6V92TA DDEC urban bus engine models made by Detroit Diesel Corporation (DDC) from model years 1985 to 1993 with power ratings of 253 and 277 hp. The notification states that the candidate equipment achieves a particulate matter (PM) level of 0.10 g/bhp-hr.

The equipment, referred to as the Cam Converter Technology (CCT™) upgrade kit, consists of a CEM II™ catalytic exhaust muffler, proprietary cam shafts, turbocharger, piston dome kits, piston skirts, ring sets, cylinder liners, blower drive gear, blower assembly, blower bypass valve, rebuilt fuel injectors, and offset key. The CCT™ kit would be available in two horsepower levels (253, and 277) for 6V92TA DDEC engines.

The CEM II is a diesel oxidation catalyst that is the same size and shape as the CEM™. However, JM states that the CEM II™ contains a catalyst with a different formulation than the original CEM, and the CCT™ kit cannot be used with the previously certified CEM™ in place of the new CEM II™. The CEM II is a direct, bolt-on replacement for the original equipment muffler, and is designed to fit the specific bus/engine combination (over 68 models are available).

The piston crowns are 15:1 compression ratio and are DDC parts. JM indicates that the original coach engine cylinder liner has a 0.95 inch inlet port. The cylinder liner of the candidate kit has 0.85 inch inlet ports. The proprietary camshafts increase the amount of time that the combustion gases stay in each cylinder, similar to internal exhaust gas recirculation. The blower drive gear is a 40 tooth gear. The blower assembly is a 100-percent by-pass blower for increased fuel efficiency. The turbocharger is a standard DDC part that has been specifically selected. The offset replaces the standard key used to mount the front pulley or gear that also holds the speed sensor pulse wheel. When the engine rebuild with the candidate kit is complete, it may be necessary to change the ECM program. The notification lists the correct ECM program, which varies by engine rotation direction, engine power rating, and diesel fuel type. The program can be changed at a local DDC distributor.

The CCT™ kit is to be used in conjunction with an engine rebuild performed in accordance with standard DDC rebuild procedures using specified engine rebuild parts. The kit is installed using standard DDC rebuild practices except where amended by JM. The specific parts and parts numbers for the components of the candidate kit are listed in the JM notification. No cylinder heads are listed as part of the kit. EPA requests comment regarding whether cylinder heads should be included as a component of the kit.

The kit instructions specifies fuel injector height, offset key size, and electronic control module (ECM) program. The JM notification contains an installation guide for the CCT upgrade kit.

JM presents exhaust emissions data from testing a DDC 6V92TA engine model, once rebuilt with the candidate kit and again rebuilt in a baseline configuration. Testing was conducted in accordance with procedures set forth at 40 CFR Part 86, Subparts N and I. The notification provides lists of the DDC parts used for rebuilding the baseline and certification test engines. Table 1 below summarizes the data.

TABLE 1.—SUMMARY OF JM TESTING

Gaseous and particulate test	Transient engine test (g/bhp-hr)		
	1991 HDDE standards	1991 6V92TA DDEC II baseline [1]	6V92TA DDEC II with CCT™ [1]
HC	1.3	0.46	0.2
CO	15.5	1.2	0.6
NO_X	5.0	4.9	5.0
PM	0.25	0.19	0.091
BSFC[2]	.....	0.483	0.489
Hp (R/O)[3]	.....	277/271	277/270
Smoke test	**Standards (percent)**	**Percent opacity**	
ACCEL	20	2.7	2.3
LUG	15	1.2	1.2
PEAK	50	3.7	3.7

[1] All 6V92TA testing was performed on engine identification number 6VF186640.
[2] Brake Specific Fuel Consumption (BSFC) is measured in units of lb/bhp-hr.
[3] Horsepower (Rated/Observed during testing).

As shown in Table 1 above, JM presents baseline test data from a 1991 model year configuration which documents PM emissions of 0.19 g/bhp-hr. The data of Table 1 indicate that, when the engine is rebuilt with the candidate CCT™ kit, PM emissions are less than 0.10 g/bhp-hr, and emissions of hydrocarbon (HC), carbon monoxide (CO), oxides of nitrogen (NO_X), and smoke opacity are less than or equal to the federal standards applicable for the 1993 model year.

Based on this testing demonstration, apparently all CCT-equipped engines would meet the 0.10 g/bhp-hr PM standard because installation of the kit results in the replacement of all emissions related parts with a specific set of parts, the combination of which results in a documented PM level of 0.09 g/bhp-hr. The PM emissions level of an original engine, prior to installation of the candidate kit, appears irrelevant because all emissions-related parts are required to be replaced upon installation of the kit. EPA requests comments on whether or not all engines for which certification is intended, will meet the 0.10 g/bhp-hr PM standard.

Both the federal and California exhaust emissions standards for NO_X were lowered to 5.0 g/bhp-hr beginning with the 1991 model year. The emissions data of the above table indicate that engines equipped with the candidate equipment can meet the 5.0 g/bhp-hr NO_X standard. Therefore, if certified, the equipment could be used for all applicable engines, including those originally certified for use in California.

The combination of the specified engine rebuild parts, proprietary camshafts, new settings of the kit, and CEM–II, results in a PM level less than 0.10 g/bhp-hr and NO_X level in compliance with the 1991 federal standard of 5.0 g/bhp-hr. EPA requests comments on whether the emissions test data presented by JM demonstrate that all engines for which certification is requested will meet the 0.10 g/bhp-hr PM standard and applicable federal and California NO_X standards with the candidate kit installed.

Even if ultimately certified by EPA, the equipment described in JM's notification may require additional review by the California Air Resources Board (CARB) before use in California. EPA recognizes that special situations may exist in California that are reflected in the unique emissions standards, engine calibrations, and fuel specifications of the State. While requirements of the federal urban bus program apply to several metropolitan areas in California, EPA understands the view of CARB that equipment certified under the urban bus program, to be used in California, must be provided with an executive order exempting it from the anti-tampering prohibitions of that State. Those interested in additional information should contact the Aftermarket Part Section of CARB, at (818) 575–6848.

No life cycle costs information has been submitted by JM, because JM does not intend certification of this equipment to trigger program requirements. If certified, no new requirements would be placed on operators, and no operator would be required to purchase this equipment as a result of certification of the candidate equipment.

Certification of the candidate JM equipment would affect operators as follows. EPA has not yet certified equipment, for the applicable DDEC engines, to comply with the 0.10 g/bhp-hr standard and as being available for less that the applicable life cycle cost. Therefore, the 0.10 g/bhp-hr PM standard has not been triggered for the applicable engines. If the candidate equipment is certified, then no new requirements would be placed on operators and no operator would be required to purchase this equipment as a result of certification.

If EPA certifies other equipment that triggers the 0.10 g/bhp-hr standard, then urban bus operators who choose to comply with compliance Option 1 of this regulation will be required to use equipment certified to the 0.10 g/bhp-hr standard no later than six months after certification, when applicable engines are rebuilt or replaced.

If the candidate CCT kit is certified, then it would be available to be used in full compliance with urban bus program requirements. Certification of the CMX™ converter/muffler manufactured by the Engelhard Corporation (60 FR 28402 ; May 31, 1995) triggered the requirement for the applicable engines, when rebuilt or replaced, to reduce PM by at least 25 percent. Until such time that the 0.10 g/bhp-hr standard is triggered, the certification of the CMX™ means that operators who elect to use compliance program 1 must use equipment certified to reduce PM emissions by at least 25 percent, when

rebuilding or replacing the applicable engines. If certified, the candidate kit would meet, and exceed, this requirement. The candidate kit could also be used in full compliance if the program requirement to use equipment certified to the 0.10 g/bhp-hr standard is triggered.

If the Agency certifies the candidate equipment, then operators who choose to comply with Program 2 and install this equipment, would use the 0.10 g/bhp-hr certification level in their calculations for fleet level attained (FLA) as specified in the program regulations.

The date of this notice initiates a 45-day period during which EPA will accept written comments relevant to whether the equipment described in the JM notification of intent to certify should be certified pursuant to the urban bus retrofit/rebuild regulations. Interested parties are encouraged to review this notification, and provide written comments during the 45-day review period. Separate comments should be provided in writing to each of the addresses listed under the Addresses section of this notice.

At a minimum, EPA expects to evaluate this notification of intent to certify, and other materials submitted as applicable, to determine whether there is adequate demonstration of compliance with: (1) the certification requirements of § 85.1406, including whether the testing accurately substantiates the claimed emission reduction or emission levels; and, (2) the requirements of § 85.1407 for a notification of intent to certify.

EPA requests that those commenting also consider these regulatory requirements, plus provide comments on any experience or knowledge concerning: (a) problems with installing, maintaining, and/or using the equipment on applicable engines; and, (b) whether the equipment is compatible with affected vehicles.

EPA will review this notification of intent to certify, along with comments received from the interested parties, and attempt to resolve or clarify issues as necessary. During the review process, EPA may add additional documents to the docket as a result of the review process. These documents will also be available for public review and comment.

Dated: May 5, 1998.

Richard D. Wilson,

Acting Assistant Administrator for Air and Radiation.

[FR Doc. 98–12849 Filed 5–13–98; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

[FRL–6013–8]

Retrofit/Rebuild Requirements for 1993 and Earlier Model Year Urban Buses; Certification of Equipment

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice of EPA certification of equipment provided by Detroit Diesel Corporation.

SUMMARY: Today's **Federal Register** notice announces EPA's decision to certify equipment to the 0.10 g/bhp-hr standard for the Urban Bus Retrofit/Rebuild Program. The equipment is provided by the Detroit Diesel Corporation (DDC).

DDC submitted to EPA a notification of intent to certify equipment, in materials signed July 16, 1997, pursuant to the program regulations at 40 CFR Part 85, Subpart O. On November 6, 1997, EPA published a notice in the **Federal Register** that the DDC notification had been received and made the notification available for public review and comment for a period of 45 days (62 FR 60077). EPA has completed its review and the Director of the Engine Programs and Compliance Division has determined that it meets all requirements for certification. Therefore, EPA certified this equipment in a letter to DDC dated April 6, 1998.

The equipment consists of the base engine components used on the 25% reduction retrofit/rebuild kit certified by DDC, components from the 25% retrofit catalyst kit certified by Engine Control Systems, Ltd. (ECS) and a TurboPac supercharger system supplied by Turbodyne Systems, Inc. that supplies additional air for combustion during engine acceleration.

The kit is applicable to 6V92TA urban bus engine models made by Detroit Diesel Corporation (DDC) from model years 1979 to 1989 and equipped with mechanical unit injectors (MUI), and may be used immediately by transit operators in compliance with program requirements. The kit would be available in three horsepower levels (253, 277, and 294).

EPA has determined that this DDC kit complies with the 0.10 gram per brake horsepower-hour (g/bhp-hr) particulate matter (PM) standard for the applicable engines. EPA has not determined that DDC's notification complies with the life cycle cost requirements of the program regulations because no life cycle costs were supplied with the application.

Today's **Federal Register** notice does not trigger any additional program requirements for transit operators. The 0.10 g/bhp-hr PM level has already been triggered for all engines covered by this notification.

The notification of intent to certify, as well as other materials specifically relevant to it, are contained in Category XX–A of Public Docket A–93–42, entitled ''Certification of Urban Bus Retrofit/Rebuild Equipment.'' This docket is located at the address listed below.

Additional details concerning this certification, the DDC's kit, and responsibilities of transit operators, are provided below.

DATES: EPA certified this equipment in a letter to DDC dated April 6, 1998. Today's **Federal Register** notice announces this certification. The 0.10 g/bhp-hr standard was triggered on March 14, 1997 (62 FR 12166) for all engines covered by this certification.

ADDRESSES: The DDC notification, as well as other material specifically relevant to it, are contained at the U.S. Environmental Protection Agency's Public Air Docket A–93–42 (Category XX–A), Room M–1500, 401 ''M'' Street SW, Washington, DC 20460.

The DDC notification of intent to certify, as well as other materials specifically relevant to it, are contained in the public docket indicated above. Docket items may be inspected from 8:00 a.m. until 5:30 p.m., Monday through Friday. As provided in 40 CFR Part 2, a reasonable fee may be charged by EPA for copying docket materials.

FOR FURTHER INFORMATION CONTACT: Anthony Erb, Engine Programs and Compliance Division (6403J), U.S. Environmental Protection Agency, 401 ''M'' St. SW, Washington, D.C. 20460. Telephone: (202) 564–9259.

SUPPLEMENTARY INFORMATION:

I. Description of the Certified Kit

The certified kit described in today's **Federal Register** notice is provided by DDC. It is certified to the 0.10 g/bhp-hr standard but does not comply with the applicable life cycle cost requirements of the program. No cost data was provided in the notification.

The certification described in today's notice applies to 1979 through 1989 model year DDC 6V92TA engines that are equipped with mechanical unit injectors (MUI) and certified to federal emissions standards. It does not apply to engines certified to California emissions standards. The impact of this decision on transit operators is discussed in more detail in the ''Transit Operator Requirements'' section below.

The kit, described further below, consists of base engine components used on the 25% reduction kit certified by DDC earlier, a catalytic exhaust muffler supplied by Engine Control Systems, Ltd. (ECS), and a TurboPac supercharger system supplied by Turbodyne Systems, Inc. that supplies additional combustion air during acceleration. The kit is available in three horsepower (hp) ratings (253, 277, and 294 hp).

For retrofit with the DDC kit, an engine is rebuilt in accordance with standard DDC rebuild procedures, using specified engine components. This component set essentially includes the equipment certified by EPA to provide a 25% particulate reduction on October 2, 1995, at 60 FR 51472. These components are provided in two separate sets of parts. The first set of components is comprised of newly manufactured parts, including a gasket kit, air inlet hose, cylinder kits (piston assemblies and cylinder liners) a by-pass valve and a truck type throttle delay. The second set of components includes Reliabilt™ remanufactured parts, including the fuel injectors, camshafts, blower assembly, turbocharger, and head assemblies. Kit usage is based on engine rotation (righthand (RH) or lefthand (LH)), engine orientation, right bank cam gear mounting (bolt or nut), and engine power output based on injector size. The only difference from the previously certified equipment according to DDC is the inclusion of a truck-style throttle delay, adjustment of the throttle delay and injector timing settings to improve driveability. Additionally, the cylinder kit components have been modified to improve durability.

The converter is the same size and shape as the catalytic converter muffler certified by ECS for the Urban Bus Program as described in the **Federal Register** on January 6, 1997 (61 FR 746), is a direct replacement for the original equipment muffler, and is designed to fit the specific bus/engine combination. The use of diesel fuel that has been mixed with crankcase oil is prohibited by DDC.

The third constituent of the kit consists of an electrically powered supercharger system which is supplied by Turbodyne Systems, Inc. This component set, referred to as the TurboPac™ supplies additional intake air during engine acceleration from low engine speeds. DDC states that in addition to decreasing PM emissions and visible smoke during engine acceleration, the supercharger also improves engine response and vehicle driveability by reducing the fuel modulation during acceleration. The basic system consists of a supercharger blower, a diverter valve, a boost pressure sensor, an electrical control box and power cables, and a throttle switch for detecting the start of the engine acceleration mode, and will be supplied in two kits. One includes those components common to all installations and a second kit to accommodate the installation requirements of the various engine and vehicle configurations.

To complete an engine rebuild two (2) base engine component kits, one (1) converter muffler kit, and two (2) supercharger kits are required. The specific kits used will depend on the engine/vehicle combination.

DDC states there are no differences in the service intervals or maintenance practices for the base engine associated with the installation of the upgrade kit. The converter/muffler requires no regularly scheduled maintenance, only an occasional cleaning if the maximum back pressure of the exhaust system is exceeded. The supercharger does not require scheduled maintenance; however, a visual inspection for air leaks is recommended whenever the engine is serviced.

Standard procedures as described in the service manual for 92 Series engines are to be used when rebuilding the base engines using the candidate equipment. No unique rebuild procedures are required.

Use of the candidate kit is restricted to 6V92TA Detroit Diesel Corporation engines manufactured from January 1979 through December 1989, equipped with mechanical unit fuel injectors (MUI), and originally certified to meet Federal emission standards. The required fuel is low sulphur (0.05% max by weight) diesel fuel, either number 1 or number 2. Complete rebuild kits will be sold by DDC through normal distribution channels.

All of the testing presented by DDC for this certification was conducted using original equipment (OE) parts, except for the converter muffler and the TurboPac components. EPA has no assurance that engines rebuilt using parts that are not (OE) would comply with the 0.10 g/bhp-hr standard. Therefore, use of engine parts that are not the specified OE parts are not covered by the certification described in today's **Federal Register** notice.

Pursuant to 40 CFR 85.1409, DDC will provide a 100,000-mile defect warranty and a 150,000-mile emissions performance warranty for the kit, and all of its components.

EPA's certification of the Engelhard Corporation's ETX™ kit (62 FR 12166; March 14, 1997) triggered the 0.10 g/bhp-hr standard for 1979–1989 6V92TA MUI engines. That kit provided the three power ratings: 253, 277, and 294 hp that are included in this certification. Consequently, the certification of the DDC kit described in today's **Federal Register** notice, does not trigger the 0.10 g/bhp-hr standard for engines included in the certification.

II. Background and Basis for Certification

In a notification of intent to certify equipment, composed of an initial document signed July 16, 1997 and subsequent documents, DDC applied for certification of the kit under the Environmental Protection Agency's (EPA) Urban Bus Retrofit/Rebuild Program. Engines applicable to the certified kit are 6V92TA urban bus engine models made by Detroit Diesel Corporation (DDC) from model years 1979 to 1989 that are equipped with mechanical unit injectors (MUI) and certified to, or rebuilt to, comply with federal emissions standards. The certifier's principal place of business is: Detroit Diesel Corporation, 13400 Outer Drive, West, Detroit, Michigan 48329–4001.

Using engine dynamometer (transient) testing in accordance with the Federal Test Procedure for heavy-duty diesel engines, DDC demonstrated compliance with the 0.10 g/bhp-hr particulate matter (PM) emissions standard. Engine dynamometer data, shown below in Table A, is the basis for the certification approval of the kit when used on applicable engines. The emissions test data is part of DDC's notification of intent to certify, which is available in the public docket located at the above-mentioned address. All testing was conducted using #2 low-sulfur diesel fuel.

TABLE A.—EXHAUST EMISSIONS SUMMARY

Gaseous and particulate test	g/bhp-hr	
	1989 HDDE standards	6V92TA MUI with DDC kit
HC	1.3	0.1
CO	15.5	0.4
NO_X	10.7	9.8
PM	0.60	0.091
BSFC [1]		0.464
Smoke Test:	Standards	
ACCEL	20%	3.3%
LUG	15%	2.5%
PEAK	50%	4.2%

[1] Brake Specific Fuel Consumption (BSFC) is measured in units of lb/bhp-hr.

The exhaust emissions data presented by DDC is from testing a Detroit Diesel Corporation (DDC) engine model 6V92TA, in accordance with procedures set forth at 40 CFR Part 86, Subparts N and I. The engine model was tested after being equipped with the DDC kit. The 6V92 engine was tested in one horsepower (hp) rating: 277hp.

The data of Table A demonstrates that the test engine, when rebuilt with the DDC kit, PM emissions are less than 0.10 g/bhp-hr and, emissions of hydrocarbon (HC), carbon monoxide (CO), NO_X and smoke opacity are within applicable federal standards.

This action applies a PM emissions level of 0.10 g/bhp-hr to all 1979 through 1989 DDC 6V92TA MUI urban bus engines, when properly equipped with the DDC kit and when using either diesel fuel #1 or #2. Table B lists the applicable engine models and certification levels associated with the certification announced in today's **Federal Register.**

TABLE B.—CERTIFICATION LEVEL OF DDC KIT

Engine models	Engine codes	Certification PM level
1979–1989 DDC 6V92TA MUI.	All certified to meet federal emissions standards.	0.10 g/bhp-hr.

All engines for which the DDC kit is intended to apply are expected to meet the 0.10 g/bhp-hr PM standard because the kit instructs the rebuilder to replace all emissions-related parts during the rebuild with DDC specified parts included in the kit, install the converter muffler and install the TurboPac system. The engine-out emissions level (upstream of the catalyst) is expected to be predictable because all emission-related parts are replaced using the DDC specified emissions-related parts and settings of the kit. As demonstrated by the test engine, the combination of the specified parts, the specified settings of the kit, the converter muffler and the TurboPac system, result in a PM level less than 0.10 g/bhp-hr.

A life cycle cost analysis is necessary only for certification of equipment that is meant to trigger a program emissions standard. Certification of Engelhard Corporation's ETX™ kit triggered the 0.10 g/bhp-hr standard for 6V92TA MUI engines, and made available kits rated at 253, 277, and 294 hp. The DDC certification does not include a cost analysis and one is not necessary for this certification. DDC states that engines equipped with the kit will have no additional maintenance or service requirements.

III. Summary and Analysis of Comments and Concerns

Comments were received from five parties in response to the **Federal Register** notice of November 6, 1997 (62 FR 60077). The commenters are Johnson Matthey Incorporated (JMI), Engelhard Corporation (Engelhard), the Washington Metropolitan Area Transit Authority (WMATA), the Maryland Department of Transportation Mass Transit Administration (MTA), and the Milwaukee County Transit System (MCTS). JMI and Engelhard provided extensive comment. JMI is a manufacturer of equipment certified to meet the 0.10 g/bhp-hr standard for the 1979–1989 6V92TA MUI engines (see 62 FR 60079; November 6, 1997). Engelhard is the manufacturer of equipment certified under the urban bus program that triggered the 0.10 g/bhp-hr standard for the 1979–1989 6V92TA MUI engines (see 62 FR 12166; March 14, 1997). WMATA, the MTA, and the MCTS are large transit bus operators in major metropolitan areas, which are subject to requirements of the urban bus program. The transits provided generally favorable comments on their experience with the equipment.

Comments or issues fell into the following general categories: (A) applicability of the kit; (B) description of the kit; (C) testing demonstration and documentation; (D) life cycle cost analysis; (E) warranty; (F) durability, and (G) in-use experience. All correspondence, comments, and other documentation are located in the public docket at the address above.

(A) Applicability

In the November 6, 1997, **Federal Register** notice, EPA stated that the information provided in DDC's notification applied to 6V92TA DDC engines manufactured from January 1979 to December 1989 equipped with mechanical unit injectors (MUI) and originally certified to meet Federal emission standards.

In comments dated December 19, 1997, Engelhard stated that DDC has failed to provide information demonstrating that this retrofit system can be applied safely to all vehicles. Engelhard commented that the electrical charging systems of urban buses can vary by make and design and asked how can we be sure that this system can be installed in all urban buses without an assessment of the charging system and information on the stress that the system that the DDC system will place on the charging system. Additionally, Engelhard commented that the Turbodyne system uses a high speed motor that draws over 300 amps for 8 seconds while the bus is accelerating. This will dramatically increase the load on the bus' electrical system and will cause premature wear of the alternator, battery and electrical systems according to Engelhard. The motor that Turbodyne uses to drive the compressor can also fail. Engelhard asked if there are any durability data or effective life data for this motor, and noted that because urban buses stop and start continuously the Turbodyne system will be operating during a large portion of the bus operating time.

According to Engelhard this system is not designed to operate continuously and the urban bus application will require it to operate much more frequently than it is designed to operate. DDC needs to provide information, demonstrating that it is reasonable to expect the Turbodyne system will remain operational for 150,000 miles. Engelhard commented that it had thoroughly tested the Turbodyne system and found air leaks and malfunctioning of the controller system occurred frequently. In its comments of December 19, 1997 JMI states that the Turbodyne system appears to have two states: on and off. Considering the performance cycle of a typical urban bus, this system would be turned on every time a bus would pull away from the curb. Since the system has a high amperage draw on the bus' electrical system long term use could prematurely wear out the battery or starter solemoid. What are the long term impacts on the life to the electrical system? Was a standard bus battery/starter system used in the test cell? How high is the amperage and could this require modifications to the bus' electrical system? Could rewiring be required and are there concerns of shorts, or fire hazards?

In response to these comments, DDC states that The TurboPac unit is intended to compensate for the inherent lag in the engine turbocharger during rapid accelerations from low speed/light load conditions. During these periods the TurboPac operates at high speed with a current draw of approximately 300 amps. At all other times when the engine is operational, the TurboPac runs at low speed in the ''standby'' condition with a current draw of about 10 amps. Accelerations sufficient to trigger high speed TurboPac operation are expected to occur quite frequently in urban bus applications. However, the duration of the high speed TurboPac operation is very short. The system limits high speed operation to a maximum of eight

seconds. In most cases the system returns to standby operation in a shorter period of time after a preset air box pressure has been achieved. DDC logged data on a pilot bus installation at MATS in Milwaukee to determine the real-world duty cycle and current draw of the TurboPac 2500. The bus was run on a city route through downtown Milwaukee in November 1997. The data logger recorded data for approximately eight hours in one second intervals. The data analyzed encompass a 3 hour time period from just before noon to approximately 3:00 p.m. This portion was chosen due to the relatively low idle time in this sample and the inability of the software to accommodate additional data. In the evaluation, when off it was assumed to draw 10 amps and when it was on it was assumed to draw 300 amps. The data based on this evaluation indicates that the TurboPac will be active in the high speed mode approximately 10% of the time. The time average draw is about 35 amps.

DDC states that in order to operate on a dedicated electrical circuit, unit power is taken directly from the battery, so there are no modification necessary to the bus electrical system. A 500 amp fuse is installed on the circuit to the controller to protect the system in case of a short. DDC began field trials of the retrofit system in July 1997. To date, eight complete retrofit units have been installed in buses and are in regular revenue operation at four major U.S. transit services. DDC stated that there have been no problems with the electrical systems or batteries on these buses. These units have almost 40,000 miles of customer service with the high mileage unit having accrued over 13,000 miles. In addition, TurboPac systems were installed on two buses operating in transit service. One of these units experienced an early failure of a hand assembled prototype controller. The other bus has operated over 18,000 miles with no failures to the TurboPac system.

DDC states that the in-use evaluation program has not revealed any problems with leaks. Consequently, no improvements have been found necessary to reduce leaks. Since leaks have not been a problem, DDC has not quantified the size of leak that would be sufficient to impair performance. With regard to the Engelhard comment concerning system leaks, DDC commented that the TurboPac system which Engelhard evaluated in early 1996 was a prototype design. In this design, the TurboPac and the engine turbocharger compressor were configured in parallel and a diverter valve was placed downstream where the two flow paths merged. During TurboPac operation, the valve was positioned to permit flow from the TurboPac to enter the engine and to block off flow from the turbocharger. When the TurboPac was not operational, the valve assumed the opposite position. In some early units, the diverter valve did not seal adequately and there was backflow through the turbocharger during TurboPac operation which resulted in reduced system performance. The current system has been completely redesigned to alleviate this problem. The TurboPac and engine turbocharger are now in a series arrangement. A check valve is placed downstream of the TurboPac and allows the engine to draw its intake air either from the TurboPac or directly from the engine air cleaner. The check valve has been shown to seal adequately and prevent backflow during TurboPac operation. DDC noted that the check valve operates in a relatively low pressure zone compared to the earlier diverter valve which was exposed to the full pressure supplied by the turbocharger.

Additional batteries or larger capacity alternators have not been installed in any of the pilot units and there have been no problems with the electrical system. DDC states that because the electrical connections for the TurboPac system are independent of the bus electrical system, it is not necessary to rewire electrical systems on buses. No fires or electrical shorts are expected and none have been reported during the pilot installations. DDC does not expect any negative impacts on the long term viability and integrity of bus electrical systems. During emission testing electrical power for the TurboPac was batter supplied.

DDC has stated that the Delco-Remy 50dn alternator rated at 270 or 300 amps is the standard in the transit industry and is the only alternator that DDC offered with the 6V–92 transit engines. DDC cannot state that no other alternator is or could be used on affected transit buses, but does state that the use of another type alternator would be extremely rare. Delco-Remy provided a statement that the 50dn alternator is an approved candidate for use with the DDC kit. It further states that the 50dn charging system is designed to operate at full capacity and that electrical demand beyond the alternators capacity will not adversely affect the alternators performance, reliability or durability.

Based on the above discussion and the responses provided by DDC concerning the comments, EPA finds no clear evidence that the DDC system is inadequately designed to operate on the urban bus engines to which it applies. Further, the in use evaluation program has demonstrated the ability to operate without adversely effecting the bus electrical systems. Therefore, EPA can find no reason based on the above comments not to grant certification of this kit. EPA further notes that DDC is required to provide a 100,000 mile defect warranty and 150,000 mile emissions performance warranty for the DDC kit and all of its components.

JMI commented that a Turbodyne representative stated publicly at APTA's Urban Bus Retrofit/Rebuild Program Panel session in Nashville, TN in August 1997, that Transit buses with routes that would require the TurboPac to operate more than 30% of the time would not be good candidates for using this system to reduce PM levels below 0.1 g/bhp-hr. JMI noted that this was not referenced in the notice of intent to certify and asked if this statement is still accurate? What data is available to substantiate DDC/Turbodyne's claim and is industry be informed of this comment? In response, Turbodyne provided information in letters dated February 23 and February 27, 1998 that during the August 1997 APTA Bus Maintenance Workshop in Nashville, a transit operator commented that the TurboPac on his routes ''would be on all the time.'' The Turbodyne representative replied that he would not recommend the TurboPac for applications that exceeded 30% high-speed duty cycle. The ceiling of a 30% duty cycle was based on the assumption that the bus alternator would not have sufficient excess capacity for this type of duty cycle. Excess alternator capacity is a direct function of the accessory load and alternator rating. In citing an example, a 270-amp system with a total electrical load including the accessories of lighting and air conditioning would be 160 amps. The excess alternator capacity in this situation would be 110 amps. Assuming a 10% duty cycle, this system would have more than sufficient excess alternator capacity to meet the average current draw from the TurboPac of 35 amps.

However, if a hypothetical duty cycle of 40% were to exist, the TurboPac would require a time-average draw of 140 amps and in this scenario the alternator would need to be upgraded before the TurboPac would be appropriate. Turbodyne stated, however, that duty cycles that exceed 30% are not expected. In practice, Turbodyne stated it would be very hard to envision a scenario that would demand 30% high speed operation for more than a few minutes. However,

DDC/Turbodyne will analyze and make recommendations for any situation in which the operator believes the vehicle electrical system capacity may be in question.

(B) Description of the DDC Kit

In its comments Engelhard asked how DDC will ensure that future rebuilds using this kit will use a new catalyst and not an existing catalyst. Will all parts be purchased from DDC? What is the price? Will the catalyst be different from the standard ECS 25% catalyst? Will the catalyst be labeled as part of the DDC kit? Can DDC ensure catalysts are not swapped between buses? In response, DDC states that a converter muffler will be part of each rebuild kit. Complete kits will be sold by DDC through normal distribution channels. It will not be possible to purchase a complete rebuild kit without a converter/muffler assembly included. Swapping of catalysts between buses should not be an issue since a new catalyst is provided with each kit. The converter muffler which will be included in the DDC rebuild kits are supplied by Engine Control Systems, LTD (ECS) and are identical to the ECS converter/mufflers certified to provide a 25% reduction in PM emissions on DDC engines on January 6, 1997 as referenced earlier. The catalyst will be labeled with an ECS serial and model number. Pricing information on the catalyst was not provided as this kit is not being certified within the cost ceiling requirements.

In its comments, JMI asked how many superchargers are actually installed on the engine? What are the physical space requirements for the supercharger(s)? Will there be adequate space for the supercharger(s) on all engines and why are two base engine component kits required?

DDC indicates that one TurboPac Supercharger unit is required for each installation. However, the equipment will be supplied in two kits, one containing components required for all installations and a second which includes those components needed to accommodate the installation requirements of the various engine and vehicle configurations. With regard to the space issue, DDC indicates that it has performed pilot installations on eight different buses which represent five different configurations and all have had adequate space to install all kit components. According to DDC, these configurations represent over 60% of the MUI buses in operation. The remaining designs have been reviewed by DDC and found to be similar.

JMI and Engelhard commented that the DDC instructions for installation tell the installer to, ''provide support to the TurboPac as required.'' JMI asked what support is required and if the TurboPac is not supported as required does this negate the warranty? Engelhard asked if this means that additional support of the unit is necessary to prevent damage to it or to keep it from contacting other engine components. Engelhard also expressed the concern that the directions for installation of the Turbodyne TurboPac are insufficient to ensure proper installation and operation of the system. Engelhard further noted that the instructions require the assembler to ''mount the controller in the engine compartment. The location of the controller must be in a position which will allow connection of the motor leads directly to the TurboPac. The location should provide easy connection to the engines starter and in a location which will receive adequate air circulation.'' Engelhard asked what is adequate air circulation? Engelhard asked if heat would damage the controller and whether the unit needs to be shielded?

In regard to the support concerns, DDC states that the motor and compressor weigh 16.5 pounds and will need to be properly supported. There are mounting holes on the unit to which the bracket can be attached. In the pilot installations, either the transit property or the DDC distributor has fabricated a simple bracket to support the unit. DDC will provide installation instructions in the assembly and installation manual provided with each kit to assist maintenance personnel in selecting appropriate support. DDC states that if the equipment is not properly installed, damage to the TurboPac due to faulty support is not warrantable. DDC states that support failure will not damage the engine because the location of the motor and compressor is sufficiently away from the engine and does not require contact of any kind with the engine components. DDC states that extreme heat would damage the controller. Therefore, the controller will be located away from exhaust system components, preferably in a area where air can circulate around it. It is not recommended that the electronic controller be shielded. DDC will provide guidance on locating the controller in the installation instructions that are provided with each kit. EPA finds that based on the pilot installation experience cited by DDC and its review of remaining designs, the guidance provided by DDC in its installation instructions should be adequate to properly support and locate the kit components. EPA further notes that failure of kit components which are installed according to DDC instructions will be covered under the warranty provisions.

Engelhard commented that DDC did not provide a component list for the retrofit engine and stated that the list is necessary for comparison of the parts used in a standard rebuild to the DDC retrofit kit. Engelhard asked if the truck check valve was installed on the test engine and whether it will be included in the DDC retrofit kit? In response DDC provided information that the build list for the test engine corresponds to ''new part kit'' number 23522349 and ''reliabilt kit'' number R3518035 included in Parts List Number 3 of the notification; TurboPac kits as defined in Parts List Number 5 and converter muffler part number 6000–005D as shown in Parts List Number 6 also in the notification. The check valve is integral to the throttle delay assembly and was included in the ''new part kit'' on the test engine.

JMI commented that the DDC application states that ''the throttle delay was set for optimum vehicle driveability.'' JMI questioned how you adjust for optimum vehicle driveability in the engine test cell? Was the throttle delay changed to account for the faster response of the engine with the TurboPac? If not, what is the rationale behind this decision? In response, DDC stated that the throttle delay is a dashpot device which delays the movement of the injector rack to the full fuel position. The setting dimension controls the rack position at which delays are incurred. A higher numerical setting dimension results in the rack being further from the full fuel position and results in more delay and poorer driveability. The minimum numeric setting dimension positions the rack closest to the full fuel position before any delay is incurred. This results in the minimum delay and the best driveability. During development testing for the retrofit system, DDC determined that the 0.10g/bhp-hr PM level and acceptable engine smoke opacity could be achieved with the minimum throttle delay setting of 0.490 inches. The orifice through which the oil is purged during engine acceleration is the same for both truck and bus throttle delays. The truck throttle delay has a smaller fill hole which slows the fill rate of the oil in the throttle delay body. Bus throttle delays have a larger fill hole to provide a more rapid fill. The use of the retrofit system has shown that the more rapid fill of the bus throttle delay is no longer required to achieve 0.10 g/bhp-hr PM and

acceptable smoke control. Therefore, a truck type throttle delay was specified in order to provide improved driveability.

JMI commented that in the notification DDC states that; ''Pursuant to 40 CFR Section 85.1406(e), * * * does not alter or render inoperative any feature of the on-board diagnostic system incorporated by the engine manufacturer.'' JMI asked what type of diagnostic systems are incorporated on MUI engines? In response, DDC states that MUI engines are not equipped with a computer which can store problem codes that can be used later by a service technician to diagnose an engine problem. The reference statement was provided by DDC as part of the standard format for notifications of intent to certify under the urban bus retrofit/rebuild program.

(c) Testing

JMI commented that the notification started that the rebuilt engine for the test program was originally a 1984 engine but it doesn't state that the engine was rebuilt to a 1984 configuration prior to testing. What was the configuration of the baseline engine and is it consistent with the claims made by DDC? Engelhard commented that DDC has not included a baseline test for comparison with the proposed retrofit kit and that this data is necessary to verify that the equipment being installed on the engine does not affect engine performance or fuel economy.

EPA notes that DDC did not perform baseline testing for this notification. Under the urban bus retrofit/rebuild program baseline testing is required when certification is requested within specified life cycle cost limitations. In such cases, baseline testing is needed to demonstrate equipment impact on fuel economy and associated life cycle costs. EPA does not require baseline testing when demonstrating compliance with the 0.10 g/bhp-hr PM standard when certification with life cycle cost requirements is not requested and if all applicable engines are to be converted to the test engine configuration during retrofit/rebuild. In view of the fact that this certification is not being made within life cycle cost limits, and all converted engines will be retrofit to the test engine configuration, baseline testing is not required for this certification.

Prior to performance of the emissions test, the test engine was rebuilt using the DDC kit. DDC stated that the test engine was in a post-rebuild configuration which is not related to a particular model year. However, DDC noted that the test engine was mechanically similar to a 1989 configuration.

JMI commented that DDC stated in the notification that the 277 hp rating was chosen because, ''it represents the engine injector combination on which the candidate equipment will be used.'' JMI commented that this statement is understandable if DDC is certifying only 277 hp engine kits. However, the DDC application also claims 0.10 g/bhp-hr PM levels for 253 hp and 294 hp engine kits. JMI asked what FTP test date is available to demonstrate that this technology is effective on 253 hp and 294 hp engine. JMI stated that the EPA should require DDC to demonstrate that they can attain 0.10 g/bhp-hr level for these two horsepower ratings before including them in DDC's application.

Additionally, Engelhard commented that DDC has not tested the worst case engine for its system. The Turbodyne system is designed to force additional air into the intake before the standard turbocharger can spool up. According to Engelhard, it is the amount of air supplied during aceleration that allows better combustion which reduces the particulate emissions during acceleration. The amount of air supplied is critical for obtaining PM reduction. The emissions data supplied by DDC is for a 277 hp engine. Engelhard states that to meet the 0.10 g/bhp-hr level, the Turbodyne system will have to supply more air for a 294 hp engine. However, DDC has provided no justification or data demonstrating that the device is large enough to accommodate the air flow requirements of the 294 hp engine. This requirement is supported by the fact that DDC uses a different turbo with a higher A/R ratio for the 294 hp engine than the 277 hp engine.

DDC stated that it selected the 277 hp engine rating for certification testing because this is the rating most commonly used in transit bus operations. DDC agrees that the 294 hp engine will require more airflow than an engine rated at 277 hp when both engines are operating at their respective full rated power. DDC also points out that the TurboPac is not intended to deliver the full airflow requirements of the engine. The purpose of the TurboPac is to provide additional air during engine accelerations to compensate for the lag of the engine turbocharger, and its air supply performance is the same for all engines regardless of power rating. DDC states that an engine at the 294 hp rating is capable of injecting more fuel than an engine at the 277 hp rating, but the difference in fueling is small. The 294 hp rating has a peak torque of 875 lb-ft at 1200 rpm while the 277 hp rating has a peak torque of 880lb-ft at 1000 rpm. At 1200 rpm, full load, under steady state conditions, the 294 hp rating delivers 71.0 lb/hr of fuel vs. 68.5 lb/hr for the 277 hp engine. DDC notes that this is only a 3.6% difference. DDC has not measured fueling differences for the two ratings during rapid accelerations, but because the throttle delay limits fueling to some fraction of the full rack fueling, the fueling difference during acceleration would be somewhat less than the steady state difference. Since the fueling difference is small, DDC believes the TurboPac will provide sufficient supplementary air to provide adequate particulate control with the 294 hp engine.

EPA's urban bus certification requirements for heavy-duty urban bus diesel engines, 40 CFR 85.1406 (a)(2)(i) states ''The test engine used must represent the 'worst case' with respect to particulate emissions of all those engine configurations for which the retrofit/rebuild equipment is being certified. The worst case engine configuration shall be the engine configuration having the highest engine-out particulate matter emission levels, when properly maintained and used, prior to installation of the retrofit/rebuild equipment.'' Based on available information, it is not clear whether an engine rated at 253 hp, 277 hp, or 294 hp would have significantly different exhaust emissions or, which would represent the worst case for this certification decision.

EPA believes that a comparison with the criteria for selecting test engines under EPA's new engine certification program is relevant. EPA's new engine certification requirements for heavy-duty diesel engines, 40 CFR § 86.090–24 (b)(3)(ii) for test engine selection state ''* * * Within each combination, the engine that features the highest fuel feed per stroke, primarily at the speed of maximum rated torque and secondarily at rated speed, will usually be selected'' for a test engine. In a facsimile dated March 7, 1998, DDC provided information on the fuel feed rate for each hp at maximum rated torque. That information shows that the fuel feed per stroke for the 277 hp engine clearly exceeds the 253 hp at maximum rated torque (88.8 mm/stroke vs. 77.4 mm/stroke). With regard to the 294 hp engine, DDC has provided information that the fuel feed per stroke for the 277 hp engine is virtually identical to the fuel feed per stroke of the 294 hp engine at maximum rated torque (88.8 vs. 88.9 mm/stroke). While a strict comparison of this data indicates that the 277 hp engine does not meet the ''highest fuel

feed per stroke'' criteria as stated, it is within one-tenth of one percent of the 294 hp rating with regard to this measurement. DDC's March 27, 1998 submission has been placed in the docket at the above address.

In conjunction with the discussion above and the following reasons, EPA believes that the 6V92TA engine equipped with the DDC kit rated at 277hp, is acceptable for compliance at the 253, 277 and 294 hp ratings. First, the 6V92TA MUI test engine is clearly the engine model for which DDC is claiming applicability of the DDC kit. Further, the hp rating of the certification is the most popular power rating. It is therefore the most representative power rating. Second, it is consistent with the use of a 277hp test engine by JMI for certification applicable to various hp ratings applicable to 6V92TA model engines (see 62 FR 60079; November 6, 1997). In EPA's approval of this JMI certification kit, EPA allowed the certification test engine at the 277 hp rating to represent additional hp ratings which were certified. No additional information was presented by JMI or Engelhard in their respective comments relative to different emission levels from the various ratings. Lacking such information EPA can find no reason to change from the decision made in the JMI certification to allow the 277 hp test engine to represent the additional ratings. Additionally, it is not clear that an engine of the DDC rated 253 hp or 294 hp would have significantly different exhaust emissions from the certified test engine. Because of the above noted reasons, and consistent with EPA's decision in that JMI certification, EPA finds that the 277 hp rating is acceptable to represent the 253 hp and the 294 hp ratings in this certification. EPA retains the authority to conduct in-use testing of any certified equipment for compliance with the 150,000 mile performance warranty on all certified equipment.

JMI commented that the test data states that the muffler was installed 6 feet from the turbocharger exit. JMI asked if this is the way it will be installed in the buses. JMI noted that the converter muffler is a direct bolt on replacement for the original muffler. With the extreme variation in diameter from muffler to muffler, how many different size catalyst elements are used? If more than one, which one was used during the FTP test? If only one, the EPA should require DDC to provide assurances that the catalyst was sized to achieve 0.1 g/bhp-hr PM for the complete range of 6V92TA MUI engines form 1979 to 1989.

DDC stated that the converter muffler was tested at a location of six feet from the turbocharger outlet. The installation on a particular urban bus will vary based on the original muffler location. DDC tested at this distance as most urban bus mufflers are installed within this distance from the turbocharger and chose this location to represent a worst case in terms of exhaust temperature. EPA accepts the placement of the converter at six feet from the turbocharger in this instance and notes that EPA has accepted this distance in previous certification approvals.

DDC stated that parts list number six in the notification provides a listing of the different converter/muffler configurations that will be used. The particular converter/muffler configuration used to generate the emission test results in the notification was a 12 inch by 23 inch oval cross section design, 22 inches in length. This unit has the minimum catalyst volume of the different converter/muffler configurations that will be used according to DDC and corresponds to part number 6000–005D of that list.

Engelhard asked how the backpressure was set for emissions testing. DDC testing was performed at Southwest Research Institute in San Antonio, Texas. With a standard muffler installed in the test cell exhaust system, the damper was closed (with the test engine at rated speed) to adjust the backpressure to 80% of the specified maximum, or 2 inches of mercury. The standard muffler was then removed, and the catalyst was installed in its place. Certification testing was conducted without changing the position of the throttling valve. The resulting backpressure was 2.7 inches of mercury with the catalyst installed. Engelhard asked where did the original muffler come from and is it a bus muffler? The muffler was provided by the testing facility and was selected to represent an urban bus muffler.

(D) Life Cycle Cost Analysis

Engelhard commented that DDC has not provided a life cycle cost calculation for this retrofit equipment. Engelhard noted that this is extremely important due to the complexity of the installation required for the Turbodyne system, the potentially expensive maintenance of the system, the detrimental effect of the huge electrical demand of the Turbodyne system on the buses charging system, and the increased fuel consumption of the Turbodyne system. Engelhard commented that this information is needed so bus companies can make a valid assessment of this technology's cost effectiveness. DDC's application also did not include prices or installation costs for any of the retrofit kits. JMI also commented on the cost of the DDC/Turbodyne kit. It asked about the labor costs to install the DDC/Turbodyne system because the addition of a supercharger is over and above what is done during a standard rebuild. Are there any periodic maintenance requirements that would increase the cost of the system? What is the impact of the DDC/Turbodyne technology on fuel consumption? Should a fuel penalty be assessed?

As stated earlier, DDC has not provided life cycle cost information in conjunction with this notification. Such a cost analysis is necessary for certification of equipment that is meant to trigger a program emissions standard. Certification of Engelhard Corporation's ETX™ kit triggered the 0.10 g/bhp-hr standard for 6V92TA MUI engines, and made available kits rated at 253, 277, and 294 hp. The DDC certification does not include a cost analysis, and one is not necessary for this certification. DDC states that engines equipped with the kit will have no additional maintenance or service requirements and the system will not have a detrimental impact on the electrical system as discussed earlier. Based on the field installations to date, DDC estimates that the installation of the TurboPac unit will average an additional eight hours of labor beyond the labor associated with a standard rebuild. However, this figure could vary depending on the specific installation requirements. No claims have been made by DDC with regard to the impact of this system on fuel economy and the impact of this system on fuel economy is undetermined. No specific information on fuel economy impact was provided in the comments. EPA notes that it is not appropriate to assess a fuel economy penalty in a certification that does not contain life cycle cost information. With regard to fuel consumption, the brake specific fuel consumption (BSFC) measured during emission testing of the DDC kit was 0.464 lb/bhp-hr. In testing conducted for the three notifications for 0.1 g/bhp-hr PM certification for 6V92TA MUI engine models that EPA has received to date, the BSFC measured during emission testing after the installation of the retrofit/rebuild kits has been between 0.438 and 0.471 lb/bhp-hr.

JMI asked if there are any components or ancillary parts that are required in order to install the DDC/Turbodyne system that are not included on any of the parts lists included with DDC's application? If so, what are the additional costs associated with these

parts? In response, DDC states that the parts list in the application does not include the electrical wire (16 AWG and 00 cable), and some nuts and bolts. DDC states that it believes these are standard items commonly available in bus repair facilities. Total cost for all of these parts is estimated by DDC to be between $20 and $40, depending on the length of the 00 cable. No additional batteries or other changes are required to the battery charging system. No rewiring of the bus electrical system is needed according to DDC.

(E) Warranty

Engelhard commented that DDC does not provide any coverage for damage resulting to other engine components, such as the charging system, due to the installation of its retrofit kit. In response, DDC notes that field evaluations have not resulted in any failures to bus charging or electrical systems. Neither DDC nor Delco-Remy anticipate that use of the TurboPac system will increase failure rates of the vehicle charging and electrical systems. Standard warranty coverages, if not expired, will remain in effect for any failures which may occur in these systems. DDC will not provide additional warranty coverage for these systems. Based on the review of comments and the in-use pilots, EPA is not award of any damage to other components as a result of the installation of this equipment and does not see reason not to approve this certification. If significant in-use problems were to develop, EPA can take action and, ultimately, has authority to decertify equipment.

(F) Durability

JMI commented that DDC stated in its notification; ''The cylinder kit components were modified to improve durability.'' JMI expressed concerns that changes to any parts of the cylinder kits could result in increased soot formation in the oil or increased oil consumption. JMI further questioned what the modifications were, how will they be made, who will make them, how DDC will control uniformity and quality, whether the change was made for all 92 series engines or just the engines with the kit and whether the parts will be made available on a nationwide basis. Engelhard commented that though durability data is not a requirement of the Urban Bus regulation, the EPA has required verification of durability and data supporting the claim that the system will last 150,000 miles.

In response DDC stated that the primary change in the cylinder kit is the elimination of a ''J-relief'' groove. The J-relief was a machining process to the lower side of the bottom compression ring groove which was designed to relieve any pressure build-up between the upper and lower compression rights. The change to the piston eliminates the machining operation. DDC states that this change has no affect on the combustion process, and will have no affect on generation of soot during the combustion process. According to DDC the change was made strictly to improve the durability of the lower compression ring. The changes have been incorporated in the cylinder kits used to service all DDC series 92 engines, whether used to service truck, bus, or nonroad engines. The new piston domes are also used on production engines. Therefore, the parts are subject to the same quality control as any other DDC production or service part. The new kits are available worldwide through DDC's distributor network.

EPA is concerned, in general, with equipment durability, and believes that certifiers will want to evaluate the durability of their equipment in order to minimize their liability resulting from the emissions defect and performance warranties. However, program regulations do not require a durability demonstration. EPA believes that DDC's explanation does not indicate a durability concern with the equipment certified in today's notice, and therefore, does not provide sufficient basis to deny certification on these grounds. EPA has the authority to conduct in-use testing of certified equipment to determine compliance with the requirements of the program. In addition, equipment certifiers must provide a 100,000 mile defect warranty and a 150,000 miles emissions performance warranty on all certified equipment

(G) In-Use Experience

The Washington Metropolitan Area Transit Authority (WMATA), the Maryland Department of Transportation Mass Transit Administration (MTA), and the Milwaukee County Transit System (MCTS) provided favorable comments on the DDC system. WMATA noted that one DDC kit was installed on September 17, 1997 and that WMATA has not encountered any installation or servicing problems with the engine and there have been no failures. The MTA commented that it has installed the DDC kit and it has performed ''flawlessly.'' The MCTS commented that it has installed five DDC kits. The first kit was installed in September 1997. To date, MCTS has not experienced ''any'' electrical component problems on the buses. By electrical problems, MCTS stated it meant any alternator, regulator, battery, or wiring problems. MCTS commented that it experienced ''one'' TurboPac electrical turbo motor failure early in the test process. MCTS commented that the DDC kit is reliable but that it was too early in the process to determine if there are any fuel or power increases.

IV. Certification

The Agency has reviewed the notification of intent to certify and other information provided by DDC, along with comments received from interested parties, and finds that the DDC kit described above:

(1) Complies with the particulate matter exhaust emissions standard of 0.10 g/bhp-hr, without causing the applicable engine families to exceed other exhaust emissions standards;

(2) Will not cause an unreasonable risk to the public health, welfare, or safety;

(3) Will not result in any additional range of parameter adjustability; and,

(4) Meets other requirements necessary for certification under the Retrofit/Rebuild Requirements for 1993 and Earlier Model Year Urban Buses (40 CFR Sections 85.1401 through 85.1415).

Therefore, today's **Federal Register** notice announces certification of the above-described DDC kit for use in the urban bus retrofit/rebuild program as discussed below in section V.

V. Transit Operator Responsibilities

Today's **Federal Register** notice announces certification of the above-described DDC kit, when properly applied, as meeting the 0.10 g/bhp-hr particulate matter standard of the Urban Bus Retrofit/Rebuild Program.

In a **Federal Register** notice dated March 14, 1997 (62 FR 12166), EPA announced certification of a retrofit/rebuild kit produced by the Engelhard Corporation (the ETX™ kit). That certification means that urban bus operators using compliance program 1 must use equipment certified to the 0.10 g/bhp-hr standard when rebuilding or replacing applicable 1979 through 1989 model year DDC 6V92TA MUI model engines after September 14, 1997. The certified DDC equipment described in today's notice may be used by operators in compliance with the 0.10 g/bhp-hr standard. Operators using compliance program 2 having applicable engines may use the certified DDC kit and claim the certification PM level from Table B above, when calculating their Fleet Level Attained (FLA). Under program 2, an operator must use sufficient certified equipment so that its actual fleet emission level complies with the target level for its fleet.

As mentioned above, certification of the Engelhard ETX™ kit triggered the 0.10 g/bhp-hr standard for applicable 1979–1989 6V92TA MUI engines. That kit provides three power ratings: 253, 277, and 294 horsepower. DDC will offer the DDC kit in these three power ratings as well: 253, 277, and 294hp.

Engines of urban buses certified to meet California emissions standards are not applicable to the DDC kit discussed in today's **Federal Register** notice. Additionally, the 0.10 g/bhp-hr PM standard is not triggered for engines certified to meet California emission standards. Operators of such urban buses, who choose to comply with program 1, are not required to use equipment certified to the 0.10 g/bhp-hr PM standard until the standard has been triggered for such engines. Operators of urban buses having engines certified to meet California emission standards, and who choose to comply with program 2, may not use the DDC kit described in today's notice to meet program requirements.

As stated in the program regulations (40 CFR 85.1401 through 85.1415), operators must, beginning January 1, 1995, maintain records for each engine in their fleet to demonstrate that they are in compliance with the requirements of the Urban Bus Retrofit/Rebuild Program. These records include purchase records, receipts, and part numbers for the parts and components used in the rebuilding or urban bus engines.

Dated: May 5, 1998.

Richard D. Wilson,

Acting Assistant Administrator for Air and Radiation.

[FR Doc. 98–12850 Filed 5–13–98; 8:45 am]

BILLING CODE 6560–50–M

ENVIRONMENTAL PROTECTION AGENCY

[FRL–6013–6]

Acid Rain Provisions

AGENCY: Environmental Protection Agency.

ACTION: Notice.

SUMMARY: EPA today announces the allocation of allowances to small diesel refineries for desulfurization of fuel during 1997. The eligibility for and calculation of allowances to small diesel refineries is in accordance with Section 410(h) of the Clean Air Act, implemented at 40 CFR part 73, subpart G.

FOR FURTHER INFORMATION CONTACT: Kathy Barylski, EPA Acid Rain Division (6204J), 401 M St., SW, Washington DC; telephone (202) 564–9074; or the Acid Rain Hotline at (202) 564–9620. Electronic copies of this rulemaking and technical support documents can be accessed through the Acid Rain Division website at www.epa.gov/acidrain.

SUPPLEMENTARY INFORMATION: EPA's Acid Rain Program was established by Title IV of the Clean Air Act Amendments of 1990 (CAAA) to reduce acid rain in the continental United States. The Acid Rain Program will achieve a 50 percent reduction in sulfur dioxide (SO_2) emissions from utility units. The SO_2 reduction program is a flexible market-based approach to environmental management. As part of this approach, EPA allocates ''allowances'' to affected utility units. Each allowance is a limited authorization to emit up to one ton of SO_2. At the end of each calendar year, each unit must hold allowances in an amount equal to or greater than its SO_2 emissions for the year. Allowances may be bought, sold, or transferred between utilities and other interested parties. Those utility units whose annual emissions are likely to exceed their allocations may install control technologies or switch to cleaner fuels to reduce SO_2 emissions or buy additional allowances.

Section 410(h) of the Clean Air Act provides allowances for small diesel refineries that desulfurize diesel fuel from October 1, 1993 through December 31, 1999. Small refineries are not otherwise affected by the Acid Rain Program and do not need the allowances to comply with any provision of the Clean Air Act. Thus, the allowances serve as a financial benefit to small diesel refineries desulfurizing diesel fuel.

The following table lists allowances to be allocated to eligible refineries for desulfurization of diesel fuel during calendar year 1997.

Refiner	Refinery/location	Allocation
Big West Oil	Flying J	1304
Cenex	Laurel, Montana	1500
Frontier	Cheyenne, Wyoming	1500
Giant	Ciniza	1500
	Giant	1151
Holly	Lea	1469
	Navajo	1420
	Montana	329
Hunt	Tuscaloosa, Alabama	1402
Inland Refining	Woods Cross, Utah	757
Kern	Bakersfield, California	1500
La Gloria	Crown Refinery, Tyler, Texas	1500
Lion	El Dorato	1500
Paramount	Paramount, California	1282
Pennzoil	Atlas	1500
	Rasville	487
Pride	Abilene, Texas	1226
Sinclair	Little America	1500
	Sinclair, Wyoming	1500
	Tulsa, Oklahoma	1500
U.S. Oil & Refining	Tacoma, Washington	1072
Witco	Golden Bear	66
Wyoming Refining	Denver, Colorado	691

A total of 27,656 allowances are allocated to 17 refiners, which produced 55,111 thousand barrels of desulfurized diesel fuel. These allowances have a compliance year of 1998.

Requests for allowances for desulfurization during 1998 are due no later than April 1, 1999. Allowances allocated in 1999 will have a compliance year of 1999.

Dated: May 7, 1998.

Edward Callahan,

Acting Director, Office of Atmospheric Programs.

[FR Doc. 98–12848 Filed 5–13–98; 8:45 am]

BILLING CODE 6560–50–U

FEDERAL ELECTION COMMISSION

Sunshine Act Meeting

* * * * *

DATE & TIME: Tuesday, May 19, 1998 at 10:00 a.m.

PLACE: 999 E Street, NW., Washington, DC.

STATUS: This meeting will be closed to the public.

ITEMS TO BE DISCUSSED:

Compliance matters pursuant to 2 U.S.C. § 437g.

Audits conducted pursuant to 2 U.S.C. § 437g, § 438(b), and Title 26, U.S.C.

Matters concerning participation in civil actions or proceedings or arbitration.

Internal personnel rules and procedures or matters affecting a particular employee.

* * * * *

DATE & TIME: Wednesday, May 20, 1998 at 10:00 a.m.

PLACE: 999 E Street, NW., Washington, DC (Ninth Floor).

STATUS: This hearing will be open to the public.

MATTER BEFORE THE COMMISSION: Perot '96, Inc.,

DATE & TIME: Thursday, May 21, 1998 at 10:00 a.m.

PLACE: 999 E Street, NW. Washington, DC (Ninth Floor).

STATUS: This Meeting Will Be Open to the Public.

ITEMS TO BE DISCUSSED:

Correction and Approval of Minutes.

Advisory Opinion 1998–07: Pennsylvania Democratic Party by C.M. Tartaglione, Acting Chairman.

Advisory Opinion 1998–08: Iowa Democratic Party by Michael Peterson, Chairman.

Advisory Opinion 1998–09: New Mexico Republican Party by John Dendahl, Chairman.

Petition for Rulemaking on Qualified Nonprofit Corporations: Draft Notice of Disposition.

Administrative Matters.

PERSON TO CONTACT FOR INFORMATION: Mr. Ron Harris, Press Officer, Telephone: (202) 694–1220.

Marjorie W. Emmons,

Secretary of the Commission.

[FR Doc. 98–13018 Filed 5–12–98; 12:34 p.m.]

BILLING CODE 6715–01–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Committee on Vital and Health Statistics: Meeting

Pursuant to the Federal Advisory Committee Act, the Department of Health and Human Services announces the following advisory committee meeting.

Name: National Committee on Vital and Health Services (NCVHS) Executive Subcommittee.

Times and Dates: 9:00 a.m.–5:00 p.m., May 21, 1998.

Place: Conference Room 503A, Hubert H. Humphrey Building, 200 Independence Avenue SW., Washington, DC. 20201.

Status: Open.

Purpose: The Executive Subcommittee will hold a work planning session on May 21. In addition to reviewing the status of current work plans and activities, the Subcommittee will plan future priorities and activities and consider future work plans and schedules. The Subcommittee also will plan the agenda for the June 16–17 meeting of the full committee.

Contact Person for More Information: Substantive information as well as an agenda for the meeting and a roster of committee members may be obtained by visiting the NCVHS website (http://aspe.os.dhhs.gov/ncvhs), where an agenda will be posted prior to the meeting. You may also call James Scanlon, NCVHS Executive Staff Director, Office of the Assistant Secretary for Planning and Evaluation, DHHS, Room 440–D. Humphrey Building, 200 Independence Avenue SW., Washington, DC 20201, telephone (202) 690–7100, or Marjorie S. Greenberg, Executive Secretary, NCVHS, NCHS, CDC, Room 1100, Presidential Building, 6525 Belcrest Road, Hyattsville, Maryland 20782, telephone (301) 436–7050.

Note: In the interest of security, the Department has instituted stringent procedures for entrance to the Hubert H. Humphrey Building by non-government employees. Thus, individuals without a government identification card may need to have the guard call for an escort to the meeting room.

Dated: May 6, 1998.

James Scanlon,

Director, Division of Data Policy.

[FR Doc. 98–12762 Filed 5–13–98; 8:45 am]

BILLING CODE 4151–04–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

CDC Advisory Committee on HIV and STD Prevention: Notice of Charter Renewal

This gives notice under the Federal Advisory Committee Act (Pub. L. 92–463) of October 6, 1972, that the CDC Advisory Committee on HIV and STD Prevention of the Department of Health and Human Services, has been renewed for a 2-year period beginning May 12, 1998, through May 11, 2000.

For further information, contact Ronald O. Valdiserri, M.D., M.P.H., Deputy Director, National Center for HIV, STD, and TB Prevention, CDC, 1600 Clifton Road NE, MS E–07, Atlanta, Georgia 30333, phone 404–639–8002, fax 404–639–8600, e-mail rov1@cdc.gov.

Dated: May 7, 1998.

John C. Burckhardt,

Acting Director, Management Analysis and Services Office Centers for Disease Control and Prevention (CDC).

[FR Doc. 98–12826 Filed 5–13–98; 8:45 am]

BILLING CODE 4163–19–U

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

Safety and Occupational Health Study Section: Meeting

In accordance with section 10(a)(2) of the Federal Advisory Committee Act (Pub. L. 92–463), the Centers for Disease Control and Prevention (CDC) announces the following committee meeting:

Name: Task Group Session of the Safety and Occupational Health Study Section (SOHSS), National Institute for Occupational Safety and Health (NIOSH).

Time and Date: 8 a.m.–5:30 p.m., August 5–7, 1998.

Place: Embassy Suites Hotel, 1900 Diagonal Road, Alexandria, Virginia, 22314.

Status: Open 8 a.m.–8:30 a.m. August 5, 1998; Closed 8:30 a.m.–5:30 p.m. August 5, 1998; Closed 8 a.m.–5:30 p.m. August 6, 1998; Closed 8 a.m.–5:30 p.m. August 7, 1998.

Purpose: A Task Group of the SOHSS will review, discuss, and evaluate grant application(s) received in response to the sponsoring Institute's numbered solicitations as follows: Request For Application Number 98044 entitled, ''Implementation of the National Occupational Research Agenda (NORA),'' which pertains to broad-based research endeavors outlined as follows: (a)

Causal research to identify and investigate the relationships between hazardous working conditions and associated occupational disease and injury; (b) the nature and magnitude of special risk factors experienced by older and/or minority workers; (c) methods research to develop more sensitive means of evaluating hazards at work sites; and (d) evaluations of the effectiveness of new approaches or combinations of techniques such as control technologies and personal protective equipment, work organization changes, worker participation programs, and training in reducing or eliminating traumatic injuries and work-related musculoskeletal injuries.

Request For Application Number 98030 entitled, ''Occupational Radiation and Energy-Related Health Research Grants,'' which pertains to research endeavors outlined as follows:

(a) Research to identify and investigate the relationships between health outcomes and occupational exposure to radiation and other hazardous agents; (b) epidemiological methods research relevant to energy-related occupational health research; and (c) research related to assessing occupational exposures. The focus of proposed research should reflect the following topical areas, emphasizing field research: (1) Retrospective exposure assessment; (2) radiation measurement issues; (3) non-cancer morbidity and mortality outcomes; (4) meta-analysis and combined analysis methodologies; (5) uncertainty analysis; (6) effects of measurement error on risk estimates; (7) studies of current workers; and (8) risk communication and worker outreach.

It is the intent of NIOSH to support broad-based research endeavors in keeping with the Institute's program goals as outlined above which will lead to improved understanding and appreciation for the magnitude of the aggregate health burden associated with occupational injuries and illnesses. It is anticipated that research funded will promote these program goals.

Matters To Be Discussed: The meeting will convene in open session from 8–8:30 a.m. on August 5, 1998, to address matters related to the conduct of Study Section business. The remainder of the meeting will proceed in closed sessions. The purpose of the closed sessions is for the Task Group to consider safety and occupational health grant applications related to the cited solicitation. These portions of the meeting will be closed to the public in accordance with provisions set forth in section 552(c)(4) and (6), title 5 U.S.C., and the Determination of the Associate Director for Management and Operations, CDC, pursuant to Public Law 92–463.

Agenda items are subject to change as priorities dictate.

Contact Person for More Information: Pervis C. Major, Ph.D., Scientific Review Administrator, Office of Extramural Coordination and Special Projects, Office of the Director, NIOSH, 1095 Willowdale Road, Morgantown, West Virginia 26505. Telephone 304/285–5979.

Dated: May 7, 1998.

John C. Burckhardt,

Acting Director, Management Analysis and Services Office, Centers for Disease Control and Prevention (CDC).

[FR Doc. 98–12825 Filed 5–13–98; 8:45 am]

BILLING CODE 4163–19–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

Oncologic Drugs Advisory Committee; Notice of Meeting

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

This notice announces a forthcoming meeting of a public advisory committee of the Food and Drug Administration (FDA). The meeting will be open to the public.

Name of Committee: Oncologic Drugs Advisory Committee.

General Function of the Committee: To provide advice and recommendations to the agency on FDA regulatory issues.

Date and Time: The meeting will be held on June 1, 1998, 8:30 a.m. to 5:30 p.m., and June 2, 1998, 8 a.m. to 5:30 p.m.

Location: Gaithersburg Hilton, Grand Ballroom, 620 Perry Pkwy., Gaithersburg, MD.

Contact Person: Karen M. Templeton-Somers, Center for Drug Evaluation and Research (HFD–21), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–443–4090, or FDA Advisory Committee Information Line, 1–800–741–8138 (301–443–0572 in the Washington, DC area), code 12542. Please call the Information Line for up-to-date information on this meeting.

Agenda: On June 1, 1998, the committee will discuss: (1) New drug application (NDA) 20–892 AD 32 (valrubicin 40 milligrams/milliliter), Anthra Pharmaceuticals, Inc., indicated for the treatment of refractory carcinoma *in situ* of the urinary bladder; and (2) NDA supplement 20–449/S–005 Taxotere® (docetaxel) for injection concentrate, Rhone-Polenc Rorer Pharmaceuticals, Inc., indicated for the treatment of patients with locally advanced or metastatic breast cancer who have failed previous chemotherapy. On June 2, 1998, the committee will discuss: (1) Biologics license application (BLA) 97–1325 ONTAK™ (denileukin diftitox) injection (DAB_{389} IL–2), Seragen, Inc., indicated for the treatment of cutaneous T-cell lymphoma (CTCL); and (2) NDA supplement 20–671/S–004 Hycamtin® (topotecan HCl) for injection, SmithKline Beecham Pharmaceuticals, indicated for the second-line treatment of patients with small cell lung cancer.

Procedure: Interested persons may present data, information, or views, orally or in writing, on issues pending before the committee. Written submissions may be made to the contact person by May 22, 1998. Oral presentations from the public will be scheduled between approximately 8:45 a.m. and 9:15 a.m., on June 1, 1998, and between approximately 8:15 a.m. and 8:45 a.m., on June 2, 1998. Time allotted for each presentation may be limited. Those desiring to make formal oral presentations should notify the contact person before May 15, 1998, and submit a brief statement of the general nature of the evidence or arguments they wish to present, the names and addresses of proposed participants, and an indication of the approximate time requested to make their presentation.

Notice of this meeting is given under the Federal Advisory Committee Act (5 U.S.C. app. 2).

Dated: May 7, 1998.

Michael A. Friedman,

Deputy Commissioner for Operations.

[FR Doc. 98–12756 Filed 5–13–98; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 98D–0284]

Guidance for Industry on Classifying Resubmissions in Response to Action Letters; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a guidance for industry entitled ''Classifying Resubmissions in Response to Action Letters.'' This guidance explains how the agency will classify resubmissions of new drug applications (NDA's) and license applications (LA's) and specifies the agency's response timeframes. The guidance also recommends procedures for making resubmissions.

DATES: Written comments may be submitted on the guidance by August 12, 1998. General comments on the agency guidance documents are welcome at any time.

ADDRESSES: Copies of this guidance for industry are available on the Internet at http://www.fda.gov/cder/guidance/index.htm, or http://www.fda.gov/cber/guidelines.htm. Submit written comments on this guidance to the Dockets Management Branch (HFD–305), Food and Drug Administration, 12420 Parklawn Dr., rm. 1–23, Rockville, MD 20857. Comments are to be identified with the docket number found in brackets in the heading of this document. After the comment period, comments may be submitted to one of the centers at the address below.

FOR FURTHER INFORMATION CONTACT:

Murray M. Lumpkin, Center for Drug Evaluation and Research (HFD–002), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–594–5400, or

Robert A. Yetter, Center for Biologics Evaluation and Research (HFM–10), 1401 Rockville Pike, Rockville, MD 20852–1448, 301–827–0373.

SUPPLEMENTARY INFORMATION: FDA is announcing the availability of a guidance for industry entitled ''Classifying Resubmissions in Response to Action Letters.'' In the Prescription Drug User Fee Act of 1992 (PDUFA), FDA committed to certain user fee performance goals, including the goal of responding to an applicant's resubmission of an original NDA or LA in 6 months or less. In her letter to Congress regarding the reauthorization of PDUFA in November 1997 as part of the Food and Drug Administration Modernization Act of 1997 (Modernization Act), the Secretary of Health and Human Services committed FDA to recognizing two classes of resubmissions: Class 1 and Class 2. This guidance describes the classification of resubmissions as Class 1 or Class 2 based on the information submitted by the applicant in response to the action letter. In addition, the guidance specifies the percentages of resubmissions in each class that will be reviewed and acted upon within a certain time period from the date the resubmission is received by FDA, based on the fiscal year in which the resubmission is received.

This guidance is being implemented immediately without prior public comment because the guidance is needed to implement the Modernization Act. However, the agency wishes to solicit comment from the public and is providing a 90-day comment period and establishing a docket for the receipt of comments.

This guidance is issued as a Level 1 guidance consistent with FDA's good guidance practices (62 FR 8961, February 27, 1997). It represents the agency's current thinking on classifying resubmissions in response to action letters. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. An alternative approach may be used if such approach satisfies the requirements of the applicable statute, regulations, or both.

Interested persons may, at any time, submit written comments on the guidance to the Dockets Management Branch (address above). Two copies of any comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with the docket number found in brackets in the heading of this document. The guidance and received comments are available for public examination in the Dockets Management Branch between 9 a.m. and 4 p.m., Monday through Friday.

Dated: May 8, 1998.

William B. Schultz,

Deputy Commissioner for Policy.

[FR Doc. 98–12830 Filed 5–13–98; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 98D–0282]

Guidance for Industry on Submitting and Reviewing Complete Responses to Clinical Holds; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a guidance for industry entitled ''Submitting and Reviewing Complete Responses to Clinical Holds.'' This guidance describes how to submit a complete response if an investigational new drug application is placed on clinical hold.

DATES: Written comments may be submitted on this guidance document by August 12, 1998. General comments on agency guidance documents are welcome at any time.

ADDRESSES: Copies of this guidance for industry are available on the Internet at http://www.fda.gov/cder/guidance/index.htm; or http://www.fda.gov/cber/guidelines.htm. Submit written comments on this guidance to the Dockets Management Branch (HFD–305), Food and Drug Administration, 12420 Parklawn Dr., rm 1–23, Rockville, MD. 20857. Comments are to be identified with the docket number found in brackets in the heading of this document. After the comment period, comments may be submitted to one of the centers at the addresses that follow.

FOR FURTHER INFORMATION CONTACT:

Murray M. Lumpkin, Center for Drug Evaluation and Research (HFD–002), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–594–5400; or

Robert A. Yetter, Center for Biologics Evaluation and Research, 1401 Rockville Pike, Rockville, MD 20852–1448, 301–827–0373.

SUPPLEMENTARY INFORMATION: FDA is announcing the availability of a guidance for industry entitled ''Submitting and Reviewing Complete Responses to Clinical Holds.'' Section 117 of the Food and Drug Administration Modernization Act of 1997 (Modernization Act), signed into law by President Clinton on November 21, 1997, provides that a written request that a clinical hold be removed shall receive a decision in writing, specifying the reasons for that decision, within 30 days after receipt of such request. In addition, the agency committed to user fee performance goals incorporating the same response time. This guidance describes how sponsors should submit responses to clinical holds so that they may be identified as complete responses and the agency can track the time to response.

This guidance document is being implemented immediately without prior public comment because the guidance is needed to implement the Modernization Act. However, the agency wishes to solicit comment from the public and is providing a 90-day comment period and establishing a docket for the receipt of comments.

This guidance for industry is a Level 1 guidance consistent with FDA's Good Guidance Practices (62 FR 8961, February 27, 1997). It represents the agency's current thinking on submitting complete responses to clinical holds. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. An alternative approach may be used if such approach satisfies the requirements of the applicable statute, regulations, or both.

The guidance and comments received in the Dockets Management Branch (address above) are available for public examination between 9 a.m. and 4 p.m., Monday through Friday.

Dated: May 8, 1998.

William B. Schultz,

Deputy Commissioner for Policy.

[FR Doc. 98–12831 Filed 5–13–98; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Care Financing Administration

[Document Identifier: HCFA–R–229]

Agency Information Collection Activities: Proposed Collection; Comment Request

In compliance with the requirement of section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995, the Health Care Financing Administration (HCFA), Department of Health and Human Services, is publishing the following summary of proposed collections for public comment. Interested persons are invited to send comments regarding the burden estimate or any other aspect of this collection of information, including any of the following subjects: (1) the necessity and utility of the proposed information collection for the proper performance of the agency's functions; (2) the accuracy of the estimated burden; (3) ways to enhance the quality, utility,and clarity of the information to be collected; and (4) the use of automated collection techniques or other forms of information technology to minimize the information collection burden.

Type of Information Collection Request: Extension of a currently approved collection; *Title of Information Collection:* Development of an Assessment System for post Acute Care; *Form No.:* HCFA–R–229, OMB #0938–0720; *Use:* The Minimum Data Set- Post Acute Care (MDS–PAC) will be used to establish patient case mix groups including classes of patients in the rehabilitation facility for the payment system. It will also provide data and seek input from the rehabilitation industry for HCFA to formulate policy and promulgate regulations. *Frequency:* On occasion; *Affected Public:* Individuals or Households, Business or other for-profit, Not-for-profit; *Number of Respondents:* 10,465; *Total Annual Responses:* 10,465; *Total Annual Hours:* 23,301.

To obtain copies of the supporting statement for the proposed paperwork collections referenced above, E-mail your request, including your address and phone number, to Paperwork@hcfa.gov, or call the Reports Clearance Office on (410) 786–1326. Written comments and recommendations for the proposed information collections must be mailed within 60 days of this notice directly to the HCFA Paperwork Clearance Officer designated at the following address: HCFA, Office of Information Services, Information Technology Investment Management Group, Division of HCFA Enterprise Standards, Attention: John Rudolph, Room C2–26–17, 7500 Security Boulevard, Baltimore, Maryland 21244–1850.

Dated: May 5, 1998.

John P. Burke III,

HCFA Reports Clearance Officer, Division of HCFA Enterprise Standards, Health Care Financing Administration.

[FR Doc. 98–12766 Filed 5–13–98; 8:45 am]

BILLING CODE 4120–03–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Care Financing Administration

[Document Identifier: HCFA–250 through HCFA–254]

Emergency Clearance: Public Information Collection Requirements Submitted to the Office of Management and Budget (OMB)

AGENCY: Health Care Financing Administration, HHS

In compliance with the requirement of section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995, the Health Care Financing Administration (HCFA), Department of Health and Human Services, is publishing the following summary of proposed collections for public comment. Interested persons are invited to send comments regarding this burden estimate or any other aspect of this collection of information, including any of the following subjects: (1) The necessity and utility of the proposed information collection for the proper performance of the agency's functions; (2) the accuracy of the estimated burden; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) the use of automated collection techniques or other forms of information technology to minimize the information collection burden.

We are, however, requesting an emergency review of the information collections referenced below. In compliance with the requirement of section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995, we have submitted to the Office of Management and Budget (OMB) the following requirements for emergency review. We are requesting an emergency review because the collection of this information is needed before the expiration of the normal time limits under OMB's regulations at 5 CFR, Part 1320. This is necessary to collect information from beneficiaries on health insurance coverage that is primary to Medicare. Collection of this information allows HCFA to identify those Medicare beneficiaries who have other group health insurance that would pay before Medicare, resulting in savings to the Medicare Trust Fund. The annual savings from the Medicare Secondary Payer (MSP) program are more than $3 billion per year. Emergency approval is needed to prevent a disruption in the information collection and to continue the savings to the Medicare Trust Fund. We cannot reasonably comply with the normal clearance procedures because public harm is likely to result because eligible individuals may not receive the health insurance protections under the statute.

HCFA is requesting OMB review and approval of this collection 15 working days after the publication of this **Federal Register** notice, with a 180-day approval period. Written comments and recommendations will be accepted from the public if received by the individuals designated below 14 working days after the publication of this notice. During this 180-day period, we will publish a separate **Federal Register** notice announcing the initiation of an extensive 60-day agency review and public comment period on these requirements. We will submit the requirements for OMB review and an extension of this emergency approval.

Type of Information Request: Reinstatement, without change, of a previously approved collection for which approval has expired;

Title of Information Collection: Medicare Secondary Payer Information Collection and Supporting Regulations in 42 CFR 489.20;

Form Number: HCFA–250 through HCFA–2545 (OMB approval #: 0938–0214);

Use: Medicare Secondary Payer (MSP) is essentially the same concept known in the private insurance industry as coordination of benefits, and refers to those situations where Medicare does not have primary responsibility for paying the medical expenses of a Medicare beneficiary. HCFA contracts with health insuring organizations, herein referred to as intermediaries and carriers, to process Medicare claims. HCFA charges its Medicare intermediaries and carriers with various tasks to detect MSP cases; develops and disseminates tools to enable them to

better perform their tasks; and monitors their performance in achievement of their assigned MSP functions. Because intermediaries and carriers are also marketing health insurance products that may have liability when Medicare is secondary, the MSP provisions create the potential for conflict of interest. Recognizing this inherent conflict, HCFA has taken steps to ensure that its intermediaries and carriers process claims in accordance with the MSP provisions, regardless of what other insurer is primary. These information collection requirements describe the MSP requirements.

Frequency: One time only;

Affected Public: Individuals or Households;

Number of Respondents: 14,204,000;

Total Annual Responses: 14,204,000;

Total Annual Hours Requested: 773,240.

• *42 CFR 489.20(f)—Third Party Identification.*

Identification and collection of information concerning proper payers during the admission process is a common business practice in the health care field. HCFA hospital reviews indicate that only one additional question is required as compared with the normal admissions process for non-Medicare patients. In addition, many hospitals have and will continue to reap significant benefits due to identification of primary payers during the admission process. This relates to the fact that a private payer's rate of payment is normally based on a percentage of charges, whereas for Medicare patients the hospital receives the Medicare payment, which is generally an amount paid under the prospective payment system.

• *Initial Enrollment Questionnaire (IEQ)—P.L. 103–432 Sec. 151*

The IEQ contractor states that the average number of IEQs mailed each calendar year is 1,903,960. The time required to complete the IEQ is approximately 15 minutes per beneficiary. Therefore, the burden is 1,903,960 × 15 minutes = 475,990 of burden hours per year. The total burden is 773,240 hours (297,250 + 475,990).

We have submitted a copy of this notice to OMB for its review of these information collections. A notice will be published in the **Federal Register** when approval is obtained.

To obtain copies of the supporting statement and any related forms for the proposed paperwork collections referenced above, access HCFA's Web Site address at http://www.hcfa.gov/regs/prdact95.htm, or E-mail your request, including your address, phone number, OMB number, and HCFA document identifier, to Paperwork@hcfa.gov, or call the Reports Clearance Office on (410) 786–1326.

Interested persons are invited to send comments regarding the burden or any other aspect of these collections of information requirements. However, as noted above, comments on these information collection requirements must be mailed and/or faxed to the designees referenced below fourteen days after the publication of this **Federal Register** notice:

Health Care Financing Administration, Office of Information Services, Information Technology Investment Management Group, Division of HCFA Enterprise Standards, Room C2–26–17, 7500 Security Boulevard, Baltimore, MD 21244–1850. Fax Number: (410) 786–1415. Attn: Louis Blank HCFA–250 through HCFA–254 and,

Office of Information and Regulatory Affairs, Office of Management and Budget, Room 10235, New Executive Office Building, Washington, DC 20503, Fax Number: (202) 395–6974 or (202) 395–5167. Attn: Allison Herron Eydt, HCFA Desk Officer.

Dated: May 6, 1998.

John P. Burke III,

HCFA Reports Clearance Officer, HCFA, Office of Information Services, Information Technology Investment Management Group, Division of HCFA Enterprise Standards.

[FR Doc. 98–12802 Filed 5–13–98; 8:45 am]

BILLING CODE 4120–03–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Care Financing Administration

[HCFA–3888–NC]

Medicare and Medicaid Programs: Request for Public Comments on the Quality Improvement System for Managed Care

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

ACTION: Solicitation of comments; notice of public meeting.

SUMMARY: The Quality Improvement System for Managed Care (QISMC) is a document that represents the best thinking on what managed care organizations contracting with Medicare and Medicaid should do to protect and improve the health and satisfaction of enrolled beneficiaries. This notice solicits comments on the review draft of the QISMC document, and informs the public of a meeting to discuss the quality improvement system initiative.

DATES: We request that comments be submitted on or before May 26, 1998.

Public Meeting: In addition to seeking written comments from the public, we will hold a public meeting on Tuesday, May 26, 1998, from 8:30 a.m. to 3:30 p.m. e.d.t.

ADDRESSES: The May 26, 1998 public meeting will be held in the Health Care Financing Administration Auditorium at 7500 Security Boulevard, Baltimore, Maryland 21207. (For details, see section III of this notice.)

Mail written comments (1 original and 3 copies) to the following address: Health Care Financing Administration, Department of Health and Human Services, Attention: HCFA–3888–NC, P.O. Box 26688, Baltimore, MD 21207.

If you prefer, you may deliver your written comments (1 original and 3 copies) to one of the following addresses:

Room 309–G, Hubert H. Humphrey Building, 200 Independence Avenue, SW., Washington, DC 20201,

or

Room C5–09–26, 7500 Security Boulevard, Baltimore, MD 21244–1850

Comments may also be submitted electronically to the following e-mail address: hcfa3888nc.hcfa.gov. E-mail comments must include the full name and address of the sender and must be submitted to the referenced address in order to be considered. All comments must be incorporated in the e-mail message because we may not be able to access attachments. Because of staffing and resource limitations, we cannot accept comments by facsimile (FAX) transmission. In commenting, please refer to file code HCFA–3888–NC. Comments received timely will be available for public inspection as they are received, generally beginning approximately 3 weeks after publication of a document, in Room 309–G of the Department's offices at 200 Independence Avenue, SW., Washington, DC, on Monday through Friday of each week from 8:30 a.m. to 5 p.m. (phone: (202) 690–7890).

FOR FURTHER INFORMATION CONTACT: Brian Agnew, (410) 786–5964.

SUPPLEMENTARY INFORMATION:

I. Background

The QISMC initiative began in 1996 with the following basic goals:

• To develop a coordinated Medicare and Medicaid quality oversight system that would reduce duplicative or conflicting efforts and send a uniform

message on quality to organizations and consumers.

• To make the most efficient use of available quality measurement and improvement tools, while allowing sufficient flexibility to incorporate new developments in the rapidly advancing state of the art.

To support the development of QISMC, HCFA contracted with the National Academy for State Health Policy to produce a conceptual framework for a unified Medicare-Medicaid quality oversight system, a set of quality standards for managed care organizations, and interpretive guidelines for these standards.

The National Academy for State Health Policy gave selected individuals and organizations the opportunity to comment on a review draft of the QISMC document in January 1998, and the breadth and depth of the comments received have convinced us that further investigation is necessary before we make any final policy decisions. Therefore, we have decided to give all interested parties an opportunity to comment on the review draft of the QISMC document.

At this time, the QISMC standards are not binding on Medicare and Medicaid managed care organizations. However, we intend to draw upon the QISMC document in establishing regulatory quality assurance requirements under Medicaid managed care and Medicare+Choice regulations yet to be published.

II. Issues To Be Resolved

As mentioned, we have already received comments from selected individuals and organizations on the review draft of the QISMC document. However, to ensure that we consider the full range of public opinion, we are using this notice as a vehicle to inform the general public that now it too has an opportunity to comment on the review draft of the QISMC document. We will consider written public comments that are received timely as we finalize the QISMC document.

The review draft of the QISMC document is available on our internet web site (http://www.hcfa.gov/quality/qlty-3e.htm). Although we welcome comments on all aspects of the draft, we are particularly interested in comments on certain issues identified as especially significant in comments received during the January 1998 comment period. These issues will be identified on our internet web site as well.

For those unable to access the QISMC document via the internet, hard copies may be obtained by calling Ms. Bronwyn Price of Casals and Associates, Inc. (C & A) at (703) 920–1234.

III. May 26, 1998 Public Meeting

In addition to seeking written comments from the public, we will hold a public meeting on Tuesday, May 26, 1998, from 8:30 a.m. to 3:30 p.m., in our auditorium at 7500 Security Boulevard, Baltimore, Maryland. In the morning, we will hold a plenary session devoted to general information about QISMC. In the afternoon, we will convene three breakout sessions: the first devoted to technical aspects of quality improvement activities, such as setting minimum performance levels and establishing the phase-in; the second devoted to issues relating to quality monitoring (such as deeming and external review); and the third devoted to issues affecting HCFA and the State Medicaid agencies in their roles as purchasers.

Because seating is limited, attendees must register for the meeting in advance. Registration must be made by May 18. In order to obtain a registration form for this meeting, please contact Ms. Jennifer Fink at C & A. Ms. Fink can be reached via telephone, (703) 920–1234; fax, (703) 920–5750; or email, jfink@casals.com. Once your registration form has been received and processed, C & A will provide you with a confirmation form. You must bring the confirmation form with you in order to be guaranteed participation in the meeting. C & A will also provide you with directions to HCFA Central Office.

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

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

Dated: May 4, 1998.

Nancy-Ann Min DeParle,

Administrator, Health Care Financing Administration.

[FR Doc. 98–13040 Filed 5–12–98; 2:54 pm]

BILLING CODE 4120–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Office of Inspector General

Program Exclusions: April 1998

AGENCY: Office of Inspector General, HHS.

ACTION: Notice of program exclusions.

During the month of April 1998, the HHS Office of Inspector General imposed exclusions in the cases set forth below. When an exclusion is imposed, no program payment is made to anyone for any items or services (other than an emergency item or service not provided in a hospital emergency room) furnished, ordered or prescribed by an excluded party under the Medicare, Medicaid, and all Federal Health Care programs. In addition, no program payment is made to any business or facility, e.g., a hospital, that submits bills for payment for items or services provided by an excluded party. Program beneficiaries remain free to decide for themselves whether they will continue to use the services of an excluded party even though no program payments will be made for items and services provided by that excluded party. The exclusions have national effect and also apply to all Executive Branch procurement and non-procurement programs and activities.

Subject, city, state	Effective date
Program-Related Convictions:	
Advanced Clinical Associates, Baltimore, MD	05/20/1998
Baig, Sharif, Grosse Ile, MI	05/20/1998
Beich, Michael N, Windham, ME	05/20/1998
Bracks, Oscar JR, Farmers Branch, TX	10/28/1997
Celestain, Vickie, Beaumont, TX	05/20/1998
Duarte, Angela, Woonsocket, RI	05/20/1998
Dworzanin, Gregory, Plymouth Twnshp, MI	05/20/1998
Goldbaum, Henry Romero, Frederick, MD	05/20/1998
Greene, Rose Marie, Baltimore, MD	05/20/1998
Hester, Angela Dailey, Ruston, LA	05/20/1998
Hunt, Aurelia Hilda, Sacramento, CA	05/20/1998
Jiggetts, Wayne R SR, Baltimore, MD	05/20/1998
Lewis, Jeffrey Blaine, Manchester, KY	07/21/1997
Missakian, Hratch, Glendale, CA	05/20/1998
Misto, Ralph L, Cranston, RI	05/20/1998
Ricci Pharmacy Inc, Brooklyn, NY	05/20/1998
Salerno, David Martin, Monroe, CT	05/20/1998
Salinski, Theodore, Chicago, IL	05/20/1998
Sazama, Gary P, Logan, UT	05/20/1998
Schoonover, Hazel, Columbus, OH	05/20/1998
Spisak, Irene P, Quincy, FL	05/20/1998
Swan, Maria, Miami, FL	05/20/1998
Terrace View Diversified Health, Seattle, WA	05/20/1998
Towanit, Pol, Blythe, CA	05/20/1998
Valdes, Daisy R, Glade Valley, NC	05/20/1998
Valdes, Maximino D, Glade Valley, NC	05/20/1998

Subject, city, state	Effective date
Weiss, Edward, New York, NY	05/20/1998
White, Kimberly Anne, Salt Lake City, UT	05/20/1998
Wikiera, John S, Woonsocket, RI	05/20/1998
Williams, Gary W, Vincennes, IN	05/20/1998
Patient Abuse/Neglect Convictions:	
Basham, Melalaine Devera, Colorado Spngs, CO	05/20/1998
Brown, Robert W, N Salt Lake, UT	05/20/1998
Carpenter, Robert D, Joanna, SC	05/20/1998
Davis, Sigmond Earl, Baltimore, MD	05/20/1998
Day, Maria, Austin, TX	05/20/1998
Dewberry, Elizabeth, Clarksdale, MS	05/20/1998
Hart, Velda Belinda, Baltimore, MD	05/20/1998
Heselton, Sharon, Saugus, MA	05/20/1998
Hough, Judy Ann, Swartz Creek, MI	05/20/1998
Huggins, Curtis Dale, Sand Springs, OK	05/20/1998
Manfredo, Louis, Johnston, RI	05/20/1998
Manville, James Ervin, McMillan, MI	05/20/1998
Mathers, Julie, N Kingstown, RI	05/20/1998
McConnaughey, William Eugene, Mountain View, AR	05/20/1998
Milam, Deborah Sue, Garland, TX	05/20/1998
Persall, Elsie, Vestaburg, MI	05/20/1998
Roy, Gerald, Colorado Spngs, CO	05/20/1998
Sanders, Felicia J, Oklahoma City, OK	05/20/1998
Sanon, Claudette, Somerville, MA	05/20/1998
Smith, Dorothy Julia, Baltimore, MD	05/20/1998
Taylor, Rachelle A, New Orleans, LA	05/20/1998
Thomas, Tawanna Ann, Arkansas AR	05/20/1998
Wall, George, Cranston, RI	05/20/1998
Winegarden, Terry Lee, Enid, OK	05/20/1998
Woodruff, Susie, Mineral Wells, TX	05/20/1998
Conviction for Health Care Fraud:	
Barner, Belinda Sue, Tucson, AZ	05/20/1998
Branch, Kelly Edward, Baltimore, MD	05/20/1998
Culligan, Thomas R IV, St Louis, MO	05/20/1998
Culligan, Lorrie Jean, St Louis, MO	05/20/1998
Grace, Sheri, Mio, MI	05/20/1998
Welch, Cora Joyce, Shreveport, LA	05/20/1998
License Revocation/Suspension/Surrendered:	
Aldrich, Edith N, Lisbon, NH	05/20/1998
Alexander, Allyson L, Mckeesport, PA	05/20/1998
Alexander, Sharon Lucille, Richmond, VA	05/20/1998
Anusavice, Gary, Shrewsbury, MA	05/20/1998
Arrington, Kay C, Richmond, VA	05/20/1998
Bailey, Lisa Perkins, Louisa, VA	05/20/1998
Bartlett, Robin D, Midlothian, VA	05/20/1998
Bayash, Frances D, Alexandria, VA	05/20/1998
Bealka, Neil M Sr, Stillwater, MN	05/20/1998
Belfield, John D, Janesville, WI	05/20/1998
Bender, Judy M, Easthampton, MA	05/20/1998
Blanchard, Darlene Kay, San Diego, CA	05/20/1998
Boyd, Justine R, Richmond, VA	05/20/1998
Brockhoff, Gayle C, Hugo, MN	05/20/1998
Brown, Richard D, Merrifield, MN	05/20/1998
Brown, Belinda T, Richmond, VA	05/20/1998
Brown, Stanley, Stony Brook, NY	05/20/1998
Burstein, David Lee, Woodland, CA	05/20/1998
Butta, Delbert, Boones Mill, VA	05/20/1998
Cacatian, Melody G, Virginia Beach, VA	05/20/1998
Caltrider, Robert S, Glen Burnie, MD	05/20/1998
Campbell, Lloyd R, Forest Park, GA	05/20/1998
Campbell, Robert E, Henderson, NV	05/20/1998
Canganelli, Vincent G, Clearwater, FL	05/20/1998
Carter, La'Keisha C, Axton, VA	05/20/1998
Castille, Joyce S, Dallas, TX	05/20/1998
Chabebe, Roberto, Elmhurst, NY	05/20/1998
Chandler, Gail, Wallingford, CT	05/20/1998
Clark, Douglas H, Concord, NC	05/20/1998
Clemmer, Anne Susan Hays, Churchville, VA	05/20/1998
Colich, Steven N, Coon Rapids, MN	05/20/1998
Converse, Joan A, Bloomington, MN	05/20/1998
Crabbs, Jerry, Crestview Hills, KY	05/20/1998
Crowder, Susan L Henderson, Clover, VA	05/20/1998
Curtiss, Audrey D, Providence Forge, VA	05/20/1998
Cutter, Gail E, Hillsboro, NH	05/20/1998
Davis, Cynthia W, Stuarts Draft, VA	05/20/1998
Defreitas-Badlu, Mary C, Ozone Park, NY	05/20/1998
Deyo, Ylonda Renee, Austin, TX	05/20/1998
Dinsmore, Peterson, Warwick, RI	05/20/1998
Doran, Jan, Mariette, PA	05/20/1998
Dorian, Carol, Waterbury, CT	05/20/1998
Eldridge, Tina Mischka, Poquoson, VA	05/20/1998
Elgin, Kimberly Mae, Charlotte Ct House, VA	05/20/1998
Elliott, Henrietta, Roanoke, VA	05/20/1998
Epps, Veronica B, Petersburg, VA	05/20/1998
Estep, Connie, Richlands, VA	05/20/1998
Feliz, Jose, Westland, MI	05/20/1998
Fogarty, Helen Moses, New York, NY	05/20/1998
Fors, Gregory C, Bemidji, MN	05/20/1998
Forti, Lewis A, Buffalo, NY	05/20/1998
Free, Kevin, Cedar Grove, NJ	05/20/1998
Freeman, Richard, Detroit, MI	05/20/1998
Gaither, Michelle, Chicago, IL	05/20/1998
Gallagher, Michael, Ionia, MI	05/20/1998
Gallagher, Ronald L, Toano, VA	05/20/1998
Gambino, Vivian M, Richmond, VA	05/20/1998
Garms, Cheryl Ann, Perry, OK	05/20/1998
Ghorieshi, Abbas, Weston, MA	05/20/1998
Ghota, Boonga, Richmond, VA	05/20/1998
Glass, Kimberley Ann, Newport News, VA	05/20/1998
Glover, Nicole N, Norfolk, VA	05/20/1998
Goldberg, Lisa A, Silver Spring, MD	05/20/1998
Goldgruber, Gail Louise, Pinole, CA	05/20/1998
Goodrich, Debra A, Seminole, FL	05/20/1998
Greenwald, Stephen M, Edina, MN	05/20/1998
Haff, Leslie A, Brainerd, MN	05/20/1998
Halverson, Terry Lynn, Minneapolis, MN	05/20/1998
Hansen, Terrence, Gilroy, CA	05/20/1998
Harroun, Cynthia D, Mankato, MN	05/20/1998
Harry, Lorleen Yvonne, Cambria Hgts, NY	05/20/1998
Harvey, Nancy C, Monterey, VA	05/20/1998
Hendricks, David Martin, Sumter, SC	05/20/1998
Honaker, Rhonda Darlene, Meadowview, VA	05/20/1998
Hopewell, Christine J, Williamsburg, VA	05/20/1998
Hopper, Cheryl Renee, Corpus Christi, TX	05/20/1998
Huff, Linda G, Gloucester, VA	05/20/1998
Hydrick, Robert, Grand Rapids, MI	05/20/1998
Jagusch, John R, Waupun, WI	05/20/1998
Jones, Judy N, Richmond, VA	05/20/1998
Jones, Geraldine B, Mora, MN	05/20/1998
Jones, Linda, Chicago, IL	05/20/1998

Subject, city, state	Effective date
Kendall, Betty, Springfield, IL	05/20/1998
Kharod, Prabhakar J, Pasadena, MD	05/20/1998
Kier, Rosalie D, Waubun, MN	05/20/1998
Kimker, Stephen C, Brooklyn Center, MN	05/20/1998
King, Jewel H, Rural Retreat, VA	05/20/1998
Kinsella, Lydia E, Oakville, CT	05/20/1998
Kouyoumdjian, Meguerdich, Ogdensburg, NY	05/20/1998
Kovar, Milan, Johnstown, NY	05/20/1998
Lacuanan, Edwin Dumlao, Yonkers, NY	05/20/1998
Landon, Mark Terry, Asheboro, NC	05/20/1998
Langford, Susan Tucker, Midlothian, VA	05/20/1998
Lanier, Edith J, Richmond, VA	05/20/1998
Leo, Jacqueline, Duluth, MN	05/20/1998
Lindsey, Tommy, Mt Morris, MI	05/20/1998
Lofton, Toni, Chicago Hgts, IL	05/20/1998
Louden, Stella, West Point, VA	05/20/1998
Lowe, James E Jr, Briarcliff Manor, NY	05/20/1998
Mabunga, Rogelio F, Seattle, WA	05/20/1998
Manis, Robin, Chesapeake, VA	05/20/1998
Marshall, Charles, Chicago, IL	05/20/1998
Mason-Pigott, Mavis, Norfolk, VA	05/20/1998
Mayer, Eve, Evanston, IL	05/20/1998
McCormack, Kris Anthony, Wetumpka, AL	05/20/1998
McNally, Marilyn R, Presque Isle, ME	05/20/1998
McWilliams, Kristin Elaine, Suffolk, VA	05/20/1998
Metcalf, John Franklin, Wickliffe, KY	05/20/1998
Miller, Tina Marie, Chesterfield, VA	05/20/1998
Millner, Toshika R, Fieldale, VA	05/20/1998
Mills, Catherine Spenser, Richmond, VA	05/20/1998
Mintz, Myron, Woodside, CA	05/20/1998
Morgan, Richard L, Newport News, VA	05/20/1998
Morris, David, Greenview, IL	05/20/1998
Muehlbauer, Michelle R, Herman, MN	05/20/1998
Newman, Carolyn E, Richmond, VA	05/20/1998
Nickerson, Sandra, Round Lake Beach, IL	05/20/1998
Noble, Mary Sue Bennett, Check, VA	05/20/1998
O'Neil, Olen Cecil, Jal, NM	05/20/1998
Paddock, Lisa A, Kennebunk, ME	05/20/1998
Pearson, Brenda S, Richmond, VA	05/20/1998
Pellert, Carol Ann, Lauren, NY	05/20/1998
Penn, Laurelia Owens, Houston, TX	05/20/1998
Perales, Maria H, Eagle Pass, TX	05/20/1998
Perconte, Salvatore Gerard, Chester, NY	05/20/1998
Perkins, Michael, Chicago, IL	05/20/1998
Peters, Jane E, Martinsville, VA	05/20/1998
Petteruti, Stephen J, Warwick, RI	05/20/1998
Piazza, Gary Gerard, Edison, NJ	05/20/1998
Pierce, Thelma Maureen, Spearman, TX	05/20/1998
Pojar, Judith A, White Bear Lake, MN	05/20/1998
Potter, William, Providence, RI	05/20/1998
Presson, Sharon Leigh, Suffolk, VA	05/20/1998
Price, Monica T, Brunchville, VA	05/20/1998
Price, Leonard A, Santa Barbara, CA	05/20/1998
Provisor, Deborah, Indianapolis, IN	05/20/1998
Pugatch, Donald, N Andover, MA	05/20/1998
Ratchford, William B, Glenview, IL	05/20/1998
Ray, Darlene Levels, Austin, TX	05/20/1998
Redd, Sharon K, Windsor, VA	05/20/1998
Ricca, Francis Martin, New York, NY	05/20/1998
Roberton, James William, Federal Way, WA	05/20/1998
Robinson, Susanne D, Manassas, VA	05/20/1998
Roby, Neil, Clarksville, MD	05/20/1998
Romuar, Benjamin, Arlington Hgts, IL	05/20/1998
Rudominer, Arnold, E Palo Alto, CA	05/20/1998
Ryan, Madonna, Naperville, IL	05/20/1998
Schermerhorn, Laura J, Mora, MN	05/20/1998
Schmoll, Carmen K, Clearwater, MN	05/20/1998
Schultz, Steven, Brooklyn, NY	05/20/1998
Schwarz, Herbert, Yonkers, NY	05/20/1998
Scott, William, Austin, IN	05/20/1998
Sears, Alexia Lou, Gran Prairie, TX	05/20/1998
Setelin, Theresa L, Glen Allen, VA	05/20/1998
Severson, Dan E, Minneapolis, MN	05/20/1998
Sharpe, Thomas, Gouverneur, NY	05/20/1998
Shorter, Dwayne L, Midlothian, VA	05/20/1998
Shultz, Richard Raymond, San Leandro, CA	05/20/1998
Simon, Franklin S, Rockaway Park, NY	05/20/1998
Smith, Sharon Richardson, Richmond, VA	05/20/1998
Speeth, Kathleen, Chapel Hill, NC	05/20/1998
Stewart-Carballo, Charles W, Fayetteville, NC	05/20/1998
Sutherland, Karen, Clarendon Hills, IL	05/20/1998
Swanson, Melanie G, Vinton, VA	05/20/1998
Talbott, Mary Mitchell, Mechanicsville, VA	05/20/1998
Tatum, Donna S, Richmond, VA	05/20/1998
Tezel, Hasan K, Binghamton, NY	05/20/1998
Toland, Alicia, E Moline, IL	05/20/1998
Turnage-Davis, Teressa, Salem, IL	05/20/1998
Valley, Shirley T, Winnisquam, NH	05/20/1998
Van De Castle, Robert L, Charlottesville, VA	05/20/1998
Vasquez, Javier A, Manchester, KY	05/20/1998
Walder, David, Pekin, IL	05/20/1998
Walker, Teresa L, Bealeton, VA	05/20/1998
Warwick, Susan R, Manassas, VA	05/20/1998
Welch, Martin, Jr, Oak Park, IL	05/20/1998
White, Sandra Wright, Suffolk, VA	05/20/1998
Williams, Carolyn A, Norfolk, VA	05/20/1998
Wittlake, Mark A, Moxee, WA	05/20/1998
Wong, Samuel, Munster, IN	05/20/1998
Wooding, Sandra R, Gretna, VA	05/20/1998
Youens, Robyn C, Nashua, NH	05/20/1998
Zamzam, Salih M, Beaver, WV	05/20/1998
Federal/State Exclusion/Suspension:	
Hanft, Cyndi, Shawnee, OK	05/20/1998
Johnson, Ray L, Boise, ID	05/20/1998
Karber, Heidi L, St Maries, ID	05/20/1998
Kim, Sung J, Yonkers, NY	05/20/1998
McDonald, Elleva Joy, Minnetonka, MN	05/20/1998
Mellenthin, Michelle, Nampa, ID	05/20/1998
Rumpel, Aimee L, Boise, ID	05/20/1998
Fraud/Kickbacks:	
Ross, Keith, Erial, NJ	01/30/1998
Sakson, Hugo, Florence, KY	05/20/1998
Owned/Controlled by Convicted/Excluded:	
Blue Med Health, Inc, Glade Valley, NC	05/20/1998
Mediview Consulting, Inc, Rocky Point, NY	05/20/1998
Tikes Enterprises Ltd, Auburn, ME	05/20/1998
Default on Heal Loan:	
Allen, Lawrence P, Temecula, CA	05/20/1998
Altvatter, Robert F, Bakersfield, CA	05/20/1998
Bailey, Brian K, Calabasas, CA	05/20/1998
Bakhit, Morad F, Medway, MA	05/20/1998

Subject, city, state	Effective date
Baptiste, Donna M, Kettering, MD	05/20/1998
Bram, Keith M, Euclid, OH	05/20/1998
Brown, Kerry S, Milwaukee, WI	05/20/1998
Brown (Troxell), Sally T, San Diego, CA	05/20/1998
Bunting, William T, Encinitas, CA	05/20/1998
Burks, Osborne David, Jr, Memphis, TN	05/20/1998
Cally, James J, Hudson, NY	05/20/1998
Campos, Helar E, Jamaica, NY	05/20/1998
Cochrane, Gregg A, San Diego, CA	05/20/1998
Crane, Steven H, W Orange, NJ	05/20/1998
Daniels, Gennaro A, Albany, NY	05/20/1998
Dates, Richard J, Elk Grove, IL	05/20/1998
Dunlap, David A, Bayonne, NJ	05/20/1998
Edwards, Peter L, Coeur D'Alene, ID	05/20/1998
Ford, Jerold R, Modesto, CA	05/20/1998
Fruin, Jeffrey W, Reseda, CA	05/20/1998
Gonzalez, Rocio Revuelta, Los Angeles, CA	05/20/1998
Hansraj, Kenneth K, Poughkeepsie, NY	05/20/1998
Johnson, Gerald A, Madison, AL	05/20/1998
Jones, Thomas P, Kennesaw, GA	05/20/1998
Kirkpatrick, Ira P, Kerrville, TX	05/20/1998
Kobulnicky, Paul JR, San Diego, CA	05/20/1998
Levitt, David M, Lake Stevens, WA	05/20/1998
Liston, Lawrence E, Bloomington, IL	02/26/1998
Mednitsky, Shari N, San Diego, CA	05/20/1998
Miller, Jerry Sydney, Watertown, NY	05/20/1998
Miller (Kustek), Alane Marie, Los Angeles, CA	05/20/1998
Miroshnichenko, Natalia, Decatur, GA	05/20/1998
Morrone, Mark J, St Petersburg, FL	05/20/1998
Muenker, Mark E, Van Nuys, CA	05/20/1998
Pratt, Edwin S JR, Yuba City, CA	05/20/1998
Quinton, Susan A, Ringold, GA	05/20/1998
Reed, Bruce J, Tampa, FL	05/20/1998
Reneau, David D, Rigby, ID	05/20/1998
Ripley, David A, George, IA	05/20/1998
Rosales, Anna Marie, Hondo, TX	05/20/1998
Saavedra, Eugene G, Littleton, CO	05/20/1998
Smith, Richard, Dania, FL	05/20/1998
Weimmer, Frederick J, Lakehurst, NJ	05/20/1998
Zilker, Wayne J, New Rochelle, NY	05/20/1998
Exclusion Based on Settlement Agreement:	
Atlantic Medical Equipment, Miami, FL	08/14/1997
Crist Yiret Medical Supply, Miami Lakes, FL	10/18/1997
Cueto, Yanet, Miami, FL	08/14/1997
Cueto, Rolando, Miami, FL	08/14/1997
Cueto Enterprises, Inc, Miami, FL	08/14/1997
Fernandez-Cano, Orestes, Miami, FL	12/17/1997
Good Choice Med Supplies, Corp, Miami, FL	08/14/1997
Hernandez, Jose F, Pembroke Pines, FL	07/15/1997
Kendall Med Home, Inc, Miami, FL	08/14/1997
Lopez, Carmen, Pembroke Pines, FL	07/15/1997
Medic Care & DME Distribution, Pembroke Pines, FL	07/15/1997
Melco Medical Equipment Dist, Miami, FL	07/15/1997
Melendez, Hector C, Miami, FL	07/15/1997
Melendez, Leonidas, Miami, FL	07/15/1997
Moreno, Martha Lucia, Miami Lakes, FL	10/18/1997
Shalom Medical Center, Miami Lakes, FL	10/18/1997
Socarras, Jenis, Miami Lakes, FL	10/18/1997
Stat Billing Services, Inc, FL	07/15/1997
Stat Medical Residential Suppl, Miami, FL	07/15/1997
Velez, Rosa, Miami, FL	07/15/1997

Dated: May 5, 1998.

Joanne Lanahan,

Director, Health Care Administrative Sanctions, Office of Inspector General.

[FR Doc. 98–12788 Filed 5–13–98; 8:45 am]

BILLING CODE 4150–04–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Proposed Collection; Comment Request; Agricultural Health Study—A Prospective Cohort Study of Cancer and Other Diseases Among Men and Women in Agriculture

SUMMARY: In compliance with the requirement of Section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995, for opportunity for public comment on proposed data collection projects, the National Cancer Institute (NCI), the National Institutes of Health (NIH) will publish periodic summaries of proposed projects to be submitted to the Office of Management and Budget (OMB) for review and approval.

Proposed Collection

Title: Agricultural Health Study—A Prospective Cohort Study of Cancer and Other Diseases Among Men and Women in Agriculture.

Type of Information Collection Request: O REINSTATEMENT, with change.

Need and Use of Information Collection: The Agricultural Health Study has assembled a cohort of over 90,000 private and commercial applicators and spouses of private applicators. Baseline information has been collected. The cohort will be contacted to update exposure information since enrollment and changes in health status and family medical history. Additional dietary information will be requested. A collection of buccal (cheek) cells is planned.

Frequency of Response: Single time reporting.

Affected Public: Individuals or households, Farms.

Type of Respondents: Private and commercial pesticide applicators and the spouses of private applicators. The annual reporting burden is as follows:

Estimated Number of Respondents: 25,271;

Estimated Number of Responses per Respondent: 1.0;

Average Burden Hours Per Response: 1.167; and

Estimated Total Annual Burden Hours Requested: 24,682.

The annualized cost to respondents is estimated at: $246,820. The Capital Costs are $12,018 and the Operating or Maintenance Costs are $3,511.

Request for Comments

Written comments and/or suggestions from the public and affected agencies are invited on one or more of the following points: (1) Evaluate whether the proposed collection of information is necessary for the proper performance of the function 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, 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 the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology.

FOR FURTHER INFORMATION CONTACT: To request more information on the proposed project or to obtain a copy of

the data collection plans and instruments, contact Michael C.R. Alavanja, Dr. P.H., Epidemiology and Biostatistics Program, Division of Cancer Etiology, National Cancer Institute, EPN 418, 6130 Executive Boulevard, Rockville, MD 20852, or call (310) 496–9093, or E-mail your request, including your address to: alavanjam@epndce.nci.nih.gov

COMMENTS DUE DATE: Comments regarding this information collection are best assured of having their full effect if received on or before July 13, 1998.

Date: May 6, 1998.

Reesa Nichols,

OMB Project Clearance Liaison.

[FR Doc. 98–12778 Filed 5–17–98; 8:45 am]

BILLING CODE 4140–01–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Notice of Meeting of the Advisory Committee to the Director, NIH

Pursuant to Pub. L. 92–463, notice is hereby given of the meeting of the Advisory Committee to the Director, NIH, June 4, 1998, Conference Room 10, Building 31, National Institutes of Health, Bethesda, Maryland 20892.

The entire meeting will be open to the public from 9:00 a.m. to adjournment. The topics proposed for discussion include: (1) Enhancing Diversity in Biomedical Research at NIH; (2) Bioengineering Conference: (3) Report from the Working Group on Research Tools; (4) Bioethics; and (5) DHHS Report on Research Misconduct. Attendance by the public will be limited to space available.

Ms. Janice Ramsden, Special Assistant to the Deputy Director, National Institutes of Health, 1 Center Drive MSC 0159, Bethesda, Maryland 20892–0159, telephone (301) 496–0959, fax (301) 496–7451, will furnish the meeting agenda, roster of committee members, and available substantive program information upon request. Any individual who requires special assistance, such as sign language interpretation or other reasonable accommodations, should contact Ms. Ramsden no later than May 29, 1998.

Dated: May 6, 1998.

LaVerne Y. Stringfield,

Committee Management Officer, NIH.

[FR Doc. 98–12774 Filed 5–13–98; 8:45 am]

BILLING CODE 4140–01–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Heart, Lung, and Blood Institute; Notice of Closed Meetings

Pursuant to Section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. Appendix 2), notice is hereby given of the following National Heart, Lung, and Blood Institute Special Emphasis Panel (SEP) meetings in conjunction with the National Institute of Dental Research and the National Institute of Arthritis and Musculoskeletal and Skin Diseases.

Name of SEP: Nutrition Academic Awards.
Date: June 10–11, 1998.
Time: 9:00 a.m.
Place: Holiday Inn Chevy Chase, 5520 Wisconsin Avenue, Bethesda, Maryland 20815.
Contact Person: Louise Corman, Ph.D., Two Rockledge Center, Room 7180, 6701 Rockledge Drive, Bethesda, Maryland 20892–7924, (301) 435–0270.
Purpose/Agenda: To review and evaluate grant applications.

Name of SEP: National Food and Nutrient Analysis Program—Interagency Agreement Protocol.
Date: June 12, 1998.
Time: 9:30 a.m.
Place: Bethesda Ramada Inn, 8400 Wisconsin Avenue, Bethesda, Maryland 20814.
Contact Person: Abby Ershow, M.D. Two Rockledge Center, Room 9186, 6701 Rockledge Drive, Bethesda, MD 20892–7924, (301) 435–0526.
Purpose/Agenda: To review and evaluate an Interagency Agreement Protocol.

Name of SEP: Heart Failure Research: New Approaches to Pathogenesis—NHLBI/NIA.
Date: June14–16, 1998.
Time: 7:00 p.m.
Place: Bethesda Marriott Hotel, 5151 Pooks Hill Road, Bethesda, Maryland 20814.
Contact Person: Diane M. Reid, M.D., Two Rockledge Center, Room 7182, 6701 Rockledge Drive, Bethesda, MD 20892–7924, (301) 435–0277.
Purpose/Agenda: To review and evaluate grant applications.

These meetings will be closed in accordance with provisions set forth in sections 552b(c)(4) and 552b(c)(b), Title 5 U.S.C. Applications and/or proposals and the discussions could reveal confidential trade secrets or commercial property such as patentable material and personal information concerning individuals associated with the applications and/or proposals, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

(Catalog of Federal Domestic Assistance Programs Nos. 93.837, Heart and Vascular Diseases Research; 93.838, Lung Diseases Research; and 93.839, Blood Diseases and Resources Research, National Institutes of Health)

Dated: May 5, 1998.

LaVerne Y. Stringfield,

Committee Management Officer, NIH.

[FR Doc. 98–12771 Filed 5–13–98; 8:45 am]

BILLING CODE 4140–01–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Heart, Lung, and Blood Institute; Notice of Closed Meetings

Pursuant to Section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. Appendix 2), notice is hereby given of the following National Heart, Lung, and Blood Institute Special Emphasis Panel (SEP) meetings:

Name of SEP: Endothelial Dysfunction in HIV Infection.
Date: June 9–10, 1998.
Time: 7:00 p.m.
Place: Holiday Inn Gaithersburg, 2 Montgomery Village Avenue, Gaithersburg, Maryland 20879.
Contact Person: Ramesh Vemuri, Ph.D., Two Rockledge Center, Room 7194, 6701 Rockledge Drive, Bethesda, Maryland 20892–7924, (301) 435–0476.
Purpose/Agenda: To review and evaluate grant applications.

Name of SEP: Molecular and Physical Characterization of the Vulnerable Plaque.
Date: June 17–18, 1998.
Time: 7:00 p.m.
Place: Bethesda Marriott Hotel, 5151 Pooks Hill Road, Bethesda, Maryland 20814.
Contact Person: Ivan Baines, Ph.D., Two Rockledge Center, Room 7184, 6701 Rockledge Drive, Bethesda, Maryland 20892–7924, (301) 435–0277.
Purpose/Agenda: To review and evaluate grant applications.

These meetings will be closed in accordance with the provisions set forth in secs. 552b(c)(4) and 552b(c)(6), Title 5, U.S.C. Applications and/or proposals and the discussions could reveal confidential trade secrets or commercial property such as patentable material and personal information concerning individuals associated with the applications and/or proposals, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

(Catalog of Federal Domestic Assistance Programs Nos. 93.837, Heart and Vascular Diseases Research; 93.838, Lung Diseases Research; and 93.839, Blood Diseases and Resources Research, National Institutes of Health)

Dated: May 7, 1998.

LaVerne Y. Stringfield,

Committee Management Officer, NIH.

[FR Doc. 98–12776 Filed 5–13–98; 8:45 am]

BILLING CODE 4140–01–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institutes of Child Health and Human Development; Notice of Meeting of the National Advisory Child Health and Human Development Council and Its Subcommittee on Planning and Policy

Pursuant to Public Law 92–463, notice is hereby given of the meeting of the National Advisory Child Health and Human Development Council on June 1–2, 1998. The meeting will be held in Building 31, Conference Room 6, National Institutes of Health, Bethesda, Maryland. The Subcommittee on Planning and Policy will be held on June 1, 1998, in Building 31, Conference Room 7, from 12:00 p.m. to 1:30 p.m. The Subcommittee meeting will be open to the public and the agenda includes program plans and the agenda for the next Council meeting. Attendance by the public will be limited space available.

The Council meeting will be open to the public on June 1 from 8:00 a.m. until 5:30 p.m. The agenda includes: (1) A report by the Director, NICHD; (2) a presentation of the new K-series awards for support of clinical research; (3) a presentation of inclusion of children in clinical research; (4) observance of the Institute's thirty-fifth anniversary, and (5) other business of the Council. The meeting will be open on June 2 upon completion of the review of applications at approximately 1:00 p.m. to adjournment if any policy issues are raised which need further discussion.

In accordance with the provisions set forth in section 552b(c)(4), and 552b(c)(6), Title 5, U.S.C. and section 10(d) of Public Law 92–463, the meeting of the full Council will be closed to the public on June 2 from 8:00 a.m. to approximately 1:00 p.m. for the review, discussion, and evaluation of individual grant applications. These applications and the discussions could reveal confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Ms. Mary Plummer, Executive Secretary, NACHHD Council, 6100 Executive Boulevard, Room 5E03, National Institutes of Health, Bethesda, Maryland, 20892–7510, 301–594–7232, will provide a summary of the meeting and a roster of Council members as well as substantive program information. Individuals who plan to attend the open session and need special assistance, such as sign language interpretation or other reasonable accommodations, should contact Ms. Plummer.

(Catalog of Federal Domestic Assistance Program Nos. [93.864, Population Research, and 93.865, Research for Mothers and Children], National Institutes of Health.)

Dated: May 5, 1998.

LaVerne Y. Stringfield,

Committee Management Officer, NIH.

[FR Doc. 98–12770 Filed 8–13–98; 8:45 am]

BILLING CODE 4140–01–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute of Arthritis and Musculoskeletal and Skin Diseases; Notice of Meeting, National Arthritis and Musculoskeletal and Skin Diseases Advisory Council

Pursuant to Public Law 92–463, notice is hereby given of a meeting of the National Arthritis and Musculoskeletal and Skin Diseases Advisory Council to provide advice to the National Institute of Arthritis and Musculoskeletal and Skin Diseases (NIAMS) on June 11, 1998, in Conference Room 6, Building 31, National Institutes of Health, Bethesda, Maryland.

The meeting will be open to the public June 11 from 8:30 a.m. to 12:00 p.m. to discuss administrative details relating to Council business and special reports. Attendance by the public will be limited to space available.

The meeting of the Advisory Council will be closed to the public on June 11 from 1:00 p.m. to adjournment in accordance with provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C. and section 10(d) of Public Law 92–463, for the review, discussion and evaluation of individual grant applications. These deliberations could reveal confidential trade secrets or commercial property, such as patentable material, and personal information concerning individuals associated with the applications, disclosure of which would constitute a clearly unwarranted invasion of personal property.

Individuals who plan to attend and need special assistance, such as sign language interpretation or other reasonable accommodations, should contact Dr. Steven Hausman, Executive Secretary, National Arthritis and Musculoskeletal and Skin Diseases Advisory Council NIAMS, Natcher Building, Room 5AS–13, Bethesda, Maryland 20892 (301) 594–2463.

A summary of the meeting and roster of the members may be obtained from the Extramural Programs Office, NIAMS, Natcher Building, Room 5AS–13, National Institutes of Health, Bethesda, Maryland 20892 (301) 594–2363.

(Catalog of Federal Domestic Assistance Program No. 93.846, Arthritis, Bone and Skin Diseases, National Institutes of Health)

Dated: May 6, 1998.

LaVerne Y. Stringfield,

Committee Management Officer, NIH.

[FR Doc. 98–12772 Filed 5–13–98; 8:45 am]

BILLING CODE 4140–01–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute of Mental Health; Notice of Closed Meetings

Pursuant to Section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. Appendix 2), notice is hereby given of the following meetings of the National Institute of Mental Health Initial Review Group:

Agenda/Purpose: To review and evaluate grant applications.

Committee Name: Violence and Traumatic Stress Review Committee.

Date: May 27–May 28, 1998.

Time: 8:30 a.m.

Place: Latham Hotel, 3000 M Street, N.W., Washington, DC 20007.

Contact person: Sheri L. Schwartzback, Parklawn, Room 9C–26, 5600 Fishers Lane, Rockville, MD 20857, Telephone: 301, 446–6470.

Committee Name: Clinical Psychopathology Review Committee.

Date: June 8–June 9, 1998.

Time: 8:30 a.m.

Place: River Inn, 924 25th Street NW, Washington, DC 20037.

Contact person: Gavin T. Wilkom, Parklawn, Room 9C–18, 5600 Fishers Lane, Rockville, MD 20857, Telephone: 301, 443–1340.

Committee Name: Child Psychopathology and Treatment Review Committee.

Date: June 11–June 12, 1998.

Time: 8:30 a.m.

Place: Holiday Inn Chevy Chase, 5520 Wisconsin Ave, Chevy Chase, MD 20815.

Contact person: W. Gregory Zimmerman, Parklawn, Room 9C–18, 5600 Fishers Lane, Rockville, MD 20857, Telephone: 301, 443–1340.

Committee Name: Child/Adolescent Development, Risk, and Prevention Review Committee.

Date: June 11–June 12, 1998.

Time: 9 a.m.

Place: St. James Hotel, 950 24th Street, N.W., Washington, DC 20037.

Contact person: Phyllis D. Artis, Parklawn, Room 9C–26, 5600 Fishers Lane, Rockville, MD 20857, Telephone: 301, 443–6470.

Committee Name: Health Behavior and Prevention Review Committee.
Date: June 17, 1998.
Time: 8:30 a.m.
Place: One Washington Circle, One Washington Circle, N.W., Washington, DC 20037.
Contact person: Monica F. Woodfork, Parklawn, Room 9C–26, 5600 Fishers Lane, Rockville, MD 20857, Telephone: 301, 443–6470.

Committee Name: Perception and Cognition Review Committee.
Date: June 18–June 19, 1998.
Time: 8:30 a.m.
Place: One Washington Circle, One Washington Circle, N.W., Washington, DC 20047.
Contact Person: Deborah A. DeMasse, Parklawn, Room 9–101, 5600 Fishers Lane, Rockville, MD 20857, Telephone: 301, 443–3936.

Committee Name: Social and Group Processes Review Committee.
Date: June 18–June 19, 1998.
Time: 8 a.m.
Place: Bethesda Holiday Inn, 8120 Wisconsin Avenue, Bethesda, MD 20814.
Contact Person: Tarsha Johnson, Parklawn, Room 9–101, 5600 Fishers Lane, Rockville, MD 20857, Telephone: 301, 443–64700.
Committee Name: Clinical Centers and Special Projects Review Committee.
Date: June 25–June 26, 1998.
Time: 8:30 a.m.
Place: Bethesda Holiday Inn, 8120 Wisconsin Avenue, Bethesda, MD 20814.

Contact Person: W. Gregory Zimmerman, Parklawn, Room 9C–18, 5600 Fishers Lane, Rockville, MD 20857 Telephone: 301, 443–1340.

Committee Name: Mental Disorders of Aging Review Committee.
Date: June 25–June 26, 1998.
Time: 8:30 a.m.
Place: Holiday Inn Chevy Chase, 5520 Wisconsin Ave, Chevy Chase, MD 20815.
Contact Person: Henry Haigler, Parklawn, Room 9C–18, 5600 Fishers Lane, Rockville, MD 20857, Telephone: 301, 443–1340.

The meeting will be closed in accordance with the provisions set forth in secs. 552b(2)(4) and 552b(c)(6), Title 5, U.S.C. Applications and/or proposals and the discussions could reveal confidential trade secrets or commercial property such as patentable material and personal information concerning individuals associated with the applications and/or proposals, the disclosure of which would constitute a clearly unwarranted invasions of personal privacy.

(Catalog of Federal Domestic Assistance Program Numbers 93.242, 93.281, 93.282)

Dated: May 6, 1998.

LaVerne Y. Stringfield,

Committee Management Officer, NIH.

[FR Doc. 98–12773 Filed 5–13–98; 8:45 am]

BILLING CODE 4140–01–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute of Nursing Research; Notice of Closed Meetings

Pursuant to Section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. Appendix 2), notice is hereby given of the following meetings:

Name of Committee: National Institute of Nursing Research Initial Review Group.
Date: June 22–23, 1998.
Time: 8:30 a.m. until adjournment.
Place: Holiday Inn Chevy Chase, 5520 Wisconsin Avenue, Chevy Chase, Maryland 20815.
Contact Person: Mary Stephens-Frazier, Ph.D., Building 45, Room 3AN–28, 45 Center Drive, Bethesda, MD 20892, (301) 594–5971.
Purpose/Agenda: To review and evaluate grant applications.

Name of Committee: National Institute of Nursing Research Special Emphasis Panel (NINR/ORMH Mentored Research Scientist Development Award for Minority Investigators.
Date: June 24, 1998.
Time: 8:30 a.m.
Place: Holiday Inn Chevy Chase, 5520 Wisconsin Avenue, Chevy Chase, Maryland 20815.
Contact Person: Mary Stephens-Frazier, Ph.D., Building 45, Room 3AN–18, 45 Center Drive, Bethesda, MD 20892, (301) 594–5971.
Purpose/Agenda: To review and evaluate grant applications.

These meetings will be closed in accordance with the provisions set forth in secs. 552b(c)(4) and 552b(c)(6), title 5, U.S.C. Applications and the discussions could reveal confidential trade secrets or commercial property such as patentable material and personal information concerning individuals associated with the applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

(Catalog of Federal Domestic Assistance Program No. 93.361, Nursing Research, National Institutes of Health)

Dated: May 7, 1998.

LaVerne Y. Stringfield,

Committee Management Officer, NIH.

[FR Doc. 98–12775 Filed 5–13–98; 8:45 am]

BILLING CODE 4140–01–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Center for Scientific Review; Notice of Closed Meetings

Pursuant to Section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. Appendix 2), notice is hereby given of the following Center for Scientific Review Special Emphasis Panel (SEP) meetings:

Purpose/Agenda: To review individual grant applications.
Name of SEP: Clinical Sciences.
Date: May 12, 1998.
Time: 1:00 p.m.
Place: NIH, Rockledge 2, Room 4114, Telephone Conference.
Contact Person: Dr. Scott Osborne, Scientific Review Administrator, 6701 Rockledge Drive, Room 4114, Bethesda, Maryland 20892, (301) 435–1782.

Name of SEP: Clinical Sciences.
Date: May 13, 1998.
Time: 1:00 p.m.
Place: NIH, Rockledge 2, Room 4114, Telephone Conference.
Contact Person: Dr. Scott Osborne, Scientific Review Administrator, 6701 Rockledge Drive, Room 4114, Bethesda, Maryland 20892, (301) 435–1782.

Name of SEP: Clinical Sciences.
Date: May 18, 1998.
Time: 1:00 p.m.
Place: NIH, Rockledge 2, Room 4114, Telephone Conference.
Contact Person: Dr. Scott Osborne, Scientific Review Administrator, 6701 Rockledge Drive, Room 4114, Bethesda, Maryland 20892, (301) 435–1782.

This notice is being published less than 15 days prior to the above meetings due to the urgent need to meet timing limitations imposed by the grant review and funding cycle.

The meetings will be closed in accordance with the provisions set forth in secs. 552b(c)(4) and 552b(c)(6), Title 5, U.S.C. Applicants and/or proposals and the discussions could reveal confidential trade secrets or commercial property such as patentable material and personal information concerning individuals associated with the applications and/or proposals, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

(Catalog of Federal Domestic Assistance Program Nos. 93.306, 93.333, 93.337, 93.393–93.396, 93.837–93.844, 93.846–93.878, 93.892, 83,893, National Institutes of Health, HHS)

Dated: May 7, 1998.

LaVerne Y. Stringfield,

Committee Management Officer, NIH.

[FR Doc. 98–12777 Filed 5–13–98; 8:45 am]

BILLING CODE 4140–01–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Public Health Service

National Toxicology Program; Availability of the Report on Carcinogens, Eighth Edition

Background

The National Toxicology Program (NTP) announces the availability of the Report on Carcinogens, Eighth Edition.

The Report on Carcinogens (RoC) is a Congressionally-mandated listing of known human carcinogens and reasonably anticipated human carcinogens and its preparation is delegated to the National Toxicology Program by the Secretary, Department of Health and Human Services (HHS). Section 301(b)(4) of the Public Health Service Act, as amended, provides that the Secretary, (HHS), shall publish a report which contains a list of all substances (1) which either are known to be human carcinogens or may reasonably be anticipated to be human carcinogens; and (2) to which a significant number of persons residing in the United States (US) are exposed. The law also states that the reports should provide available information on the nature of exposures, the estimated number of persons exposed and the extent to which the implementation of Federal regulations decreases the risk to public health from exposure to these chemicals.

The new entries for the 8th RoC have undergone a multiphased peer review process involving two Federal scientific review groups and one non-government, scientific peer review body (a subcommittee of the NTP Board of Scientific Counselors) which met in an open, public meeting that included a public comment session. All data relevant to the criteria for inclusion of candidate agents, substances or mixtures in the RoC have been evaluated by the three scientific review committees.

In the 8th RoC, the NTP is adding 14 agents, substances or mixtures to the existing list. In addition, thiotepa, which is currently listed in previous Reports on Carcinogens as reasonably anticipated to be a human carcinogen is moved to the known human carcinogen list. These agents, substances or mixtures are provided in the following table with their Chemical Abstracts Services (CAS) Registry numbers and listing.

Hard copies of the 8th RoC, or the 8th RoC Summary (which contains the same information that is in the full Report with the exception of specific information on regulations promulgated by regulatory health agencies) can be obtained by contacting the NIEHS Environmental Health Information Service, ATTN: Order Processing, P.O. Box 12510, Research Triangle Park, NC 27709–2510, fax number (919) 541–0763, email: ehis@niehs.nih.gov. The 8th RoC Summary is also available on the internet and can be accessed from the NIEHS Environmental Health Information Service Home Page at: http:///ehis.niehs.nih.gov/ or from the NTP Home Page at: http://ntp-server.niehs.nih.gov//.

Questions or comments concerning the 8th RoC should be directed to: Dr. C.W. Jameson, National Toxicology Program, Report on Carcinogens, MD EC–14, P.O. Box 12233, Research Triangle Park, NC 27709; phone: (919) 541–4096, fax: (919) 541–2242, email: jameson@niehs.nih.gov.

Kenneth Olden,

Director, National Toxicology Program.

SUMMARY FOR AGENTS, SUBSTANCES OR MIXTURES NEWLY LISTED IN THE REPORT ON CARCINOGENS, EIGHTH EDITION

Chemical/CAS number	Primary uses	Newly listed as
AZACITIDINE/320-67-2	Used as a cytostatic agent in the treatment of acute leukemia	Reasonably Anticipated to be a Human Carcinogen
p-CHLORO-o-TOLUIDINE and its HCl salt/95-69-2.	Used to produce azo dyes for cotton, silk acetate and nylon and as intermediate in production of Pigment Red 7 and Pigment Yellow 49. Also an impurity in and a metabolite of the pesticide chlordimeform.	Reasonably Anticipated to be a Human Carcinogen.
CHLOROZOTOCIN/54749-90-5	Used as a cytostatic agent in the treatment of cancers of the stomach, large intestine pancreas and lung; melanoma; and multiple myeloma.	Reasonably Anticipated to be a Human Carcinogen.
CYCLOSPORIN/59865-13-3	Used as an immunosuppressive agent in the prevention and treatment of graft-vs-host reactions in bone marrow transplantation and for the prevention of rejection of kidney, heart, and liver transplants.	Known to be a Human Carcinogen.
DANTHRON/(1,8-Dihydroxyanthraquinone) 117-10-2.	Used as a laxative and as an intermediate in the manufacture of dyes	Reasonably Anticipated to be a Human Carcinogen
1,6-DINITROPYRENE/42397-64-8	Not used commercially, detected in ambient atmospheric samples and as a constituent of diesel exhaust.	Reasonably Anticipated to be a Human Carcinogen
1,8-DINITROPYRENE/42397-65-9	Not used commercially, detected in ambient atmospheric samples and as a constituent of diesel exhaust.	Reasonably Anticipated to be a Human Carcinogen
DISPERSE BLUE 1/(1,4,5,8-Tetraaminoanthraquinone) 2475-45-8.	Used as an anthraquinone based dyestuff in hair color formulations and in coloring fabrics and plastics.	Reasonably Anticipated to be a Human Carcinogen
FURAN/100-00-9	Used as an intermediate in the synthesis and production of other organic compounds.	Reasonably Anticipated to be a Human Carcinogen
O-NITROANISOLE/91-23-6	Used a a precursor in the synthesis of o-anisidine which is used in the manufacture of over 100 azo dyes.	Reasonably Anticipated to be a Human Carcinogen.
6-NITROCHRYSENE/7495-02-8	Not used commercially, detected in ambient atmospheric samples	Reasonably Anticipated to be a Human Carcinogen.
1-NITROPYRENE/5522-43-0	Not used commercially, detected in ambient atmospheric samples and as a constituent of diesel and gasoline engine exhaust.	Reasonably Anticipated to be a Human Carcinogen.
4-NITROPYRENE/57835-92-4	Not used commercially, detected in ambient atmospheric samples	Reasonably Anticipated to be a Human Carcinogen.
THIOTEPA/52-24-4	Used as a cytostatic agent in the treatment of lymphomas and a variety of solid tumors, such as breast and ovary. It has also been used at high doses in combination chemotherapy with cyclophosphamide in patients with refractory malignancies treated with autologous bone transplantation.	Known to be a Human Carcinogen.

SUMMARY FOR AGENTS, SUBSTANCES OR MIXTURES NEWLY LISTED IN THE REPORT ON CARCINOGENS, EIGHTH EDITION—Continued

Chemical/CAS number	Primary uses	Newly listed as
1,2,3-TRICHLOROPROPANE/96-18-4.	Used as a polymer crosslinking agent, paint and varnish remover, solvent and degreasing agent. It has been found as an impurity in certain nematicides and soil fumigants and has been detected in drinking and ground water in various parts of the United States.	Reasonably Anticipated to be a Human Carcinogen.

[FR Doc. 98–12779 Filed 5–13–98; 8:45 am]

BILLING CODE 4140–01–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Substance Abuse and Mental Health Services Administration Agency Information Collection Activities: Submission for OMB Review; Comment Request

Periodically, the Substance Abuse and Mental Health Services Administration (SAMHSA) will publish a list of information collection requests under OMB review, in compliance with the Paperwork Reduction Act (44 U.S.C. Chapter 35). To request a copy of these documents, call the SAMHSA Reports Clearance Officer on (301) 443–7978.

Community Mental Health Centers (CMHC) Construction Grantee Checklist—0930–0104—Extension, no change—Recipients of Federal CMHC construction funds are obligated to use the constructed facilities to provide mental health services. The CMHS Act was repealed in 1981 except for the provision requiring grantees to continue using the facilities for mental health purposes for a 20-year period. In order for the Center for Mental Health Services to monitor compliance of construction grantees the grantees are required to submit an annual report. The Checklist enables grantees to supply necessary information efficiently and with a minimum of burden.

	Annual respondents	Responses/ respondent	Hours per response	Annual burden
CMHS Grantee Construction Checklist [42 CFR 54.209(h), 42 CFR 54.213, 42 CFR 54.214]	*68	1	.33	22

*Average over the 3-year approval period as grantees with service obligations continue to complete their period of obligation.

Written comments and recommendations concerning the proposed information collection should be sent within 30 days of this notice to: Daniel Chenok, Human Resources and Housing Branch, Office of Management and Budget, New Executive Office Building, Room 10235, Washington, D.C. 20503.

Dated: May 7, 1998.

Richard Kopanda,

Executive Officer, SAMHSA.

[FR Doc. 98–12824 Filed 5–13–98; 8:45 am]

BILLING CODE 4162–20–P

DEPARTMENT OF THE INTERIOR

Fish and Wildlife Service

Endangered and Threatened Species Permit Applications

AGENCY: Fish and Wildlife Service, Interior.

ACTION: Notice of receipt of applications.

The following applicants have applied for permits to conduct certain activities with endangered species. This notice is provided pursuant to section 10(c) of the Endangered Species Act of 1973, as amended (16 U.S.C. 1531, *et seq.*).

Applicant: The Raptor Resource Project, Ridgeway, Iowa; Robert Anderson, Director.

The applicant requests a permit to take (capture, handle, draw blood, and release) peregrine falcon (*Falco peregrinus*) in the states of Iowa, Minnesota, and Wisconsin. Activities are proposed for the purpose of scientific research aimed at enhancement and survival of the species in the wild.

Written data or comments should be submitted to the Regional Director, U.S. Fish and Wildlife Service, Ecological Services Operations, 1 Federal Drive, Fort Snelling, Minnesota 55111–4056, and must be received within 30 days of the date of this publication.

Documents and other information submitted with these applications are available for review by any party who submits a written request for a copy of such documents to the following office within 30 days of the date of publication of this notice: U.S. Fish and Wildlife Service, Ecological Services Operations, 1 Federal Drive, Fort Snelling, Minnesota 55111-4056. Telephone: (612/713–5332); FAX: (612/713–5292).

Dated: May 7, 1998.

Matthias A. Kerschbaum,

Acting Assistant Regional Director, IL, IN, MO (Ecological Services), Region 3, Fort Snelling, Minnesota.

[FR Doc. 98–12804 Filed 5–13–98; 8:45 am]

BILLING CODE 4310–55–P

DEPARTMENT OF THE INTERIOR

Bureau of Land Management

[WO–350–1540–01]

Extension of Approved Information Collection, OMB Number 1004–0009

AGENCY: Bureau of Land Management, Interior.

ACTION: Notice and request for comments.

SUMMARY: In accordance with the Paperwork Reduction Act of 1995, the Bureau of Land Management (BLM) is announcing its intention to request an extension of existing approval to collect certain information from applicants who wish to acquire a Land Use Authorization (form 2920–1) on public lands under the Federal Land Policy and Management Act (FLPMA) of 1976. The regulations at 43 CFR 2920 provide for non-Federal use of Bureau-administered land by means of lease or

permit. Uses include agriculture, trade, or manufacturing concerns and business uses such as outdoor recreation concession. The BLM will determine the validity of uses proposed by private individuals and other qualified proponents from information provided by the proponent on the Land Use Application and Permit form.

DATES: Comments on the proposed information collection must be received by July 13, 1998 to be considered.

ADDRESSES: Comments may be mailed to: Director (420), Bureau of Land Management, 1849 C Street NW, Room 401LS, Washington, DC 20240.

Comments may be sent via Internet to: Wo Comment@wo.blm.gov Please include ''ATTN: 1004–0009'' and your name and return address in your Internet message.

Comments may be hand-delivered to the Bureau of Land Management Administrative Record, Room 401, 1620 L Street, NW, Washington, DC.

Comments will be available for public review at the L Street address during regular business hours (7:45 a.m. to 4:15 p.m.), Monday through Friday.

FOR FURTHER INFORMATION CONTACT: Carl C. Gammon, (202) 452–7777.

SUPPLEMENTARY INFORMATION: In accordance with 5 CFR 1320.12(a), BLM is required to provide 60-day notice in the **Federal Register** concerning a collection of information contained in a published current rule to solicit comments on (a) 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; (b) 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; (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 the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology. The BLM will receive and analyze any comments sent in response to this notice and include them with its request for approval from the Office of Management and Budget under 44 U.S.C. 3501 *et seq*.

The FLPMA of 1976 (43 U.S.C. 1732, 1740), provides for issuance of land use authorizations which may include leases or permits, to eligible proponents. The BLM has implemented the provisions of this requirement through the issuance of 43 CFR 2922.2–1, which provides for the submission of the ''Land Use Application and Permit,'' or application, Form 2920–1. The information collected on the application is used by the BLM to identify the proposed land use and activities, describe all facilities for which authorization is sought, to identify the location, to determine a schedule for construction and to identify access requirements. Since the information collected is unique to each application, no other suitable means of information collection has been identified which could gather the information at a lesser burden. If the BLM fails to properly collect the required information, the BLM will reject the application.

Based on BLM's experience administering the activities described above, approximately 620 applications (577 Permits, 43 Leases) are received annually. It will take an average of 30 minutes for over 94 percent of the applicants to supply the needed information. For the other 6 percent of the applicants who are applying for leases, the average burden is 121 hours to supply the necessary information. The range in burden hours is due to the fact that a lease application, because of its nature, requires more time on the part of an applicant to supply the needed information. For example, a lease application to construct a multi-million dollar ski facility could involve construction drawings, site and facility plans, other Federal and State licenses and permits, and other preauthorizing requirements involving many days to process. Conversely, a relatively routine application (permit) to use public lands for agricultural purposes could be processed in ½ an hour.

The estimated total annual burden on new respondents is about 5,955 hours.

All responses to this notice will be summarized and included in the request for Office of Management and Budget approval. All comments will also become a matter of public record.

Dated: April 30, 1998.

Carole J. Smith,

Bureau of Land Management, Information Clearance Officer.

[FR Doc. 98–12787 Filed 5–13–98; 8:45 am]

BILLING CODE 4310–84–M

DEPARTMENT OF THE INTERIOR

Bureau of Land Management

[CA–010–1220–00]

Meeting of the Central California Resource Advisory Council

AGENCY: Bureau of Land Management, Department of the Interior.

ACTION: Meeting of the Central California Resource Advisory Council.

SUMMARY: Pursuant to the authorities in the Federal Advisory Committee Act (Pub. L. 92–463) and the Federal Land Policy and Management Act of 1976 (sec. 309), the Bureau of Land Management Resource Advisory Council for Central California will meet in Coalinga, California.

DATES: May 21–22, 1998.

ADDRESSES: Thursday, May 21 field trip begins at 9 a.m. at the Oak Flat Campground on Clear Creek Canyon Road in southern San Benito County. Friday, May 22 session begins at 8 a.m. in Room 8 of the Speech/Arts Building, West Hills Community College, 300 Cherry Lane, Coalinga, California.

SUPPLEMENTARY INFORMATION: The 12 member Central California Resource Advisory Council is appointed by the Secretary of the Interior to advise the Bureau of Land Management on public land issues. On Thursday morning, May 21, the Council will tour the Clear Creek Management Area with the State of California Off Highway Motor Vehicle Commission. In the afternoon, the Council will visit public land at the Joaquin Rocks. Discussion will involve land use planning, and the unique plants and minerals of the area. The Council will meet in Room SA–8 of West Hills College in Coalinga beginning at 8 a.m. Thursday, May 22. Items to be discussed include noxious weeds, and the proposed Carrizo Plain Natural Area National Conservation Area designation and how it will affect oil exploration of the area. A public comment period is scheduled for 10 a.m. Friday when may address the Council about any public and issue. Written comments will also be accepted at the address below. After lunch, the Council will tour the public lands of the Panoche Hills in western Fresno County. The public is welcome to attend Resource Advisory Council meetings. Those wishing to participate in the field trips must supply their own transportation, food and drink.

FOR FURTHER INFORMATION CONTACT: Larry Mercer, Public Affairs Officer, Bureau of Land Management, 3801

Pegasus Drive, Bakersfield, CA 93308, telephone 805–391–6010.

Dated: May 4, 1998.

John Skibinski,

Assistant Field Office Manager.

[FR Doc. 98–12878 Filed 5–13–98; 8:45 am]

BILLING CODE 4310–40–M

DEPARTMENT OF THE INTERIOR

Bureau of Land Management

[ID–990–1020–00]

Resource Advisory Council Meeting

AGENCY: Bureau of Land Management, Upper Columbia—Salmon Clearwater Districts, Idaho.

ACTION: Notice of Resource Advisory Council Meeting.

SUMMARY: In accordance with the Federal Land Policy and Management Act and the Federal Advisory Committee Act of 1972 (FACA), 5 U.S.C. Appendix, the Bureau of Land Management (BLM) announces the meeting of the Upper Columbia—Salmon Clearwater Districts Resource Advisory Council (RAC) on Thursday, June 18, 1998 and Friday, June 19, 1998 in Missoula, Montana.

Agenda items include: Election of officers; update and briefing on the weed issue; an update from the recreation subgroup and other matters as time permits. The meeting will begin at 1:00 p.m. (MDT), June 18, 1998 at the 4B's Inn and Conference Center, 3803 Brooks Rd., Missoula, Montana. The public may address the Council during the public comment period from 2:00 p.m.–2:30 p.m. on June 18, 1998.

SUPPLEMENTARY INFORMATION: All Resource Advisory Council meetings are open to the public. Interested persons may make oral statements to the Council, or written statements may be submitted for the Council's consideration. Depending on the number of persons wishing to make oral statements, a per-person time limit may be established by the District Manager.

The Council's responsibilities include providing long-range planning and establishing resource management priorities.

FOR FURTHER INFORMATION CONTACT: Ted Graf (208) 769-5004.

Dated: May 4, 1998.

Ted Graf,

Acting District Manager.

[FR Doc. 98–12881 Filed 5–13–98; 8:45 am]

BILLING CODE 4310–66–M

DEPARTMENT OF THE INTERIOR

Bureau of Land Management

[CO–935–1430–01; COC34289]

Realty Action: Section 302 Lease; Classification in Grand County, Colorado

AGENCY: Bureau of Land Management, Department of the Interior.

ACTION: The proposed leasing of public land for a Non-Competitive Lease in Grand County.

SUMMARY: In response to a request from the Silver Creek Holdings, Colorado, the following public lands have been examined and found suitable for leasing under the provisions of Section 302, of the Federal Land Policy and Management Act (FLPMA) of 1976 and 43 CFR 2920. Other lands in the vicinity are currently leased to Silver Creek Ski Area for ski trails and associated facilities.

Affected Public Land

Sixth Principal Meridian, Colorado

T. 1N., R. 76W.,
Sec. 9, Lots 3, 6 (W½), 7 (E½), 8 and 9
approximately 135.73 acres.

The affected public lands would be used for the development of an 18-hole championship golf course. This would enable Silver Creek Holdings to achieve the primary goal of their Master Plan Vision, prepared in 1997/1998, to develop amenities which will provide year-round use of the Silver Creek community. These lands were selected to reduce the impact on wetlands and wildlife habitat in the original proposal by Silver Creek. Appropriate federal and local permits and approvals have been acquired or are in the review stage. The lease of these lands will serve important public and private objectives which cannot be achieved on lands other than public lands administered by the Bureau of Land Management. The Bureau of Land Management would amend the existing 30 year lease to Silver Creek.

FOR FURTHER INFORMATION CONTACT: Other information concerning this proposed lease is available for review by contacting Madeline Dzielak at the Kremmling Resource Area Office at 1116 Park Avenue, PO Box 68, Kremmling, Colorado, 80459, (970) 724–3437.

SUPPLEMENTARY INFORMATION: Publication of this notice in the **Federal Register** segregates the public land from the operation of the public land laws, including the mining laws, except for conveyance under Section 302 of the Federal Land Policy and Management Act sale and exchange, for a period of two years from the date of publication of this notice. The segregative effect shall terminate upon issuance of a lease, upon rejection of the application, or two years from the date of publication of this notice.

For a period of 45 days from the date of publication of this notice interested parties may submit comments to the District Manager, Grand Junction District Office, Bureau of Land Management, 2815 H Road, Grand Junction, CO 81506. Any adverse comments will be evaluated by the State Director, who may sustain, vacate, or modify this realty action. In the absence of any adverse comments, this realty action will become the final determination of the Department of the Interior.

Dated: April 29, 1998.

Mark T. Morse,

District Manager.

[FR Doc. 98–12882 Filed 5–13–98; 8:45 am]

BILLING CODE 4310–JB–M

DEPARTMENT OF THE INTERIOR

Bureau of Land Management

[NV–930–1430–01; N–62223]

Notice of Realty Action; Nevada

AGENCY: Bureau of Land Management.

ACTION: Notice.

SUMMARY: The following described land in Elko County, Nevada has been examined and found suitable for classification for lease/purchase under the Recreation and Public Purposes Act (R&PP) of June 14, 1926, as amended (43 U.S.C. 869 *et seq.*). The lands will not be offered for lease/purchase until at least 60 days after the date of publication of this Notice in the **Federal Register**.

Mount Diablo Meridian, Nevada

T. 33 N., R. 55 E.,
Sec. 6, lot 8, 9, 10, 14, 15.
Containing 182.82 acres, more or less.

DATES: The land will become segregated on May 14, 1998. Comments are due in this office by June 29, 1998.

FOR FURTHER INFORMATION CONTACT: Detailed information concerning this action is available for review at the Bureau of Land Management, Elko Field Office, 3900 Idaho Street, Elko, Nevada.

SUPPLEMENTARY INFORMATION: The City of Elko, Nevada intends to use the land to construct an effluent storage reservoir. The lease/patent, when issued, will be subject to the provisions

of the Recreation and Public Purposes Act, applicable regulations of the Secretary of the Interior, and will contain the following reservations to the United States:

1. A right-of-way thereof for ditches and canals constructed by the authority of the United States; Act of August 30, 1890 (43 U.S.C. 945).

2. All mineral deposits in the lands so patented, and to it, or persons authorized by it, the right to prospect for, mine and remove such deposits from the same under applicable laws and regulations to be established by the Secretary of Interior. The land is not required for any Federal purpose. The classification and subsequent lease/conveyance are consistent with the Bureau's planning for the area. Upon publication of this Notice of Realty Action in the **Federal Register**, the subject lands will be segregated from all forms of appropriation under the public land laws, including locations under the mining laws, except for recreation and public purposes. The segregative effect shall terminate upon issuance of a patent or as specified in an opening order to be published in the **Federal Register**, whichever occurs first. For a period of 45 days from the date of publication of this notice in the **Federal Register**, interested parties may submit comments to the District Manager, Elko Field Office, 3900 Idaho Street, Elko, NV 89801. Any objections will be evaluated by the State Director, who may sustain, vacate or modify this realty action. In the absence of timely filed objections, the classification of the lands described in this Notice will become effective July 13, 1998.

Classification Comments

Interested parties may submit comments involving the suitability of the land for lease/conveyance under the Recreation and Public Purposed Act. Comments on the classification are restricted to whether the land is physically suited for the proposal, whether the use will maximize the future use or uses of the land, whether the use is consistent with local planning and zoning, or if the use is consistent with State and Federal programs.

Application Comments

Interested parties may submit comments regarding the specific use proposed in the application and plan of development, whether the BLM followed proper administrative procedures in reaching the decision, or any other factor not directly related to the suitability of the land for lease/purchase under the Recreation and Public Purposes Act.

Dated: May 4, 1998.

Helen Hankins,

District Manager.

[FR Doc. 98–12796 Filed 5–13–98; 8:45 am]

BILLING CODE 4310–HC–P

DEPARTMENT OF THE INTERIOR

Bureau of Land Management

[ES–960–1420–00] ES–49627, Group 31, Illinois

Notice of Filing of Plat of Survey; Illinois

The plat of the dependent resurvey of a portion of the east boundary, portions of the subdivisional lines and the survey of the Lock and Dam No. 26 acquisition boundary, Township 6 North, Range 11 West, Third Principal Meridian, Illinois, will be officially filed in Eastern States, Springfield, Virginia at 7:30 a.m., on June 19, 1998.

The survey was requested by the U.S. Army Corps of Engineers.

All inquiries or protests concerning the technical aspects of the survey must be sent to the Chief Cadastral Surveyor, Eastern States, Bureau of Land Management, 7450 Boston Boulevard, Springfield, Virginia 22153, prior to 7:30 a.m., June 19, 1998.

Copies of the plat will be made available upon request and prepayment of the reproduction fee of $2.75 per copy.

Dated: May 8, 1998.

Stephen G. Kopach,

Chief Cadastral Surveyor.

[FR Doc. 98–12870 Filed 5–13–98; 8:45 am]

BILLING CODE 4310–6J–P

DEPARTMENT OF THE INTERIOR

Bureau of Land Management

[ES–960–1420–00] ES–49629, Group 175, Minnesota

Notice of Filing of Plat of Survey; Minnesota

The plat of the survey of Four Islands in Five Island Lake in sections 20 and 21, Township 62 North, Range 23 West, 4th Principal Meridian, Minnesota, will be officially filed in Eastern States, Springfield, Virginia at 7:30 a.m., on June 22, 1998.

The survey was executed in response to the applications for survey submitted by Marcene Wiebusch Anderson, Key Largo, Florida, Rowena Hawkinson, Cook, Minnesota, and Byron B. Meyers, Barrington, Illinois.

All inquiries or protests concerning the technical aspects of the survey must be sent to the Chief Cadastral Surveyor, Eastern States, Bureau of Land Management, 7450 Boston Boulevard, Springfield, Virginia 22153, prior to 7:30 a.m., June 22, 1998.

Copies of the plat will be made available upon request and prepayment of the appropriate fee.

Dated: May 6, 1998.

Stephen G. Kopach,

Chief Cadastral Surveyor.

[FR Doc. 98–12877 Filed 5–13–98; 8:45 am]

BILLING CODE 4310–GJ–P

DEPARTMENT OF THE INTERIOR

Bureau of Land Management

[OR–957–00–1420–00: G8–0184]

Filing of Plats of Survey: Oregon/Washington

AGENCY: Bureau of Land Management, Interior.

ACTION: Notice.

SUMMARY: The plats of survey of he following described lands are scheduled to be officially filed in the Oregon State Office, Portland, Oregon, thirty (30) calendars days from the date of this publication.

Willamette Meridian

Oregon

T. 7S., R. 2 E., accepted April 1, 1998
T. 30 S., R. 4 W., accepted March 13, 1998
T. 29 S., R. 7 W., accepted April 13, 1998
T 10 S., R. 20 W., accepted April 13, 1998
T 30 S., R. 10 W., accepted April 17, 1998
T. 6 S., R. 11 W., Accepted April 13, 1998
T. 30 S., R. 15 W., Accepted April 17, 1988

Washington

T. 10 N., R. 11 E., accepted April 23, 1998
T. 11 N., R. 11 E., accepted April 23, 1998
T. 25 N., R. 21 E., accepted April 3, 1998

If protests against a survey, as shown on any of the above palt(s), are received prior to the date of official filing, the filing will be stayed pending consideration of the protests(s) A plat will not be officially filed until the day after all protests have been dismissed and become final or appeals from the dismissal affirmed.

The plat(s) will be placed in the open files of the Oregon State Office, Bureau of Land Management, 1515 S.W. 5th Avenue, Portland, Oregon 97201, and will be available to the public as a matter of information only. Copies of the plat(s) may be obtained from the above office upon required payment. A person or party who wishes to protest against a survey must file with the State Director, Bureau of Land Management, Poland, Oregon, a notice that they wish

to protest prior to the proposed official filing date given above. A statement of reasons or a protest may be filed with the notice of protest to the State Director, or the statement of reasons must be filed with the State Director within thirty (30) days after the proposed official filing date.

The above-listed plats represent dependent resurveys, survey and subdivision.

FOR FURTHER INFORMATION CONTACT: Bureau of Land Management, (1515 S.W. 5th Avenue) P.O. Box 2965, Portland, Oregon 97208).

Dated: May 7, 1998.

Robert D. DeViney, Jr.,

Chief, Branch of Realty and Records Services.

[FR Doc. 98–12875 Filed 5–13–98; 8:45 am]

BILLING CODE 4310–33–M

DEPARTMENT OF THE INTERIOR

Bureau of Land Management

[OR–958–1430–01; GP8–0086; OR–52939]

Proposed Withdrawal and Opportunity for Public Meeting; Oregon

AGENCY: Bureau of Land Management, Interior.

ACTION: Notice.

SUMMARY: The Bureau of Land Management proposes to withdraw 196.01 acres of lands, of which 184.60 acres are public lands and 11.41 acres are non-Federal lands, to protect the facilities and unique values of the Row River Trail. This notice closes the lands for up to 2 years from surface entry and mining. The public lands have been and will remain open to mineral leasing. Upon acquisition, the non-Federal lands will be opened to the mineral leasing laws.

EFFECTIVE DATE: Comments and requests for a public meeting must be received by August 13, 1998.

ADDRESSES: Comments and meetings requests should be sent to the Oregon/Washington State Director, BLM, P.O. Box 2965, Portland, Oregon 97208–2965.

FOR FURTHER INFORMATION CONTACT: Charles R. Roy, BLM Oregon/Washington State Office, 503–952–6189.

SUPPLEMENTARY INFORMATION: On April 17, 1998, a petition was approved allowing the Bureau of Land Management to file an application to withdraw the following described public lands and non-Federal lands from settlement, sale, location, or entry under the general land laws, including the United States mining laws (30 U.S.C. Ch. 2 (1994)), but not from leasing under the mineral leasing laws, subject to valid existing rights:

Willamette Meridian

Public Lands

T. 21 S., R. 1 W.,
Sec. 31, lot 2 of Tract No. 38.

The portions of the following lands as more particularly identified and described by metes and bounds in the official records of the Bureau of Land Management, Oregon/Washington State Office and the Eugene District Office, Eugene, Oregon:

T. 21 S., R. 1 W.,
Sec. 19, lots 1, 2, 4, and 5, SE¼NW¼, NE¼SW¼, and Donation Land Claim No. 37;
Sec. 30, lots 1, 2, 3, and 4, SE¼SW¼, and Donation Land Claim No. 37;
Sec. 31, NW¼NE¼, NE¼NW¼;
Sec. 32, SW¼.
T. 20 S., R. 2 W.,
Sec. 30, lots 3, 4, and 6, and Donation Land Claim Nos. 40 and 42;
Sec. 31, Donation Land Claim No. 39;
Sec. 32, lots 1 and 3, S½NE¼, NE¼NW¼, and Donation Land Claim Nos. 38 and 39;
Sec. 33, lots 2, 6, and 7, and Donation Land Claim Nos. 41, 43, and 45;
Sec. 34, Donation Land Claim No. 43.
T. 21 S., R. 2 W.,
Sec. 2, lots 1 and 2, and Donation Land Claim No. 44;
Sec. 3, lot 2, SE¼NE¼, and Donation Land Claim Nos. 40 and 44;
Sec. 11, Donation Land Claim Nos. 42 and 45;
Sec. 13, Donation Land Claim Nos. 42 and 43;
Sec. 14, lot 1 and Donation Land Claim No. 42;
Sec. 24, lots 1 and 2.
T. 22 S., R. 1 W.,
Sec. 5, N½NE¼, SW¼NE¼, and SE¼NW¼.
T. 21 S., R. 3 W.,
Sec. 1, lot 4 and Donation Land Claim No. 60.
T. 20 S., R. 3 W.,
Sec. 25, Donation Land Claim 74;
Sec. 26, Donation Land Claim Nos. 65, 66, and 74.

The areas described aggregate approximately 184.60 acres in Lane County.

Non-Federal Lands

T. 21 S., R. 1 W.,
Sec. 31, lot 1 of Tract 38.

The following lands as more particularly identified and described by metes and bounds in the official records of the Bureau of Land Management, Oregon/Washington State Office and the Eugene District Office, Eugene, Oregon:

T. 21 S., R. 1 W.,
Sec. 19, lot 1;
Sec. 31, SE¼NE¼;
Sec. 32, W½NW¼.

The areas described aggregate approximately 11.41 acres in Lane County.

The purpose of the proposed withdrawal is to protect the facilities and unique recreational values of the approximate 14 miles of improved recreational trail converted from an abandoned railroad right-of-way.

For a period of 90 days from the date of publication of this notice, all persons who wish to submit comments, suggestions, or objections in connection with the proposed withdrawal may present their views in writing to the State Director at the address indicated above.

Notice is hereby given that an opportunity for a public meeting is afforded in connection with the proposed withdrawal. All interested parties who desire a public meeting for the purpose of being heard on the proposed withdrawal must submit a written request to the State Director at the address indicated above within 90 days from the publication of this notice. Upon determination by the authorized officer that a public meeting will be held, a notice of the time and place will be published in the **Federal Register** at least 30 days before the scheduled date of the meeting.

The application will be processed in accordance with the regulations set forth in 43 CFR 2300.

For a period of 2 years from the date of publication of this notice in the **Federal Register**, the lands will be segregated as specified above unless the application is denied or canceled or the withdrawal is approved prior to that date. The temporary land uses which may be permitted during this segregative period include licenses, permits, rights-of-way, and disposal of vegetative resources other than under the mining laws.

Dated May 5, 1998.

Robert D. DeViney, Jr.,

Chief, Branch of Realty and Records Services.

[FR Doc. 98–12871 Filed 5–13–98; 8:45 am]

BILLING CODE 4310–33–P

DEPARTMENT OF JUSTICE

President's Advisory Board on Race

ACTION: President's Advisory Board on Race; Notice of meeting.

SUMMARY: This revises the notice of May 6, 1998 regarding the President's Advisory Board on Race meeting on May 19, 1998.

The Advisory Board will meet from 10:00 a.m. until approximately 1:00 p.m. at the Dorothy Betts Marvin Theater in the Marvin Center, 800 21st Street, NW., Washington, DC. The agenda includes remarks from Attorney

General Janet Reno and a roundtable discussion of issues relating to race, crime and the administration of justice.

The public is welcome to attend the Advisory Board meeting on a first-come, first-seated basis. Members of the public may also submit to the contact person, any time before or after the meeting, written statements to the Board. Written comments may be submitted by mail, telegram, facsimile, or electronic mail, and should contain the writer's name, address and commercial, government, or organizational affiliation, if any. The address of the President's Initiative on Race is 725 17th Street, N.W., Washington, DC 20503. The electronic mail address is http://www.whitehouse.gov/initiatives/OneAmerica.

FOR FURTHER INFORMATION CONTACT: Comments or questions regarding this meeting may be directed to Randy D. Ayers, (202) 395–1010, or via facsimiles, (202) 395–1020.

Dated: May 11, 1998.

Randy D. Ayers,

Executive Officer.

[FR Doc. 98–12879 Filed 5–13–98; 8:45 am]

BILLING CODE 4410–13–M

DEPARTMENT OF JUSTICE

National Advisory Council on Violence Against Women

AGENCY: United States Department of Justice and United States Department of Health and Human Services.

ACTION: Notice of meeting.

SUMMARY: The National Advisory Council on Violence Against Women, co-chaired by the Attorney General and Secretary of Health and Human Services, will meet May 29, 1998 in Room 800 of the United States Department of Health and Human Services, 200 Independent Avenue, NW, Washington DC 20201. Scheduled to begin at 8:30 a.m. and adjourn at 4:30 p.m., the meeting will include opening remarks by the Attorney General and Secretary Shalala, presentation on violence against women resource centers, committee meetings, and an afternoon plenary session.

Committee meetings and the plenary session will be open to the public on a space-available basis. Reservations are required and a photo ID will be requested for admittance. To reserve a space and advise of any special needs, interested persons should call Mr. Jerry Silverman at the Department of Health and Human Services at (202) 690–6461. Sign language interpreters will be provided. Anyone wishing to submit written questions to this session should notify the Department of Health and Human Services, Office of the Secretary by Tuesday, May 26, 1997. The notification may be delivered by mail, telegram, or facsimile or in person. It should contain the requestor's name and his or her corporate designation, consumer affiliation, or government designation along with a short statement describing the topic to be addressed. Interested parties are encouraged to attend.

FOR FURTHER INFORMATION CONTACT: Questions regarding this meeting may be sent to the Office of the Secretary, United States Department of Health and Human Services, Room 615F, 200 Independence Avenue, NW, Washington, DC 20201 or directed to Mr. Jerry Silverman, telephone (202) 690–6461, facsimile (202) 690–5514.

Bonnie J. Campbell,

Director, Violence Against Women Office, United States Department of Justice.

[FR Doc. 98–12789 Filed 5–13–98; 8:45 am]

BILLING CODE 4410–BB–M

DEPARTMENT OF JUSTICE

Notice of Lodging of Consent Decree Pursuant to the Comprehensive Environmental Response Compensation and Liability Act of 1980, as Amended, and the Resource Conservation and Recovery Act

Notice is hereby given that a proposed consent decree in the action entitled *United States* v. *PO Corporation,* Civil Action No. 98CV10759 EFH, was lodged on April 30, 1998, with the United States District Court for the District of Massachusetts. The proposed consent decree resolves the United States's claims against PQ Corporation, Nyacol Products, Inc., Robert Lurie, and Thomas O'Connor at the Nyanza Chemical Waste Dump Superfund Site, Located in Ashland, Massachusetts (''Site''), under the Comprehensive Environmental Response, Compensation, and Liability Act (''CERCLA''), 42 U.S.C. § 9601 *et seq.* and the Resource Conservation and Recovery Act, 42 U.S.C. § 6973. Defendants PQ, NPI, Lurie and O'Connor are current or former owners and operator of the Site. The consent decree will also resolve the claims of the Commonwealth of Massachusetts (''Commonwealth'') in connection with the Site under CERCLA and the Massachusetts Oil and Hazardous material Release Prevention and Response Act, M.G.L. c. 21E. Finally, the consent decree will also resolve the claims of the United States and the Commonwealth against Robert Lurie and Thomas O'Connor under M.G.L. c. 109A.

Under the proposed consent decree, the settlers jointly will make payments to the United States and the Commonwealth in the amount of $8,000,000, plus interest. Of the total payments, $923,077 will be paid to the United States and the Commonwealth in connection with claims for natural resource damages at the Site. The remaining money will be paid 80% to the United States and 20% the Commonwealth as reimbursement for response costs incurred and to be incurred at the Site.

The Department of Justice will receive, for a period of up to thirty days from the date of this publication, comments relating to the proposed consent decree. Any comments should be addressed to the Assistant Attorney General for the Environment and Natural Resources Division, Department of Justice, P.O. Box 7611, Ben Franklin Station, Washington, D.C. 20044, and should refer to *United States* v. *PO Corporation,* DOJ Ref. Number 90–11–2–340e. Commenters may request an opportunity for a public meeting in the affected area, in accordance with Section 7003(d) of RCRA, 42 U.S.C. § 6973.

The proposed consent decree may be examined at the Environmental Protection Agency, One Congress Street, Boston, Massachusetts (contact Joanna Jerison at 617–565–3350) and at the Consent Decree Library, 1120 G Street, N.W., 4th Floor, Washington, D.C. 20005, 202–624–0892. A copy of the proposed consent decree may be obtained in person or by mail from the Consent Decree Library, 1120 G Street, N.W., 4th Floor, Washington, D.C. 20005. In requesting a copy, please refer to the referenced case and enclose a check in the amount of $18.00 (72 pages at 25 cents per page reproduction costs), payable to the Consent Decree Library.

Joel M. Gross,

Section Chief, Environmental Enforcement Section, Environment and Natural Resources Division.

[FR Doc. 98–12874 Filed 5–13–98; 8:45 am]

BILLING CODE 4410–15–M

DEPARTMENT OF JUSTICE

Notice of Lodging of Consent Decree Under the Clean Water Act and the Clean Air Act

Under 28 CFR 50.7 notice is hereby given that on April 8, 1998, a proposed Consent Decree (''Decree'') in *United States and League of Women Voters of*

New Orleans, et al. v. *Sewerage & Water Board of New Orleans, et al.*, Civil Action No. 93–3212, was lodged with the United States District Court for the Eastern District of Louisiana.

In this action the United States sought civil penalties and injunctive relief for violations of the Clean Air Act and the Clean Water Act that occurred at the East Bank Sewage Treatment Plant and its collection system in New Orleans, Louisiana. The League of Women Voters, Lake Ponchartrain Basin Foundation, Orleans Audubon Society, and Louisiana Environmental Action Network also were Plaintiff-Intervenors in this action, and the State of Louisiana was a statutory Defendant.

Under the Decree, the Sewerage & Water Board of New Orleans (''Board'') and the City of New Orleans agreed to perform Clean Water Act remedial measures, estimated at more than $200 million, including renovating the sewer collection system, implementing a preventive maintenance program, improving reporting procedures for unauthorized discharges from the sewer collection system, implementing a response action plan when sewage is discharged, and conducting storm sewer monitoring. The Board agreed to Clean Air Act remedial measures contained in the Operation and Maintenance Plan for the Fluidized Bed Incinerator at the East Bank Sewage Treatment Plant. The Board also agreed to pay a civil penalty of $1.5 million and to perform a $2 million Supplemental Environmental Project that creates wetlands and a vegetative buffer at an abandoned local beach area. The Decree does not resolve the contingent liability of the State under Section 309(e) of the Act, 33 U.S.C. 1319(e).

The Department of Justice will receive for a period of thirty (30) days from the date of this publication comments relating to the Decree. Comments should be addressed to the Assistant Attorney General of the environment and Natural Resources Division, Department of Justice, Washington, D.C. 20530, and should refer to *United States and the League of Women Voters of New Orleans, et al.* v. *Sewerage & Water Board of New Orleans, et al.*, D.J. Ref. No. 90–5–1–1–4032.

The Decree may be examined at the Office of the United States Attorney, Hale Boggs Building, Room 210, 501 Magazine Street, New Orleans, Louisiana, 70130, at U.S. EPA Region 6, 1445 Ross Avenue, Dallas, Texas 75202, and at the Consent Decree Library, 1120 G Street, NW, 4th Floor, Washington, DC 20005, (202) 624–0892. A copy of the Decree may be obtained in person or by mail from the Consent Decree Library, 1120 G Street, NW, 4th Floor, Washington, DC 20005. In requesting a copy, please indicate whether you want the text of the Decree only, the Decree with all attachments (except oversize maps) in black and white, or the Decree with all attachments (except oversize maps) in color. Enclose a check in the amount of $15,75 for the text of the Decree only, $527.00 for the Decree with all attachments (except oversize maps) in black and white, $785.00 for the Decree with all attachments (except oversize maps) in color, payable to the Consent Decree Library. Reproduction costs are 25 cents per page for normal pages and $1.15 per page for color copies. For copies of the oversize maps, please add on additional $325.000 to the total amount.

Joel M. Gross,

Chief, Environmental Enforcement Section, Environment and Natural Resources Division.

[FR Doc. 98–12790 Filed 5–13–98; 8:45 am]

BILLING CODE 4410–15–M

DEPARTMENT OF LABOR

Employment and Training Administration

Interstate Arrangement for Combining Employment and Wages

ACTION: Notice.

SUMMARY: The Department of Labor, as part of its continuing effort to reduce paperwork and respondent burden conducts a preclearance consultation program to provide the general public and Federal agencies with an opportunity to comment on proposed and/or continuing collections of information in accordance with the Paperwork Reduction Act of 1995 (PRA95) (44 U.S.C. 3506 (C)(2)(A)). This program helps to ensure that requested data can be provided in the desired format, reporting burden (time and financial resources) is minimized, collection instruments are clearly understood, and the impact of collection requirements on respondents can be properly assessed. Currently, the Employment and Training Administration is soliciting comments concerning the proposed extension of the Interstate Arrangement For Combining Employment and Wages, ETA 586.

A copy of the proposed information collection request (ICR) can be obtained by contacting the office listed below in the addressee section of this notice.

DATES: Written comments must be submitted to the office listed in the addressee section below on or before July 13, 1998. The Department of Labor is particularly interested in comments which:

- Evaluate whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility;
- Evaluate the accuracy of the agency's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used;
- Enhance the quality, utility, and clarity of the information to be collected; and
- Minimize the burden of the collection of information on those who are to respond, including through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology, e.g., permitting electronic submissions of responses.

ADDRESSES: Mary E. Montgomery, Unemployment Insurance Service, Employment and Training Administration, U.S. Department of Labor, Room S–4516, 200 Constitution Avenue, NW., Washington, DC. 20210, telephone number (202) 219–5340, ext. 178 (this is not a toll-free number).

SUPPLEMENTARY INFORMATION:

I. Background

Section 3304(a)(9)(B), of the Internal Revenue Code (IRC) of 1986, requires States to participate in an arrangement for combining employment and wages covered under the different State laws for the purpose of determining unemployed workers' entitlement to unemployment compensation. The Interstate Arrangement For Combining Employment and Wages (CWC), promulgated at 20 CFR part 616, requires the prompt transfer of all available employment and wages between States upon request. The Benefit Payment Promptness Standard, 20 CFR part 640, requires the prompt payment of unemployment compensation including benefits paid under the CWC arrangement. The ETA 586 report provides the ETA/Unemployment Insurance Service with information necessary to measure the scope and effect of the CWC program and monitor the performance of each State in responding to wage transfer requests and the payment of benefits.

II. Current Actions

This information is necessary in order for ETA to analyze program performance, know when program

performance action plans are needed and to target technical assistance resources. Without this report, it would be impossible for the ETA to identify activity under the CWC program and carry out the Secretary's responsibility for oversight.

Type of Review: Extension without change.

Agency: Employment and Training Administration.

Title: Interstate Arrangement for Combining Employment and Wages.

OMB Number: 1205–0029.

Agency Number: ETA 586.

Recordkeeping: 3 years.

Affected Public: State Government.

Cite/Reference/Form: ETA Handbook No. 401, ETA 586.

Total Respondents: 53.

Frequency: Quarterly.

Total Responses: 212.

Average Time per Response: 4 hours.

Estimated Total Burden Hours: 848.

Total Burden Cost (capital/startup): N/A.

Total Burden Cost: $16,960.00.

Comments submitted in response to this comment request will be summarized and/or included in the request for Office of Management and Budget approval of the information collection request; they will also become a matter of public record.

Dated: May 6, 1998.

Grace A. Kilbane,

Director, Unemployment Insurance Service.

[FR Doc. 98–12859 Filed 5–13–98; 8:45 am]

BILLING CODE 4510–30–M

NATIONAL CREDIT UNION ADMINISTRATION

Sunshine Act Meeting

Notice of Previously Held Meeting

TIME AND DATE: 10:30 a.m., Tuesday, May 12, 1998.

PLACE: Board Room, 7th Floor, Room 7047, 1775 Duke Street, Alexandria, VA 22314–3428.

STATUS: Closed.

MATTERS CONSIDERED:

1. Personnel Matter Related to the OPM Report. Closed pursuant to exemptions (2) and (6).

2. Personnel Action. Closed pursuant to exemptions (2) and (6).

The Board voted unanimously that Agency business required that a meeting be held with less than the usual seven days advance notice, that it be closed to the public, and that earlier announcement of this was not possible.

The Board voted unanimously to close the meeting under the exemptions stated above. Deputy General Counsel James Engel certified that the meeting could be closed under those exemptions.

FOR FURTHER INFORMATION CONTACT: Becky Baker, Secretary of the Board, Telephone (703) 518–6304.

Becky Baker,

Secretary of the Board.

[FR Doc. 98–13052 Filed 5–12–98; 3:46 pm]

BILLING CODE 7535–01–M

NATIONAL SCIENCE FOUNDATION

Comment Request: National Science Foundation Proposal/Award Information—Grant Proposal Guide

AGENCY: National Science Foundation.

ACTION: Notice.

SUMMARY: National Science Foundation is announcing plans to request renewed clearance of this collection. In accordance with the requirement of Section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995, we are providing opportunity for public comment on this action. After obtaining and considering public comment, NSF will prepare the submission requesting OMB clearance of this collection for no longer than 3 years.

SEND COMMENTS TO: Gail A. McHenry, Reports Clearance Officer, National Science Foundation, 4201 Wilson Boulevard, Suite 245, Arlington, Virginia 22230 or send email to gmchenry@nsf.gov. Written comments should be received within 60 days of the date of this notice.

FOR FURTHER INFORMATION CONTACT: Mrs. McHenry on (703) 306–1125 x2010 or send email to gmchenry@nsf.gov. You may also obtain a copy of the data collection instrument and instructions from Mrs. McHenry.

Comments are invited on (a) whether the proposed collection of information is necessary for the proper performance of the functions of the Agency, including whether the information shall have practical utility; (b) the accuracy of the Agency's estimate of the burden of the proposed collection of information; (c) ways to enhance the quality, utility, and clarity of the information on respondents, including through the use of automated collection techniques or other forms of information technology.

Proposed Project

''National Sciences Foundation Proposal/Award Information—Grant Proposal Guide.'' The missions of the NSF are to:increase the Nation's base of scientific and engineering knowledge and strengthen its ability to support research in all areas of science and engineering; and promote innovative science and engineering education programs that can better prepare the Nation to meet the challenges of the future. The Foundation is committed to ensuring the Nation's supply of scientists, engineers, and science educators, In its role as leading Federal supporter of science and engineering, NSF also has an important role in national science policy planning.

Use of the Information

The regular submission of proposals to the Foundation is part of the collection of information and is used to help NSF fulfill this responsibility by initating and supporting merit-selected research and education projects in all the scientific and engeering disciplines. NSF receives more than 30,000 proposals annually for new projects, and makes approximately 10,000 new awards. Support is made primarily through grants, contracts, and other agreements awarded to approximately 2,800 colleges, universities, academic consortia, nonprofit institutions, and small businesses. The awards are based mainly on evaluations of proposal merit submitted to the Foundation (proposal review is cleared under OMB Control No. 3145–0060).

The Foundation has a continuing commitment to monitor the operations of its information collection to identify and address excessive reporting burdens as well as to identify any real or apparent inequities based on gender, race, ethnicity, or disability of the proposed principal investigator(s)/project director(s) or the co-principal investigator(s)/co-project director(s).

Burden on the Public

The Foundation estimates that an average of 120 hours is expended for each proposal submitted. An estimated 38,000 proposals are expected during the course of one year. These figures compute to an estimated 4,560,000 public burden hours annually.

Dated: May 8, 1998.

Gail A. McHenry,

NSF Reports Clearance Officer.

[FR Doc. 98–12829 Filed 5–13–98; 8:45 am]

BILLING CODE 7555–01–M

NATIONAL SCIENCE FOUNDATION

Notice of Permit Modification Issued Under the Antarctic Conservation Act of 1978

AGENCY: National Science Foundation.

ACTION: Notice of permit modification issued under the Antarctic Conservation of 1978, Public Law 95–541.

SUMMARY: The National Science Foundation (NSF) is required to publish notice of permits issued under the Antarctic Conservation of 1978. This is the required notice.

FOR FURTHER INFORMATION CONTACT: Nadene G. Kennedy, Permit Officer, Office of Polar Programs, Rm. 755, National Science Foundation, 4201 Wilson Boulevard, Arlington, VA 22230.

SUPPLEMENTARY INFORMATION: On March 24, 1998 notice was published in the **Federal Register** of a request for modification to permit 95WM1–NSFA/ASA for waste management activities at all U.S. Antarctic Program facilities in Antarctica. The requested modification would make Antarctic Support Associates sole holder of the permit. The requested modification has been granted. All special conditions of the original permit remain the same except for the deletion of references to Naval Support Force Antarctica (NSFA).

Nadene G. Kennedy,

Permit Officer.

[FR Doc. 98–12862 Filed 5–13–98; 8:45 am]

BILLING CODE 7555–01–M

NATIONAL SCIENCE FOUNDATION

Special Emphasis Panel in Bioengineering and Environmental Systems; Notice of Meeting

In accordance with the Federal Advisory Committee Act (Pub. L. 92–463, as amended), the National Science Foundation announces the following meeting.

Name: Special Emphasis Panel in Bioengineering and Environmental Systems (No. 97–87).

Date and Time: June 2–3, 1998; 8:30 am–5:00 pm.

Place: National Science Foundation, 4201 Wilson Boulevard, Room 530, Arlington, VA 22230.

Type of Meeting: Closed.

Contact Person: Fred G. Heineken, Program Director, Biotechnology Engineering, Division of Bioengineering and Environmental Systems, National Science Foundation, 4201 Wilson Boulevard, Arlington, VA 22230, Telephone: (703) 306–1318.

Purpose of Meeting: To provide advice and recommendations concerning proposals submitted to NSF for financial support.

Agenda: To review and evaluate the 1998 Biotechnology proposals as part of the selection process for awards.

Reason for Closing: The proposals being reviewed include information of a proprietary or confidential nature, including technical information; financial data, such as salaries; and personal information concerning individuals associated with the proposals. These matters are exempt under 5 U.S.C. 552b(c), (4) and (6) of the Government in the Sunshine Act.

Dated: May 11, 1998.

M. Rebecca Winkler,

Committee Management Officer.

[FR Doc. 98–12864 Filed 5–13–98; 8:45 am]

BILLING CODE 7555–01–M

NATIONAL SCIENCE FOUNDATION

Special Emphasis Panel in Biological Infrastructure; Notice of Meeting

In accordance with the Federal Advisory Committee Act (Pub. L. 92–463, as amended), the National Science Foundation announces the following meeting:

Name: Special Emphasis Panel in Biological Infrastructure (1754).

Date & Time: June 2–5, 1998; 9am–5pm daily.

Place: Room 1235, NSF, 4201 Wilson Boulevard, Arlington, Virginia.

Type of Meeting: Closed.

Contact Person: Dr. Judith Verbeke, Program Director, Plant Genome Research, Division of Biological Infrastructure, Room 615, NSF, 4201 Wilson Boulevard, Arlington, VA 22230, (703) 306–1470.

Purpose of Meeting: To provide advance and recommendations concerning proposals submitted to the NSF for financial support.

Agenda: To review and evaluate Plant Genome Research proposals as part of the selection process for awards.

Reason for Closing: The proposals being reviewed include information of a proprietary or confidential nature, including technical information; financial data, such as salaries; and personal information concerning individuals associated with the proposals. These matters are exempt under 5 U.S.C. 552b(c) (4) and (6) of the Government Sunshine Act.

Dated: May 11, 1998.

M. Rebecca Winkler,

Committee Management Officer.

[FR Doc. 98–12867 Filed 5–13–98; 8:45 am]

BILLING CODE 7555–01–M

NATIONAL SCIENCE FOUNDATION

Special Emphasis Panel in Design, Manufacture, and Industrial Innovation; Notice of Meeting

In accordance with the Federal Advisory Committee Act (Pub. L. 92–463, as amended) the National Science Foundation announces the following meeting:

Name: Special Emphasis Panel in Design, Manufacture, and Industrial Innovation—(1194).

Date and Time: June 2, 3, 4, 1998, 8:00 a.m.—5:30 p.m.

Place: Rooms 310, 320, 330, 340, 360, 375, 380, 580, and 730, National Science Foundation, 4201 Wilson Boulevard, Arlington, VA 22230.

Type of meeting: Closed.

CONTACT PERSON: Dr. George A. Hazelrigg, Program Director, Design and Integration Engineering Program, Dr. Delcie Durham, Program Director, Materials Processing and Manufacturing Program, Dr. Ming Leu, Program Director, Manufacturing Machines and Equipment Program, (703) 306–1330, National Science Foundation, 4201 Wilson Boulevard, Arlington, VA 22230.

Purpose of Meeting: To provide advice and recommendations concerning proposals submitted to the NSF for financial support.

Agenda: To review and evaluate Unsolicited proposals as part of the selection process for awards.

Reason for closing: The proposals being reviewed include information of proprietary or confidential nature, including technical information, financial data such as salaries, and personal information concerning individuals associated with the proposals. These matters that are exempt under 5 U.S.C. 552bc (4) and (6) of the Government in the Sunshine Act.

Dated: May 11, 1998.

M. Rebecca Winkler,

Committee Management Officer.

[FR Doc. 98–12866 Filed 5–13–98; 8:45 am]

BILLING CODE 7555–01–M

NATIONAL SCIENCE FOUNDATION

Special Emphasis Panel in Electrical and Communications Systems; Notice of Meeting

In accordance with the Federal Advisory Committee Act (Pub. L. 92–463, as amended), the National Science Foundation announces the following meeting:

Name: Special Emphasis Panel in Electrical and Communications System (1196).

Date and Time: June 2–3, 1998: 8:30 a.m. to 5:00 p.m.

Place: Room 320, National Science Foundation, 4201 Wilson Boulevard, Arlington, VA 22230.

Type of Meeting: Closed.

Contact Persons: Dr. Tien P. Lee, Program Director, Physical Foundations of Enabling Technologies (PEET), Division of Electrical and Communications Systems, National Science Foundations, 4201 Wilson Boulevard, Room 675, Arlington, VA 22230. Telephone: (703) 306-1339.

Purpose: To provide advice and recommendations concerning proposals submitted to NSF for financial support.

Agenda: To review and evaluate research proposals in the Physical Foundations of Enabling Technologies program as part of the selection process for awards.

Reason for Closing: The proposals being reviewed include information of a proprietary or confidential nature, including technical information; financial data, such as

salaries; and personal information concerning individuals associated with the proposals. These matters are within exemptions 4 and 6 of 5 U.S.C. 552b.(c)(4) and (6) the Government in the Sunshine Act.

Dated: May 11, 1998.

M. Rebecca Winkler,

Committee Management Officer.

[FR Doc. 98–12865 Filed 5–13–98; 8:45 am]

BILLING CODE 7555–01–M

NATIONAL SCIENCE FOUNDATION

Special Emphasis Panel in Integrative Activities; Notice of Meeting

In accordance with the Federal Advisory Committee Act (Pub. L. 92–463, as amended), the National Science Foundation announces the following meeting:

Name: Special Emphasis Panel in Intergrative Activities (1373).

Date and Time: June 1 & 2, 1998, 8:30 a.m.–5:00 p.m.

Place: Rooms 330 and 340, NSF, 4201 Wilson Blvd., Arlington, Va.

Type of Meeting: Closed.

Contact Person: Dr. Nathaniel G. Pitts, Director, Office of Integrative Activities, Room 1270, 4201 Wilson Blvd, Arlington, Virginia 22230; Telephone: (703) 306–1040.

Purpose of Meeting: To provide advice and recommendations concerning proposals submitted to NSF for financial support.

Agenda: To review and evaluate applications submitted to the Collaboratives to Integrate Research and Education (CIRE).

Reason for Closing: The proposals being reviewed include information of a proprietary or confidential nature, including technical information, financial data such as salaries, and personal information concerning individuals associated with the proposals. These matters are exempt under 5 U.S.C. 552b(c)(4) and (6) of the Government in the Sunshine Act.

Dated: May 11, 1998.

M. Rebecca Winkler,

Committee Management Officer.

[FR Doc. 98–12863 Filed 5–13–98; 8:45 am]

BILLING CODE 7555–01–M

NATIONAL SCIENCE FOUNDATION

Special Emphasis Panel; Notice of Meeting

In accordance with the Federal Advisory Committee Act (Pub. L. 92–463, as amended), the National Science Foundation announces the following meeting.

Name: Special Emphasis Panel in Physics (1208).

Date and Time: June 4–5, 1998 from 8:00 am to 5:00 pm.

Place: University of Rochester, River Campus, B&L Building, Rochester, NY 14627.

Type of Meeting: Closed.

Contact Person: Dr. Barry Schneider, Program Director for Theoretical Physics, National Science Foundation, 4201 Wilson Blvd., Arlington, VA 22230. Telephone: (703) 306–1808.

Purpose of Meeting: To provide advice and recommendations concerning further NSF support of the Center for Theoretical and Computational Research in Optical Science (CTR) at the University of Rochester.

Agenda: To review and evaluate the progress and future plans of the Rochester Theory Center.

Reason For Closing: The proposals being reviewed include information of a proprietary or confidential nature, including technical information; information on personnel and proprietary date for present and future subcontracts. These matters are exempt under 5 U.S.C. 552b(c), (4) and (6) of the Government in the Sunshine Act.

Dated: May 11, 1998.

M. Rebecca Winkler,

Committee Management Officer.

[FR Doc. 98–12868 Filed 5–13–98; 8:45 am]

BILLING CODE 7555–01–M

NUCLEAR REGULATORY COMMISSION

[Docket No. 50–482]

Wolf Creek Nuclear Operating Corporation; 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–42, issued to Wolf Creek Nuclear Operating Corporation (the licensee), for operation of the Wolf Creek Nuclear Generating Station, located in Coffee County, Kansas .

The proposed amendment would add a new action statement to Technical Specification 3/4.3.2, Table 3.3–3, Functional Unit 7.b., Refueling Water Storage Tank Level—Low-Low Coincident with Safety Injection.

On May 5, 1998, Wolf Creek Nuclear Operating Corporation (WCNOC) control room personnel were reviewing the technical specifications associated with the refueling water storage tank (RWST) level, instrumentation and the performance of surveillance procedure, STS IC–201, ''Analog Channel Operational Test 7300 Process Instrumentation Protection Set 1 (Red).'' During that review, control room personnel identified that when the RWST level channel is taken into the test position, the channel is actually put in a tripped condition. However, the associated Technical Specification Action Statement (TS 3.3–2, Functional Unit 7.b, Action 16) for an inoperable channel indicates that the inoperable channel must be placed in the bypass condition. There is no time limit allowance for placing an inoperable channel in the bypass condition associated with Action 16. Since this surveillance would render the channel inoperable, and there is no way of performing the surveillance with the channel in the bypass condition, WCNOC personnel determined that a technical specification amendment would be needed to allow the surveillance test to be completed.

The RWST level instrumentation analog channel operational test (STS IC–201) was last performed on February 5, 1998. The surveillance is required by Technical Specification Surveillance Requirement 4.3.2.1 to be performed on a quarterly basis. Taking into account the extra 25 percent allowance from Technical Specification 4.0.2, this surveillance would go overdue, rendering the channel inoperable, on May 31, 1998. The first surveillance test (STS IC–202) for an RWST level channel would go overdue on May 29, 1998, and another channel surveillance test (STS IC–203) will go overdue on May 30, 1998. With two channels being inoperable, entry into Technical Specification 3.0.3 would be required, forcing shutdown of Wolf Creek Generating Station (WCGS). The time between initial discovery of this event (May 5, 1998) and the date when a forced shutdown of WCGS (May 30, 1998) is less than 30 days; therefore, there is not enough time for normal processing of an amendment.

WCNOC believes that, given the circumstances surrounding the discovery of this event and the complexity of the instrumentation function, WCNOC has made a best effort to submit a timely application for this amendment. WCNOC has not delayed any actions in order to create the need for exigency and therefore take advantage of the procedure described in 10 CFR 50.91 for exigent amendments. WCNOC believes that this exigent amendment is unavoidable and meets the criterion of 10 CFR 50.91(a)(6) for an exigent request.

The staff finds the licensee acted in a timely manner, the licensee has not abused the exigent provisions and there is not sufficient time to process this amendment request in the routine manner as described in 10 CFR 50.91 without causing an unnecessary plant shutdown.

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.

Pursuant to 10 CFR 50.91(a)(6) for amendments to be granted under exigent circumstances, the NRC staff must determine 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 new Action Statement 30 for Functional Unit 7.b. of Table 3.3–3, Automatic Switchover to Containment Sump or RWST Level Low-Low Coincident with Safety Injection, reflects the current plant design and testing practices. As discussed in License Amendment No. 43 and associated submittals, the increase in allowed outage time was evaluated and the associated unavailability and risk was shown to be equivalent to, or less than, that of other functional units evaluated in WCAP–10271, Supplement 2, Revision 1. The proposed change does not change any previously evaluated accident and therefore does not involve an increase in the probability or 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.

The proposed change will not result in physical alteration to any plant system nor will there be a change in the method by which any safety-related plant system performs its safety function. The proposed change does not alter the functioning of the Engineered Safety Features Actuation System (ESFAS) or change the manner in which the ESFAS provides plant protection. Therefore, there is no 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.

The proposed change does not alter any safety limits, limiting safety system settings, or limiting conditions for operation. The proposed change will not involve a significant reduction in any 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 by 4:30 p.m. eastern time on May 28, 1998 will be considered in making any final determination.

Normally, the Commission will not issue the amendment until the expiration of the 14-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 14-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. 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 and Directives Branch, Division of Administrative 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 6D59, 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 June 15, 1998, 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 rooms located at the Emporia State University, William Allen While Library, 1200 Commercial Street, Emporia, Kansas 66801 and at the Washburn University School of Law Library, Topeka, Kansas 66621. 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 a 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 the amendment is issued before the expiration of the 30-day hearing period, the Commission will make a final determination on the issue of no significant hazards consideration. If a hearing is requested, 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: Rulemakings and Adjudications Staff, or may be delivered to the Commission's Public Document Room, the Gelman Building, 2120 L Street, NW., Washington, DC, by the above date. 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, Esq., 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 8, 1998, as supplemented by letter dated May 11, 1998, 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 rooms, located at the Emporia State University, William Allen While Library, 1200 Commercial Street, Emporia, Kansas 66801 and at the Washburn University School of Law Library, Topeka, Kansas 66621.

Dated at Rockville, Maryland, this 11th day of May 1998.

For the Nuclear Regulatory Commission.

Kristine M. Thomas,

Project Manager, Project Directorate IV–2, Division of Reactor Projects—III/IV, Office of Nuclear Reactor Regulation.

[FR Doc. 98–12965 Filed 5–13–98; 8:45 am]

BILLING CODE 7590–01–P

RAILROAD RETIREMENT BOARD

Proposed Collection; Comment Request

SUMMARY: In accordance with the requirement of Section 3506 (c)(2)(A) of the Paperwork Reduction Act of 1995 which provides opportunity for public comment on new or revised data collections, the Railroad Retirement Board (RRB) will publish periodic summaries of proposed data collections.

Comments are invited on: (a) Whether the proposed information collection is necessary for the proper performance of the functions of the agency, including whether the information has practical utility; (b) the accuracy of the RRB's estimate of the burden of the collection of the information; (c) ways to enhance the quality, utility, and clarity of the information to be collected; and (d) ways to minimize the burden related to the collection of information on respondents, including the use of automated collection techniques or other forms of information technology.

Title and purpose of information collection: Railroad Service and Compensation Reports; OMB 3220–0008 Under Section 6 of the Railroad Unemployment Insurance Act (RUIA) and Section 9 of the Railroad Retirement (Act (RRA), the Railroad Retirement Board (RRB) maintains for each railroad employee a record of compensation paid to that employee by all railroad employers for whom the employee worked after 1936. This record, which is used by the RRB to determine eligibility for, and amount of, benefits due under the laws it administers, is conclusive as to the amount of compensation paid to an employee during such period(s) covered by the report(s) of the compensation by the employee's railroad employer(s), except in cases when an employee files a protests pertaining to his or her reported compensation within the statute of limitations cited in Section 6 of the RRA and Section 9 of the RRA.

To enable the RRB to establish and maintain the record of compensation, employers are required to file with the RRB, in such manner and form and at such times as the RRB prescribes, reports of compensation of employees. The information reporting requirements are prescribed in 20 CFR 209.6. The RRB utilizes Form BA–3a, Annual Report of Compensation and Form BA–4, Report of Creditable Compensation Adjustments, to secure the required information from railroad employees. Employers have the option of submitting the reports on the aforementioned forms, or, in like format, on magnetic tape, tape cartridges or PC diskettes as outlines in the RRB's Reporting Instructions to Employers. Submission of the reports is mandatory. One response is required of each respondent. No changes are proposed to Form BA–3a or BA–4.

The completion time for Form BA–3a is estimated oat 85 hours per response. The completion time for Form BA–4 is estimated at 60 minutes per response.

Additional Information or Comments: To request more information or to obtain a copy of the information collection justification, forms, and/or supporting material, please call the RRB Clearance Officer at (312) 751–3363. Comments regarding the information collection should be addressed to Ronald J. Hodapp, Railroad Retirement Board, 844 N. Rush Street, Chicago, Illinois 60611–2092. Written comments should be received within 60 days of this notice.

Chuck Mierzwa,

Clearance Officer.

[FR Doc. 98–12765 Filed 5–13–98; 8:45 am]

BILLING CODE 7905–01–M

SECURITIES AND EXCHANGE COMMISSION

[Investment Company Act Release No. 23175; 812–11096]

Pax World Fund, Incorporated, et al.; Notice of Application

May 7, 1998.

AGENCY: Securities and Exchange Commission (''Commission'').

ACTION: Notice of application for an order under sections 12(d)(1)(J) of the Investment Company Act of 1940 (the ''Act'') for an exemption from section 12(d)(1) (A) and (B) of the Act, under sections 6(c) and 17(b) of the Act for an exemption from section 17(a) of the Act, and under section 17(d) of the Act and rule 17d–1 under the Act.

SUMMARY OF APPLICATION: The requested order would permit certain registered open-end management investment companies to invest excess cash in an affiliated money market fund.

APPLICANTS: Pax World Fund, Incorporated (''PWF''), Pax World Growth Fund, Inc. (''PWGF''), Pax World Money Market Fund, Inc. (''PWMMF''), and Pax World Management Corp. (''PWMC'').

FILING DATES: The application was filed on April 2, 1998. Applicants have agreed to file an amendment during the notice period, the substance of which is reflected in this notice.

HEARING OR NOTIFICATION OF HEARING: An order granting the application will be issued unless the Commission orders a hearing. Interested persons may request a hearing by writing to the Commission's Secretary and serving applicants with a copy of the request, personally or by mail. Hearing requests should be received by the Commission by 5:30 p.m. on June 1, 1998, and should be accompanied by proof of service on applicants, in the form of an affidavit or, for lawyers, a certificate of service. Hearing requests should state the nature of the writer's interest, the reason for the request, and the issues contested. Persons who wish to be notified of a hearing may request notification by writing to the Commission's Secretary.

ADDRESSES: Secretary, Securities and Exchange Commission, 450 Fifth Street, N.W., Washington, D.C. 20549. Applicants, 222 State Street, Portsmouth, NH 03801–3853.

FOR FURTHER INFORMATION CONTACT: Kathleen L. Knisely, Staff Attorney, at (202) 942–0517, or George J. Zornada, Branch Chief, at (202) 942–0564 (Division of Investment Management, Office of Investment Company Regulation).

SUPPLEMENTARY INFORMATION: The following is a summary of the application. The complete application may be obtained for a fee at the Commission's Public Reference Branch, 450 Fifth Street, N.W., Washington, D.C. 20459 (tel. 202–942–8090).

Applicants' Representations

1. PWF and PWGF are open-end management investment companies registered under the Act and organized as Delaware corporations. PWMC, a Delaware corporation, serves as the investment adviser to PWF and PWGF. H.G. Wellington Capital Management (''HGW'') serves as investment sub-adviser to PGWF. HGW and PWMC are registered under the Investment Advisers Act of 1940 (''Advisers Act'').

2. PWMMF is an open-end management investment company registered under the Act and organized as a Maryland corporation. PWMMF seeks to maintain a stable net asset value and is subject to rule 2a–7 under the Act. PWMC serves as investment adviser to PWMMF. Reich & Tang Asset Management, L.P. (''R&T'') serves as investment sub-adviser to PWMMF. R&T is registered under the Advisers Act. (PWMC, HGW, and R&T, collectively, the ''Investment Advisers'').

3. PWF and PWGF have, or may be expected to have, uninvested cash (''Uninvested Cash'') held by their custodian. Uninvested Cash may result from a variety of sources, including dividends or interest received on portfolio securities, unsettled securities transactions, reserves held for investment strategy purposes, scheduled maturity of investments, liquidation of investment securities to meet anticipated redemptions, dividend payments, or new monies received from investors. Currently, PWF and PWGF may invest Uninvested Cash directly in individual short-term money market instruments.

4. PWF and PWGF (the ''Investing Funds'') wish to have the flexibility to invest their Uninvested Cash in PWMMF.[1] Any investment of Uninvested Cash in shares of PWMMF will be in accordance with each Investing Fund's investment restrictions and will be consistent with each Investing Fund's policies as set forth in its prospectuses and statements of additional information. Applicants believe that the proposed transactions may reduce transaction costs, create more liquidity, increase returns, and diversify holdings.

Applicants' Legal Analysis

1. Section 12(d)(1)(A) of the Act provides that no registered investment company may acquire securities of another investment company if such securities represent more than 3% of the acquired company's outstanding voting stock, more than 5% of the acquiring company's total assets, or if such securities, together with the securities of other acquired investment companies, represent more than 10% of the acquiring company's outstanding total assets. Section 12(d)(1)(B) of the Act provides that no registered open-end investment company may sell its securities to another investment company if the sale will cause the acquiring company to own more than 3% of the acquired company's voting stock, or if the sale will cause more than 10% of the acquired company's voting stock to be owned by the investment company.

2. Section 12(d)(1)(J) of the Act provides that the Commission may exempt any person, security, or transaction (or classes thereof) from any provision of section 12(d)(1) if and to the extent that such exemption is consistent with the public interest and the protection of investors.

3. Applicants request relief under section 12(d)(1)(J) to permit the Investing Funds to use Uninvested Cash to acquire shares of PWMMF in excess of the percentage limitations in section 12(d)(1)(A), provided however, that in all cases the Investing Fund's aggregate investment of Uninvested Cash in shares of PWMMF will not exceed 25% of the Investing Fund's total assets at any time. Applicants also request relief to permit PWMMF to sell its securities to an Investing Fund in excess of the percentage limitations in section 12(d)(1)(B). Applicants represent that PWMMF will not acquire securities of any other investment company in excess of the limitation contained in section 12(d)(1)(A) of the Act.

4. Applicants believe that the proposed arrangement does not result in the abuses that sections 12(d)(1)(A) and (B) were intended to prevent. Applicants represent that the proposed arrangement will not result in an inappropriate layering of fees because shares of PWMMF sold to the Investing Funds will not be subject to a sales load, redemption fee, asset-based distribution fee or service fee. In addition, the Investment Advisers will waive their investment advisory fees for each Investing Fund in an amount that offsets the amount of the advisory fees of PWMMF incurred by the Investing Fund.

5. Section 17(a) of the Act makes it unlawful for any affiliated person of a registered investment company, acting as principal, to sell or purchase any security to or from the company. Section 2(a)(3) of the Act defines an affiliated person of an investment company to include any investment adviser to the investment company and any person directly or indirectly controlling, controlled by, or under common control with the investment adviser. The Investing Funds and PWMMF share a common investment adviser and thus may be deemed to be under common control. As a result, section 17(a) would prohibit the sale of the shares of PWMMF to the Investing Funds, and the redemption of the shares by PWMMF.

6. Section 17(b) of the Act authorizes the Commission to exempt a transaction from section 17(a) of the Act if the terms of the proposed transaction, including the consideration to be paid or received, are reasonable and fair and do not involve overreaching on the part of any person concerned, the proposed transaction is consistent with the policy of each investment company concerned, and with the general purposes of the Act.

7. Section 6(c) of the Act permits the Commission to exempt persons or transactions from any provision of the Act, if the exemption is necessary or appropriate in the public interest and consistent with the protection of investors and the purposes fairly intended by the policy and provisions of the Act.

8. Applicants submit that their request for relief satisfies the standards in sections 17(b) and 6(c). Applicants state that the Investing Funds will retain their ability to invest Uninvested Cash directly in money market instruments as authorized by their respective investment objectives and policies, if they believe they can obtain a higher rate of return, or for any other reason. Similarly, PWMMF has the right to discontinue selling shares to any of the Investing Funds if PWMMF's board of directors determines that such sale would adversely affect its portfolio management and operations. In addition, applicants note that shares of PWMMF will be purchased and redeemed at their net asset value, the same consideration paid and received for these shares by any other shareholder.

9. Section 17(d) of the Act and rule 17d–1 under the Act prohibit an affiliated person of an investment company, acting as principal, from participating or effecting any transaction in connection with any joint enterprise or joint arrangement in which the investment company participates. Applicants believe that each Investing Fund, by participating in the proposed transactions, and each Investment Adviser of an Investing Fund, by managing the assets of the Investing Funds and PWMMF, could be deemed to be participating in a joint arrangement within the meaning of section 17(d) and rule 17d–1 under the Act.

10. In considering whether to grant an exemption under rule 17d–1, the Commission considers whether the investment company's participation in such joint enterprise is consistent with the provisions, policies, and purposes of the Act, and the extent to which such participation is on a basis different from or less advantageous than that of other participants. Applicants submit that the Funds will participate in the proposed transactions on a basis not different from or less advantageous than that of any other participant and that the transactions will be consistent with the Act.

Applicants' Conditions

Applicants agree that any order granting the requested relief shall be subject to the following conditions:

1. Shares of PWMMF sold to and redeemed by the Investing Funds will not be subject to a sales load, redemption fee, distribution fee under a plan adopted in accordance with rule 12b–1 under the Act, or service fee (as defined in rule 2830(b)(9) of the NASD's Conduct Rules).

2. The Investment Advisers will waive their advisory fee for each Investing Fund in an amount that offsets the amount of the advisory fees of PWMMF incurred by the Investing Fund.

3. Each Investing Fund will invest Uninvested Cash in, and hold shares of, PWMMF only to the extent that the Investing Fund's aggregate investment in PWMMF does not exceed 25% of the Investing Fund's total assets. For purposes of this limitation, each Investing Fund or series thereof will be treated as a separate investment company.

4. Investment in shares of PWMMF will be in accordance with each Investing Fund's respective socially responsible criteria and investment restrictions, if any, and will be consistent with each Investing Fund's policies as set forth in its prospectuses and statements of additional information.

5. Each Investing Fund and any future fund that may rely on the order requested hereunder will be advised by PWMC or an entity controlling, controlled by, or under common control with PWMC.

6. PWMMF shall not acquire securities of any other investment company in excess of the limits contained in section 12(d)(1)(A) of the Act.

For the Commission, by the Division of Investment Management, under delegated authority.

Margaret H. McFarland,

Deputy Secretary.

[FR Doc. 98–12810 Filed 5–13–98; 8:45 am]

BILLING CODE 8010–01–M

SECURITIES AND EXCHANGE COMMISISON

Issuer Delisting; Notice of Application To Withdraw From Listing and Registration; (Rogers Cantel Inc., 10½% Senior Secured Notes Due 2006; 9⅜% Senior Secured Debentures Due 2008; 9¾ Senior Secured Debentures Due 2016) File No. 1–14393

May 8, 1998.

Rogers Cantel Inc. (''Company'') has filed an application with the Securities and Exchange Commission (''Commission''), pursuant to Section 12(d) of the Securities Exchange Act of 1934 (''Exchange Act'') and Rule 12d2–2(d) promulgated thereunder, to withdraw the above specified securities (''Securities'') [1] from listing and registration on the New York Stock Exchange, Inc. (''NYSE'' or ''Exchange'').

The reasons cited in the application for withdrawing the Securities from listing and registration include the following:

The Securities were issued pursuant to three indentures, each dated May 30, 1996, and qualified under the Trust Indenture Act of 1939, between the Company and The Chase Manhattan Bank (formerly Chemical Bank) as U.S. Trustee and CIBC Mellon Trust Company (formerly The R–M Trust Company) as Canadian Trustee and were sold in May 1996 pursuant to the Registration Statement filed with the Commission pursuant to the Securities Act of 1933. The Securities are registered pursuant to Section 12(b) of the Exchange Act and are listed for trading on the NYSE. There are currently Cdn$160,000,000 of the 2006 Notes, US$510,000,000 of the 2008 Debentures; and US$175,000,000 of the

[1] When referred to individually, the Securities are identified by their due dates (*i.e.*, the ''2006 Notes'', the ''2008 Debentures'', and the ''2016 Debentures'').

2016 Debentures issued and outstanding for trading on the NYSE.

The Company believes that this application to withdraw the Securities from listing and registration on the NYSE under Section 12(b) of the Exchange Act should be granted for the following reasons:

1. The Securities are held by a small number of holders. As of each of January 1, 1997, and October 3, 1997, there were eight registered holders of the 2006 Notes, one registered holder of the 2008 Debentures, and one registered holder of the 2016 Debentures. Moreover, there are fewer than 300 holders of record in aggregate of the Securities and of all other registered securities of the Company.

2. There has been no reported trading in the Securities. No trading in the Securities has been reported on the NYSE since their original issuance in May 1996, and, because of the small number of holders, the Company believes that it is unlikely that there will be any significant public interest in trading the Securities on the NYSE in the future.

Any interested person may, on or before May 29, 1998, submit by letter to the Secretary of the Securities and Exchange Commission, 450 Fifth Street, NW., Washington, DC 20549, facts bearing upon whether the application has been made in accordance with the rules of the Exchange and what terms, if any, should be imposed by the Commission for the protection of investors. The Commission, based on the information submitted to it, will issue an order granting the application after the date mentioned above, unless the Commission determines to order a hearing on the matter.

For the Commission, by the Division of Market Regulation, pursuant to delegated authority.

Jonathan G. Katz,

Secretary.

[FR Doc. 98–12856 Filed 5–13–98; 8:45 am]

BILLING CODE 8010–01–M

SECURITIES AND EXCHANGE COMMISSION

Issuer Delisting; Notice of Application To Withdraw From Listing and Registration; (Teletouch Communications, Inc., Common Stock, $.001 Par Value; Class A Redeemable Common Stock Purchase Warrants) File No. 1–13436

May 8, 1998.

Teletouch Communications, Inc. (''Company'') has filed an application with the Securities and Exchange Commission (''Commission''), pursuant to Section 12(d) of the Securities Exchange Act of 1934 (''Act'') and Rule 12d2–2(d) promulgated thereunder, to withdraw the above specified securities (''Securities'') from listing and registration on the Boston Stock Exchange, Inc. (''BSE'' or ''Exchange'').

The reasons cited in the application for withdrawing the Securities form listing and registration include the following:

The Company's Securities have been listed for trading on the BSE pursuant to a Registration Statement on Form 8–A which became effective on December 23, 1994. Subsequently, pursuant to a Registration Statement on Form 8–A, at the opening of business on April 6, 1998, trading in the Securities commenced on the American Stock Exchange, Inc. (''Amex'').

The Company has complied with all rules and requirements of the BSE relating to the withdrawal of its Securities from listing and registration on the BSE, setting forth in detail to the BSE the reasons for and facts supporting such proposed withdrawal. In making the decision to withdraw its Securities from listing and registration on the BSE, the Company considered the direct and indirect costs and expenses attendant on maintaining the dual listing of its Securities on the Amex and the BSE. The Company does not see any particular advantage in the dual trading of its Securities and believes that dual listing would fragment the market for its Securities.

By letter dated April 24, 1998, from the Company's counsel to the BSE, the Company set forth its reasons for seeking withdrawal therefrom. By letter dated April 24, 1998, the BSE informed the Company that it has no objection to the withdrawal of the Company's Securities from listing and registration on the BSE.

By reason of Section 12(b) of the Act and the rules and regulations thereunder, the company shall continue to be obligated to file reports under Section 13 of the Act with the Commission and the Amex.

Any interested person may, on or before May 29, 1998, submit by letter to the Secretary of the Securities and Exchange Commission, 450 Fifth Street, N.W., Washington, D.C. 20549, facts bearing upon whether the application has been made in accordance with the rules of the Exchange and what terms, if any, should be imposed by the Commission for the protection of investors. The Commission, based on the information submitted to it, will issue an order granting the application after the date mentioned above, unless the Commission determines to order a hearing on the matter.

For the Commission, by the Division of Market Regulation, pursuant to delegated authority.

Jonathan G. Katz,

Secretary.

[FR Doc. 98–12858 Filed 5–13–98; 8:45 am]

BILLING CODE 8010–01–M

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–39976; File No. SR–PCX–98–22]

Self-Regulatory Organizations; Notice of Filing and Immediate Effectiveness of Proposed Rule Change by the Pacific Exchange, Inc., Relating to Rule Changes for Specialist Performance Evaluations

May 8, 1998.

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 April 29, 1998,[1] the Pacific Exchange Incorporated (''PCX'' 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 Exchange has designated the proposed rule change as constituting a ''non-controversial'' rule change under paragraph (e)(6) of Rule 19b–4 under the Act which renders the proposal effective upon receipt of this filing by the Commission.[2] 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

PCX is proposing to modify Rule 5.36(d), Commentary .03 and Rule 5.37 to codify previously approved changes to the Exchange's Specialist Evaluation

[1] On May 5, 1998, the Exchange filed Amendment No. 1, technical in nature, to the proposed rule change, the substance of which is incorporated into the notice. *See* letter from Jeffrey S. Norris, Manager, Regulatory Development and Oversight, PCX, to Sharon M. Lawson, Senior Special Counsel, Market Regulation, Commission, dated May 4, 1998 (''Amendment No. 1'').

[2] The Exchange has represented that this proposed rule change: (i) will not significantly affect the protection of investors or the public interest; (ii) will not impose any significant burden on competition; and (iii) will not become operative for 30 days after the date of this filing. The Exchange also has provided at least five business days' notice to the Commission of its intent to file this proposed rule change, as required by Rule 19b–4(e)(6) under the Act.

Program and to modify language regarding the imposition of restrictions and the procedures on certain specialists. The text of the proposed rule change is available at the Office of the Secretary, PCX, and at the Commission.

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

On December 22, 1997, the Commission approved a one-year extension of the Exchange's pilot program for the evaluation of Equity specialists.[3] The filing established an overall score and individual passing scores for specialists, replaced the ''Bettering the Quote'' criterion with ''Price Improvement,'' and lowered the weighting of the ''Specialist Evaluation Questionnaire'' criterion from 15% to 10% so that Price Improvement could be given a weight of 10%. The Commission stated in footnote 14 of the Approval Release that the PCX intended to file changes to its rules to reflect these modifications. This filing would codify those changes.

In addition, the proposed rule change clarifies the language regarding the applicability of restrictions on specialists who fail to obtain an overall or individual passing score minimum. The following are examples of the language changes: mitigating circumstances language was taken out of the rule and language was added to indicate that decisions will now be done on a case-by-case basis; the language regarding the formal and informal meeting process was made clear; and other technical changes were made. In addition, rule language that had made it mandatory for the Equity Allocation Committee (''EAC'') to apply restrictions to specialists in the bottom 10% was eliminated because the Exchange believes it was necessary due to the other changes to the Specialist Evaluation Performance Program establishing an overall passing score and individual passing scores. However, the Exchange kept the discretion to look at specialists that ranked in the bottom 10% in order to have the ability to review specialists that continually fall in the bottom 10% even though they passed the other standards. Changes were made that now give discretion to the Equity Allocation Committee to decide: (1) whether to meet with the specialists who are ranked in the bottom 10% of their respective trading floors; and (2) whether restrictions should be imposed if the EAC does meet with the specialists in the bottom 10%.

The Exchange intends to file with the Commission by October 30, 1998, a proposal to extend the pilot beyond January 1, 1999, as well as a report describing its experience with the pilot.

2. Statutory Basis

The Exchange believes the proposed rule change is consistent with Section 6(b)[4] of the Act, in general, and furthers the objectives of Section 6(b)(5) of the Act,[5] in particular, in that it is designated to promote just and equitable principles of trade.

B. Self-Regulatory Organization's Statement on Burden on Competition

The Exchange does not believe that the proposed rule change will impose any burden on competition.

C. Self-Regulatory Organization's Statement on Comments on the Proposed Rule Change Received From Members, Participants, or Others

Written comments on the proposed rule change were neither solicited nor received.

III. Date of Effectiveness of the Proposed Rule Change and Timing for Commission Action

This proposed rule change has been filed by the Exchange as a ''noncontroversial'' rule change pursuant to paragraph (e)(6) of Rule 19b–4.[6] Consequently, because the proposed rule change: (1) does not significantly affect the protection of investors or the public interest; (2) does not impose any significant burden on competition; and (3) does not become operative until 30 days after the date of filing, and the Exchange provided the Commission written notice of its intent to file the proposed rule change at least five days prior to the filing date, it has become effective pursuant to Section 19(b)(3)(A) of the Act[7] and subpararaph (e)(6) of Rule 19b–4 thereunder.

At any time within 60 days of the filing of such 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, including whether the proposed rule change is consistent with the Act. 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 in the Commission's Public Reference Room. 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–PCX–98–22 and should be submitted by June 4, 1998.

For the Commission, by the Division of Market Regulation, pursuant to delegated authority.[8]

Margaret H. McFarland,

Deputy Secretary.

[FR Doc. 98–12857 Filed 5–13–98; 8:45 am]

BILLING CODE 8010–01–M

[3] *See* Securities Exchange Act Release No. 39477 (December 22, 1997), 62 FR 68334 (December 30, 1997) (''Approval Release'').

[4] 15 U.S.C. 78f(b).

[5] 15 U.S.C. 78f(b)(5).

[6] 17 CFR 240.19b–4(e)(6).

[7] 15 U.S.C. 78s(b)(3)(A).

[8] 17 CFR 200.30–3(a)(12).

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–39975; File No. SR-PHLX-98–03]

Self-Regulatory Organizations; Order Approving Proposed Rule Change by the Philadelphia Stock Exchange, Inc., Relating to Trading Disputes and Floor Official Rulings

May 7, 1998.

I. Introduction

Pursuant to Section 19(b)(1) of the Securities Exchange Act of 1934 (''Act''),[1] and Rule 19b–4 thereunder,[2] the Philadelphia Stock Exchange, Inc. (''PHLX'' or ''Exchange'') filed with the Securities and Exchange Commission (''SEC'' or ''Commission'') a proposal to replace the current text of PHLX Rule 124, ''Disputes,'' with new text. In the filing, the PHLX also proposed to adopt Floor Procedure Advice (''Advice'') F–27, ''Floor Official Rulings—Options'' and F–27, ''Floor Official Rulings—Equity'' (together, the ''Advices''), which incorporate and expand upon the provisions of PHLX Rule 124. On March 3, 1998, the PHLX amended its proposal.[3] Notice of the proposed rule change and Amendment No. 1 to the proposed rule change were published for comment in the **Federal Register** on March 17, 1998.[4] No comments were received regarding the proposal. This order approves the proposed rule change, as amended.

II. Description of the Proposal

The PHLX proposes to codify its current procedures regarding floor officials' rulings by replacing the text of PHLX Rule 124[5] with new text and adopting two Advices. The Advices will be published in the PHLX's Floor Procedure Advice handbook. According to the PHLX, the proposal will incorporate expressly into the PHLX's rules the Exchange's current procedures for resolving trading disputes and the role of floor officials in resolving trading disputes.

New PHLX Rule 124 also acknowledges that, in addition to resolving trading disputes, floor officials may issue citations for violations of Floor Procedure Advices pursuant to PHLX Rule 970, ''Floor Procedure Advices: Violations, Penalties, and Procedures,'' and for violations of the PHLX's order and decorum regulations, pursuant to PHLX Rule 60, ''Assessments for Breach of Regulations.'' The PHLX's proposal contains two provisions applicable to all rulings by floor officials. First, the Advices set forth a conflict of interest provision which states that a floor official should not render a decision or authorize a citation where the floor official was involved in or affected by the dispute, or in any situation where the floor official is not able to objectively and fairly render a decision. Second, PHLX Rule 124(b) states that all rulings by floor officials are effective immediately and must be complied with promptly. Failure to comply promptly with a ruling concerning a trading dispute may result in a referral to the PHLX's Business Conduct Committee (''BCC''). Failure to comply with a floor official's ruling issued pursuant to PHLX Rule 60 or PHLX Rule 970 may result in an additional violation of those rules. For example, a first violation for disorderly conduct that does not cease promptly after the floor official issues the violation will result in a second violation, also for disorderly conduct.

The remaining provisions of new PHLX Rule 124 concern trading disputes. Specifically, new PHLX Rule 124(a) states that disputes occurring on and relating to the trading floor, if not settled by agreement between the interested members, shall be settled, if practicable, by vote of the members knowing of the transaction; if not so settled, the disputes shall be settled by a floor official summoned to the trading crowd. In resolving trading disputes, floor officials may institute the course of action deemed to be most fair to all parties under the circumstances at the time. A floor official may direct the execution of an order on the floor or adjust the transaction terms or participants to an executed order. In addition, two floor officials may nullify a transaction if they determine that the transaction violated certain enumerated PHLX rules.[6] The Advices state that floor officials need not render decisions unless the request for a ruling is made within a reasonable period of time.

PHLX Rule 124(c) identifies the procedures for review of floor officials' rulings. Specifically, PHLX Rule 124(c) states that floor officials' rulings issued under the PHLX's order and decorum regulations are reviewable pursuant to PHLX Rule 60, and that floor officials' rulings issued under Floor Procedure Advices are reviewable pursuant to PHLX Rule 970. Floor officials' rulings in connection with trading disputes are reviewable pursuant to the procedures established in new PHLX Rule 124(d).

Under PHLX Rule 124(d), floor officials' rulings for options and FCO trading are reviewable by a minimum of three members of the applicable Subcommittee on Rules and Rulings or by the Chairperson of the applicable standing committee[7] (or his or her designee) if three Subcommittee members cannot be convened promptly. With respect to equity trading, floor officials' rulings are reviewable by a minimum of three members of the Floor Procedure Committee, or the Chairperson of the Floor Procedure Committee (or his or her designee) if three members cannot be convened promptly. This will be the designated review panel for floor officials' rulings.

The Advices state that a member must submit a request for review of a floor official's ruling to the Director of the PHLX's Market Surveillance Department (or his or her designee) within 15 minutes from the time the contested ruling was rendered.[8] Floor officials'

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[1] 15 U.S.C. 78s(b)(1).

[2] 17 CFR 240.19b–4.

[3] *See* Letter from Linda S. Christie, Counsel, PHLX, to Yvonne Fraticelli, Attorney, Division of Market Regulation (''Division''), Commission, dated March 3, 1998 (''Amendment No. 1''). Amendment No. 1 revises the text of PHLX Rule 124 to make the rule consistent with the Advices. Specifically, Amendment No. 1 modifies the text of PHLX Rule 124 to indicate that two options floor officials (rather than one floor official) may nullify a transaction if they determine that the transaction violated any of the following PHLX Rules: 1014, ''Obligations and Restrictions Applicable to Specialists and ROTs;'' 1015, ''Quotation Guarantees;'' 1017, ''Priority and Parity at Openings in Options;'' 1033, ''Bids and Offers—Premium;'' or 1080, ''PHLX Automated Options Market (AUTOM) and Automatic Execution System (AUTO-X).'' In addition, Amendment No. 1 indicates that two equity floor officials (rather than one floor official) may nullify a transaction if they determine that the transaction violated any of the following PHLX Rules: 110, ''Bids and Offers—Precedence;'' 111. ''Bids and Offers Binding;'' 118. ''Bids and Offers Outside Best Bid and Offer;'' 119. ''Precedence of Highest Bid;'' 120, ''Precedence of Offers at Same Price;'' 126, '''Crossing' Orders;'' 203, ''Agreement of Specialist;'' 218, ''Customer's Order Receives Priority;'' 229, ''Philadelphia Stock Exchange Automated Communication and Execution System (PACE);'' 232, ''Handling Orders When the Primary Market is Not Open for Free Trading (EXP, PPS, GTX Orders);'' or 455, ''Short Sales.''

[4] *See* Securities Exchange Act Release No. 39741 (March 11, 1998), 63 FR 13087.

[5] Currently, PHLX Rule 124 states that ''[d]isputes arising on bids or offers, if not settled by agreement between the members interested, shall be settled, if practicable, by vote of the members knowing of the transaction in question; if not so settled, they shall be settled by the Committee.'' The ''Committee'' is the applicable floor standing committee. The applicable standing committees are the Floor Procedure Committee for the equity floor; the Options Committee for the equity option floor and the index option floor; and the Foreign Currency Options (''FCO'') Committee for the FCO floor.

[6] *See* Amendment No. 1, *supra* note 3.

[7] *See* note 5, *supra*, for a description of the jurisdiction of the standing committee.

[8] The review panel will try to meet as soon as practicable after notice of a request for a review of a floor official's rulings. The PHLX notes, however, that this time frame will apply to the extent practicable under the circumstances, particularly if

rulings may be sustained, overturned, or modified by a majority vote of the review panel members present.[9] In making the determination, the review panel may consider facts and circumstances not available to the ruling floor official as well as actions taken by the parties in reliance on the floor official's ruling (*e.g.*, cover, hedge, and related trading activity). Decisions of the review panel are final and may be appealed to the PHLX's Board of Governors as a final decision of the standing floor committee pursuant to PHLX By-Law Article XI, ''Appeals.'' The PHLX notes that neither floor officials' rulings or reviews of floor officials' rulings preclude a person from seeking redress through the PHLX's arbitration facilities.[10]

The Advices reiterate the provisions in PHLX Rule 124 and provide additional details regarding the operation of PHLX Rule 124. Among other things, the Advices state that floor officials shall try to be prompt in rendering decisions. However, a floor official may delay rendering a ruling until discovery is completed if the floor official determines that the benefits of further discovery as to the facts and circumstances of the matter under review outweigh the monetary risks of a delayed ruling.

III. Discussion

The Commission finds that the proposed rule change is consistent with the Act and, in particular, with Section 6(b)(5) of the Act, in that the proposed rule change is designed to prevent fraudulent and manipulative acts and practices, to promote just and equitable principles of trade, and, in general, to protect investors and the public interest.[11] According to the PHLX, the proposal codifies the Exchange's existing procedures for resolving trading disputes, including the role and authority of floor officials in resolving trading disputes and the means for appealing floor officials' decisions. By codifying the Exchange's procedures for resolving trading disputes, the Commission believes that the proposal will help to ensure that PHLX members are aware of the PHLX's rules governing the resolution of trading disputes and will facilitate compliance with those rules. In addition, the Commission believes that the trading dispute resolution procedures in PHLX Rule 124 and the Advices will help to ensure that the PHLX's markets function in a fair, orderly, and efficient manner.

PHLX Rule 124(a) allows a member to summon a floor official to settle a dispute on the trading floor if neither the interested members or members with knowledge of the transaction are able to resolve the dispute. The Commission notes that the trading dispute resolution authority granted to floor officials under PHLX Rule 124 and the accompanying Advices is similar to the authority granted to floor officials under the rules of other securities exchanges.[12]

In addition, the Commission believes that several requirements in PHLX Rule 124 and the Advices will provide members and floor officials with guidance concerning the resolution of trading disputes and help to enhance the fairness, accuracy, and integrity of floor officials' decisions. In this regard, PHLX Rule 124(a) and the Advices require a floor official resolving a trading dispute to institute the course of action he or she deems to be most fair to all parties under the circumstances at the time. In addition, the Advices allow a floor official to delay rendering a ruling if the floor official believes that the benefits of further discovery concerning the facts and circumstances of a matter outweigh the monetary risks of a delayed ruling. The Advices also establish a conflict of interest provision applicable to all ruling by floor officials.[13] Specifically, the Advices state that a floor official should not render a decision or authorize a citation when the floor official was involved in or affected by dispute, or in any situation where the floor official is not able to objectively and fairly render a decision.

The Commission believes that the proposal will provide additional clarity to the process of resolving trading disputes by specifying the remedies available to floor officials resolving such disputes. In this regard, PHLX Rule 124(a) and the Advices state that a floor official resolving a trading dispute may direct the execution of an order on the floor or adjust the transaction terms or participants to an executed order. In addition, two floor officials may nullify a transaction if they conclude that the transaction violated any of the PHLX rules enumerated in PHLX Rule 124(a)[14] and in the Advices. The Commission believes that permitting floor officials to nullify transactions only for violations of these enumerated rules will provide guidance to floor officials concerning the circumstances under which it may be appropriate to nullify a trade. In addition, requiring the approval of two floor officials to nullify a transaction will help to ensure that this remedy is used appropriately.[15]

The Commission believes that several provisions in new PHLX Rule 124(b) and in the Advices will facilitate the enforcement of floor officials' rulings. In this regard, PHLX Rule 124(b) and the Advices indicate that all rulings by floor officials are effective immediately and must be complied with promptly. Moreover, PHLX Rule 124(b) and the Advices note that failure to comply with a floor official's ruling in a trading dispute may result in a referral to the PHLX's BCC, and failure to comply with rulings issued pursuant to PHLX Rule 60 or to Floor Procedure Advices may result in the finding of an additional violation of those rules.

PHLX Rule 124 and the Advices also specify the procedures for requesting a ruling from a floor official and for appealing a floor official's ruling in connection with a trading dispute.[16] As noted above, PHLX Rule 124(a) allows a member to summon a floor official to resolve a trading dispute. The Advices state that floor officials need not render a decision unless the request for a ruling was made within a reasonable period of time. In addition, the Advices indicate that a member must submit a request for review of a floor official's ruling to the PHLX's Director of Market Surveillance

convening a review panel proves to be difficult due to the time of day, heavy trading volume, or scheduling conflicts. In addition, the PHLX notes that, in connection with options trading, the obligations to maintain a fair and orderly market or the due diligence requirements of PHLX Rule 1063 may prevail over the obligation of a floor official to provide a ruling or attend a review.

[9] *See* PHLX rule 124(d).

[10] *See* PHLX Rule 950, ''Arbitration.''

[11] *See* 15 U.S.C. 78f(b)(5). In approving this rule change, the Commission has considered the proposal's impact on efficiency, competition, and capital formation. 15 U.S.C. 78c(f).

[12] *See e.g.*, NYSE Rule 75, ''Disputes as to Bids and Offers'' (allowing a floor official to settle disputes concerning bids or offers that are not settled by agreement between the interested members); and Amex Rule 22(c) (allowing a floor official to resolve market disputes submitted to him by members).

[13] As noted above, the conflict of interest provision applies to floor officials' actions pursuant to PHLX Rules 60 and 970, as well as to floor officials' rulings pursuant to PHLX Rule 124.

[14] *See* Amendment No. 1, *supra* note 3.

[15] The Commission notes that the rules of the Chicago Board Options Exchange, Inc. (''CBOE'') also permit two floor officials to nullify a transaction. Specifically, Interpretation and Policy .05 to CBOE Rule 6.20, ''Admission to and Conduct on the Trading Floor,'' allows two floor officials to nullify a transaction or adjust its terms if they determine that the transaction violated any of the following CBOE rules: (1) 6.43 (manner of bidding and offering); (2) 6.45 (priority of bids and offers); (3) 6.46 (transactions outside the book's last quoted range); (4) 6.47 (priority on split price transactions); or (5) 8.51 (trading crowd firm disseminated market quotes).

[16] Floor officials' rulings issued pursuant to the PHLX's order and decorum regulations are reviewable pursuant to PHLX Rule 60; floor officials' rulings issued pursuant to Floor Procedure Advices are reviewable pursuant to PHLX Rule 970. *See* PHLX Rule 124(c).

(or his or her designee) within 15 minutes from the time the contested ruling was rendered.[17] The Commission believes that these provisions will facilitate the prompt resolution of trading disputes while providing members with an adequate opportunity to obtain a ruling from a floor official or to appeal a floor official's ruling. In addition, the Commission notes that these procedures are described in the Advises, which will be readily available to members in the PHLX's Floor Procedure Handbook. Accordingly, the Commission believes that PHLX members will have sufficient notice of the Exchange's procedures for obtaining a ruling from a floor official and appealing a floor official's decision.

Under PHLX Rule 124(d), a review panel, consisting of either three members of the applicable Subcommittee on Rules and Rulings (in the case of options trading) or three members of the Floor Procedure Committee (in the case of equity trading),[18] may sustain, overturn or modify a floor official's ruling. In making its decision, the review panel may consider facts and circumstances not available to the ruling floor official and action taken by the parties in reliance on the floor official's ruling (*e.g.*, cover, hedge, and related trading activity). A member may appeal the review panel's decision to the Exchange's Board of Governors pursuant to PHLX By-law Article XI. The Commission believes that these procedures will provide for prompt and effective review of floor officials' rulings in trading disputes and help to ensure that trading disputes are resolved fairly.

IV. Conclusion

It is therefore ordered, pursuant to Section 19(b)(2) of the Act,[19] that the proposed rule change (SR–PHLX–98–03) is approved.

For the Commission, by the Division of Market Regulation, pursuant to delegated authority.[20]

[17] According to the PHLX, a ''reasonable period of time'' will depend on market and trading floor conditions (*e.g.*, volume, systems functioning, and quotation updating). Floor officials will determine what constitutes a reasonable period of time for requesting a ruling. The PHLX believes that it is necessary to provide floor officials with flexibility in making this determination. Telephone conversation between Linda S. Christie, Counsel, PHLX, and Yvonne Fraticelli, Attorney, Division, Commission, on April 27, 1998.

[18] If three committee members cannot be convened promptly, the Chairperson of the applicable committee, or his or her designee, may review the ruling. *See* PHLX Rule 124(d).

[19] 15 U.S.C. 78s(b)(2).

[20] 17 CFR 200.30–3(a)(12).

Margaret H. McFarland,

Deputy Secretary.

[FR Doc. 98–12809 Filed 5–13–98; 8:45 am]

BILLING CODE 8010–01–M

SOCIAL SECURITY ADMINISTRATION

Agency Information Collection Activities; Submissions for OMB Review

This notice lists information collection packages that have been sent to the Office of Management and Budget (OMB) for clearance, in compliance with Public Law 104–13 effective October 1, 1995, The Paperwork Reduction Act of 1995.

Wage Reports and Pension Information—0960–0547. The information obtained through Regulation OR–418P, found in 20 CFR, section 422.122(b), is used by SSA to identify the requester of pension plan information and to confirm that the individual is entitled to the data we provide. The respondents are requesters of pension plan information.

Number of Respondents: 1,211.

Frequency of Response: 1.

Average Burden Per Response: 30 minutes.

Estimated Annual Burden: 606 hours.

Written comments and recommendations regarding the information collection(s) should be directed within 30 days to the OMB Desk Officer and SSA Reports Clearance Officer at the following addresses:

(OMB) Office of Management and Budget, OIRA, Attn: Laura Oliven, New Executive Office Building, Room 10230, 725 17th St., NW, Washington, D.C. 20503

(SSA) Social Security Administration, DCFAM, Attn: Nicholas E. Tagliareni, 1-A–21 Operations Bldg., 6401 Security Blvd., Baltimore, MD 21235.

To receive a copy of any of the forms or clearance packages, call the SSA Reports Clearance Officer on (410) 965–4125 or write to him at the address listed above.

Dated: May 8, 1998.

Nicholas E. Tagliareni,

Reports Clearance Officer, Social Security Administration.

[FR Doc. 98–12834 Filed 5–13–98; 8:45 am]

BILLING CODE 4190–29–P

DEPARTMENT OF STATE

Office of the Secretary

[Public Notice 2812]

Determination and Certification Under Section 40A of the Arms Export Control Act

Pursuant to Section 40A of the Arms Export Control Act (Pub. L. 90–629), as added by the Antiterrorism and Effective Death Penalty Act of 1996 (Pub. L. 104–132) (22 U.S.C. 2771 *et. seq.*,) and Executive Order 11958, as amended, I hereby determine and certify to the Congress that the following countries are not cooperating fully with United States antiterrorism efforts:

Afghanistan;
Cuba;
Iran;
Iraq;
Libya;
North Korea;
Sudan; and
Syria.

This determination and certification shall be transmitted to the Congress and published in the **Federal Register**.

Dated: May 4, 1998.

Strobe Talbott,

Acting Secretary of State.

[FR Doc. 98–12795 Filed 5–13–98; 8:45 am]

BILLING CODE 4710–10–M

DEPARTMENT OF STATE

Bureau of Oceans and International Environmental and Scientific Affairs

[Public Notice 2813]

Government Activities on International Harmonization of Chemical Classification and Labeling Systems; Public Meeting

AGENCY: Bureau of Oceans and International Environmental and Scientific Affairs (OES), Department of State.

ACTION: Notice of a public meeting regarding Government Activities on International Harmonization of Chemical Classification and Labeling Systems.

SUMMARY: This public meeting will provide an update on current activities related to international harmonization since the previous public meeting, conducted January 23, 1998. (See Department of State Public Notice 2708, on page 1987 of the **Federal Register** of January 13, 1998.) The meeting will also offer interested organizations and individuals the opportunity to provide

information and views for consideration in the development of United States Government policy positions. For more complete information on the harmonization process, please refer to State Department Public Notice 2526, pages 15951–15957 of the **Federal Register** of April 3, 1997.

The meeting will take place from 10 a.m. until noon on June 16 in Room N5437 CD, U.S. Department of Labor, 200 Constitution Avenue NW, Washington, DC. Attendees should use the entrance at C and Third Streets NW. To facilitate entry, please have a picture ID available and/or a U.S. Government building pass if applicable.

FOR FURTHER INFORMATION CONTACT: For further information or to submit written comments or information, please contact Mary Frances Lowe, U.S. Department of State, OES/ENV, Room 4325, 2201 C Street NW, Washington, DC 20520. Phone (202) 736–4660, fax (202) 647–5947. A public docket is also available for review (OSHA docket H-022H.)

SUPPLEMENTARY INFORMATION: The Department of State is announcing a public meeting of the interagency committee concerned with the international harmonization of chemical hazard classification and labeling systems (an effort often referred to as the ''globally harmonized system'' or GHS). The purpose of the meeting is to provide interested groups and individuals with an update on activities since the January 23, 1998, public meeting, a preview of key upcoming international meetings, and an opportunity to submit additional information and comments for consideration in developing U.S. Government positions. Representatives of the following agencies participate in the interagency group: the Department of State, the Environmental Protection Agency, the Department of Transportation, the Occupational Safety and Health Administration, the Consumer Product Safety Commission, the Food and Drug Administration, the Department of Commerce, the Department of Agriculture, the Office of the U.S. Trade Representative, and the National Institute of Environmental Health Sciences.

The Agenda of the public meeting will include:

I. Introduction

2. Reports on recent international meetings

—Meeting of the Organization for Economic Cooperation and Development (OECD) Aquatic Toxicity Working Group, April 20–21, in London, UK.

—Meeting of the OECD Advisory Group on Harmonization of Classification and Labelling, April 22–24, in London, UK. This meeting focused on classification criteria proposals for health and environmental endpoints including skin and eye irritation/corrosion, target organ toxicity, reproductive toxicity, aquatic toxicity, acute toxicity, and the review of an integrated document to be comprised of introductory sections on cross-cutting issues and individual chapters on each covered endpoint. The goal is to have the integrated proposal and other issues resolved as much as possible before a high level OECD meeting, now scheduled for September 3–4, 1998, in Paris, France.

—First meeting of the Inter-Organization Program for the Sound Management of Chemicals (IOMC) Working Group concerning the Implementation of the Globally Harmonised System of Classification and Labelling, May 21–22, in London, UK. This working group is charged with identifying the functions of the institutional ''body'' or organization required to oversee the maintenance and updating of the GHS on an ongoing basis. A background paper prepared by the UK has been circulated and placed in the docket.

3. Preparation for upcoming meetings

—First meeting of the IOMC/International Labour Organisation Working Group for the Harmonization of Chemical Hazard Communication, June 22, in London, UK. This meeting will focus on the elaboration of terms of reference work plan and time table for the hazard communication elements of the GHS.

—IOMC Coordinating Group for the Harmonization of Chemical Classification Systems, June 23–24, London, UK. This group provides overall management direction to the development of the GHS. Among the agenda items is further consideration of a paper clarifying the scope and application of the GHS discussed at the last two Coordinating Group meetings, in June and November, 1997. The original paper, U.S. comments, and a report of the November 1997 meeting are in the public docket. A revised version is expected later this month and will be placed in the docket, along with other papers received for the June 23–24 meeting.

—OECD Working Group on Mixtures, June 25–27, in London, UK. This group is charged with developing harmonized approaches for the classification of mixtures. This will be its second meeting, and participants will be discussing areas for harmonization based on a detailed review document outlining the components of major existing hazard classification systems for mixtures.

—Meeting of the UN Subcommittee of Experts on the Transport of Dangerous Goods, June 29–July 9, in Geneva, Switzerland. The Subcommittee has hosted the working group developing classification criteria proposals for physical hazards and largely completed this work in December 1997. It is also involved in consideration of OECD proposals on acute toxicity classifications, the institutional framework for the ongoing maintenance of the GHS, and hazard communication issues as they relate to goods in transport.

4. Public Comments

5. Concluding Remarks

Interested parties are invited to submit their comments as soon as possible for consideration in the development of U.S. positions for the international meetings listed above, and to present their views orally and/or in writing at the public meeting. Participants in the meeting may also address other topics relating to harmonization of chemical classification and labeling systems and are particularly invited to identify issues of concern to specific sectors that may be affected by the GHS.

All written comments will be placed in the public docket (OSHA docket H–022H). The docket is open from 10 a.m. until 4 p.m., Monday through Friday, and is located at the Department of Labor, Room 2625, Constitution Avenue, NW., Washington, DC (Telephone: 202–219–7894; Fax: 202–219–5046). The public may also consult the docket to review previous Federal Register notices, comments received, Questions and Answers about the GHS, a response to comments on the April 3 **Federal Register** notice, and other relevant documents.

Dated: May 11, 1998.

Michael Metelits,

Director, Office of Environmental Policy, Bureau of Oceans and International Environmental and Scientific Affairs.

[FR Doc. 98–12840 Filed 5–13–98; 8:45 am]

BILLING CODE 4710–09–M

DEPARTMENT OF STATE

[Public Notice #2816]

United States International Telecommunications Advisory Committee; Telecommunication Standardization Sector (ITAC–T) National Committee and Study Group D; Meeting

The Department of State announces that a meeting of the United States International Telecommunications Advisory Committee (ITAC), will be held as follows: Study Group D on Wednesday, May 20, 1998 and the National committee on Monday, June 29 and July 22, 1998, all beginning at 9:30 a.m. and scheduled for all day, in Room 1408 of the Department of State, 22nd and C Streets, NW., Washington, D.C.

The purpose of ITAC is to advise the Department on policy, technical, and operational matters and to provide strategic planning recommendations, with respect to international telecommunication and information issues. The purpose of these meetings is to develop United States positions for upcoming ITU–T meetings dealing with standards activities of the International Telecommunication Union (ITU). In particular, the Study Group D meeting will include preparation for the planned meeting of ITU–T Study Group 8, to be held June 9–18, and other issues within the jurisdiction of Study Group D. The National Committee meetings will include preparation for the Telecommunication Sector Advisory Group meeting to be held September 7–11, 1998. Questions regarding the agenda or ITAC–T Sector activities in general may be directed to the Study Group D Chair, Gary Fereno, telephone 703 607–6166 or the National Committee Chair, Marion Gordon, 202 647–0197.

All participants may join in discussions, subject to instructions of the chair. In this regard, entry to the building is controlled. If you wish to attend, please send a fax to (202 647–7407) at least 24 hours before the meeting, providing name, affiliation, date of birth, and social security number, to arrange for pre-clearance. One of the following valid photo IDs is required for admittance to the State Department building: US driver's license with picture, passport, Government ID. Enter from the C Street Main Lobby.

Dated: May 6, 1998.

Richard E. Shrum,

Executive Director, ITAC.

[FR Doc. 98–12944 Filed 5–12–98; 10:30 am]

BILLING CODE 4710–45–M

DEPARTMENT OF STATE

[Public Notice #2814]

Shipping Coordinating Committee, Council and Associated Bodies; Notice of Meeting

The Shipping Coordinating Committee (SHC) will conduct an open meeting at 9:00 AM on Tuesday, June 2nd, in Room 2415, at U.S. Coast Guard Headquarters, 2100 Second Street, SW, Washington, DC 20593–0001. The purpose of the meeting is to finalize preparations for the 80th session of Council, and the 45th session of Technical Cooperation Committee of the International Maritime Organization (IMO) which is scheduled for 15–19 June 1998, at the IMO Headquarters in London. At the meeting, discussions will focus on papers received and draft U.S. positions. Among other things, the items of particular interest are:

a. Reports of the IMO committees
b. Review of the IMO technical cooperation activities
c. Relations with the United Nations
d. Reports for World Maritime University and International Maritime Law Institute
e. Administrative and financial matters.

Members of the public may attend these meetings up to the seating capacity of the room. Interested persons may seek information by writing: Mr. Gene F. Hammel, U.S. Coast Guard Headquarters (G–CI), 2100 Second Street, SW; Room 2114, Washington, DC 20593–0001, by calling: (202) 267–2280, or by faxing: (202) 267–4588.

Dated: May 1, 1998.

Stephen M. Miller,

Executive Secretary, Shipping Coordinating Committee.

[FR Doc. 98–12869 Filed 5–13–98; 8:45 am]

BILLING CODE 4710–07–M

OFFICE OF THE UNITED STATES TRADE REPRESENTATIVE

Notice of Meeting of the Advisory Committee for Trade Policy and Negotiations

AGENCY: Office of the United States Trade Representative.

ACTION: Notice that the June 11, 1998, meeting of the Advisory Committee for Trade Policy and Negotiations will be held from 10:00 a.m. to 2:00 p.m. The meeting will be closed to the public from 10:00 a.m. to 1:30 p.m. and open to the public from 1:30 p.m. to 2:00 p.m.

SUMMARY: The Advisory Committee for Trade Policy and Negotiation will hold a meeting on June 11, 1998 from 10:00 a.m. to 2:00 p.m. The meeting will be closed to the public from 10:00 a.m. to 1:30 p.m. The meeting will include a review and discussion of current issues which influence U.S. trade policy. Pursuant to Section 2155(f)(2) of Title 19 of the United States Code, I have determined that this meeting will be concerned with matters the disclosure of which would seriously compromise the development by the United States Government of trade policy, priorities, negotiating objectives or bargaining positions with respect to the operation of any trade agreement and other matters arising in connection with the development, implementation and administration of the trade policy of the United States. The meeting will be open to the public and press from 1:30 p.m. to 2:00 p.m. when trade policy issues will be discussed. Attendance during this part of the meeting is for observation only. Individuals who are not members of the committee will not be invited to comment.

DATES: The meeting is scheduled for June 11, 1998, unless otherwise notified.

ADDRESSES: The meeting will be held at the Madison Hotel in the Dolly Madison Room, located at 15th & M Streets NW, Washington, D.C, unless otherwise notified.

FOR FURTHER INFORMATION CONTACT: Bill Daley, Office of the United States Trade Representative, (202) 395–6120.

Charlene Barshefsky,

United States Trade Representative.

[FR Doc. 98–12837 Filed 5–13–98; 8:45 am]

BILLING CODE 3190–01–M

DEPARTMENT OF TRANSPORTATION

Federal Highway Administration

Environmental Impact Statement: Tarrant County, TX

AGENCY: Federal Highway Administration (FHWA), DOT.

ACTION: Notice of Intent.

SUMMARY: The FHWA is issuing a third notice to advise the public that the scope of the environmental impact statement (EIS) for the proposed State highway 121 (SH 121) project in Tarrant County, Texas, will be revised.

FOR FURTHER INFORMATION CONTACT: Walter C. Waidelich, District Engineer, Federal Highway Administration, 826 Federal Office Building, 300 E 8th Street, Austin, Texas 78701 Telephone: (512) 916–5988 or Dianna F. Noble, Director, Environmental Affairs Division, Texas Department of

Transportation, 125 East 11th Street, Austin, Texas 78701–2483 Telephone: (512) 416–2734.

SUPPLEMENTARY INFORMATION: The project was initially planned to be studied in a single EIS with limits from Interstate Highway 35 West (IH 35W) in Fort Worth, Tarrant County, to State Highway 174 (SH 174) in Johnson County. A first Notice of Intent (NOI) was published in the August 4, 1988, Federal Register with the SH 121 EIS limits being proposed for the South Section of the project. A second NOI was published in the April 5, 1990, **Federal Register** with the SH 121 EIS limits being proposed for the North Section of the project. This third NOI will change the scope of the EIS. The result will be a change of the limits and scope of the freeway project with portions that are proposed to be developed as a toll road where it is determined to be economically feasible. The limits of the EIS for the proposed project are now portions of the North and the South Sections of SH 121 and will extend from Interstate Highway 30 (IH 30) in Fort Worth to Farm-to-Market Road 1187 (FM 1187), all within Tarrant County. The previous documentation was subdivided into a Draft Environmental Impact Statement (DEIS) for the North Section with another DEIS for the South Section. The DEIS for South Section was completed and a public hearing was held but a Record of Decision was not issued. The DEIS for the North Section was not completed and work was suspended. The new EIS for the proposed facility will cover a part of the South Section from IH 20 to FM 1187 and part of the North Section from IH 30 to IH 20. Companion documentation is being prepared separately for the remainder of the North Section of the proposed facility from IH 35W to IH 30 in Fort Worth, Tarrant County, as well as the remainder of the South Section of the proposed facility from FM 1187 in Tarrant County to U.S. Highway 67 (US 67) in Cleburne; Johnson County.

Numerous public involvement activities have taken place during the development of the proposed project and will continue until a general consensus is reached on a preferred alternative. Many alternatives and routes have been considered. Among the alternatives considered for a proposed project are build nothing, freeway development, and toll road development.

To ensure that the full range of issues related to this proposed action are addressed and all significant issues identified, comments and suggestions are invited from all interested parties. Comments or questions concerning the proposed action and the EIS should be directed to the FHWA or TxDOT at the address provided.

(Catalog of Federal Domestic Assistance Program Number 20.205, Highway Research, Planning and Construction. The regulations implementing Executive Order 12372 regarding intergovernmental consultation on Federal programs and activities apply to this program)

Walter C. Waidelich,

District Engineer.

[FR Doc. 98–12876 Filed 5–13–98; 8:45 am]

BILLING CODE 4910–22–M

DEPARTMENT OF TRANSPORTATION

Federal Railroad Administration

Petition for Waiver of Compliance

In accordance with 49 CFR 211.9 and 211.41, notice is hereby given that the Federal Railroad Administration (FRA) received from the Burlington Northern Santa Fe Railroad (BNSF) a request for a waiver of compliance with certain requirements of the Code of Federal Regulations. The petition is described below, including the regulatory provisions involved, and the nature of the relief being requested.

Burlington Northern Santa Fe Railroad, Docket Number RST–97–6

This notice covers the request of the BNSF to be relieved of compliance with Section 213.57(b) of the Federal Track Safety Standards (49 CFR 213) for the operation of National Passenger Corporation (Amtrak) trains at up to five (5) inches of unbalance on the former Santa Fe Railroad. Since 1994, Amtrak trains have been operatings at up to 4 inches of unbalance or cant deficiency on the former Burlington Northern Railroad. This petition would extend the waiver to the former Santa Fe Railroad and increase the level of unbalance from 4 inches to 5 inches.

Section 213.57(b) refers to the maximum allowable train operating speeds on non-tangent track as a function of existing curvature and superelevation and, further, introduces the concept of unbalanced superelevation (cant deficiency) in particular modes of train operation. The idea of trains negotiating curved track at speeds producing either positive or negative unbalance was discussed previously in the **Federal Register** (52 FR 38035 on October 13, 1987). Currently, Section 213.57(b) permits a maximum of 3 inches to be used as the underbalance term in the formulation of curve/speed tables by track maintenance engineers defining intermediate train speeds and curved track superelevations for any route between two points.

BNSF petitioned for permission to substitute the value of 5 inches instead of 3 inches in determining maximum train speeds on track owned by the railroad and used under contract by Amtrak in the provision of transcontinental passenger train service. BNSF is requesting the waiver to assist Amtrak in improving its operating efficiency.

Interested parties may submit written views, data, or comments on this petition. FRA does not anticipate scheduling a public hearing in connection with these proceedings since the facts do not appear to warrant a hearing. If any interested party desires an opportunity for comment, they should notify FRA, in writing, before the end of the comment period and specify the basis for their request.

All communications concerning these proceedings should identify the appropriate docket number (e.g., Waiver Petition Docket Number RST–97–6), and must be submitted in triplicate to the Docket Clerk, Chief Counsel, Federal Railroad Administration, Nassif Building, 400 Seventh Street, SW, Washington, DC 20590. Communications received within 30 days from the publication of this notice will be considered by FRA before final action is taken. Comments received after that date will be considered as far as practicable. All written communications concerning these proceedings are available for examination during regular business hours (9 a.m.—5 p.m.) at FRA's offices at 1120 Vermont Avenue, NW, Room 7051, Washington, DC 20005.

Issued in Washington, DC on May 4, 1998.

Grady C. Cothen, Jr.,

Deputy Associate Administrator for Safety Standards and Program Development.

[FR Doc. 98–12767 Filed 5–13–98; 8:45 am]

BILLING CODE 4910–06–P

DEPARTMENT OF TRANSPORTATION

Federal Railroad Administration

[FRA Docket No. RST–97–5]

Petition for Exemption or Waiver of Compliance With the Requirements of Section 213.233(c) of the Federal Track Safety Standards; New Jersey Transit Rail Operations, Inc.

In accordance with 49 CFR 211.41, notice is hereby given that the New Jersey Transit Rail Operations, Incorporated, (NJT) has submitted a petition, dated December 3, 1997, for a

waiver of compliance with certain requirements of Title 49, Code of Federal Regulations, Part 213: Track Safety Standards.

The purpose of the petition is to request of the Federal Railroad Administration (FRA) relief from compliance with the provisions of 49 CFR 213.233(c) of the Federal Track Safety Standards. The petitioner requests approval to eliminate one of two weekly visual track inspections required by this section for track carrying passenger traffic. Petitioner proposes, in the interest of equivalent safety, to substitute for the eliminated visual inspection the operation of a track geometry measuring vehicle over the affected main track and sidings on a quarterly basis. Such equipment does not operate over the tracks of the petitioner today.

Interested parties are invited to participate in these proceedings by submitting written views, data or comments. FRA does not anticipate scheduling a public hearing in connection with these proceedings since the facts do not appear to warrant a hearing. If any interested party desires an opportunity for oral comment, they should notify FRA, in writing, before the end of the comment period and specify the basis for their request.

All communications concerning these proceedings should identify the appropriate docket number (e.g., Waiver Petition Number RST–97–5 and must be submitted in triplicate to the Docket Clerk, Office of Chief Counsel, Federal Railroad Administration, 400 Seventh Street, SW, Washington, DC 20590. Communications received within 30 days of publication of this notice will be considered by FRA before final action is taken. Comments received after that date will be considered as far as practicable. All written communications concerning these proceedings are available for examination during regular business hours (9:00 a.m. to 5:00 p.m.) in Room 7051, 1120 Vermont Avenue, NW, Washington, DC, 20005.

Issued in Washington, D.C. on May 4, 1998.

Grady C. Cothen, Jr.,

Deputy Associate Administrator for Safety Standards and Program Development.

[FR Doc. 98–12768 Filed 5–13–98; 8:45 am]

BILLING CODE 4910–06–P

DEPARTMENT OF TRANSPORTATION

Surface Transportation Board

[STB Docket Nos. AB–32 (Sub–No. 86X) and AB–355 (Sub-No. 24X)]

Boston and Maine Corporation—Abandonment Exemption—in Middlesex County, MA and Springfield Terminal Railway Company—Discontinuance of Service Exemption—in Middlesex County, MA

Boston & Maine Corporation (B&M) and Springfield Terminal Railway Company (ST) have filed a notice of exemption under 49 CFR Part 1152 Subpart F—*Exempt Abandonments and Discontinuances* for B&M to abandon and ST to discontinue service over a 1.82-mile line of railroad known as the Watertown Branch from milepost 5.85 (Engineering Station 87+90) to milepost 7.67 (Engineering Station 184+25) in Middlesex County, MA. The line traverses United States Postal Service Zip Code 02172.[1]

B&M and ST have certified that: (1) No local traffic has moved over the line for at least 2 years; (2) any overhead traffic has been rerouted over other lines; (3) no formal complaint filed by a user of rail service on the line (or by a state or local government entity acting on behalf of such user) regarding cessation of service over the line either is pending with the Surface Transportation Board (Board) or with any U.S. District Court or has been decided in favor of complainant within the 2-year period; and (4) the requirements at 49 CFR 1105.7 (environmental reports), 49 CFR 1105.8 (historic reports), 49 CFR 1105.11 (transmittal letter), 49 CFR 1105.12 (newspaper publication), and 49 CFR 1152.50(d)(1) (notice to governmental agencies) have been met.

As a condition to this exemption, any employee adversely affected by the abandonment shall be protected under *Oregon Short Line R. Co.—Abandonment—Goshen,* 360 I.C.C. 91 (1979). To address whether this condition adequately protects affected employees, a petition for partial revocation under 49 U.S.C. 10502(d) must be filed. Provided no formal expression of intent to file an offer of financial assistance (OFA) has been received, this exemption will be effective on June 13, 1998, unless stayed pending reconsideration. Petitions to stay that do not involve environmental issues,[2] formal expressions of intent to file an OFA under 49 CFR 1152.27(c)(2),[3] and trail use/rail banking requests under 49 CFR 1152.29 must be filed by May 26, 1998. Petitions to reopen or requests for public use conditions under 49 CFR 1152.28 must be filed by June 3, 1998, with: Surface Transportation Board, Office of the Secretary, Case Control Unit, 1925 K Street, NW., Washington, DC 20423.

A copy of any petition filed with the Board should be sent to applicant representative: John R. Nadolny, Esq., Boston and Maine Corporation, Law Department, Iron Horse Park, North Billerica, MA 01862.

If the verified notice contains false or misleading information, the exemption is void *ab initio.*

B&M and ST have filed an environmental report which addresses the effects of the abandonment and discontinuance, if any, on the environment and historic resources. The Section of Environmental Analysis (SEA) will issue an environmental assessment (EA) by May 19, 1998. Interested persons may obtain a copy of the EA by writing to SEA (Room 500, Surface Transportation Board, Washington, DC 20423) or by calling SEA, at (202) 565–1545. Comments on environmental and historic preservation matters must be filed within 15 days after the EA becomes available to the public.

Environmental, historic preservation, public use, or trail use/rail banking conditions will be imposed, where appropriate, in a subsequent decision.

Pursuant to the provisions of 49 CFR 1152.29(e)(2), B&M shall file a notice of consummation with the Board to signify that it has exercised the authority granted and fully abandoned the line. If consummation has not been effected by B&M's filing of a notice of consummation by May 14, 1999, and there are no legal or regulatory barriers to consummation, the authority to abandon will automatically expire.

Decided: May 6, 1998.

[1] On May 1, 1998, B&M informed the Board of the actual mileposts in addition to the Engineering Stations identified in its verified notice.

[2] The Board will grant a stay if an informed decision on environmental issues (whether raised by a party or by the Board's Section of Environmental Analysis in its independent investigation) cannot be made before the exemption's effective date. See *Exemption of Out-of-Service Rail Lines,* 5 I.C.C.2d 377 (1989). Any request for a stay should be filed as soon as possible so that the Board may take appropriate action before the exemption's effective date.

[3] Each offer of financial assistance must be accompanied by the filing fee, which currently is set at $1,000. See 49 CFR 1002.2(f)(25).

By the Board, David M. Konschnik, Director, Office of Proceedings.

Vernon A. Williams,

Secretary.

[FR Doc. 98–12696 Filed 5–13–98; 8:45 am]

BILLING CODE 4915–00–P

DEPARTMENT OF THE TREASURY

Office of Thrift Supervision

[AC–17: OTS No. 0325]

First Kansas Federal Savings Association, Osawatomie, KS; Approval of Conversion Application

Notice is hereby given that on May 4, 1998, the Director, Corporate Activities, Office of Thrift Supervision, or her designee, acting pursuant to delegated authority, approved the application of First Kansas Federal Savings Association, Osawatomie, Kansas, to convert to the stock form of organization. Copies of the application are available for inspection at the Dissemination Branch, Office of Thrift Supervision, 1700 G Street, NW, Washington, DC 20552, and the Midwest Regional Office, Office of Thrift Supervision, 122 W. John Carpenter Freeway, Suite 600, Irving, Texas 75039–2010.

Dated: May 8, 1998.

By the Office of Thrift Supervision.

Nadine Y. Washington,

Corporate Secretary.

[FR Doc. 98–12817 Filed 5–13–98; 8:45 am]

BILLING CODE 6720–01–M

Corrections

Federal Register
Vol. 63, No. 93
Thursday, May 14, 1998

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 HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

Clinical Laboratory Improvement Advisory Committee (CLIAC): Meeting

Correction

In notice document 98–12235 appearing on page 25863, in the issue of Monday, May 11, 1998, make the following correction:

On page 25863, in the third column, in the thirteenth line ''FAX 770/ 488-1129.'' should read ''FAX 770/488-8282.''

BILLING CODE 1505-01-D

federal register

Thursday
May 14, 1998

Part II

Environmental Protection Agency

Guidelines for Ecological Risk Assessment; Notice

ENVIRONMENTAL PROTECTION AGENCY

[FRL–6011–2]

Guidelines for Ecological Risk Assessment

AGENCY: Environmental Protection Agency.

ACTION: Notice of availability of final Guidelines for Ecological Risk Assessment.

SUMMARY: The U.S. Environmental Protection Agency (EPA) is today publishing in final form a document entitled Guidelines for Ecological Risk Assessment (hereafter ''Guidelines''). These Guidelines were developed as part of an interoffice program by a Technical Panel of the Risk Assessment Forum. These 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.

These Guidelines were prepared during a time of increasing interest in the field of ecological risk assessment and reflect input from many sources both within and outside the Agency. The Guidelines expand upon and replace the previously published EPA report Framework for Ecological Risk Assessment (EPA/630/R–92/001, February 1992), which proposed principles and terminology for the ecological risk assessment process. From 1992 to 1994, the Agency focused on identifying a structure for the Guidelines and the issues that the document would address. EPA sponsored public and Agency colloquia, developed peer-reviewed ecological assessment case studies, and prepared a set of peer-reviewed issue papers highlighting important principles and approaches. Drafts of the proposed Guidelines underwent formal external peer review and were reviewed by the Agency's Risk Assessment Forum, by Federal interagency subcommittees of the Committee on Environment and Natural Resources of the Office of Science and Technology Policy, and by the Agency's Science Advisory Board (SAB). The proposed Guidelines were published for public comment in 1996 (61 FR 47552–47631, September 9, 1996). The final Guidelines incorporate revisions based on the comments received from the public and the SAB on the proposed Guidelines. EPA appreciates the efforts of all participants in the process and has tried to address their recommendations in these Guidelines.

DATES: The Guidelines will be effective on April 30, 1998.

ADDRESSES: The Guidelines will be made available in several ways:

(1) The electronic version will be accessible on the EPA National Center for Environmental Assessment home page on the Internet at http://www.epa.gov/ncea/.

(2) 3½″ high-density computer diskettes in WordPerfect 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–95/002Fa) when ordering.

(3) This notice contains the full document. (However, because of **Federal Register** format limitations, text boxes that would normally be included at their point of reference in the document are instead listed at the end of the Guidelines as text notes.) Copies of the Guidelines 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 PB No. (PB98–117849) when ordering.

FOR FURTHER INFORMATION, CONTACT: Dr. Bill van der Schalie, National Center for Environmental Assessment-Washington Office (8623), U.S. Environmental Protection Agency, 401 M Street, SW, Washington, DC 20460; telephone: 202–564–3371; e-mail: Eco-Guidelines@epamail.epa.gov.

SUPPLEMENTARY INFORMATION: 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 flexible 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 decision making 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 the U.S. Environmental Protection Agency'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 also may be useful to others outside the Agency. These Guidelines expand on and replace the 1992 report *Framework for Ecological Risk Assessment* (referred to as the Framework Report; see Appendix A). They were written by a Forum technical panel and have been revised on the basis of extensive comments from outside peer reviewers as well as Agency staff. The Guidelines retain the Framework Report's broad scope, while expanding on some 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 (default assumptions) to bridge gaps in knowledge. EPA will revisit guidelines documents as experience and scientific consensus evolve. The Agency recognizes that ecological risk assessment is only one tool in the overall management of ecological risks. Therefore, there are ongoing efforts within the Agency to develop other tools and processes that can contribute to an overall approach to ecological risk management, addressing topics such as ecological benefits assessment and cost-benefit analyses.

Ecological risk assessment includes three primary phases: Problem formulation, analysis, and risk characterization. In problem formulation, risk assessors evaluate goals and select assessment endpoints, prepare the conceptual model, and develop an analysis plan. During the analysis phase, assessors evaluate exposure to stressors and the relationship between stressor levels and ecological effects. In the third phase, risk characterization, assessors estimate risk through integration of exposure and stressor-response profiles, describe risk by discussing lines of evidence and determining ecological adversity, and prepare a report. The interface among risk assessors, risk managers, and interested parties during planning at the beginning and communication of risk at the end of the risk assessment is critical to ensure that the results of the assessment can be used to support a management decision. Because of the diverse expertise required (especially in complex ecological risk assessments), risk assessors and risk managers frequently work in multidisciplinary teams.

Both risk managers and risk assessors bring valuable perspectives to the initial

planning activities for an ecological risk assessment. Risk managers charged with protecting the environment can identify information they need to develop their decision, risk assessors can ensure that science is effectively used to address ecological concerns, and together they can evaluate whether a risk assessment can address identified problems. However, this 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 introduce undue bias.

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 an interactive, nonlinear process, substantial reevaluation is expected to occur during the development of all problem formulation products.

The analysis phase includes two principal activities: Characterization of exposure and characterization of ecological effects. The process is flexible, and interaction between the two evaluations is essential. Both activities evaluate available data for scientific credibility and relevance to assessment endpoints and the conceptual model. Exposure characterization describes sources of stressors, their distribution in the environment, and their contact or co-occurrence with ecological receptors. Ecological effects characterization evaluates stressor-response relationships or evidence that exposure to stressors causes an observed response. The bulk of quantitative uncertainty analysis is performed in the analysis phase, although uncertainty is an important consideration throughout the entire risk assessment. The analysis phase products are summary profiles that describe exposure and the stressor-response relationships.

Risk characterization is the final phase of an ecological risk assessment. During this phase, risk assessors estimate ecological risks, indicate the overall degree of confidence in the risk estimates, cite evidence supporting the risk estimates, and interpret the adversity of ecological effects. To ensure mutual understanding between risk assessors and managers, a good risk characterization will express results clearly, articulate major assumptions and uncertainties, identify reasonable alternative interpretations, and separate scientific conclusions from policy judgments. Risk managers use risk assessment results, along with other factors (e.g., economic or legal concerns), in making risk management decisions and as a basis for communicating risks to interested parties and the general public.

After completion of the risk assessment, risk managers may consider whether follow-up activities are required. They may decide on risk mitigation measures, then develop a monitoring plan to determine whether the procedures reduced risk or whether ecological recovery is occurring. Managers may also elect to conduct another planned tier or iteration of the risk assessment if necessary to support a management decision.

Dated: April 30, 1998.

Carol M. Browner,

Administrator.

Part A: Guidelines for Ecological Risk Assessment

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1. Introduction

Ecological risk assessment is a 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). The process is used to systematically evaluate and organize data, information, assumptions, and uncertainties in order to help understand and predict the relationships between stressors and ecological effects in a way that is useful for environmental decision making. An assessment may involve chemical, physical, or biological stressors, and one stressor or many stressors may be considered.

Ecological risk assessments are developed within a risk management context to evaluate human-induced changes that are considered undesirable. As a result, these Guidelines focus on stressors and adverse effects generated or influenced by anthropogenic activity. Defining adversity is important because a stressor may cause adverse effects on one ecosystem component but be neutral or even beneficial to other components. Changes often considered undesirable are those that alter important structural or functional characteristics or components of ecosystems. An evaluation of adversity may include a consideration of the type, intensity, and scale of the effect as well as the potential for recovery. The acceptability of adverse effects is determined by risk managers. Although intended to evaluate adverse effects, the ecological risk assessment process can be adapted to predict beneficial changes or risk from natural events.

Descriptions of the likelihood of adverse effects may range from qualitative judgments to quantitative probabilities. Although risk assessments may include quantitative risk estimates, quantitation of risks is not always possible. It is better to convey conclusions (and associated uncertainties) qualitatively than to ignore them because they are not easily understood or estimated.

Ecological risk assessments can be used to predict the likelihood of future adverse effects (prospective) or evaluate the likelihood that effects are caused by past exposure to stressors (retrospective). In many cases, both approaches are included in a single risk assessment. For example, a retrospective risk assessment designed to evaluate the cause for amphibian population declines may also be used to predict the effects of future management actions. Combined retrospective and prospective risk assessments are typical in situations where ecosystems have a history of previous impacts and the potential for future effects from multiple chemical, physical, or biological stressors. Other terminology related to ecological risk assessment is referenced in text note 1–1.

1.1. The Ecological Risk Assessment Process

The ecological risk assessment process is based on two major elements: Characterization of effects and characterization of exposure. These provide the focus for conducting the three phases of risk assessment: Problem formulation, analysis, and risk characterization.

The overall ecological risk assessment process [1] is shown in figure 1–1. The format remains consistent with the diagram from the 1992 report Framework for Ecological Risk Assessment (referred to as the Framework Report). However, the process and products within each phase have been refined, and these changes are detailed in figure 1–2. The three phases of risk assessment are enclosed by a dark solid line. Boxes outside this line identify critical activities that influence why and how a risk assessment is conducted and how it will be used.

[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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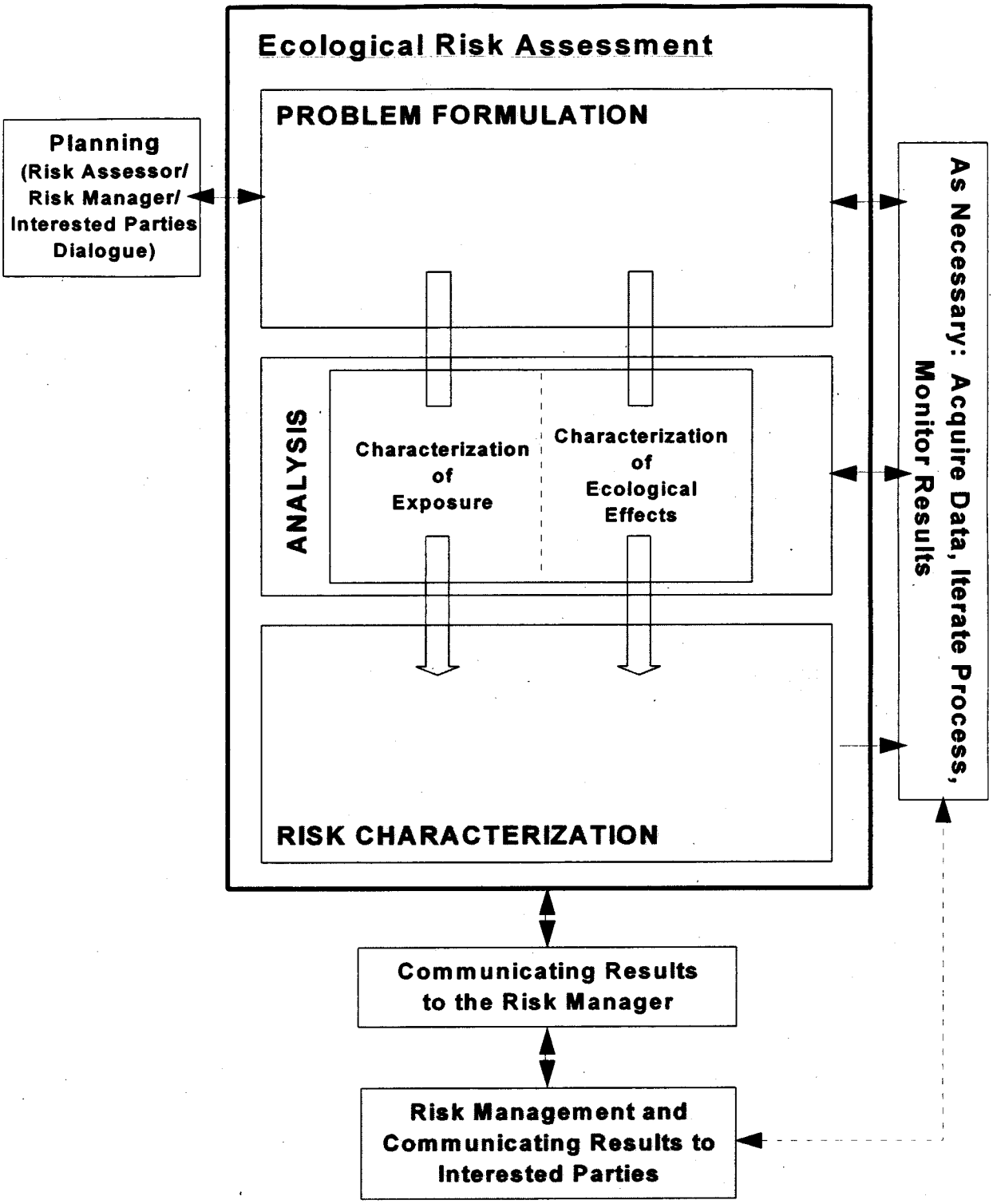

Figure 1-1. The framework for ecological risk assessment (modified from U.S. EPA, 1992a).

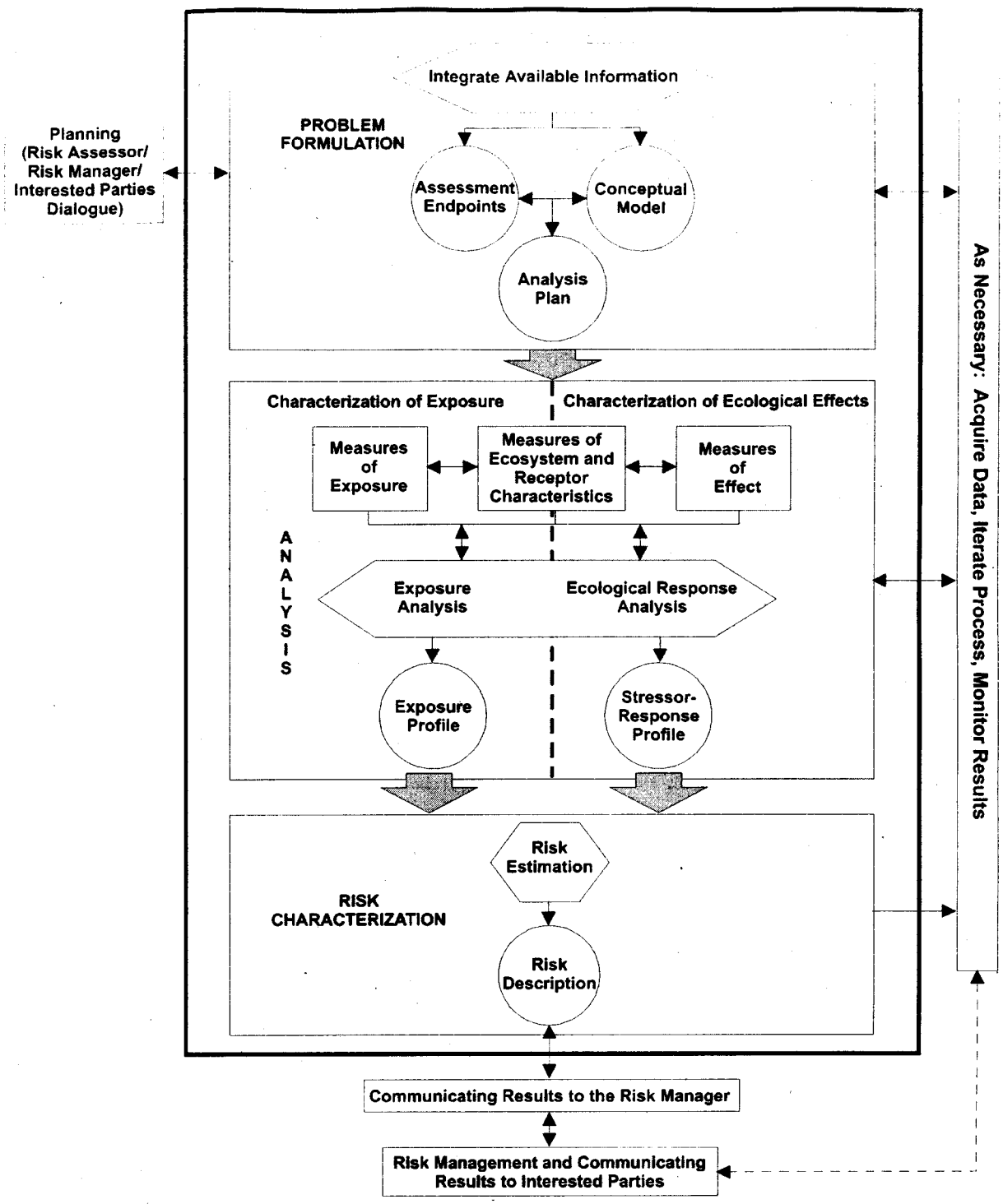

Figure 1-2. The ecological risk assessment framework, with an expanded view of each phase. Within each phase, rectangles designate inputs, hexagons indicate actions, and circles represent outputs. Problem formulation, analysis, and risk characterization are discussed in sections 3, 4, and 5, respectively. Sections 2 and 6 describe interactions between risk assessors and risk managers.

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Problem formulation, the first phase, is shown at the top. In problem formulation, the purpose for the assessment is articulated, the problem is defined, and a plan for analyzing and characterizing risk is determined. Initial work in problem formulation includes the integration of available information on sources, stressors, effects, and ecosystem and receptor characteristics. From this information two products are generated: Assessment endpoints and conceptual models. Either product may be generated first (the order depends on the type of risk assessment), but both are needed to complete an analysis plan, the final product of problem formulation.

Analysis, shown in the middle box, is directed by the products of problem formulation. During the analysis phase, data are evaluated to determine how exposure to stressors is likely to occur (characterization of exposure) and, given this exposure, the potential and type of ecological effects that can be expected (characterization of ecological effects). The first step in analysis is to determine the strengths and limitations of data on exposure, effects, and ecosystem and receptor characteristics. Data are then analyzed to characterize the nature of potential or actual exposure and the ecological responses under the circumstances defined in the conceptual model(s). The products from these analyses are two profiles, one for exposure and one for stressor response. These products provide the basis for risk characterization.

During risk characterization, shown in the third box, the exposure and stressor-response profiles are integrated through the risk estimation process. Risk characterization includes a summary of assumptions, scientific uncertainties, and strengths and limitations of the analyses. The final product is a risk description in which the results of the integration are presented, including an interpretation of ecological adversity and descriptions of uncertainty and lines of evidence.

Although problem formulation, analysis, and risk characterization are presented sequentially, ecological risk assessments are frequently iterative. Something learned during analysis or risk characterization can lead to a reevaluation of problem formulation or new data collection and analysis (see text note 1–2).

Interactions among risk assessors, risk managers, and other interested parties are shown in two places in the diagram. The side box on the upper left represents planning, where agreements are made about the management goals, the purpose for the risk assessment, and the resources available to conduct the work. The box following risk characterization represents when the results of the risk assessment are formally communicated by risk assessors to risk managers. Risk managers generally communicate risk assessment results to interested parties. These activities are shown outside the ecological risk assessment process diagram to emphasize that risk assessment and risk management are two distinct activities. The former involves the evaluation of the likelihood of adverse effects, while the latter 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.

The bar along the right side of figure 1–2 highlights data acquisition, iteration, and monitoring. Monitoring data provide important input to all phases of a risk assessment. They can provide the impetus for a risk assessment by identifying changes in ecological condition. They can also be used to evaluate a risk assessment's predictions. For example, follow-up studies could determine whether mitigation efforts were effective, help verify whether source reduction was effective, or determine the extent and nature of ecological recovery. It is important for risk assessors and risk managers to use monitoring results to evaluate risk assessment predictions so they can gain experience and help improve the risk assessment and risk management process (Commission on Risk Assessment and Risk Management, 1997).

Even though the risk assessment focuses on data analysis and interpretation, acquiring the appropriate quantity and quality of data for use in the process is critical. If data are unavailable, the risk assessment may stop until data are obtained. The process is more often iterative than linear, since the evaluation of new data or information may require revisiting a part of the process or conducting a new assessment (see text note 2–8). The dotted line between the side bar and the risk management box indicates that additional data acquisition, iteration, or monitoring, while important, are not always required.

1.2. Ecological Risk Assessment in a Management Context

Ecological risk assessments are designed and conducted to provide information to risk managers about the potential adverse effects of different management decisions. Attempts to eliminate risks associated with human activities in the face of uncertainties and potentially high costs present a challenge to risk managers (Ruckelshaus, 1983; Suter, 1993a). Although many considerations and sources of information are used by managers in the decision process, ecological risk assessments are unique in providing a scientific evaluation of ecological risk that explicitly addresses uncertainty.

1.2.1. Contributions of Ecological Risk Assessment to Environmental Decision Making

At EPA, ecological risk assessments are used to support many types of management actions, including the regulation of hazardous waste sites, industrial chemicals, and pesticides, or the management of watersheds or other ecosystems affected by multiple nonchemical and chemical stressors. The ecological risk assessment process has several features that contribute to effective environmental decision making:

- Through an iterative process, new information can be incorporated into risk assessments, which can be used to improve environmental decision making. This feature is consistent with adaptive management principles (Holling, 1978) used in managing natural resources.
- Risk assessments can be used to express changes in ecological effects as a function of changes in exposure to stressors. This capability may be particularly useful to the decision maker who must evaluate tradeoffs, examine different alternatives, or determine the extent to which stressors must be reduced to achieve a given outcome.
- Risk assessments explicitly evaluate uncertainty. Uncertainty analysis describes the degree of confidence in the assessment and can help the risk manager focus research on those areas that will lead to the greatest reductions in uncertainty.
- Risk assessments provide a basis for comparing, ranking, and prioritizing risks. The results can also be used in cost-benefit and cost-effectiveness analyses that offer additional interpretation of the effects of alternative management options.
- Risk assessments consider management goals and objectives as well as scientific issues in developing assessment endpoints and conceptual models during problem formulation. Such initial planning activities help ensure that results will be useful to risk managers.

1.2.2. Factors Affecting the Value of Ecological Risk Assessment for Environmental Decision Making

The wide use and important advantages of ecological risk assessments do not mean they are the sole determinants of management decisions; risk managers consider many factors. Legal mandates and political, social, and economic considerations may lead risk managers to make decisions that are more or less protective. Reducing risk to the lowest level may be too expensive or not technically feasible. Thus, although ecological risk assessments provide critical information to risk managers, they are only part of the environmental decision-making process.

In some cases, it may be desirable to broaden the scope of a risk assessment during the planning phase. A risk assessment that is too narrowly focused on one type of stressor in a system (e.g., chemicals) could fail to consider more important stressors (e.g., habitat alteration). However, options for modifying the scope of a risk assessment may be limited when the scope is defined by statute.

In other situations, management alternatives may be available that completely circumvent the need for a risk assessment. For example, the risks associated with building a hydroelectric dam may be avoided by considering alternatives for meeting power needs that do not involve a new dam. In these situations, the risk assessment may be redirected to assess the new alternative, or one may not be needed at all.

1.3. Scope and Intended Audience

These Guidelines describe general principles and give examples to show how ecological risk assessment can be applied to a wide range of systems, stressors, and biological, spatial, and temporal scales. They describe the strengths and limitations of alternative approaches and emphasize processes and approaches for analyzing data rather than specifying data collection techniques, methods, or models. They do not provide detailed guidance, nor are they prescriptive. This approach, although intended to promote consistency, provides flexibility to permit EPA's offices and regions to develop specific guidance suited to their needs.

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 documents on specific ecological risk assessment topics following publication of these Guidelines.

The interface between risk assessors and risk managers is discussed in the Guidelines. However, details on the use of ecological risk assessment in the risk management process are beyond the scope of these Guidelines. Other EPA publications discuss how ecological concerns have been addressed in decision making at EPA (U.S. EPA, 1994a), propose ecological entities that may be important to protect (U.S. EPA, 1997a), and provide an introduction to ecological risk assessment for risk managers (U.S. EPA, 1995a).

Policies in this document are intended as internal guidance for EPA. Risk assessors and risk managers at EPA are the primary audience, although these Guidelines may be useful to others outside the Agency. This document is not a regulation and is not intended for EPA regulations. The Guidelines set forth current scientific thinking and approaches for conducting and evaluating ecological risk assessments. They are not intended, nor can they be relied upon, to create any rights enforceable by any party in litigation with the United States. As with other EPA guidelines (e.g., 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 evolve.

These Guidelines replace the Framework Report (U.S. EPA, 1992a). They expand on and modify framework concepts to reflect Agency experience since the Framework Report was published (see Appendix A).

1.4. Guidelines Organization

These Guidelines follow the ecological risk assessment format as presented in figures 1–1 and 1–2. Section 2 (planning) describes the dialogue among risk assessors, risk managers, and interested parties before the risk assessment begins. Section 3 (problem formulation) describes how management goals are interpreted, assessment endpoints selected, conceptual models constructed, and analysis plans developed. Section 4 (analysis) addresses how to evaluate potential exposure of receptors and the relationship between stressor levels and ecological effects. Section 5 (risk characterization) describes the process of estimating risk through the integration of exposure and stressor-response profiles and discusses lines of evidence, interpretation of adversity, and uncertainty. Finally, section 6 (on relating ecological information to risk management decisions) addresses communicating the results of the risk assessment to risk managers.

2. Planning the Risk Assessment

Ecological risk assessments are conducted to transform scientific data into meaningful information about the risk of human activities to the environment. Their purpose is to enable risk managers to make informed environmental decisions. To ensure that risk assessments meet this need, risk managers and risk assessors (see text notes 2–1 and 2–2) and, where appropriate, interested parties (see text note 2–3), engage in a planning dialogue as a critical first step toward initiating problem formulation (see figure 1–2).

The planning dialogue is the beginning of a necessary interface between risk managers and risk assessors. However, it is imperative to remember that planning remains distinct from the scientific conduct of a risk assessment. This distinction helps ensure that political and social issues, though helping define the objectives for the assessment, do not bias the scientific evaluation of risk.

The first step in planning may be to determine if a risk assessment is the best option for supporting the decision. Risk managers and risk assessors both consider the potential value of conducting a risk assessment to address identified problems. Their discussion explores 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. In some cases, a risk assessment may add little value to the decision process because management alternatives may be available that completely circumvent the need for a risk assessment (see section 1.2.2). In other cases, the need for a risk assessment may be investigated through a simple tiered risk evaluation based on minimal data and a simple model (see section 2.2.2).

Once the decision is made to conduct a risk assessment, the next step is to ensure that all key participants are appropriately involved. Risk management may be carried out by one decision maker in an agency such as EPA or it may be implemented by several risk managers working together as a team (see text note 2–1). Likewise, risk assessment may be conducted by a single risk assessor or a team of risk assessors (see text note 2–2). In some cases, interested parties play an important role (see text note 2–3).

Careful consideration up front about who will participate, and the character of that participation, will determine the success of planning.

2.1. The Roles of Risk Managers, Risk Assessors, and Interested Parties in Planning

During the planning dialogue, risk managers and risk assessors each bring important perspectives to the table. Risk managers, charged with protecting human health and the environment, help ensure that risk assessments provide information relevant to their decisions by describing why the risk assessment is needed, what decisions it will influence, and what they want to receive from the risk assessor. It is also helpful for managers to consider and communicate problems they have encountered in the past when trying to use risk assessments for decision making.

In turn, risk assessors ensure that scientific information is effectively used to address ecological and management concerns. Risk assessors describe what they can provide to the risk manager, where problems are likely to occur, and where uncertainty may be problematic. In addition, risk assessors may provide insights to risk managers about alternative management options likely to achieve stated goals because the options are ecologically grounded.

In some risk assessments, interested parties also take an active role in planning, particularly in goal development. The National Research Council describes participation by interested parties in risk assessment as an iterative process of ''analysis'' and ''deliberation'' (NRC, 1996). Interested parties may communicate their concerns to risk managers about the environment, economics, cultural changes, or other values potentially at risk from environmental management activities. Where they have the ability to increase or mitigate risk to ecological values of concern that are identified, interested parties may become part of the risk management team (see text note 2–1). However, involvement by interested parties is not always needed or appropriate. It depends on the purpose of the risk assessment, the regulatory requirements, and the characteristics of the management problem (see section 2.2.1). When interested parties become risk managers on a team, they directly participate in planning.

During planning, 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 requirements, and publicly perceived environmental values to interpret the goals for use in the ecological risk assessment. Examples of questions that risk managers and risk assessors may address during planning are provided in text note 2–4.

2.2. Products of Planning

The characteristics of an ecological risk assessment are directly determined by agreements reached by risk managers and risk assessors during planning dialogues. These agreements are the products of planning. They include (1) clearly established and articulated management goals, (2) characterization of decisions to be made within the context of the management goals, and (3) agreement on the scope, complexity, and focus of the risk assessment, including the expected output and the technical and financial support available to complete it.

2.2.1. Management Goals

Management goals are statements about the desired condition of ecological values of concern. They may range from ''maintain a sustainable aquatic community'' (see text notes 2–5 and 2–6) to ''restore a wetland'' or ''prevent toxicity.'' Management goals driving a specific risk assessment may come from the law, interpretations of the law by regulators, desired outcomes voiced by community leaders and the public, and interests expressed by affected parties. All involve input from the public. However, the process used to establish management goals influences how well they provide guidance to a risk assessment team, how they foster community participation, and whether the larger affected community will support implementation of management decisions to achieve the goal.

A majority of Agency risk assessments incorporate legally established management goals found in enabling legislation. In these cases, goals were derived through public debate among interested parties when the law was enacted. Such management goals (e.g., the Clean Water Act goals to ''protect and restore the chemical, physical and biological integrity of the Nation's waters'') are often open to considerable interpretation and rarely provide sufficient guidance to a risk assessor. To address this, the Agency has interpreted these goals into regulations and guidance for implementation at the national scale (e.g., water quality criteria, see text note 3–17). Mandated goals may be interpreted by Agency managers and staff into a particular risk assessment format and then applied consistently across stressors of the same type (e.g., evaluation of new chemicals). In cases where laws and regulations are specifically applied to a particular site, interaction between risk assessors and risk managers is needed to translate the law and regulations into management goals appropriate for the site or ecosystem of concern (e.g., Superfund site cleanup).

Although this approach has been effective, most regulations and guidance are stated in terms of measures or specific actions that must or must not be taken rather than establishing a value-based management goal or desired state. As environmental protection efforts shift from implementing controls toward achieving measurable environmental results, value-based management goals at the national scale will be increasingly important as guidance for risk assessors. Such goals as ''no unreasonable effects on bird survival'' or ''maintaining areal extent of wetlands'' will provide a basis for risk assessment design (see also U.S. EPA, 1997a, for additional examples and discussion).

The ''place-based'' or ''community-based'' approach for managing ecological resources recommended in the Edgewater Consensus (U.S. EPA, 1994b) generally requires that management goals be developed for each assessment. Management goals for ''places'' such as watersheds are formed as a consensus based on diverse values reflected in Federal, State, tribal, and local regulations and on constituency-group and public concerns. Public meetings, constituency-group meetings, evaluation of resource management organizational charters, and other means of looking for shared goals may be necessary to reach consensus among these diverse groups, commonly called ''stakeholders'' (see text note 2–3). However, goals derived by consensus are normally general. For use in a risk assessment, risk assessors must interpret the goals into more specific objectives about what must occur in a place in order for the goal to be achieved and identify ecological values that can be measured or estimated in the ecosystem of concern (see text note 2–6). For these risk assessments, the interpretation is unique to the ecosystem being assessed and is done on a case-by-case basis as part of the planning process. Risk assessors and risk managers should agree on the interpretations.

Early discussion on and selection of clearly established management goals provide risk assessors with a fuller understanding of how different risk management options under

consideration may result in achieving the goal. Such information helps the risk assessor identify and gather critical data and information. Regardless of how management goals are established, those that explicitly define ecological values to be protected provide the best foundation for identifying actions to reduce risk and generating risk assessment objectives. The objectives for the risk assessment derive from the type of management decisions to be made.

2.2.2. Management Options To Achieve Goals

Risk managers must implement decisions to achieve management goals (see text note 2–7). These risk management decisions may establish national policy applied consistently across the country (e.g., premanufacture notices (PMN) for new chemicals, protection of endangered species) or be applied to a specific site (e.g., hazardous waste site cleanup level) or management concern (e.g., number of combined sewer overflow events allowable per year) intended to achieve an environmental goal when implemented. Management decisions often begin as one of several management options identified during planning. Management options may range from preventing the introduction of a stressor to restoration of affected ecological values. When several options are defined during planning for a particular problem (e.g., leave alone, clean up, or pave a contaminated site), risk assessments can be used to predict potential risk across the range of these management options and, in some cases, combined with cost-benefit analyses to aid decision making. When risk assessors are made aware of possible options, they can use them to ensure that the risk assessment addresses a sufficient breadth of issues.

Explicitly stated management options provide a framework for defining the scope, focus, and conduct of a risk assessment. Some risk assessments are specifically designed to determine if a preestablished decision criterion is exceeded (e.g., see the data quality objectives process, U.S. EPA, 1994c, and section 3.5.2 for more details). Decision criteria often contain inherent assumptions about exposure, the range of possible stressors, or conditions under which the targeted stressor is operating. To ensure that decision options include appropriate assumptions and the risk assessment is designed to address management issues, these assumptions need to be clearly stated.

Decision criteria are often used within a tiering framework to determine how extensive a risk assessment should be. Early screening tiers may have predetermined decision criteria to answer whether a potential risk exists. Later tiers frequently do not because the management question changes from ''yes-no'' to questions of ''what, where, and how great is the risk.'' Results from these risk assessments require risk managers to evaluate risk characterization and generate a decision, perhaps through formal decision analysis (e.g., Clemen, 1996), or managers may request an iteration of the risk assessment to address issues of continuing concern (see text note 2–8).

Risk assessments designed to support management initiatives for a region or watershed where multiple stressors, ecological values, and political and economic factors influence decision making require great flexibility and more complex iterative risk assessments. They generally require an examination of ecological processes most influenced by diverse human actions. Risk assessments used in this application are often based on a general goal statement and multiple potential decisions. These require significant planning to determine which array of management decisions may be addressed and to establish the purpose, scope, and complexity of the risk assessment.

2.2.3. Scope and Complexity of the Risk Assessment

Although the purpose for conducting a risk assessment determines whether it is national, regional, or local in scope, resource availability determines its extent, complexity, and the level of confidence in results that can be expected. Each risk assessment is constrained by the availability of valid data and scientific understanding, expertise, time, and financial resources. Risk managers and risk assessors consider the nature of the decision (e.g., national policy, local impact), available resources, opportunities for increasing the resource base (e.g., partnering, new data collection, alternative analytical tools), potential characteristics of the risk assessment team, and the output that will provide the best information for the required decisions (see text note 2–9). They must often be flexible in determining what level of effort is warranted for a risk assessment. The most detailed assessment process is neither applicable nor necessary in every instance. Screening assessments may be the appropriate level of effort. One approach for determining the needed level of effort in the risk assessment is to set up tiered evaluations, as discussed in section 2.2.2. Where tiers are used, specific descriptions of management questions and decision criteria should be included in the plan.

Part of the agreement on scope and complexity is based on the maximum uncertainty that can be tolerated for the decision the risk assessment supports. Risk assessments completed in response to legal mandates and likely to be challenged in court often require rigorous attention to potential sources of uncertainty to help ensure that conclusions from the assessment can be defended. A frank discussion is needed between the risk manager and risk assessor on the sources of uncertainty and ways uncertainty can be reduced (if necessary or possible) through selective investment of resources. Resource planning may account for the iterative nature of risk assessment or include explicitly defined steps, such as tiers that represent increasing cost and complexity, each tier designed to increase understanding and reduce uncertainty. Advice 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, 1994c).

2.3. Planning Summary

The planning phase is complete when agreements are reached on (1) the management goals for ecological values, (2) the range of management options the risk assessment is to support, (3) objectives for the risk assessment, including criteria for success, (4) the focus and scope of the assessment, and (5) resource availability. 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 the temporal scale (e.g., the time frame over which stressors or effects will be evaluated).

In mandated risk assessments, planning agreements may be codified in regulations, and little documentation of agreements is warranted. In others, a summary of planning agreements may be important for ensuring that the risk assessment remains consistent with its original intent. A summary can provide a point of reference for determining if early decisions need to be changed in response to new information. There is no predetermined format, length, or complexity for a planning summary. It is a useful reference only and should be tailored to the risk assessment it represents. However, a summary will help ensure quality communication

between risk managers and risk assessors and will document agreed-upon decisions.

Once planning is complete, the formal process of risk assessment begins. During problem formulation, risk assessors should continue the dialogue with risk managers, particularly following assessment endpoint selection and completion of the analysis plan. At these points, potential problems can be identified before the risk assessment proceeds.

3. Problem Formulation Phase

Problem formulation is a process for generating and evaluating preliminary hypotheses about why ecological effects have occurred, or may occur, from human activities. It provides the foundation for the entire ecological risk assessment. Early in problem formulation, objectives for the risk assessment are refined. Then the nature of the problem is evaluated and a plan for analyzing data and characterizing risk is developed. Any deficiencies in problem formulation will compromise all subsequent work on the risk assessment (see text note 3–1). The quality of the assessment will depend in part on the team conducting the assessment and its responsiveness to the risk manager's needs.

The makeup of the risk assessment team assembled to conduct problem formulation depends on the requirements of the risk assessment. The team should include professionals with expertise directly related to the level and type of problem under consideration and the ecosystem where the problem is likely to occur. Teams may range from one individual calculating a simple quotient where the information and algorithm are clearly established to a large interdisciplinary, interagency team typical of ecosystem-level risk assessments involving multiple stressors and ecological values.

Involvement by the risk management team and other interested parties in problem formulation can be most valuable during final selection of assessment endpoints, review of the conceptual models, and adjustments to the analysis plan. The degree of participation is commensurate with the complexity of the risk assessment and the magnitude of the risk management decision to be faced. Participation normally consists of approval and refinement rather than technical input (but see text note 2–3). The format used to involve risk managers needs to gain from, and be responsive to, their input without compromising the scientific validity of the risk assessment. The level of involvement by interested parties in problem formulation is determined by risk managers.

3.1. Products of Problem Formulation

Problem formulation results in 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 between several stressors and assessment endpoints, and (3) an analysis plan. The first step toward developing these products is to integrate available information as shown in the hexagon in figure 3–1; the products are shown as circles. While the assessment of available information is begun up front in problem formulation and the analysis plan is the final product, the order in which assessment endpoints and conceptual models are produced depends on why the risk assessment was initiated (see section 3.2). To enhance clarity, the following discussion is presented as a linear progression. However, problem formulation is frequently interactive and iterative rather than linear. Reevaluation may occur during any part of problem formulation.

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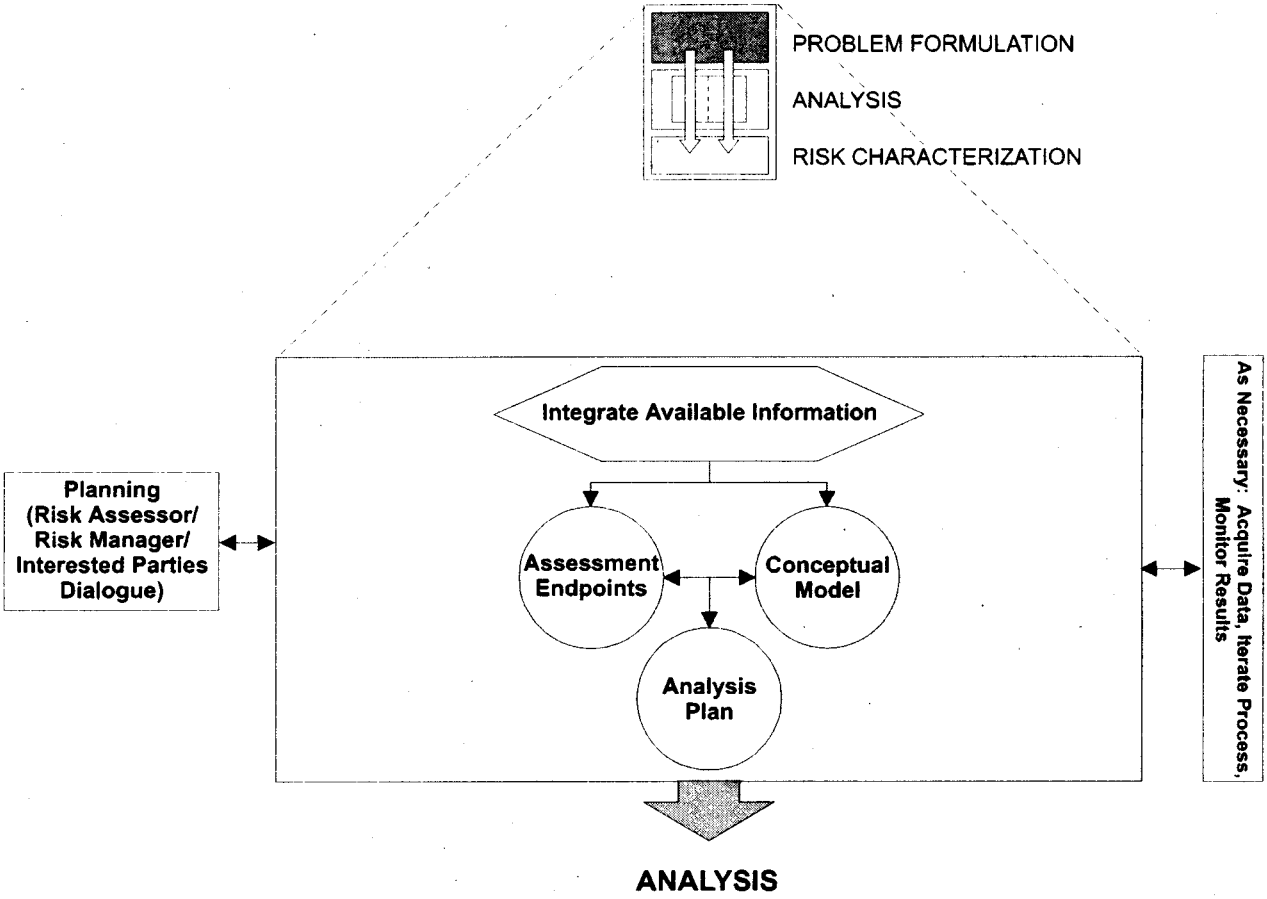

Figure 3-1. Problem formulation phase.

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3.2. Integration of Available Information

The foundation for problem formulation is based on how well available information on stressor sources and characteristics, exposure opportunities, characteristics of the ecosystem(s) potentially at risk, and ecological effects are integrated and used (see figure 3–1). Integration of available information is an iterative process that normally occurs throughout problem formulation. Initial evaluations often provide the basis for generating preliminary conceptual models or assessment endpoints, which in turn may lead risk assessors to seek other types of available information not previously recognized as needed.

The quality and quantity of information determine the course of problem formulation. When key information is of the appropriate type and sufficient quality and quantity, problem formulation can proceed effectively. When data are unavailable, the risk assessment may be suspended while additional data are collected or, if this is not possible, may be developed on the basis of what is known and what can be extrapolated from what is known. Risk assessments are frequently begun without all needed information, in which case the problem formulation process helps identify missing data and provides a framework for further data collection. Where data are few, the limitations of conclusions, or uncertainty, from the risk assessment should be clearly articulated in risk characterization (see text note 3–2).

The impetus for an ecological risk assessment influences what information is available at the outset and what information should be collected. For example, a risk assessment can be initiated because a known or potential stressor may enter the environment. Risk assessors evaluating a source or stressor will seek data on the effects with which the stressor might be associated and the ecosystems in which it will likely be introduced or found. If an observed adverse effect or change in ecological condition initiates the assessment, risk assessors will seek information about potential stressors and sources that could have caused the effect. When a risk assessment is initiated because of a desire to better manage an ecological value or entity (e.g., species, communities, ecosystems, or places), risk assessors will seek information on the specific condition or effect of interest, the characteristics of relevant ecosystems, and potential stressors and sources (see text note 3–3).

Information (actual, inferred, or estimated) is initially integrated in a scoping process that provides the foundation for developing problem formulation. Knowledge gained during scoping is used to identify missing information and potential assessment endpoints, and it provides the basis for early conceptualization of the problem being assessed. As problem formulation proceeds, information quality and applicability to the particular problem of concern are increasingly scrutinized. Where appropriate, further iterations may result in a comprehensive evaluation that helps risk assessors generate an array of risk hypotheses (see section 3.4.1). Once analysis plans are being formed, data validity becomes a significant factor for risk assessors to evaluate (see section 4.1 for a discussion of assessing data quality). Thus an evaluation of available information is an ongoing activity throughout problem formulation. The level of effort is driven by the type of assessment.

As the complexity and spatial scale of a risk assessment increase, information needs often escalate. Risk assessors consider the ways ecosystem 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 effort to understand 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 our limited knowledge of ecosystems and the stressors influencing them, the process of problem formulation offers a systematic approach for organizing and evaluating available information on stressors and possible effects. It can function as a preliminary risk assessment that is useful to risk assessors and decision makers. Text note 3–4 provides a series of questions that risk assessors should attempt to answer. 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 an analysis plan (discussed below). Early recognition that the reasons for initiating the risk assessment affect the order in which products are generated will help facilitate the development of problem formulation (see text note 3–3).

3.3. Selecting Assessment Endpoints

Assessment endpoints are explicit expressions of the actual environmental value that is to be protected, operationally defined by an ecological entity and its attributes (see section 3.3.2). Assessment endpoints are critical to problem formulation because they structure the assessment to address management concerns and are central to conceptual model development. Their relevance is determined by how well they target susceptible ecological entities. Their ability to support risk management decisions depends on whether they are measurable ecosystem characteristics that adequately represent management goals. The selection of ecological concerns and assessment endpoints at EPA has traditionally been done internally by individual Agency program offices (U.S. EPA, 1994a). More recently, interested and affected parties have helped identify management concerns and assessment endpoints in efforts to implement watershed or community-based environmental protection.

This section provides guidance on selecting and defining assessment endpoints. It is presented in two parts. Section 3.3.1 establishes three criteria (ecological relevance, susceptibility, and relevance to management goals) for determining how to select, among a broad array of possibilities, the specific ecological characteristics to target in the risk assessment that are responsive to general management goals and are scientifically defensible. Section 3.3.2 then provides specific guidance on how to convert selected ecological characteristics into operationally defined assessment endpoints that include both a defined entity and specific attributes amenable to measurement.

3.3.1. Criteria for Selection

All ecosystems are diverse, with many levels of ecological organization (e.g., individuals, populations, communities, ecosystems, landscapes) and multiple ecosystem processes. It is rarely clear which of these characteristics are most critical to ecosystem function, nor do professionals or the public always agree on which are most valuable. As a result, it is often a challenge to consider the array of possibilities and choose which ecological characteristics to protect to meet management goals. Those choices are critical, however, because they become the basis for defining assessment endpoints, the transition between broad management goals and the specific measures used in a risk assessment.

Three principal criteria are used to select ecological values that may be appropriate for assessment endpoints: (1) Ecological relevance, (2) susceptibility to known or potential stressors, and (3) relevance to management goals. Of these, ecological relevance and susceptibility are essential for selecting assessment endpoints that are scientifically defensible. However, to increase the likelihood that the risk assessment will be used in management decisions, assessment endpoints are more effective when they also reflect societal values and management goals. Given the complex functioning of ecosystems and the interdependence of ecological entities, it is likely that potential assessment endpoints can be identified that are both responsive to management goals and meet scientific criteria. 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). Ecologically relevant endpoints may be identified at any level of organization (e.g., individual, population, community, ecosystem, landscape). The consequences of changes in these endpoints may be quantified (e.g., alteration of community structure from the loss of a keystone species) or inferred (e.g., survival of individuals is needed to maintain populations). Ecological entities are not ecologically relevant unless they are currently, or were historically, part of the ecosystem under consideration.

Ecologically relevant endpoints often help sustain the natural structure, function, and biodiversity of an ecosystem or its components. They may contribute to the food base (e.g., primary production), provide habitat (e.g., for food or reproduction), 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). In landscape-level risk assessments, careful selection of assessment endpoints that address both species of concern and landscape-level ecosystem processes becomes important. It may be possible to select one or more species and an ecosystem process to represent larger functional community or ecosystem processes.

Ecological relevance is linked to the nature and intensity of potential effects, the spatial and temporal scales where effects may occur, and the potential for recovery (see Determining Ecological Adversity, section 5.2.2). It is also linked to the level of ecological organization that could be adversely affected (see U.S. EPA, 1997a, for a discussion of how different levels of organization are used by the Agency in defining assessment endpoints). When changes in selected ecosystem entities are likely to cause multiple or widespread effects, such entities can be powerful components of assessment endpoints. They are particularly valuable when risk assessors are trying to identify the potential cascade of adverse effects that could result from loss or reduction of a species or a change in ecosystem function (see text note 3–6). Although a cascade of effects may be predictable, it is often difficult to predict the nature of all potential effects. Determining ecological relevance in specific cases requires professional judgment based on site-specific information, preliminary surveys, or other available information.

3.3.1.2. Susceptibility to Known or Potential Stressors

Ecological resources are considered susceptible when they are sensitive to a stressor to which they are, or may be, exposed. Susceptibility can often be identified early in problem formulation, but not always. Risk assessors may be required to use their best professional judgment to select the most likely candidates (see text note 3–7).

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 (e.g., chemical sensitivity is influenced by individual physiology and metabolic pathways). Sensitivity is also influenced by individual and community life-history characteristics. For example, stream species assemblages that depend on cobble and gravel habitat for reproduction are sensitive to fine sediments that fill in spaces between cobbles. Species with long life cycles and low reproductive rates are often more vulnerable to extinction from increases in mortality than species 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 species with smaller home ranges that are encompassed 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 migration and genetic exchange among subpopulations. Such life-history characteristics are important to consider when evaluating potential sensitivity.

Sensitivity can 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 instance, Pacific salmon eggs and fry are very sensitive to fine-grain sedimentation in river beds because they can be smothered. Age-dependent sensitivity, however, is not only in the young. In many species, events like migration (e.g., in birds) and molting (e.g., in harbor seals) represent significant energy investments that increase vulnerability to stressors. Finally, sensitivity may be enhanced 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). To determine how sensitivity at a particular life stage is critical to population parameters or community-level assessment endpoints may require further evaluation.

Measures of sensitivity may include mortality or adverse reproductive effects from exposure to toxics. Other possible measures of sensitivity include behavioral abnormalities; avoidance of significant food sources and nesting sites; 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 second key determinant in susceptibility. Exposure can mean co-occurrence, contact, or the absence of contact, depending on the stressor and assessment endpoint. Questions concerning where a stressor originates, how it moves through the environment, and how it comes in contact with the assessment endpoint are evaluated to determine susceptibility (see section 4.2 for more discussion on characterizing exposure). The amount and conditions of exposure directly influence how an ecological entity will respond to a stressor. Thus, to determine which entities are susceptible, it is important that the assessor consider the proximity of an ecological value to stressors of concern, the timing of exposure (both in terms of frequency and duration), and the intensity of exposure occurring during sensitive periods.

Adverse effects of a particular stressor may be important during one part of an organism's life cycle, such as early development or reproduction. They 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 (see text note 3–8).

Exposure may occur in one place or time, but effects may not be observed until another place or time. Both life-history characteristics and the circumstances of exposure influence susceptibility in this case. For instance, the temperature of the egg incubation medium of marine turtles affects the sex ratio of hatchlings, but population impacts are not observed until years later when the cohort of affected turtles begins to reproduce. Delayed effects and multiple-stressor exposures add complexity to evaluations of susceptibility (e.g., although toxicity tests may determine receptor sensitivity to one stressor, 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 or other ecological entity is unlikely to be directly or indirectly exposed to the stressor of concern, or to the secondary effects of stressor exposure, it may be inappropriate as an assessment endpoint (see text note 3–7).

3.3.1.3. Relevance to Management Goals

Ultimately, the effectiveness of a risk assessment depends on whether it is used and improves the quality of management decisions. Risk managers are more willing to use a risk assessment for making decisions when it is based on ecological values that people care about. Thus, candidates for assessment endpoints include endangered species or ecosystems, commercially or recreationally important species, functional attributes that support food sources or flood control (e.g., wetland water sequestration), aesthetic values such as clean air in national parks, or the existence of charismatic species such as eagles or whales. However, selection of assessment endpoints based on public perceptions alone could lead to management decisions that do not consider important ecological information. While responsiveness to the public is important, it does not obviate the requirement for scientific validity.

The challenge is to find ecological values that meet the necessary scientific rigor as assessment endpoints that are also recognized as valuable by risk managers and the public. As an illustration, suppose an assessment is designed to evaluate the risk of applying pesticide around a lake to control insects. At this lake, however, midges are susceptible to the pesticide and form the base of a complex food web that supports a native fish population popular with sportsmen. While both midges and fish represent key components of the aquatic community, selecting the fishery as the value for defining the assessment endpoint targets both ecological and community concerns. Selecting midges would not. The risk assessment can then characterize the risk to the fishery if the midge population is adversely affected. This choice maintains the scientific validity of the risk assessment while being responsive to management concerns. In those cases where a critical assessment endpoint is identified that is unpopular with the public, the risk assessor may find it necessary to present a persuasive case in its favor to risk managers based on scientific arguments.

Practical issues may influence what values are selected as potential assessment endpoints, such as what is required by statute (e.g., endangered species) or whether it is possible to achieve a particular management goal. For example, in a river already impounded throughout its reach by multiple dams, goals for reestablishing spawning habitat for free-living anadromous salmon may be feasible only if dams are removed. If this will not be considered, selection of other ecological values as potential endpoints in this highly modified system may be the only option. Another concern may be whether it is possible to directly measure important variables. Where it is possible to directly measure attributes of an assessment endpoint, extrapolation is unnecessary, thus preventing the introduction of a source of uncertainty. Assessment endpoints that cannot be measured directly but can be represented by measures that are easily monitored and modeled may still provide a good foundation for a risk assessment. However, while established measurement protocols are convenient and useful, they do not determine whether an assessment endpoint is appropriate. Data availability alone is not an adequate criterion for selection.

To ensure scientific validity, risk assessors are responsible for selecting and defining potential assessment endpoints based on an understanding of the ecosystem of concern. Risk managers and risk assessors should then come to agreement on the final selection.

3.3.2. Defining Assessment Endpoints

Once ecological values are selected as potential assessment endpoints, they need to be operationally defined. Two elements are required to define an assessment endpoint. The first is the identification of the specific valued ecological entity. This can be a species (e.g., eelgrass, piping plover), a functional group of species (e.g., piscivores), a community (e.g., benthic invertebrates), an ecosystem (e.g., lake), a specific valued habitat (e.g., wet meadows), a unique place (e.g., a remnant of native prairie), or other entity of concern. The second is the characteristic about the entity of concern that is important to protect and potentially at risk. Thus, it is necessary to define what is important for piping plovers (e.g., nesting and feeding conditions), a lake (e.g., nutrient cycling), or wet meadow (e.g., endemic plant community diversity). For an assessment endpoint to serve as a clear interpretation of the management goals and the basis for measurement in the risk assessment, both an entity and an attribute are required.

What distinguishes assessment endpoints from management goals is their neutrality and specificity. Assessment endpoints do not represent a desired achievement (i.e., goal). As such, they do not contain words like ''protect,'' ''maintain,'' or ''restore,'' or indicate a direction for change such as ''loss'' or ''increase.'' Instead they are ecological values defined by specific entities and their measurable attributes, providing a framework for measuring stress-response relationships. When goals are very broad it may be difficult to select appropriate assessment endpoints until the goal is broken down into multiple management objectives. A series of management objectives can clarify the inherent assumptions within the goal and help a risk assessor determine which ecological entities and attributes best represent each objective (see text box 2–6). From this, multiple assessment endpoints may be selected. See text note 3–9 for examples of management goals and assessment endpoints.

Assessment endpoints may or may not be distinguishable from measures, depending on the assessment endpoints selected and the type of measures. While it is the entity that influences the scale and character of a risk assessment, it is the attributes of an assessment endpoint that determine what to measure. Sometimes direct measures of effect can be collected on the attribute of concern. Where this occurs, the assessment endpoint and measure of

effect are the same and no extrapolation is necessary (e.g., if the assessment endpoint is ''reproductive success of blue jays,'' egg production and fledgling success could potentially be directly measured under different stressor exposure scenarios). In other cases, direct measures may not be possible (e.g., toxicity in endangered species) and surrogate measures of effect must be selected. Thus, 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. For practical reasons, it may be helpful to use assessment endpoints that have well-developed test methods, field measurement techniques, and predictive models (see Suter, 1993a). However, it is not necessary for methods to be standardized protocols, nor should assessment endpoints be selected simply because standardized protocols are readily available. The appropriate measures to use are generally identified during conceptual model development and specified in the analysis plan. Measures of ecosystem characteristics and exposure are determined by the entity and attributes selected and serve as important information in conceptual model development. See section 3.5.1 for issues surrounding the selection of measures.

Clearly defined assessment endpoints provide direction and boundaries for the risk assessment and can minimize miscommunication and reduce uncertainty; where they are poorly defined, inappropriate, or at the incorrect scale, they can be very problematic. Endpoints 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 is too vague for an 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 or processes for an ecosystem and describing attributes that best represent integrity for that system. Assessment endpoints that are too narrowly defined may not support effective risk management. If an assessment is focused only on protecting the habitat of an endangered species, for example, the risk assessment may overlook other equally important characteristics of the ecosystem and fail to include critical variables (see text note 3–8). Finally, the assessment endpoint could fail to represent the ecosystem at risk. For instance, selecting a game fish that grows well in reservoirs may meet a ''fishable'' management goal, but it 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 ''fishable'' goals and may be highly desired by local fishermen, a reservoir species does not represent the ecosystem at risk. Substituting ''reproducing populations of indigenous salmonids'' for a vague ''viable fish populations'' assessment endpoint could therefore prevent the development of an inappropriate risk assessment.

When well selected, assessment endpoints become powerful tools in the risk assessment process. One endpoint that is sensitive to many of the identified stressors, yet responds in different ways to different stressors, may provide an opportunity to consider the combined effects of multiple stressors while still distinguishing their effects. For example, fish population recruitment may be adversely affected at several life stages, in different habitats, through different ways, and by different stressors. Therefore, measures of effect, exposure, and ecosystem and receptor characteristics could be chosen to evaluate recruitment and provide a basis for distinguishing different stressors, individual effects, and their combined effects.

The assessment endpoint can provide a basis for comparing a range of stressors if carefully selected. 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 also allowed the risk assessors 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., changes in the abundance of 1-year-old fish from exposure to toxicity, fishing pressure, and habitat loss). This is especially true when selecting assessment endpoints for multiple stressors. However, in situations where multiple stressors act on the structure and function of aquatic and terrestrial communities in a watershed, an array of assessment endpoints that represent the community and associated ecological processes is more effective than a single endpoint. When based on differing susceptibility to an array of stressors, carefully selected assessment endpoints can help risk assessors distinguish the effects of diverse stressors. Exposure to multiple stressors may lead to effects at different levels of biological organization, for a cascade of adverse effects that should be considered.

Professional judgment and an understanding of the characteristics and function of an ecosystem are important for translating general goals into usable assessment endpoints. The less information available, the more critical it is to have informed professionals help in the selection. Common problems encountered in selecting assessment endpoints are summarized in text note 3–10.

Final assessment endpoint selection is an important risk manager-risk assessor checkpoint during problem formulation. Risk assessors and risk managers should agree that selected assessment endpoints effectively represent the management goals. In addition, the scientific rationale for their selection should be made explicit in the risk assessment.

3.4. Conceptual Models

A conceptual model in problem formulation is a written description and visual representation of predicted relationships between ecological entities and the stressors to which they may be exposed. Conceptual models represent many relationships. They may include ecosystem processes that influence receptor responses or exposure scenarios that qualitatively link land-use activities to stressors. They may describe primary, secondary, and tertiary exposure pathways (see section 4.2) or co-occurrence among exposure pathways, ecological effects, and ecological receptors. Multiple conceptual models may be generated to address several issues in a given risk assessment. Some of the benefits gained by developing conceptual models are featured in text note 3–11.

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 are known at the outset (refer to section 3.2 and text note 3–3). The process of creating conceptual models helps identify the unknown elements.

The complexity of the conceptual model depends on the complexity of the problem: the number of stressors, number of assessment endpoints, nature of effects, and characteristics of the ecosystem. For single stressors and single assessment endpoints, conceptual models may be simple. In some cases,

the same basic conceptual model may be used repeatedly (e.g., in EPA's new chemical risk assessments). However, when conceptual models are used to describe pathways of individual stressors and assessment endpoints and the interaction of multiple and diverse stressors and assessment endpoints (e.g., assessments initiated to protect ecological values), more complex models and several submodels will often be needed. In this case, it can be helpful to create models that also represent expected ecosystem characteristics and function when stressors are not present.

Conceptual models consist of two principal components:

- A set of risk hypotheses that describe predicted relationships among 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, or suppositions tentatively accepted to provide a basis for evaluation. Risk hypotheses are specific assumptions about potential risk to assessment endpoints (see text note 3–12) and may be based on theory and logic, empirical data, mathematical models, or probability models. They are formulated using a combination of professional judgment and available 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 before they occur, or they may postulate why observed ecological effects occurred and ultimately what caused the effect. Depending on the scope of the risk assessment, 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. Risk hypotheses represent relationships in the conceptual model and are not designed for statistically testing null and alternative hypotheses. However, they can be used to generate questions appropriate for research.

Although risk hypotheses are valuable even when information is limited, the amount and quality of data and information 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 between 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 normally broad, identifying as many potential relationships as possible. As more information is incorporated, the plausibility of specific 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 hypotheses are documented. Examples of risk hypotheses are provided in text note 3–13.

3.4.2. Conceptual Model Diagrams

Conceptual model diagrams are a visual representation of risk hypotheses. They are useful tools for communicating important pathways clearly and concisely and can be used to generate new questions about relationships that help formulate plausible risk hypotheses.

Typical conceptual model diagrams are flow diagrams containing boxes and arrows to illustrate relationships (see Appendix C). When this approach is used, 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. Pictorial representations can be very effective (e.g., Bradley and Smith, 1989). Regardless of the configuration, a diagram's usefulness is linked to the detailed written descriptions and justifications for the relationships shown. Without this, diagrams can misrepresent the processes they are intended to illustrate.

When developing conceptual model diagrams, factors to consider include the number of relationships depicted, the comprehensiveness of the information, the certainty surrounding a linkage, and the potential for measurement. The number of relationships that can be depicted in one flow diagram depends on their complexity. Several models that increasingly show more detail for smaller portions can be more effective than trying to create one model that shows everything at the finest detail. Flow diagrams that highlight data abundance or scarcity can provide insights on how the analyses should be approached and can be used to show the risk assessor's confidence in the relationship. They can also show 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, the risk characterization may misrepresent actual risks. Uncertainty arises from lack of knowledge about how the ecosystem functions, failure to identify and interrelate temporal and spatial parameters, omission of stressors, or overlooking secondary effects. In some cases, little may be known about how a stressor moves through the environment or causes adverse effects. Multiple stressors are the norm and a source of confounding variables, particularly for conceptual models that focus on a single stressor. Professionals may not agree on the appropriate conceptual model configuration. 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 explored by considering alternative relationships. If more than one conceptual model is plausible, the risk assessor may evaluate whether it is feasible to follow separate models through analysis or whether the models can be combined to create a better model.

Conceptual models should be presented to risk managers to ensure that they communicate well and address managers' concerns. This check for completeness and clarity is a way to assess the need for changes before analysis begins. It is also valuable to revisit and where necessary revise conceptual models during risk

assessments to incorporate new information and recheck the rationale. If this is not feasible, it is helpful to present any new information during risk characterization along with associated uncertainties.

Throughout 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 description of the nature of the uncertainties should be summarized at the close of problem formulation. See text note 3–14 for recommendations on how to address uncertainty.

3.5. Analysis Plan

The analysis plan is the final stage of problem formulation. During analysis planning, risk hypotheses are evaluated to determine how they will be assessed using available and new data. The plan includes a delineation of the assessment design, data needs, measures, and methods for conducting the analysis phase of the risk assessment. Analysis plans may be brief or extensive depending on the assessment. For some assessments (e.g., EPA's new chemical assessments), the analysis plan is already part of the established protocol and a new plan is generally unnecessary. As risk assessments become more unique and complex, the importance of a good analysis plan increases.

The analysis plan includes pathways and relationships identified during problem formulation that will be pursued during the analysis phase. Those hypotheses considered more likely to contribute to risk are targeted. The rationale for selecting and omitting risk hypotheses is incorporated into the plan and includes acknowledgment of data gaps and uncertainties. It also may include a comparison of the level of confidence needed for the management decision with that expected from alternative analyses in order to determine data needs and evaluate which analytical approach is best. When new data are needed, the feasibility of obtaining them can be taken into account.

Identification of the most critical relationships to evaluate in a risk assessment is based on the relationship of assessment endpoints to ecosystem structure and function, the relative importance or influence and mode of action of stressors on assessment endpoints, and other variables influencing ecological adversity (see section 5.2.2). However, final selection of relationships that can be pursued in analysis is based on the strength of known relationships between stressors and effects, the completeness of known exposure pathways, and the quality and availability of data.

In situations where data are few and new data cannot be collected, it may be possible to extrapolate from existing data. Extrapolation allows the use of data collected from other locations or organisms where similar problems exist. For example, the relationship between nutrient availability and algal growth is well established and consistent. This relationship can be acknowledged despite differences in how it is manifested in particular ecosystems. When extrapolating from data, it is important to identify the source of the data, justify the extrapolation method, and discuss recognized uncertainties.

A phased, or tiered, risk assessment approach (see section 2.2) can facilitate management decisions in cases involving minimal data sets. However, where few data are available, recommendations for new data collection should be part of the analysis plan. When new data are needed and cannot be obtained, relationships that cannot be assessed are a source of uncertainty and should be described in the analysis plan and later discussed in risk characterization.

When determining what data to analyze and how to analyze them, consider how these analyses may increase understanding and confidence in the conclusions of the risk assessment and address risk management questions. During selection, risk assessors may ask questions such as: How relevant will the results be to the assessment endpoint(s) and conceptual model(s)? Are there sufficient data of high quality to conduct the analyses with confidence? How will the analyses help establish cause-and-effect relationships? How will results be presented to address managers' questions? Where are uncertainties likely to become a problem? Consideration of these questions during analysis planning will improve future characterization of risk (see section 5.2.1 for discussion of lines of evidence).

3.5.1. Selecting Measures

Assessment endpoints and conceptual models help risk assessors identify measurable attributes to quantify and predict change. However, determining what measures to use to evaluate risk hypotheses is both challenging and critical to the success of a risk assessment. There are three categories of measures. Measures of effect are measurable changes in an attribute of an assessment endpoint or its surrogate in response to a stressor to which it is exposed (formerly measurement endpoints; see text note 3–15). Measures of exposure are measures of stressor existence and movement in the environment and their contact or co-occurrence with the assessment endpoint. Measures of ecosystem and receptor characteristics are measures of ecosystem characteristics that influence the behavior and location of entities selected as the assessment endpoint, the distribution of a stressor, and life-history characteristics of the assessment endpoint or its surrogate that may affect exposure or response to the stressor. Examples of the three types of measures are provided in text note 3–16 (see also Appendix A.2.1).

The selection of appropriate measures is particularly complicated when a cascade of ecological effects is likely to occur from a stressor. In these cases, the effect on one entity (i.e., the measure of effect) may become a stressor for other ecological entities (i.e., become a measure of exposure) and may result in impacts on one or more assessment endpoints. For example, if a pesticide reduces earthworm populations, change in earthworm population density could be the direct measure of effect of toxicity and in some cases may be an assessment endpoint. However, the reduction of worm populations may then become a secondary stressor to which worm-eating birds become exposed, measured as lowered food supply. This exposure may then result in a secondary measurable effect of starvation of young. In this case, although ''bird fledgling success'' may be an assessment endpoint that could be measured directly, measures of earthworm density, pesticide residue in earthworms and other food sources, availability of alternative foods, nest site quality, and competition for nests from other bird species may all be useful measurements.

When direct measurement of assessment endpoint responses is not possible, the selection of surrogate measures is necessary. The selection of what, where, and how to measure surrogate responses determines whether the risk assessment is still relevant to management decisions about an assessment endpoint. As an example, an assessment may be conducted to evaluate the potential risk of a pesticide used on seeds to an endangered species of seed-eating bird. The assessment endpoint entity is the endangered species. Example attributes include feeding behavior, survival, growth, and reproduction. While it may be possible

to directly collect measures of exposure and assessment endpoint life-history characteristics on the endangered species, it would not be appropriate to expose the endangered species to the pesticide to measure sensitivity. In this case, to evaluate susceptibility, the most appropriate surrogate measures would be on seed-eating birds with similar life-history characteristics and phylogeny. While insectivorous birds may serve as an adequate surrogate measure for determining the sensitivity of the endangered bird to the pesticide, they do not address issues of exposure.

Problem formulations based on assessment endpoints and selected measures that address both sensitivity and likely exposure to stressors will be relevant to management concerns. If assessment endpoints are not susceptible, their use in assessing risk can lead to poor management decisions (see section 3.3.1). To highlight the relationships among goals, assessment endpoints, and measures, text note 3–17 illustrates how these are related in water quality criteria. In this example, it is instructive to note that although water quality criteria are considered risk-based, they are not full risk assessments. Water quality criteria provide an effects benchmark for decision making and do not incorporate measures of exposure in the environment. 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). Such assumptions embedded in decision rules are important to articulate (see section 3.5.2).

The analysis plan provides a synopsis of measures that will be used to evaluate risk hypotheses. The plan is strongest when it contains explicit statements for how measures were selected, what they are intended to evaluate, and which analyses they support. Uncertainties associated with selected measures and analyses and plans for addressing them should be included in the plan when possible.

3.5.2. Ensuring That Planned Analyses Meet Risk Managers' Needs

The analysis plan is a risk manager-risk assessor checkpoint. Risk assessors and risk managers review the plan to ensure that the analyses will provide information the manager can use for decision making. These discussions may also identify what can and cannot be done on the basis of a preliminary evaluation of problem formulation. A reiteration of the planning discussion helps ensure that the appropriate balance of requirements for the decision, data availability, and resource constraints is established for the risk assessment. This is also an appropriate time to conduct a technical review of the planning outcome.

Analysis plans include the analytical methods planned and the nature of the risk characterization options and considerations to be generated (e.g., quotients, narrative discussion, stressor-response curve with probabilities). A description of how data analyses will distinguish among risk hypotheses, the kinds of analyses to be used, and rationale for why different hypotheses were selected and eliminated are included. Potential extrapolations, model characteristics, types of data (including quality), and planned analyses (with specific tests for different types of data) are described. Finally, the plan includes a discussion of how results will be presented upon completion and the basis used for data selection.

Analysis planning is similar to the data quality objectives (DQO) process (see text note 3–18), which emphasizes identifying the problem by establishing study boundaries and determining necessary data quality, quantity, and applicability to the problem being evaluated (U.S. EPA, 1994c). The most important difference between problem formulation and the DQO process is the presence of a decision rule in a DQO 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 (often used in tiered assessments; see also section 2.2.2). This approach provides the basis for establishing null and alternative hypotheses appropriate for statistical testing for significance that can be effective in this application. While this approach is sometimes appropriate, only certain kinds of risk assessments are 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 (see Suter, 1996).

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 the problem is clearly defined and there are enough data to proceed, analysis begins.

4. Analysis Phase

Analysis is a process that examines the two primary components of risk, exposure and effects, and their relationships between each other and ecosystem characteristics. The objective is to provide the ingredients necessary for determining or predicting ecological responses to stressors under exposure conditions of interest.

Analysis connects problem formulation with risk characterization. The assessment endpoints and conceptual models developed during problem formulation provide the focus and structure for the analyses. Analysis phase products are summary profiles that describe exposure and the relationship between the stressor(s) and response. These profiles provide the basis for estimating and describing risks in risk characterization.

At the beginning of the analysis phase, the information needs identified during problem formulation should have already been addressed (text note 4–1). During the analysis phase (figure 4–1), the risk assessor:

- Selects the data that will be used on the basis of their utility for evaluating the risk hypotheses (section 4.1)
- Analyzes exposure by examining the sources of stressors, the distribution of stressors in the environment, and the extent of co-occurrence or contact (section 4.2)
- Analyzes effects by examining stressor-response relationships, the evidence for causality, and the relationship between measures of effect and assessment endpoints (section 4.3)
- Summarizes the conclusions about exposure (section 4.2.2) and effects (section 4.3.2).

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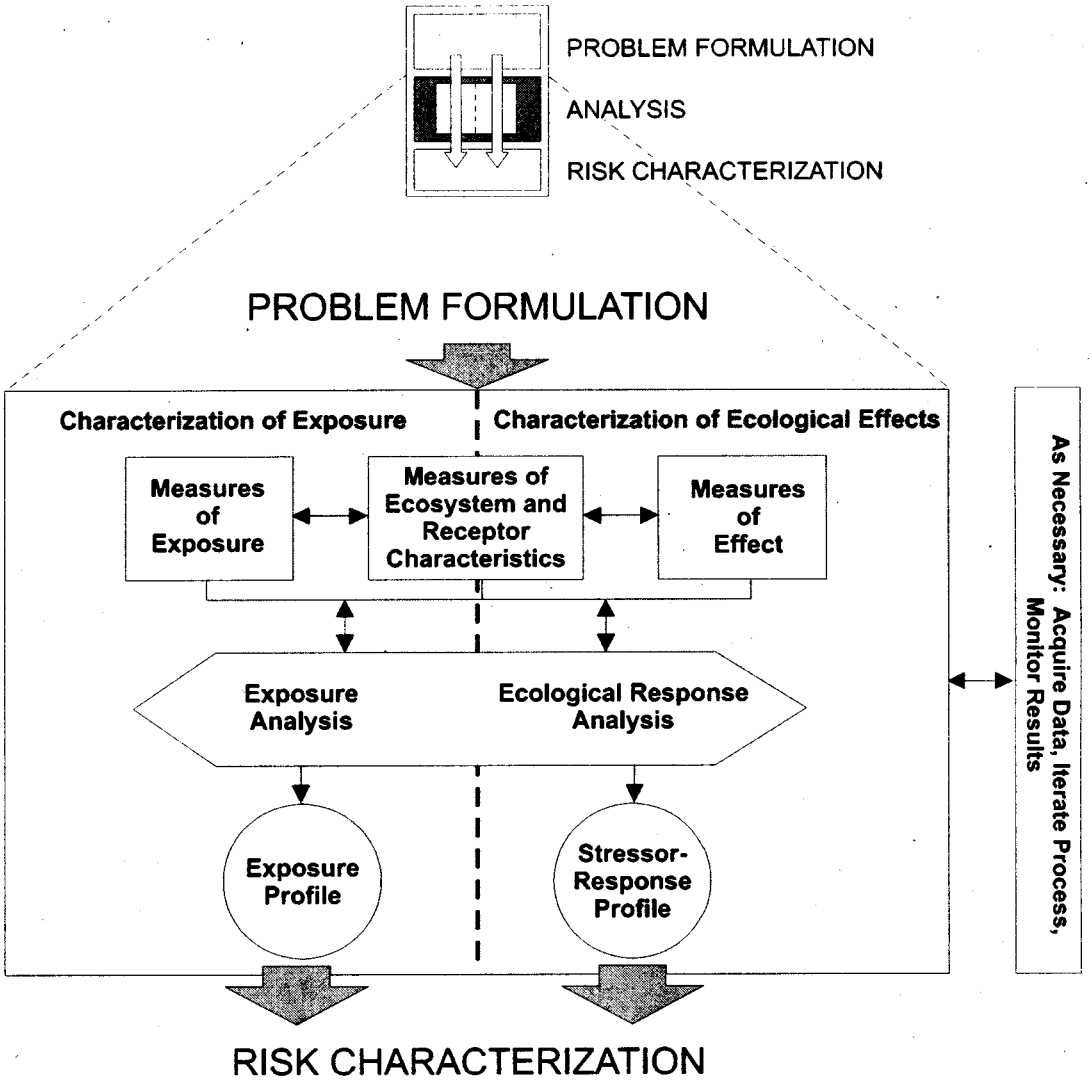

Figure 4-1. Analysis phase.

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The analysis phase is flexible, with substantial interaction between the effects and exposure characterizations as illustrated by the dotted line in figure 4–1. In particular, when secondary stressors and effects are of concern, exposure and effects analyses are conducted iteratively for different ecological entities, and they can become intertwined and difficult to differentiate. In the bottomland hardwoods assessment, for example (Appendix D), potential changes in the plant and animal communities under different flooding scenarios were examined. Risk assessors combined the stressor-response and exposure analyses 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 analysis and risk estimation can become blurred. The model results developed for the bottomland hardwoods assessment were used directly in risk characterization.

The nature of the stressor influences the types of analyses conducted. The results may range from highly quantitative to qualitative, depending on the stressor and the scope of the assessment. For chemical stressors, exposure estimates emphasize contact and uptake into the organism, and effects estimations often entail extrapolation from test organisms to the organism of interest. For physical stressors, the initial disturbance may cause primary effects on the assessment endpoint (e.g., loss of wetland acreage). In many cases, however, secondary effects (e.g., decline of wildlife populations that depend on wetlands) may be the principal concern. The point of view depends on the assessment endpoints. 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 is an evaluation of 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 always be quantified with confidence; therefore, they may be assessed qualitatively by eliciting expert opinion (Simberloff and Alexander, 1994).

4.1. Evaluating Data and Models for Analysis

At the beginning of the analysis phase, the assessor critically examines the data and models to ensure that they can be used to evaluate the conceptual model developed in problem formulation (see sections 4.1.1 and 4.1.2). Section 4.1.3 addresses uncertainty evaluation.

4.1.1. Strengths and Limitations of Different Types of Data

Many types of data can be used for risk assessment. Data may come from laboratory or field studies or may be produced as output from a model. Familiarity with the strengths and limitations of different types of data can help assessors build on strengths and avoid pitfalls. Such a strategy improves confidence in the conclusions of the 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 may be less variable and smaller differences easier to detect. However, the controls may limit the range of responses (e.g., animals cannot seek alternative food sources), so they may not reflect responses in the environment. In addition, larger-scale processes are difficult to replicate in the laboratory.

Field observational studies (surveys) measure biological changes in uncontrolled situations. Ecologists observe patterns and processes in the field and often use statistical techniques (e.g., correlation, clustering, factor analysis) to describe an association between a disturbance and an ecological effect. For instance, physical attributes of streams and their watersheds have been associated with changes in stream communities (Richards et al., 1997). Field surveys are often reported as status and trend studies. Messer et al. (1991) correlated a biotic index with acid concentrations to describe the extent and proportion of lakes likely to be impacted.

Field surveys usually represent exposures and effects (including secondary effects) better than estimates generated from laboratory studies or theoretical models. Field data are more important for assessments of multiple stressors or where site-specific factors significantly influence exposure. They are also often useful for analyses of larger geographic scales and higher levels of biological organization. Field survey data are not always necessary or feasible to collect for screening-level or prospective assessments.

Field surveys should be designed with sufficient statistical rigor to define one or more of the following:

- Exposure in the system of interest
- Differences in measures of effect between reference sites and study areas
- Lack of differences. Because conditions are not controlled in field studies, variability may be higher and it may be difficult to detect differences. For this reason, it is important to verify that studies have sufficient power to detect important differences.

Field surveys are most useful for linking stressors with effects when stressor and effect levels are measured concurrently. The presence of confounding factors can make it difficult to attribute observed effects to specific stressors. For this reason, field studies designed to minimize effects of potentially confounding factors are preferred, and the evidence for causality should be carefully evaluated (see section 4.3.1.2). In addition, because treatments may not be randomly applied or replicated, classical statistical methods need to be applied with caution (Hurlbert, 1984; Stewart-Oaten et al., 1986; Wiens and Parker, 1995; Eberhardt and Thomas, 1991). Intermediate between laboratory and field are studies that use environmental media collected from the field to examine 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 and reported as indices. 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.

Indices also have several drawbacks, many of which are associated with combining heterogeneous variables. 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. To investigate causality, such indices may need to be separated into their

components, or analyzed using multivariate methods (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. Measures of exposure and effects 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 particularly useful in assessments of stressors not yet released (i.e., prospective assessments). 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 toxicity evaluation for 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 a compound for which data are lacking. More advanced applications use quantitative structure-activity relationships (QSARs), which mathematically model 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, use of these data may be the only option available.

Even though models may be developed and used as part of the risk assessment, sometimes the risk assessor relies on output of a previously developed model. Models are particularly useful when measurements cannot be taken, for example, when predicting the effects of a chemical yet to be manufactured. They can also provide estimates for times or locations that are impractical to measure and can provide a basis for extrapolating beyond the range of observation. Because models simplify reality, they may omit 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 section 2.2). 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 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. Tiered data should be evaluated in light of the decision they are intended to support; data collected for early tiers may not support more sophisticated needs.

4.1.2. Evaluating Measurement or Modeling Studies

The assessor's first task in the analysis phase is to carefully evaluate studies to determine whether they can support the objectives of the risk assessment. Each study should include a description of the purpose, methods used to collect data, and results of the work. The assessor evaluates the utility of studies by carefully comparing study objectives with those of the risk assessment for consistency. In addition, the assessor should determine whether the intended objectives were met and whether the data are of sufficient quality to support the risk assessment. This is a good opportunity to note the confidence in the information and the implications of different studies for use in the risk characterization, when the overall confidence in the assessment is discussed. Finally, the risk assessor should identify areas where existing data do not meet risk assessment needs. In these cases, collecting additional data is recommended.

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 may also refer to Smith and Shugart, 1994; U.S. EPA, 1994d; and U.S. EPA, 1990, for more information on evaluating data and models.

A study's documentation determines whether it can be evaluated for its utility in 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. Ideally, one should be able 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, any parameter estimation techniques, and tables or graphs of results.

Study descriptions may not provide all the information needed to evaluate their utility for risk assessment. Assessors should communicate with the principal investigator or other study participants to gain information on study plans and their implementation. Useful questions for evaluating studies are shown in text note 4–3.

4.1.2.1. Evaluating the Purpose and Scope of the Study

Assessors should pay particular attention to the objectives and scope of studies that were designed for purposes other than the risk assessment at hand. This can identify important uncertainties and ensure that the information is used appropriately. 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 measures of effects identified in problem formulation, to support a causal argument they must be linked with stressors. In the best case, this means that the stressor was measured at the same time and place as the effect.

Similarly, a model may have been developed for purposes other than risk assessment. Its 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 is of 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 identified during problem formulation. In addition, the range of variability explored in the study should be compared with that of the risk assessment. A study that examines animal habitat needs in the winter, for example, may miss important breeding-season

requirements. Studies that minimize the amount of extrapolation needed are preferred. These are studies that represent:

- The measures identified in the analysis plan (i.e., measures of exposure, effects, and ecosystem and receptor characteristics)
- The time frame of interest
- 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 assessor evaluates study design and implementation to determine whether the study objectives were met and the information is of sufficient quality to support 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 of an effects study is whether it has enough statistical 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).

Part of the exercise examines whether 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 identification and control of potentially confounding variables and careful reference site selection. (A discussion of reference site selection is beyond the scope of these Guidelines; however, it has been identified as a candidate topic for future development.)
- For models, issues include the program's structure and logic and the correct specification of algorithms in the model code (U.S. EPA, 1994d).

Evaluation is easier if standard methods or quality assurance/quality control (QA/QC) protocols are available and followed by the study. However, the assessor should still consider whether the identified precision and accuracy goals were achieved and whether they are appropriate for the risk assessment. For instance, detection limits identified for one environmental matrix may not be achievable for another, and thus it may not be possible to detect concentrations of interest. Study results can still be useful even if a standard method was not used. However, this places 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 a 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 the credibility of assessments by explicitly describing the magnitude and direction of uncertainties, and they provide the basis for efficient data collection or application of refined methods. Uncertainties characterized during the analysis phase are used during risk characterization, when risks are estimated (section 5.1) and the confidence in different lines of evidence is described (see section 5.2.1).

This section discusses sources of uncertainty relevant to the analysis of ecological exposure and effects; source and example strategies are shown in text note 4–4. Section 3.4.3 discusses uncertainty in conceptual model development. Readers are also referred to the discussion of uncertainties in the exposure assessment guidelines (U.S. EPA, 1992b).

Sources of uncertainty that are encountered when evaluating information include unclear communication of the data or its manipulation and errors in the information itself (descriptive errors). These are usually characterized by critically examining the sources of information and documenting the decisions made when handling it. The documentation should allow the reader to make an independent judgment about the validity of the assessor's decisions.

Sources of uncertainty that primarily arise 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 a characteristic's true heterogeneity. Examples include the variability in soil organic carbon, seasonal differences in animal diets, or differences in chemical sensitivity in different species. Variability 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 a study's ability to detect effects. Properly designed studies will specify sample sizes large enough 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 thus far been applied primarily in human epidemiology and are still controversial (Mann, 1990).

Interest in quantifying spatial uncertainty has increased with the increasing use of geographic information systems (GIS). Strategies include verifying the locations of remotely sensed features and ensuring that the spatial resolution of data or a method is commensurate with the needs of the assessment. A growing literature is addressing other analytical challenges often associated with using spatial data (e.g., collinearity and autocorrelation, boundary and scale effects, lack of true replication) (Johnson and Gage, 1997; Fotheringham and Rogerson, 1993; Wiens and Parker, 1995). Large-scale assessments generally require aggregating information at smaller scales. It is not known how aggregation affects uncertainty (Hunsaker et al., 1990).

Nearly every assessment must treat situations where data are unavailable or available only for parameters other than those of interest. Examples include using laboratory data to estimate a wild animal's response to a stressor or using a bioaccumulation measurement from a different ecosystem. These data gaps are usually bridged with a combination of scientific analyses, scientific judgment, and perhaps policy decisions. In deriving an ambient water quality criterion (text note 3–17), for example, 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 defines the extent to which individual species should be protected (e.g., 90% vs. 95% of the species). It is important to distinguish these elements.

Data gaps can often be filled by completing additional studies on the unknown parameter. When possible, the necessary data should be collected. At the least, opportunities for filling data gaps should be noted and carried through to risk characterization. Data or knowledge gaps that are so large that they preclude the analysis of either exposure or ecological effects should also be noted and discussed in risk characterization.

An important objective is to distinguish variability from uncertainties that arise from lack of knowledge (e.g., uncertainty about a quantity's true value) (U.S. EPA, 1995b). This distinction facilitates the interpretation and communication of results. For instance, in their food web models of herons and mink, MacIntosh et al. (1994) separated expected variability in individual animals' feeding habits from the uncertainty in the mean concentration of chemical in prey species. They could then place error bounds on the exposure distribution for 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 model development and application include process model structure and the relationships between variables in empirical models. Process model descriptions should include assumptions, simplifications, and aggregations of variables (see text note 4–5). Empirical model descriptions should include the rationale for selection and model performance statistics (e.g., goodness of fit). Uncertainty in process or empirical models can be quantitatively evaluated by comparing model results to measurements taken in the system of interest or by comparing the results of different models.

Methods for analyzing and describing uncertainty can range from simple to complex. When little is known, a useful approach is to estimate exposure and effects based on alternative sets of assumptions (scenarios). Each scenario is carried through to risk characterization, where the underlying assumptions and the scenario's plausibility are discussed. Results can be presented as a series of point estimates with different aspects of uncertainty reflected in each. Classical statistical methods (e.g., confidence limits, percentiles) can readily describe parameter uncertainty. For models, 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 in the results. The availability of software for Monte Carlo analysis has greatly increased the use of probabilistic methods; readers are encouraged to follow suggested best practices (e.g., U.S. EPA, 1996a, 1997b). 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). The Agency does not endorse the use of any one method and cautions 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 potential or actual contact or co-occurrence of stressors with receptors. It is based on measures of exposure and ecosystem and receptor characteristics that 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 exposure profile to be useful, it should be compatible with the stressor-response relationship generated in the effects characterization.

4.2.1. Exposure Analyses

Exposure is contact or co-occurrence between a stressor and a receptor. The objective is to describe exposure 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(s) to the receptors (i.e., describe the exposure pathway).

A complete picture of how, when, and where exposure occurs or has occurred is developed by evaluating sources and releases, the distribution of the stressor in the environment, and the extent and pattern of contact or co-occurrence. The order of these topics here is not necessarily the order in which they are executed. The assessor may start with information about tissue residues, for example, and attempt to link these residues with a source.

4.2.1.1. Describe the Source(s)

A source can be defined in two general ways: as the place where the stressor originates or is released (e.g., a smokestack, historically contaminated sediments) or the management practice or action (e.g., dredging) that produces stressors. In some assessments, the original sources may no longer exist and the source may be defined as the current location of the stressors. For example, contaminated sediments might be considered a source because the industrial plant that produced the contaminants no longer operates. A 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.

Exposure analyses may start with the source when it is known, begin with known exposures and attempt to link them to sources, or start with known stressors and attempt to identify sources and quantify contact. In any case, the objective of this step is to identify the sources, evaluate what stressors are generated, and identify other potential sources. Text note 4–6 provides some useful questions to ask when describing sources.

In addition to identifying sources, the assessor examines the intensity, timing, and location of stressors' release. The location of a source and the environmental media that first receive stressors are two attributes that deserve particular attention. For chemical stressors, the source characterization should also consider whether other constituents emitted by a source influence transport, transformation, or bioavailability of the stressor of interest. 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), for example. 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, so it

may be necessary to characterize these as well. Many chemicals occur naturally (e.g., most metals), are generally widespread from 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 instance, construction activities may release fine sediments into a stream in addition to those coming from a naturally undercut bank. Human activities may also 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 assessment scope identified during planning determines how multiple sources are evaluated. Options include (in order of increasing complexity):

- Focus only on the source under evaluation and calculate the 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 introduced 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. In their risk analysis of Chilean log importation, for example, the assessment team concluded that the beetle *Hylurgus ligniperda* had a high potential for entry into the United States. Their conclusion was based on the beetle's attraction to freshly cut logs and tendency to burrow under the bark, which would provide protection during transport (USDA, 1993).

4.2.1.2. Describe the Distribution of the Stressors or Disturbed Environment

The second objective of exposure analysis is to describe the spatial and temporal distribution of stressors 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 when receptors co-occur with or contact stressors, this characterization is a prerequisite for estimating exposure. Stressor distribution in the environment is examined by evaluating pathways from the source as well as the formation and subsequent distribution of secondary stressors (see text note 4–7).

4.2.1.2.1. Evaluating Transport Pathways

Stressors can be transported via many pathways (see text note 4–8). A careful evaluation can help ensure that measurements are taken in the appropriate media and locations and that models include the most important processes.

For a chemical stressor, the evaluation usually begins by determining into which media it can partition. Key considerations include physicochemical properties such as solubility and vapor pressure. For example, chemicals with low solubility in water 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 chemical mixture constituents may have different properties, the analysis should 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 (including bioaccumulation) is beyond the scope of these Guidelines; readers are referred to the exposure assessment guidelines (U.S. EPA, 1992b) for additional information. The topics of bioaccumulation and biomagnification have been identified as candidates for further development.

The attributes of physical stressors also influence where they will go. The size of suspended particles determines where they will eventually deposit in a stream, for example. Physical stressors that eliminate ecosystems or portions of them (e.g., fishing activities or the construction of dams) may require no modeling of pathways—the fish are harvested or the valley is flooded. For these direct disturbances, the challenge is usually to evaluate secondary stressors and effects.

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 primarily a function of reproductive rates and motility. 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. Some biological stressors can use both strategies, which may make dispersal rates very difficult to predict. The evaluation should consider factors such as vector availability, attributes that enhance dispersal (e.g., ability to fly, adhere to objects, disperse reproductive units), and habitat or host needs.

For biological stressors, assessors should consider the additional factors of survival and reproduction. Organisms use a wide range of strategies to survive in adverse conditions; for example, fungi form resting stages such as sclerotia and chlamydospores and some amphibians become 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 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 should be interpreted with caution, and the uncertainty should be addressed by using several different scenarios.

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. Other cases need more professional judgment. When evaluating the likelihood that an introduced organism will become established, for instance, it is useful to know whether the ecosystem is generally similar to or different from the one where the biological stressor originated. Professional judgment is used to determine which characteristics of the current and original ecosystems should be compared.

4.2.1.2.2. Evaluating Secondary Stressors

Secondary stressors can greatly alter conclusions about risk; they may be of

greater or lesser concern than the primary stressor. Secondary stressor evaluation is usually part of exposure characterization; however, it should be coordinated with the ecological effects characterization to ensure that all potentially important secondary stressors are considered.

For chemicals, the evaluation usually focuses on metabolites, biodegradation products, or chemicals formed through abiotic processes. As an example, microbial action increases the bioaccumulation of mercury by transforming inorganic forms to organic species. 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. Secondary stressors can also be formed through ecosystem processes. Nutrient inputs into an estuary can decrease dissolved oxygen concentrations because they increase primary production and subsequent decomposition. Although 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., oil degradation by microorganisms) and transport processes (e.g., volatilization). Although they may be difficult to distinguish, the assessor should be aware that these two different processes will largely determine if secondary stressors are likely to be formed. A combination of these factors will also determine how much of the secondary stressor(s) may be bioavailable to receptors. These considerations reinforce the need to have a chemical risk assessment team experienced in physical/chemical as well as biological processes.

Physical disturbances can also generate secondary stressors, and identifying the specific consequences that will affect the assessment endpoint can be a difficult task. The removal of riparian vegetation, for example, can generate many secondary stressors, including increased nutrients, stream temperature, sedimentation, and altered stream flow. However, it may be the temperature change that is most responsible for adult salmon mortality in a particular stream.

Stressor distribution in the environment can be described using measurements, models, or a combination of the two. If stressors have already been released, direct measurement of environmental media or a combination of modeling and measurement is preferred. Models enhance the ability to investigate the consequences of different management scenarios and may be necessary if measurements are not possible or practicable. They are also useful if a quantitative relationship of sources and stressors is desired. As examples, land use activities have been related to downstream suspended solids concentrations (Oberts, 1981), and downstream flood peaks have been predicted from the extent of wetlands in a watershed (Novitski, 1979; Johnston et al., 1990). Considerations for evaluating data collection and modeling studies are discussed in section 4.1. For chemical stressors, readers may also refer to the exposure assessment guidelines (U.S. EPA, 1992b). For biological stressors, distribution may be difficult to predict quantitatively. If it cannot be measured, it 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 provides the foundation for estimating the contact or co-occurrence of the stressor with ecological entities. When contact is known to have occurred, describing the stressor's environmental distribution can help identify potential sources and ensure that all important exposures are addressed.

4.2.1.3. Describe Contact or Co-Occurrence

The third objective is to describe the extent and pattern of co-occurrence or contact between stressors and receptors (i.e., exposure). This is critical—if there is no exposure, there can be no risk. Therefore, assessors should be careful to include situations where exposure may occur in the future, where exposure has occurred in the past but is not currently evident (e.g., in some retrospective assessments), and where ecosystem components important for food or habitat are or may be exposed, resulting in impacts to the valued entity (e.g., see figure D–2). Exposure can be described in terms of stressor and receptor co-occurrence, actual stressor contact with receptors, or stressor uptake by a receptor. The terms in which exposure is described depend on how the stressor causes adverse effects and how the stressor-response relationship is described. Relevant questions for examining contact or co-occurrence are shown in text note 4–9.

Co-occurrence is particularly useful for evaluating stressors that can cause effects without physically contacting ecological receptors. Whooping cranes provide a case in point: they use sandbars in rivers for their resting areas, and they prefer sandbars with unobstructed views. Manmade obstructions such as bridges can interfere with resting behavior without ever actually contacting the birds. Co-occurrence is evaluated by comparing stressor distributions with that of the receptor. For instance, stressor location maps may be overlaid with maps of ecological receptors (e.g., bridge placement overlaid on maps showing historical crane resting habitat). Co-occurrence of a biological stressor and receptor may be used to evaluate exposure when, for example, introduced species and native species compete for the same resources. GIS has provided new tools for evaluating co-occurrence.

Most stressors must contact receptors to cause an effect. For example, tree roots must contact flood waters before their growth is impaired. Contact is a function of the amount or extent of a stressor in an environmental medium and activity or behavior of the receptors. For biological stressors, risk assessors usually rely on professional judgment; contact is often assumed to occur in areas and during times where the stressor and receptor are both present. Contact variables such as the mode of transmission between organisms may influence the contact between biological stressors and receptors.

For chemicals, contact is quantified as the amount of a chemical ingested, inhaled, or in material applied to the skin (potential dose). In its simplest form, it is quantified as an environmental concentration, with the assumptions that the chemical is well mixed or that the organism moves randomly through the medium. This approach is commonly used for respired media (water for aquatic organisms, air for terrestrial organisms). For ingested media (food, soil), another common approach combines modeled or measured contaminant concentrations with assumptions or parameters describing the contact rate (U.S. EPA, 1993a) (see text note 4–10).

Finally, some stressors must not only be contacted but also must be internally absorbed. A toxicant that causes liver tumors in fish, for example, must be absorbed and reach the target organ to cause the effect. Uptake is evaluated by considering the amount of stressor internally absorbed by an organism. It is a function of the stressor (e.g., a chemical's form or a pathogen's size), the medium (sorptive properties or presence of solvents), the biological membrane (integrity, permeability), and the organism (sickness, active uptake) (Suter et al., 1994). Because of

interactions between 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 (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 4–11). 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 uptake estimates in risk calculations. 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, naturally anoxic areas above contaminated sediments in an estuary may reduce the time bottom-feeding fish spend in contact with sediments and thereby reduce their exposure to contaminants. Biotic interactions can also influence exposure. For example, competition for high-quality resources may force some organisms into disturbed areas. The interaction between exposure and receptor behavior can influence both initial and subsequent exposures. Some chemicals reduce the prey's ability to escape predators, for instance, 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 should 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, some threshold intensity is exceeded, or intensity is integrated. If exposure occurs as repeated discrete events of about the same duration, frequency is the important temporal dimension of exposure (e.g., the frequency of high-flow events in streams). If the repeated events have significant and variable durations, both duration and frequency should be considered. In addition, the timing of exposure, including the order or sequence of events, can be an important factor. Adirondack Mountain 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, intensity and time are often combined by averaging intensity over time. The duration over which intensity is averaged is determined by considering 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 (U.S. EPA, 1992b). 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 toxicodynamic 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 paved habitat, 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, landscape ecology and GIS have greatly expanded the options for analyzing and presenting the spatial dimension of exposure (e.g., Pastorok et al., 1996).

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 an exposure profile. Exposure should be described in terms of intensity, space, and time in units that can be combined with the effects assessment. The assessor should summarize the paths of stressors from the source to the receptors, completing the exposure pathway. Depending on the risk assessment, the profile may be a written document or a module of a larger process model. 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 (see text note 4–12).

The profile should describe the applicable exposure pathways. If exposure can occur through many pathways, it may be useful to rank them, perhaps by contribution to total exposure. As an illustration, consider an assessment of risks to grebes feeding in 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 identify the ecological entity that the exposure estimates represent. For example, the exposure estimates may describe the local population of grebes feeding on a specific lake during the summer months.

The assessor should explain how each of the three general dimensions of exposure (intensity, time, and space) was treated. 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 exposure can vary depending on receptor attributes or stressor levels. For instance, the exposure may be higher for grebes eating a larger proportion of bigger, more contaminated fish. 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 B–1 and B–2). Figures 5–3 to 5–5 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. Descriptors discussed in U.S. EPA, 1992b, are recommended, 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 (e.g., 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, completing the exposure profile. It is one of the products of the analysis phase and 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

To characterize ecological effects, the assessor describes the effects elicited by a stressor, links them to the assessment endpoints, and evaluates how they change with varying stressor levels. The characterization begins by evaluating effects data to specify the effects that are elicited, verify that they 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, the assessor conducts an ecological response analysis (section 4.3.1), evaluating how the magnitude of the effects change with varying stressor levels and the evidence that the stressor causes the effect, and then linking the effects with the assessment endpoint. Conclusions are summarized in a stressor-response profile (section 4.3.2).

4.3.1. Ecological Response Analysis

Ecological response analysis examines three primary elements: the relationship between stressor levels and ecological effects (section 4.3.1.1), the plausibility that effects may occur or are occurring as a result of exposure to stressors (section 4.3.1.2), and linkages between measurable ecological effects and assessment endpoints when the latter cannot be directly measured (section 4.3.1.3).

4.3.1.1. Stressor-Response Analysis

To evaluate ecological risks, one must understand the relationships between stressors and resulting 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 needed to determine the presence or absence of an effects threshold or for evaluating incremental risks, or stressor-response curves may be used as input for 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 (see section 4.3.1.3). Text note 4–13 provides some questions for stressor-response analysis.

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). More complex relationships are shown in figure 4–3, which illustrates a range of projected responses of zooplankton populations to pesticide exposure based on laboratory tests. In field studies, the complexity of these responses could increase even further, considering factors such as potential indirect effects of pesticides on zooplankton populations (e.g., competitive interactions between species). More complex patterns can also occur at higher levels of biological organization; ecosystems may respond to stressors with abrupt shifts to new community or system types (Holling, 1978).

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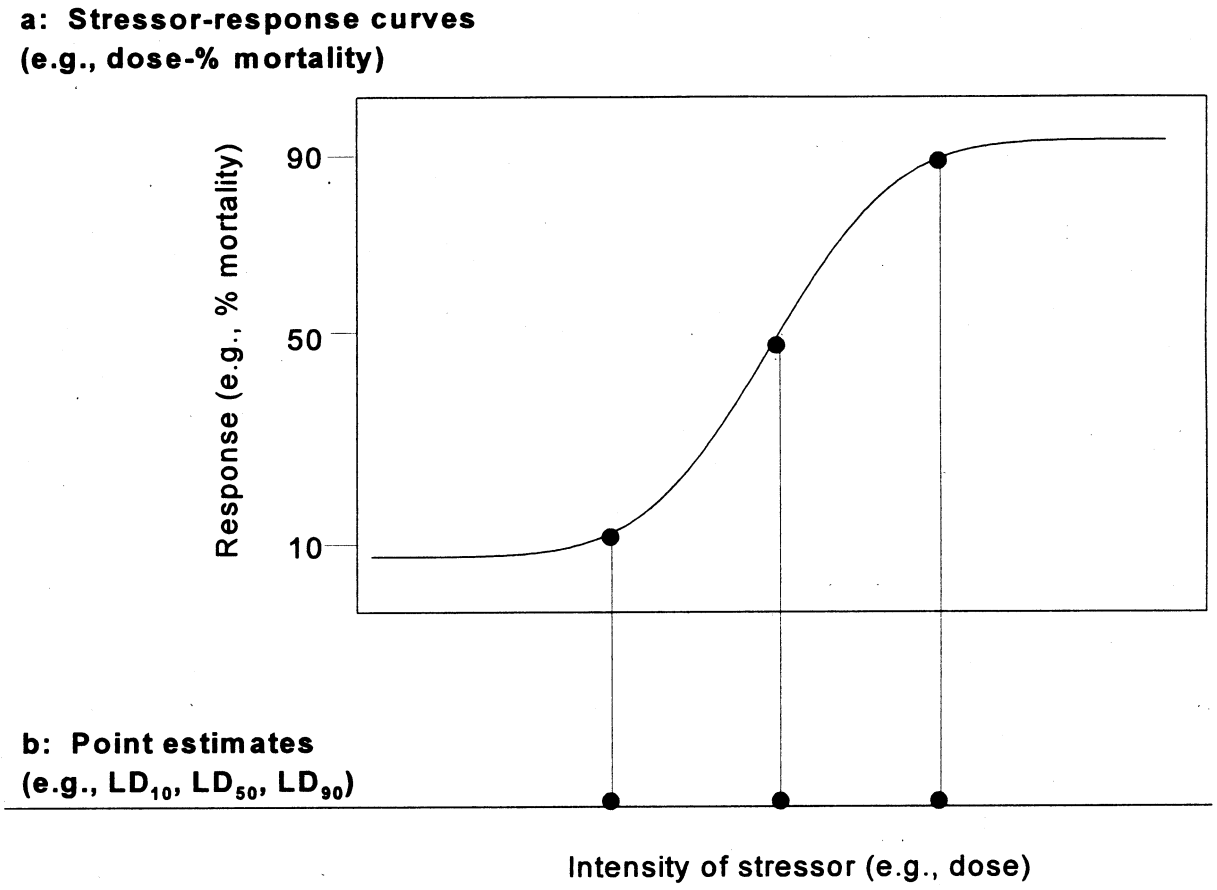

Figure 4-2. A simple example of a stressor-response relationship. Substantially more complex relationships are typical of many ecological risk assessments, given the range of stressors, endpoints, and environmental situations often encountered.

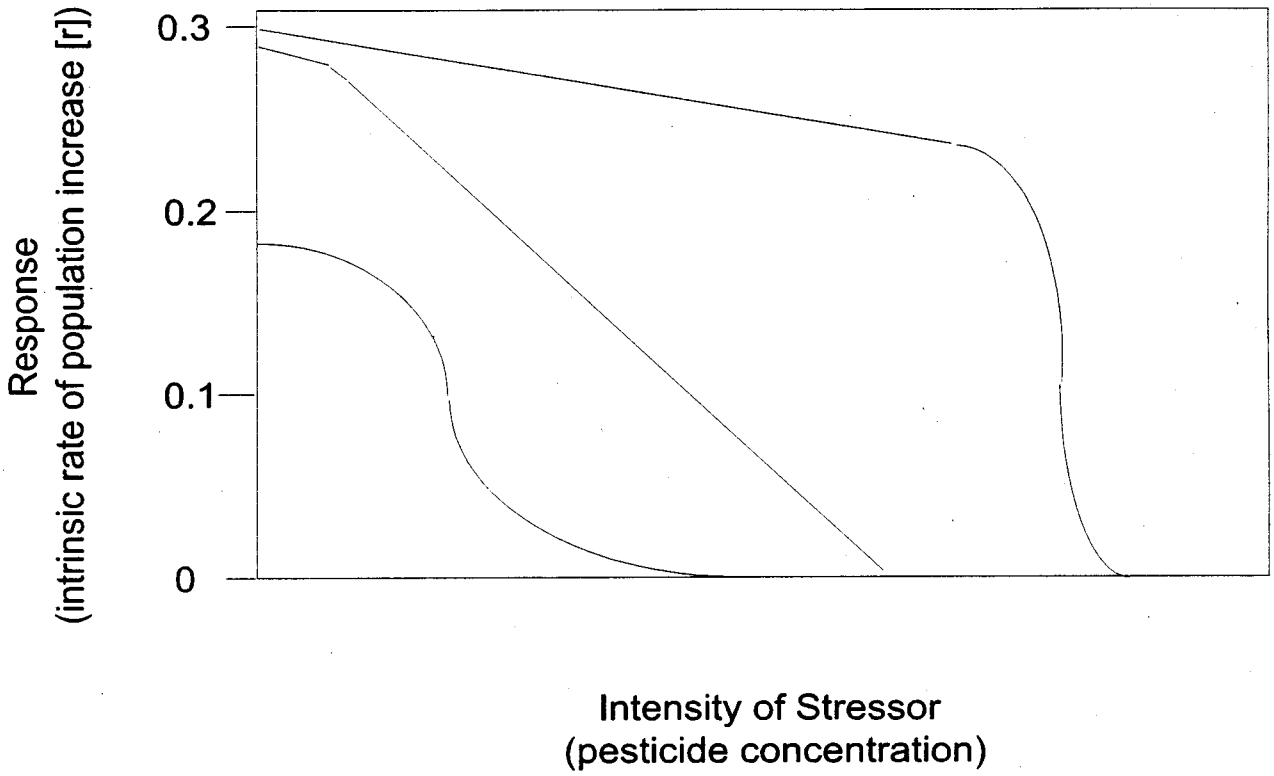

Figure 4-3. Variations in stressor-response relationships. These curves illustrate a range of responses to pesticide exposure of the intrinsic rate of increase of zooplankton populations (adapted from Schindler, 1987).

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In simple cases, one response variable (e.g., mortality, incidence of abnormalities) is analyzed, 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 techniques may be useful. These 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. While quantifying stressor-response relationships is encouraged, qualitative evaluations are also possible (text note 4–14).

Stressor-response relationships can be described using intensity, time, or space. Intensity is probably the most familiar of these and is often used for chemicals (e.g., dose, concentration). Exposure duration 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 hours). As noted in text note 4–14, the timing of exposure was the critical dimension in evaluating the relationship between seed germination and soil moisture (Pearlstine et al., 1985). The spatial dimension is often of concern for physical stressors. For instance, the 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 tree growth 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 milliliter; propagules per unit of substrate) may be related to 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, 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, this is often not the case for toxicity tests with wildlife species.

Risk assessors sometimes use curve-fitting analyses to determine particular levels of effect. 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 4–15) are frequently selected because the level of uncertainty is minimized at the midpoint of the regression curve. While a 50% effect level 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 5–3). 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'' stressor levels 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 3–12). An example of this approach for deriving chemical no-effect levels is provided in text note 4–16. A feature 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 (see section 4.1.1). 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. In contrast with observational studies, an advantage of experimental field studies is that treatments can be replicated, increasing the confidence that observed differences are due to the treatment.

Experimental data can be combined to generate multiple-point estimates that can be displayed as cumulative distribution functions. Figure 5–5 shows an example for species sensitivity derived from multiple-point estimates (EC_5s) for freshwater algae (and one vascular plant species) exposed to an herbicide. These distributions can help identify 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, 1986a)), 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 them 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 to 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 (response to the stressor(s)). 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 describes considerations for evaluating causality based on criteria developed by Fox (1991) primarily for observational data 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 (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 4–17 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 to evaluate available information.

The strength of association between stressor and response is often the main reason that adverse effects such as bird kills are linked to specific events or actions. 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 effects that decrease with distance from 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-and-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, an association's occurrence in more than one species and population is very strong evidence for causation. An example would be the many bird species killed by carbofuran applications (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 or diagnostic 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 elicit many 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 (see text note 4–18) may be useful. For chemicals, ecotoxicologists have slightly modified Koch's postulates to provide evidence of causality (Suter, 1993a). 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 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.

Woodman and Cowling (1987) provide a specific example of a causal evaluation. They proposed three rules for establishing the effects of airborne pollutants on the health and productivity of forests: (1) The injury or dysfunction symptoms observed in the case of individual trees in the forest must be associated consistently with the presence of the suspected causal factors, (2) the same injury or dysfunction symptoms must be seen when healthy trees are exposed to the suspected causal factors under controlled conditions, and (3) natural variation in resistance and susceptibility observed in forest trees also must be seen when clones of the same trees are exposed to the suspected causal factors under controlled conditions.

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 a mixture's toxicity relates to that 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 cause toxic effects. By using fractionation and other methods, the TIE approach can help identify chemicals responsible for toxicity and show the relative contributions 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 it also requires additional assumptions about the relationship between effects of the synthetic mixture and those of the environmental mixture. (See section 5.1.3 for additional discussion of mixtures.)

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 them are needed. Risk assessors may make these linkages in the analysis phase or, especially when linkages rely on professional judgment, work with measures of effect through risk estimation (in risk characterization) and then connect them with assessment endpoints. Common extrapolations used to link measures of effect with assessment endpoints are shown in text note 4–19.

4.3.1.3.1. General Considerations

During the preparation of the analysis plan, 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 4–20 before proceeding with specific extrapolation approaches.

The nature of the risk assessment and the type and amount of data that are available largely determine how conservative a risk assessment will be. The early stages of a tiered risk assessment typically use conservative estimates because the data needed to adequately assess exposure and effects are usually lacking. When a risk has been identified, subsequent tiers use additional data to address the uncertainties that were incorporated into the initial assessment(s) (see text note 2–8).

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 herbivores may extrapolate between 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 planned. If spatial scales are broadened, additional receptors may need to be included in extrapolation models. If a stressor persists for an extended time, it may be necessary to extrapolate short-term responses over a longer exposure period, 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 them in a manner consistent with sound ecological principles and use enough appropriate data. 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 between two species may be more credible if factors such as similarities in food preferences, body mass, physiology, and seasonal behavior (e.g., mating and migration habits) are considered (Sample et al., 1996). Rote or biologically implausible extrapolations will erode the assessment's overall credibility.

Finally, many extrapolation methods are limited by the availability of suitable databases. Although many data are available for chemical stressors and aquatic species, they do not exist for all taxa or effects. Chemical effects databases for wildlife, amphibians, and 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 professional judgment. This 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 rely on some level of understanding of the underlying operations of the system of interest.

4.3.1.3.2. Judgment Approaches for Linking Measures of Effect to Assessment Endpoints.

Professional-judgment approaches rely on the professional expertise of risk assessors, expert panels, or others to relate changes in measures of effect to changes in assessment endpoints. They are essential when databases are inadequate to support empirical models and process models are unavailable or inappropriate. Professional-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 professional-judgment extrapolations between species, from laboratory data to field effects, and between geographic areas.

Because of the uncertainty in predicting the effects of biological stressors such as introduced species, professional-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 4–21 summarizes some of the considerations for risk assessors when extrapolating from laboratory 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 professional 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 exposures to chemical stressors can be accurately estimated and are expected to be similar (e.g., see text note 4–21), 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 factors.

For physical stressors that have natural counterparts, such as fire, flooding, or temperature variations, effects may depend on the difference between human-caused and 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 strengthened 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 effects from one system to another.

Bedford and Preston (1988), Detenbeck et al. (1992), Gibbs (1993), Gilbert (1987), Gosselink et al. (1990), Preston and Bedford (1988), and Risser (1988) may be useful to risk assessors concerned with effects in different geographical areas.

4.3.1.3.3. Empirical and Process-Based Approaches for Linking Measures of Effect to Assessment Endpoints

A variety of empirical and process-based approaches are 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 measures of effects 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.

4.3.1.3.3.1. Empirical Approaches

Empirical approaches are derived from experimental data or observations 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 measures of effects 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 been developed most frequently for chemicals because extensive ecotoxicologic databases are 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, they vary inversely with the quantity and type of measures of effects data available (Zeeman, 1995). They 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, 1995c).

Despite 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 judgment, and policy judgment (see section 4.1.3). It is important to differentiate these three elements when documenting the basis for the uncertainty factors used.

Empirical data can be used to facilitate extrapolations between 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 between freshwater and marine fish and arthropods. As Suter notes (1993a), the uncertainties associated with extrapolating between orders, classes, and phyla tend to be very high. However, one can extrapolate 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.

In addition to taxonomic databases, dose-scaling or allometric regression is used to extrapolate the effects of a chemical stressor to another species. Allometry is the study of change in the proportions of various parts of an organism as a consequence of growth and development. Processes that influence toxicokinetics (e.g., renal clearance, basal metabolic rate, food consumption) tend to vary across species according to allometric scaling factors that can be expressed as a nonlinear function of body weight. These scaling factors can be used to estimate bioaccumulation and to improve interspecies extrapolations (Newman, 1995; Kenaga, 1973; U.S. EPA 1992c, 1995d). Although allometric relationships are commonly used for human health risk assessments, they have not been applied as extensively to ecological effects (Suter, 1993a). For chemical stressors, allometric relationships can enable an assessor to estimate toxic effects to species not commonly tested, such as native mammals. It is important that the assessor consider the taxonomic relationship between the known species and the one of interest. The closer they are related, the more likely 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.

4.3.1.3.3.2. 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, 1990). They can help answer questions about short- or long-term changes of population size and structure and can help estimate the probability that a population will decline below or grow above a specified abundance (Ginzburg et al., 1982; Ferson et al., 1989). The latter application may be useful when assessing the effects of biological stressors such as introduced or pest species. Barnthouse et al. (1986) and Wiegert and Bartell (1994) present excellent reviews of population models. Emlen (1989) has reviewed population models that can be used for terrestrial risk assessment.

Proper use of 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 are important (Hassell, 1986) and should be considered in the uncertainty analysis.

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. They 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 ecosystem.

Risk assessors should determine the appropriate degree of aggregation in population or multispecies model parameters based both on the input data available and on the desired output of the model (also see text note 4–5). 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 uncertainty discussion.

4.3.2. Stressor-Response Profile

The final product of ecological response analysis is a summary profile of what has been learned. This may be a written document or a module of a larger process model. 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. Profile compilation also provides an opportunity to verify that the assessment endpoints and measures of effect identified in the conceptual model were evaluated.

Risk assessors should address several questions in the stressor-response profile (text note 4–22). Affected ecological entities may 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 may 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 were provided in section 4.3.1.1. Other information such as the spatial area or time to recovery may also be appropriate. Causal analyses are important, especially for assessments that include field observational data.

Ideally, the stressor-response profile should express effects in terms of the assessment endpoint, but this is not always possible. Where it is necessary to use qualitative extrapolations between assessment endpoints and measures of effect, the stressor-response profile may contain information only 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 clearly describe any uncertainties associated with the ecological response analysis. If it was necessary to extrapolate from measures of effect to the assessment endpoint, both the extrapolation and its basis should be described. Similarly, if a benchmark or similar reference dose or concentration was calculated, the extrapolations and uncertainties associated with its development need to be discussed. 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 Lokke (1991), and Okkerman et al. (1993). Finally, the assessor should clearly describe major assumptions and default values used in the 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 and is the culmination of the planning, problem formulation, and analysis of predicted or observed adverse ecological effects related to the assessment endpoints. Completing risk characterization allows risk assessors to clarify the relationships between stressors, effects, and ecological entities and to reach conclusions regarding the occurrence of exposure and the adversity of existing or anticipated effects. Here, risk assessors first use the results of the analysis phase to develop an estimate of the risk posed to the ecological entities included in the assessment endpoints identified in problem formulation (section 5.1). After estimating the risk, the assessor describes the risk estimate in the context of the significance of any adverse effects and lines of evidence supporting their likelihood (section 5.2). Finally, the assessor identifies and summarizes the uncertainties, assumptions, and qualifiers in the risk assessment and reports the conclusions to risk managers (section 5.3).

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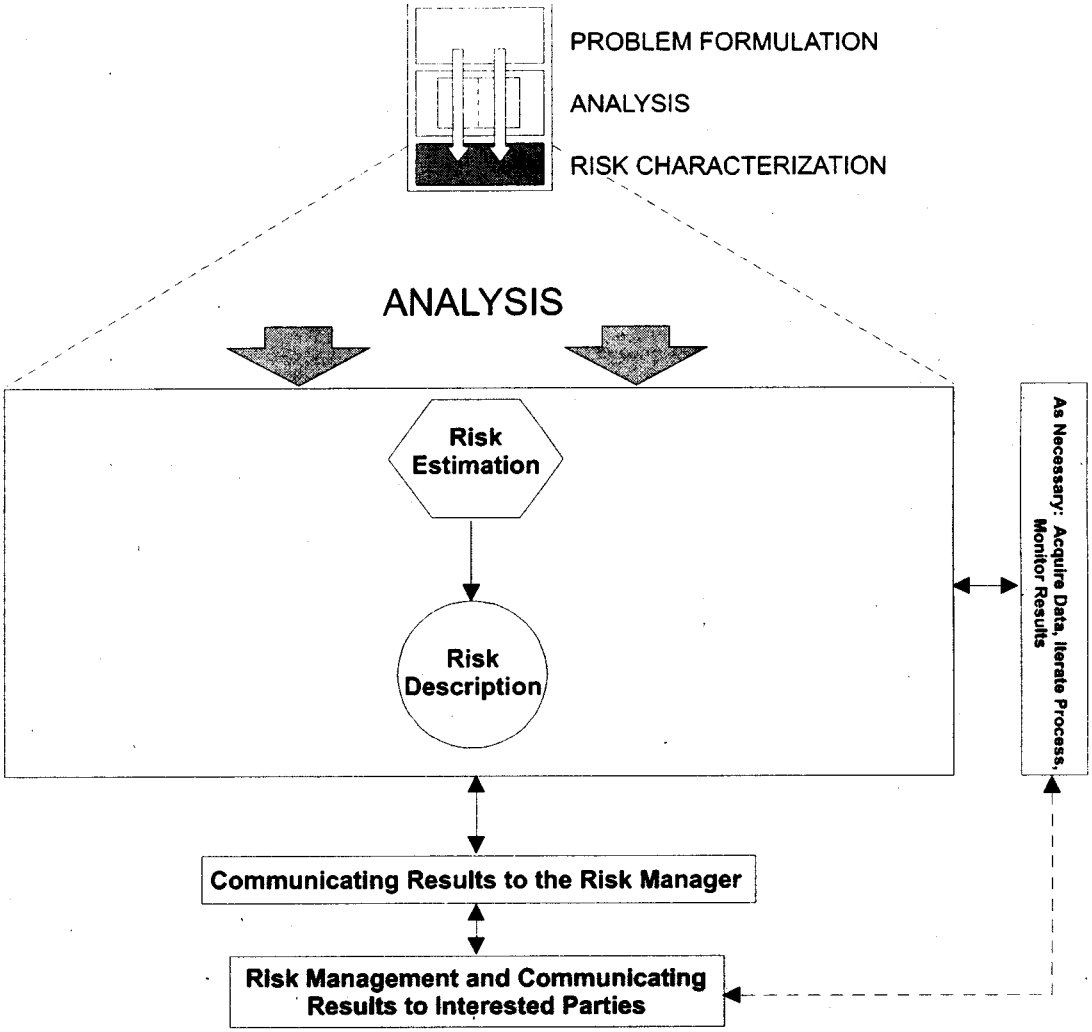

Figure 5-1. Risk characterization.

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Conclusions presented in the risk characterization should provide clear information to risk managers in order to be useful for environmental decision making (NRC, 1994; see section 6). If the risks are not sufficiently defined to support a management decision, risk managers may elect to proceed with another iteration of one or more phases of the risk assessment process. Reevaluating the conceptual model (and associated risk hypotheses) or conducting additional studies may improve the risk estimate. Alternatively, a monitoring program may help managers evaluate the consequences of a risk management decision.

5.1. Risk Estimation

Risk estimation is the process of integrating exposure and effects data and evaluating any associated uncertainties. The process uses exposure and stressor-response profiles developed according to the analysis plan (section 3.5). Risk estimates can be developed using one or more of the following techniques: (1) Field observational studies, (2) categorical rankings, (3) comparisons of single-point exposure and effects estimates, (4) comparisons incorporating the entire stressor-response relationship, (5) incorporation of variability in exposure and/or effects estimates, and (6) process models that rely partially or entirely on theoretical approximations of exposure and effects. These techniques are described in the following sections.

5.1.1. Results of Field Observational Studies

Field observational studies (surveys) can serve as risk estimation techniques because they provide empirical evidence linking exposure to effects. Field surveys measure biological changes in natural settings through collection of exposure and effects data for ecological entities identified in problem formulation.

A major advantage of field surveys is that they can be used to evaluate multiple stressors and complex ecosystem relationships that cannot be replicated in the laboratory. Field surveys are designed to delineate both exposures and effects (including secondary effects) found in natural systems, whereas estimates generated from laboratory studies generally delineate either exposures or effects under controlled or prescribed conditions (see text note 5–1).

While field studies may best represent reality, as with other kinds of studies they can be limited by (1) a lack of replication, (2) bias in obtaining representative samples, or (3) failure to measure critical components of the system or random variations. Further, a lack of observed effects in a field survey may occur because the measurements lack the sensitivity to detect ecological effects. See section 4.1.1 for additional discussion of the strengths and limitations of different types of data.

Several assumptions or qualifications need to be clearly articulated when describing the results of field surveys. A primary qualification is whether a causal relationship between stressors and effects (section 4.3.1.2) is supported. Unless causal relationships are carefully examined, conclusions about effects that are observed may be inaccurate because the effects are caused by factors unrelated to the stressor(s) of concern. In addition, field surveys taken at one point in time are usually not predictive; they describe effects associated only with exposure scenarios associated with past and existing conditions.

5.1.2. Categories and Rankings

In some cases, professional judgment or other qualitative evaluation techniques may be used to rank risks 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 are not easily expressed in quantitative terms. The U.S. Forest Service risk assessment of pest introduction from importation of logs from Chile used qualitative categories owing to limitations in both the exposure and effects data for the introduced species of concern as well as the resources available for the assessment (see text note 5–2).

Ranking techniques can be used to translate qualitative judgment into a mathematical comparison. These methods are frequently used in comparative risk exercises. For example, Harris et al. (1994) evaluated risk reduction opportunities in Green Bay (Lake Michigan), Wisconsin, employing an expert panel to compare the relative risk of several stressors against their potential effects. Mathematical analysis based on fuzzy set theory was used to rank the risk from each stressor from a number of perspectives, including degree of immediate risk, duration of impacts, and prevention and remediation management. The results served to rank potential environmental risks from stressors based on best professional judgment.

5.1.3. Single-Point Exposure and Effects Comparisons

When sufficient data are available to quantify exposure and effects estimates, the simplest approach for comparing the estimates is a ratio (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 (see text note 5–3).

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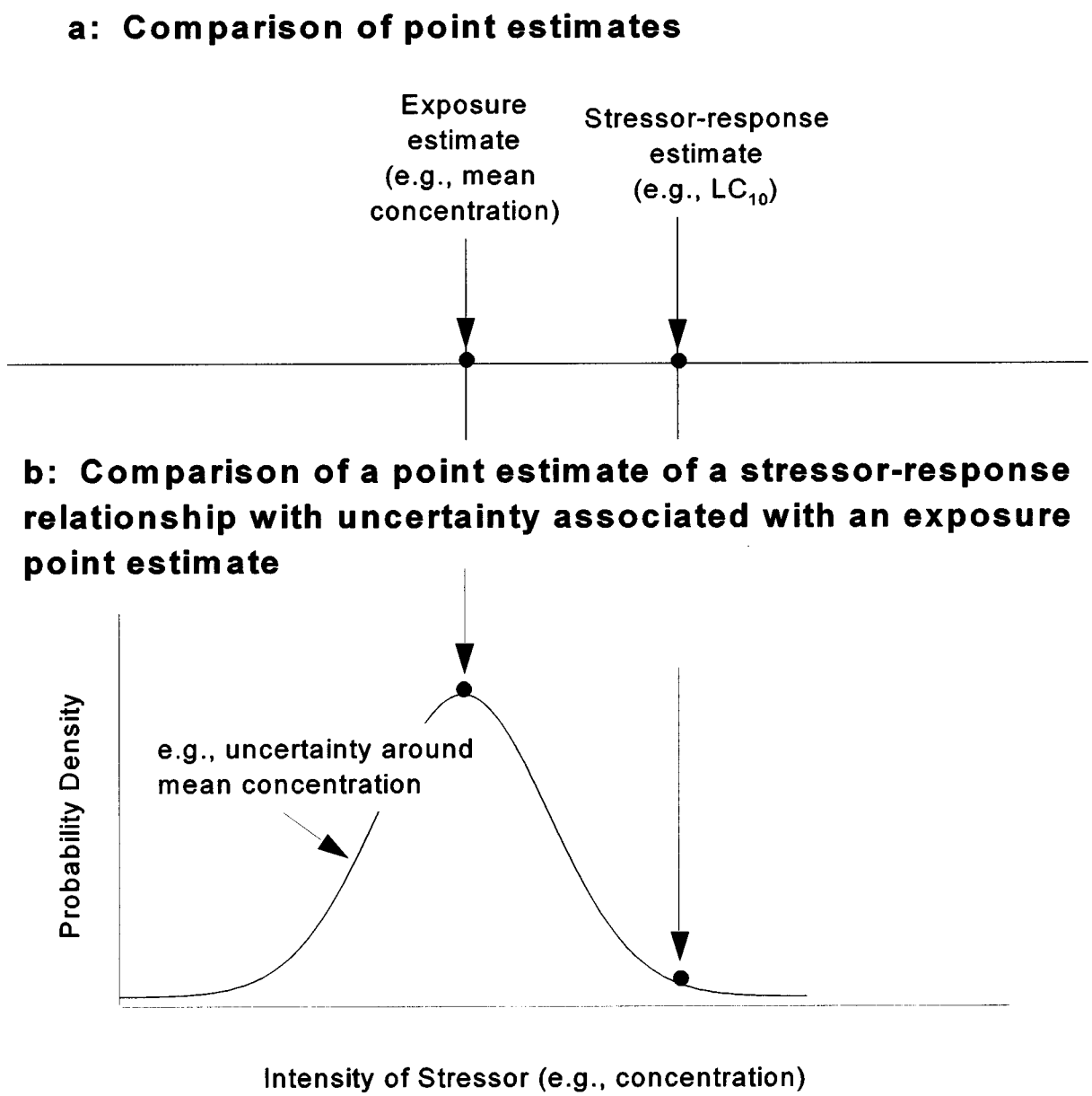

Figure 5-2. Risk estimation techniques. a. Comparison of exposure and stressor-response point estimates. b. Comparison of a point estimate from the stressor-response relationship with uncertainty associated with an exposure point estimate.

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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. It 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: quotients for the individual constituents in a mixture are generated by dividing each exposure level by a corresponding toxicity endpoint (e.g., LC_{50}, EC_{50}, NOAEL). Although the toxicity of a chemical mixture may be greater than or less than predicted from the toxicities of individual constituents of the mixture, a quotient addition approach assumes that toxicities are additive or approximately additive. This assumption may be most applicable when the modes of action of chemicals in a mixture are similar, but there is evidence that even with chemicals having dissimilar modes of action, additive or near-additive interactions are common (Könemann, 1981; Broderius, 1991; Broderius et al., 1995; Hermens et al., 1984a, b; McCarty and Mackay, 1993; Sawyer and Safe, 1985). However, caution should be used when assuming that chemicals in a mixture act independently of one another, since many of the supporting studies were conducted with aquatic organisms, and so may not be relevant for other endpoints, exposure scenarios, or species. When the modes of action for constituent chemicals are unknown, the assumptions and rationale concerning chemical interactions should be clearly stated.

A number of limitations restrict application of the quotient method (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 an incremental 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.

Other limitations of quotients may be caused by deficiencies in the problem formulation and analysis phases. 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.

In addition, the quotient method may not be the most appropriate method for predicting secondary effects (although such effects may be inferred). Interactions and effects beyond what are predicted from the simple quotient may be critical to characterizing the full extent of impacts from exposure to the stressors (e.g., bioaccumulation, eutrophication, loss of prey species, opportunities for invasive species).

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). Some uncertainties, however, 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 5–4. Further discussion of comparisons between point estimates of effects and distributions of exposure may be found in Suter et al., 1983.

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?

5.1.4. Comparisons Incorporating the Entire Stressor-Response Relationship

If a curve relating the stressor level to the magnitude of response is available, 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.

There are advantages and limitations to comparing a stressor-response curve with an exposure distribution. The slope 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. Comparing exposure and stressor-response curves provides a predictive ability lacking in the quotient method. Like the quotient method, however, limitations from the problem formulation and analysis phases may limit the utility of the results. These limitations may include not fully considering secondary effects, assuming the exposure pattern used to derive the stressor-response curve is comparable to the environmental exposure pattern, and failure to consider uncertainties, such as extrapolations from tested species to the species or community of concern.

5.1.5. Comparisons Incorporating Variability in Exposure and/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 estimate risks to moderately or highly exposed members of a population being investigated, while variability in effects can be used to estimate risks to average or sensitive population members. A major advantage of this approach is its ability to predict changes in the magnitude and likelihood of effects for different exposure scenarios and thus provide 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 5–5 and figure 5–5 illustrate the use of cumulative exposure and effects distributions for estimating risk.

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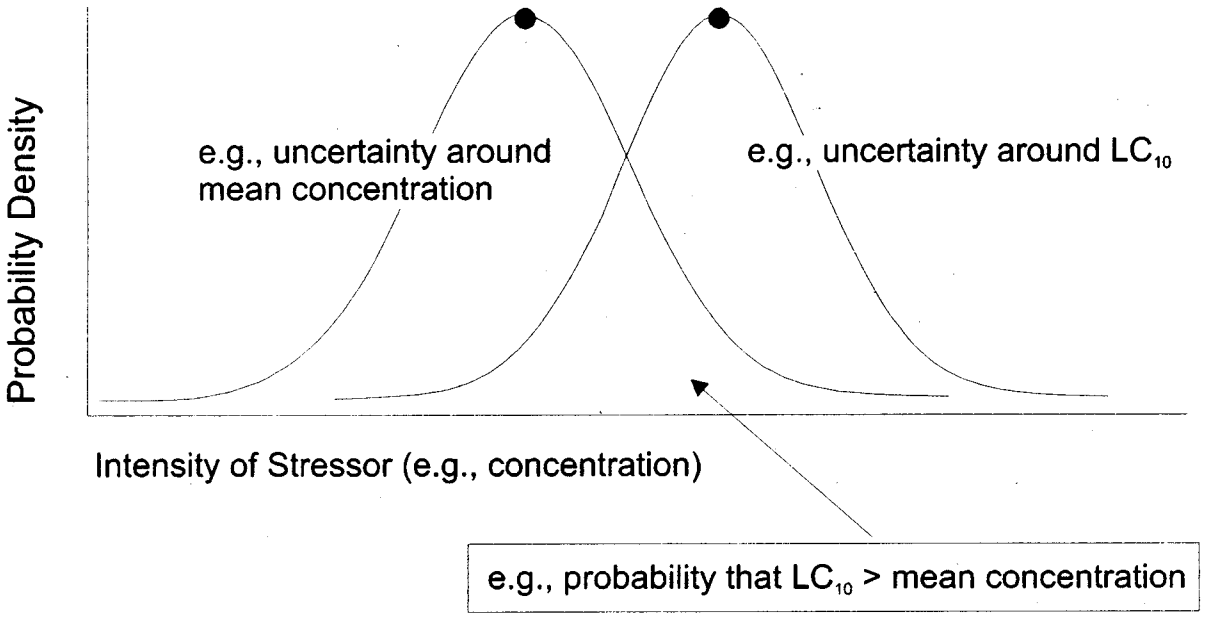

Figure 5-3. Risk estimation techniques: comparison of point estimates with associated uncertainties.

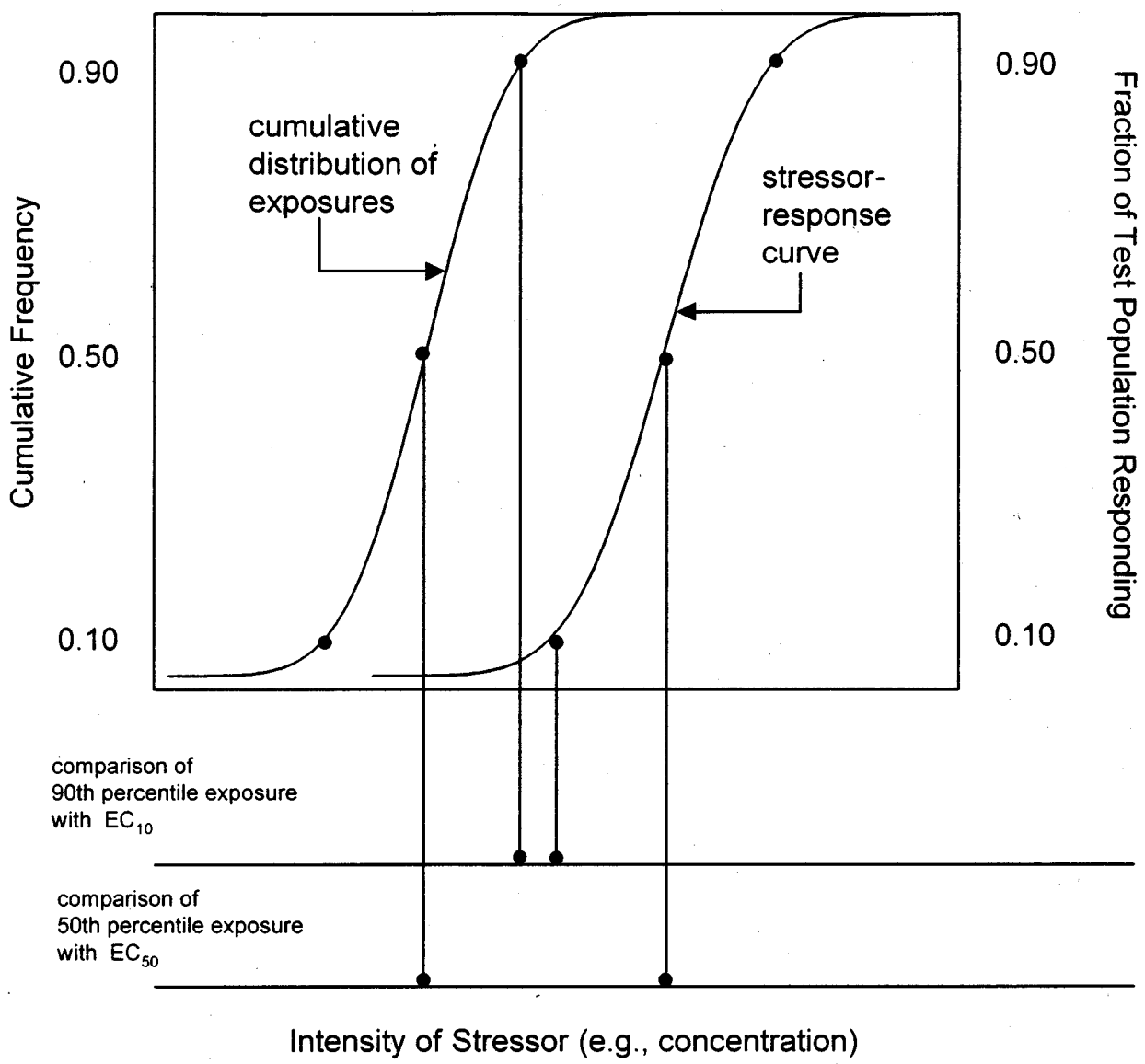

Figure 5-4. Risk estimation techniques: stressor-response curve versus a cumulative distribution of exposures.

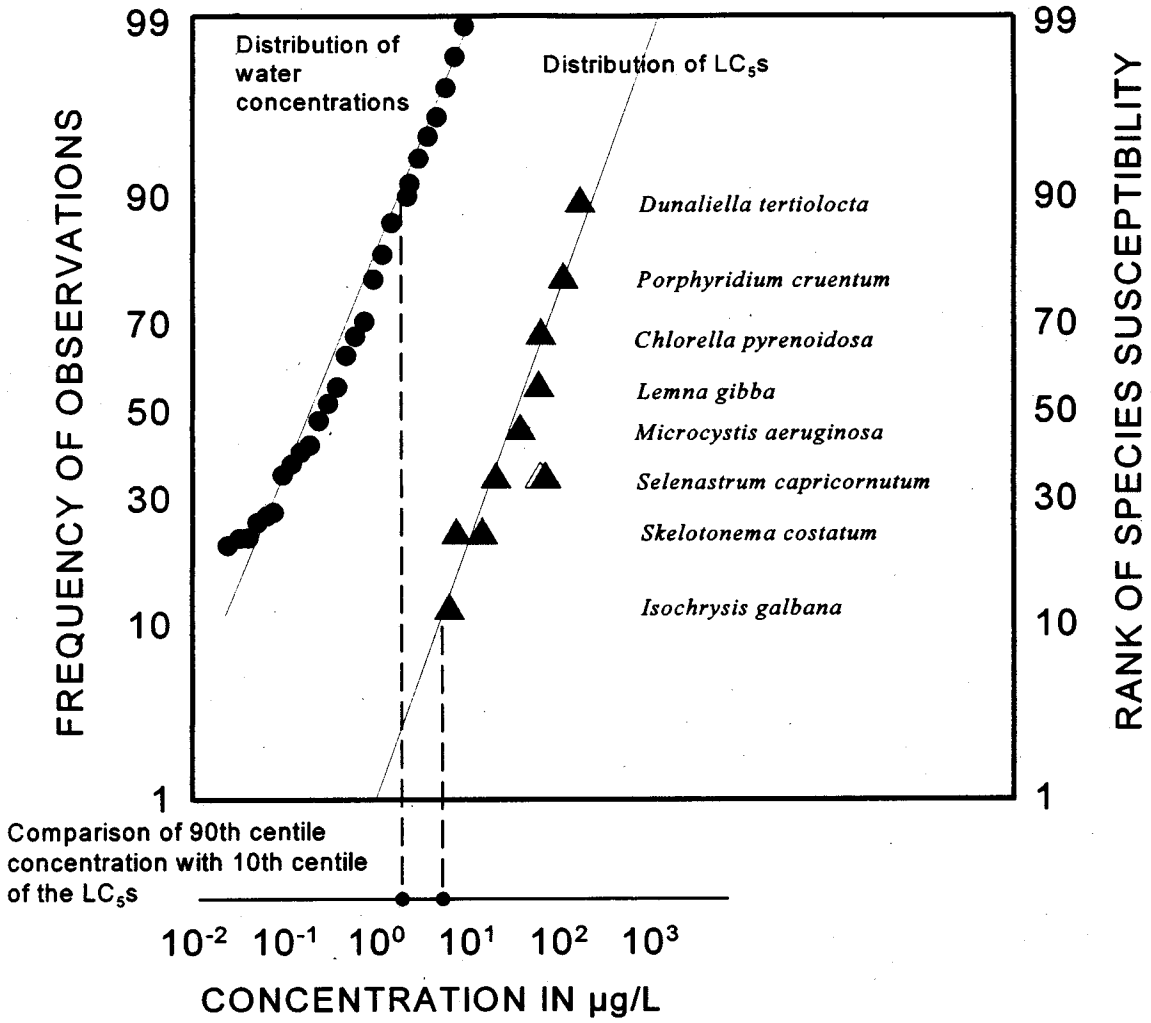

Figure 5-5. Risk estimation techniques: comparison of exposure distribution of an herbicide in surface waters with freshwater single-species toxicity data. See text note 5-4 for further discussion. Redrawn from Baker et al., 1994. (Centile ranks for species LC_5 data were obtained using the formula (100 x *n*/[N+1]), where *n* is the rank number of the LC_5 and *N* is the total number of data points in the set; adapted from Parkhurst et al., 1995).

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5.1.6. Application of 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 in both analysis (see section 4.1.2) and risk characterization. For illustrative purposes, it is useful to distinguish between analysis process models, which focus individually on either exposure or effects evaluations, and risk estimation process models, which integrate exposure and effects information (see text note 5–6). The assessment of risks associated with long-term changes in hydrologic conditions in bottomland forest wetlands in Louisiana using the FORFLO model (Appendix D) linked the attributes and placement of levees and corresponding water level measurements (exposure) with changes in forest community structure and wildlife habitat suitability (effects).

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 techniques based solely 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 can forecast the combined effects of multiple stressors, such as the effects of multiple chemicals on fish population sustainability (Barnthouse et al., 1990).

Process model outputs may be point estimates, distributions, or correlations; in all cases, risk assessors should interpret them with care. They may imply a higher level of certainty than is appropriate and are all too often 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), particularly with respect to the risk hypotheses presented in problem formulation.

5.2. Risk Description

Following preparation of the risk estimate, risk assessors need to interpret and discuss the available information about risks to the assessment endpoints. Risk description includes an evaluation of the lines of evidence supporting or refuting the risk estimate(s) and an interpretation of the significance of the adverse effects on the assessment endpoints. During the analysis phase, the risk assessor may have established the relationship between the assessment endpoints and measures of effect and associated lines of evidence in quantifiable, easily described terms (section 4.3.1.3). If not, the risk assessor can relate the available lines of evidence to the assessment endpoints using qualitative links. Regardless of the risk estimation technique, the technical narrative supporting the risk estimate is as important as the risk estimate itself.

5.2.1. Lines of Evidence

The development of lines of evidence provides both a process and a framework for reaching a conclusion regarding confidence in the risk estimate. It is not the kind of proof demanded by experimentalists (Fox, 1991), nor is it a rigorous examination of weights of evidence. (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.) The phrase lines of evidence is used to de-emphasize the balancing of opposing factors based on assignment of quantitative values to reach a conclusion about a ''weight'' in favor of a more inclusive approach, which evaluates all available information, even evidence that may be qualitative in nature. It is important that risk assessors provide a thorough representation of all lines of evidence developed in the risk assessment rather than simply reduce their interpretation and description of the ecological effects that may result from exposure to stressors to a system of numeric calculations and results.

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, or field observational studies.

There are three principal categories of factors for risk assessors to consider when evaluating lines of evidence: (1) Adequacy and quality of data, (2) degree and type of uncertainty associated with the evidence, and (3) relationship of the evidence to the risk assessment questions (see also sections 3 and 4).

Data quality directly influences how confident risk assessors can be in the results of a study and conclusions they may draw from it. Specific concerns to consider for individual lines of evidence include whether the experimental design was appropriate for the questions posed in a particular study and whether data quality objectives were clear and adhered to. An evaluation of the scientific understanding of natural variability in the attributes of the ecological entities under consideration is important in determining whether there were sufficient data to satisfy the analyses chosen and to determine if the analyses were sufficiently sensitive and robust to identify stressor-caused perturbations.

Directly related to data quality issues is the evaluation of the relative uncertainties of each line of evidence. One major source of uncertainty comes from extrapolations. The greater the number of extrapolations, the more uncertainty introduced into a study. For example, were extrapolations used to infer effects in one species from another, or from one temporal or spatial scale to another? Were conclusions drawn from extrapolations from laboratory to field effects, or were field effects inferred from limited information, such as chemical structure-activity relationships? Were no-effect or low-effect levels used to address likelihood of effects? Risk assessors should consider these and any other sources of uncertainty when evaluating the relative importance of particular lines of evidence.

Finally, how directly lines of evidence relate to the questions asked in the risk assessment may determine their relative importance in terms of the ecological entity and the attributes of the assessment endpoint. Lines of evidence directly related to the risk hypotheses, and those that establish a cause-and-effect relationship based on a definitive mechanism rather than associations alone, are likely to be of greatest importance.

The evaluation process, however, involves more than just listing the evidence that supports or refutes the risk estimate. The risk assessor should carefully examine each factor and evaluate its contribution in the context of the risk assessment. The importance of lines of evidence is that each and every factor is described and interpreted. Data or study results are often not reported or carried forward in the risk assessment because they are of insufficient quality. If such data or results are eliminated from the evaluation process, however, valuable information may be lost with respect to

needed improvements in methodologies or recommendations for further studies.

As a case in point, consider the two lines of evidence described for the carbofuran example (see text notes 5–1 and 5–3), field studies and quotients. 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 (see figure D–1). The quotients, however, 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 (see text note 5–1). Nevertheless, because of the strong evidence of causal relationships from the field studies and consistency with the laboratory-derived quotient, confidence in a conclusion of high risk to the assessment endpoint is supported.

Sometimes lines of evidence do not point toward the same conclusion. It is important to investigate possible reasons for any disagreement rather than ignore inconvenient evidence. A starting point is 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 iteration of the risk assessment process and collection of additional data may help resolve uncertainties, this option is not always available.

Lines of evidence that are to be evaluated during risk characterization should be defined early in the risk assessment (during problem formulation) through the development of the conceptual model and selection of assessment endpoints. Further, the analysis plan should incorporate measures that will contribute to the interpretation of the lines of evidence, including methods of reviewing, analyzing, and summarizing the uncertainty in the risk assessment.

Also, risk assessments often rely solely on laboratory or in situ bioassays to assess adverse effects that may occur as a result of exposure to stressors. Although they may not be manifested in the field, ecological effects demonstrated in the laboratory should not be discounted as a line of evidence.

5.2.2. Determining Ecological Adversity

At this point in risk characterization, the changes expected in the assessment endpoints have been estimated and the supporting lines of evidence evaluated. The next step is to interpret whether these changes are considered adverse. Adverse ecological effects, in this context, represent changes that are undesirable because they alter valued structural or functional attributes of the ecological entities under consideration. The risk assessor evaluates the degree of adversity, which is often a difficult task and is frequently based on the risk assessor's professional judgment.

When the results of the risk assessment are discussed with the risk manager (section 6), other factors, such as the economic, legal, or social consequences of ecological damage, should be considered. The risk manager will use all of this information to determine whether a particular adverse effect is acceptable and may also find it useful when communicating the risk to interested parties.

The following are criteria for evaluating adverse changes in assessment endpoints:

- Nature of effects and intensity of effects
- Spatial and temporal scale
- Potential for recovery.

The extent to which the criteria are evaluated depends on the scope and complexity of the risk assessment. Understanding the underlying assumptions and science policy judgments, however, 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 this is considered adverse should be clearly understood. In addition, any evaluation of adversity should examine all relevant criteria, since none are considered singularly determinative.

To distinguish adverse ecological changes from those within the normal pattern of ecosystem variability or those resulting 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 (see 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 of various periods (e.g., bird migration, tides) are very important in natural systems and may mask or delay stressor-related effects. 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 should then consider other lines of evidence in reaching their conclusions.

It is also important to consider the location of the effect within the biological hierarchy and the mechanisms that may result in ecological changes. The risk assessor may rely on mechanistic explanations to describe complex ecological interactions and the resulting effects that otherwise may be masked by variability in the ecological components.

The boundaries (global, landscape, ecosystem, organism) of the risk assessment are initially identified in the analysis plan prepared during problem formulation. These spatial and temporal scales are further defined in the analysis phase, where specific exposure and effects scenarios are evaluated. 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 and regional 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 these microhabitats may result in adverse effects to the entire system.

Spatial factors are important for many species because of the linkages between ecological landscapes and population dynamics. Linkages between landscapes can provide refuge for affected populations, and organisms may require 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 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 responses to a stressor may be delayed. Thus, it is important to distinguish a stressor's long-term impacts from its 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 some aspect of its condition prior to a stressor's introduction. (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, constantly changing in response to changes in the physical environment (e.g., weather, natural disturbances) 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 should be carefully defined. Examples might include productivity declines in a eutrophic system, reestablishment of a species at a particular density, species recolonization of a damaged habitat, or the restoration of health of diseased organisms. The Agency considered the recovery rate of biological communities in streams and rivers from disturbances in setting exceedance frequencies for chemical stressors in waste effluents (U.S. EPA, 1991).

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., stream recovery from sewage effluent discharge), frequently irreversible (e.g., establishment of introduced species), and always irreversible (e.g., extinction). Risk assessors should consider the potential irreversibility of significant structural or functional changes in ecosystems or ecosystem components when evaluating adversity. Physical alterations such as deforestation in the coastal hills of Venezuela in recent history and in Britain during the Neolithic period, for example, changed soil structure and seed sources such that forests cannot easily grow again (Fisher and Woodmansee, 1994).

The relative rate of recovery can also be estimated. For instance, 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 decades, a benthic invertebrate community in years, and a planktonic community in weeks to months.

Risk assessors should note natural disturbance patterns when evaluating the likelihood of recovery from anthropogenic stressors. Alternatively, if an ecosystem has become adapted to a disturbance pattern, it may be affected when the disturbance is removed (e.g., fire-maintained grasslands). The lack of natural analogs makes it difficult to predict recovery from uniquely anthropogenic stressors (e.g., synthetic chemicals).

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 the cleanup efforts themselves affect the recovery.

5.3. Reporting Risks

When risk characterization is complete, 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). 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.

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 in text note 5–8, risk assessors should judge the level of detail required. The report need not be overly complex or lengthy; it is most important that the information required to support a risk management decision be presented clearly and concisely.

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, 1995b). 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 interested parties and the general 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 risk management decisions and as a basis for communicating risks to interested parties and the general public.

Mutual understanding between risk assessors and risk managers regarding risk assessment results can be facilitated if the questions listed in text note 6–1 are addressed. Risk managers need to know the major risks 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. Insufficient resources, lack of consensus, or other factors may preclude preparation of a detailed and well-documented risk characterization. If this is the case, the risk assessor should clearly articulate any issues, obstacles, and correctable deficiencies for the risk manager's consideration.

In making decisions regarding ecological risks, risk managers consider other information, such as social, economic, political, or legal issues in combination with risk assessment results. For example, the risk assessment results may be used as part of an ecological cost-benefit analysis, which may require translating resources (identified through the assessment endpoints) into monetary values. Traditional economic considerations may only partially address changes in ecological resources that are not considered commodities, intergenerational resource values, or issues of long-term or irreversible effects (U.S. EPA, 1995a; Costanza et al., 1997); however, they may provide a means of comparing the results of the risk assessment in commensurate units such as costs. Risk managers may also consider alternative strategies for reducing risks, such as risk mitigation options or substitutions based on relative risk comparisons. 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 pesticide. Further, by comparing the risk of a new pesticide to other pesticides currently in use during the registration process, lower overall risk may result. Finally, risk managers consider and incorporate public opinion and political demands into their decisions. Collectively, these other factors may render very high risks acceptable or very low risks unacceptable.

Risk characterization provides the basis for communicating ecological risks to interested parties and the general public. This task is usually the responsibility of risk managers, but it may be shared with risk assessors. 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. Irrespective of the specific format, 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, 1995a).

Managers should clearly describe the sources and causes of risks and 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, 1995a). Other risk communication considerations are provided in text note 6–2.

Along with 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 in its 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 support a final management decision. Another option is to proceed with the decision, implement the selected management alternative, and develop a monitoring plan to evaluate the results (see section 1). If the decision is to mitigate risks through exposure reduction, for example, monitoring could help determine whether the desired reduction in exposure (and effects) is achieved.

7. Text Notes

Text Note 1–1. Related Terminology

The following terms overlap to varying degrees with the 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. This diagram represents a flexible process, as illustrated by the examples below.

- In problem formulation, an assessment may begin with a consideration of endpoints, stressors, or ecological effects. Problem formulation is generally interactive and iterative, not linear.
- In the analysis phase, characterization of exposure and effects frequently become intertwined, as when an initial exposure leads to a cascade of additional exposures and secondary effects. The analysis phase should foster 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 2–1. Who Are Risk Managers?

Risk managers are individuals and organizations who have the responsibility, 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 decision maker in agencies such as EPA or State environmental offices who has legal authority to protect or manage a resource. However, risk managers may include a diverse group of interested parties who also have the ability to take action to reduce or mitigate risk. In situations where a complex of ecosystem values (e.g., watershed resources) is at risk from multiple stressors, and management will be implemented through community action, these groups may function as risk management teams. Risk management teams may include decision officials in Federal, State, local, and tribal governments; commercial, industrial, and private organizations; leaders of constituency groups; and other sectors of the public such as property owners. 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 team. When a specific risk assessment process is well defined through regulations and guidance, one trained individual may be able to complete a risk assessment given sufficient information (e.g., premanufacture notice of a chemical). However, for complex risk assessments, one individual can rarely 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 locations, stressors, ecosystems, scientific issues, and other expertise as needed, depending on the type of assessment.

Text Note 2–3. Who Are Interested Parties?

Interested parties (commonly called ''stakeholders'') may include Federal, State, tribal, and municipal governments, industrial leaders, environmental groups, small-business owners, landowners, and other segments of society concerned about an environmental issue at hand or attempting to influence risk management decisions. Their involvement, particularly during management goal development, may be key to successful implementation of management plans since implementation is more likely to occur when backed by consensus. Large diverse groups may require trained facilitators and consensus-building techniques to reach agreement.

In some cases, interested parties may provide important information to risk assessors. Local knowledge, particularly in rural communities, and traditional knowledge of native peoples can provide valuable insights about ecological characteristics of a place, past conditions, and current changes. This knowledge should be considered when assessing available information during problem formulation (see section 3.2).

The context of involvement by interested parties can vary widely and may or may not be appropriate for a particular risk assessment. Interested parties may be limited to providing input to goal development, or they may become risk managers, depending on the degree to which they can take action to manage risk and the regulatory context of the decision. When and how interested parties influence risk assessments and risk management are areas of current discussion (NRC, 1996). See additional information in text note 2–1 and section 2.1.

Text Note 2–4. Questions Addressed by Risk Managers and Risk Assessors

Questions Principally for Risk Managers to Answer

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 (e.g., entities and ecosystem characteristics) of concern?

What are the policy considerations (law, corporate stewardship, societal concerns, environmental justice, intergenerational equity)?

What precedents are set by similar risk assessments and previous decisions?

What is the context of the assessment (e.g., industrial site, national park)?

What resources (e.g., personnel, time, money) are available?

What level of uncertainty is acceptable?

Questions Principally for Risk Assessors to Answer

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 of 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 2–5. Sustainability as a Management Goal

To sustain is to keep in existence, maintain, or prolong. Sustainability is used as a management goal in a variety of settings (see U.S. EPA, 1995a). Sustainability and other concepts such as biotic or community integrity may be very useful as guiding principles for management goals. However, in each case these principles should be explicitly defined and interpreted for a place 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

A key challenge for risk assessors when dealing with a general management goal is interpreting the goal for a risk assessment. This can be done by generating a set of management objectives that represent what must be achieved in a particular ecosystem in order for the goal to be met. An example of this process was developed in the Waquoit Bay watershed risk assessment (U.S. EPA, 1996b).

Waquoit Bay is a small estuary on Cape Cod showing signs of degradation, including loss of eelgrass, fish, and shellfish and an increase in 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 shellfish populations and (2) reverse ongoing degradation of ecological resources in the watershed.

To interpret this goal for the risk assessment, it was converted into 10 management objectives that defined what must be true in the watershed for the goal to be achieved and provide the foundation for management decisions. The management objectives are:

- Reduce or eliminate hypoxic or anoxic events.
- Prevent toxic levels of contamination in water, sediments, and biota.
- Restore and maintain self-sustaining native fish populations and their habitat.
- Reestablish viable eelgrass beds and associated aquatic communities in the bay.
- Reestablish a self-sustaining scallop population in the bay that can support a viable sport fishery.
- Protect shellfish beds from bacterial contamination that results in closures.
- Reduce or eliminate nuisance macroalgal growth.
- Prevent eutrophication of rivers and ponds.
- Maintain diversity of native biotic communities.
- Maintain diversity of water-dependent wildlife.

From these objectives, eight ecological entities and their attributes in the bay were selected as assessment endpoints (see section 3.3.2) to best represent the management goals and objectives, one of which is areal extent and patch size of eelgrass beds. Eelgrass was selected because (1) scallops and other benthic organisms and juvenile finfish depend directly on eelgrass beds for survival, (2) eelgrass is highly sensitive to excess macroalgal growth, and (3) abundant eelgrass represents a healthy bay to human users.

Text Note 2–7. What Is the Difference Between a Management Goal and Management Decision?

Management goals are desired characteristics of ecological values that the public wants to protect. Clean water, protection of endangered species, maintenance of ecological integrity, clear mountain views, and fishing opportunities are all possible management goals. Management decisions determine the means to achieve the end goal. For instance, a goal may be ''fishable, swimmable'' waters. The management options under consideration to achieve that goal may include increasing enforcement of point-source discharges, restoring fish habitat, designing alternative sewage treatment facilities, or implementing all of the above.

Text Note 2–8. Tiers and Iteration: When Is a Risk Assessment Done?

Risk assessments range from very simple to complex and resource demanding. How is it possible to decide the level of effort? How many times should the risk assessor revisit data and assessment issues? When is the risk assessment done?

Many of these questions can be addressed by designing a set of tiered assessments. These are preplanned and prescribed sets of risk assessments of progressive data and resource intensity. The outcome of a given tier is to either make a management decision, often based on decision criteria, or continue to the next level of effort. Many risk assessors and public and private organizations use this approach (e.g., see Gaudet, 1994; European Community, 1993; Cowan et al., 1995; Baker et al., 1994; Urban and Cook, 1986; Lynch et al., 1994).

An iteration is an unprescribed reevaluation of information that may occur at any time during a risk assessment, including tiered assessments. It is done in response to an identified need, new information, or questions raised while conducting an assessment. As such, iteration is a normal characteristic of risk assessments but is not a formal planned step. An iteration may include redoing the risk assessment with new assumptions and new data.

Setting up tiered assessments and decision criteria may reduce the need for iteration. Up-front planning and careful development of problem formulation will also reduce the need for revisiting data, assumptions, and models. However, there are no rules to dictate how many iterations will be necessary to answer management questions or ensure scientific validity. A risk assessment can be considered complete when risk managers have sufficient information and confidence in the results of the risk assessment to make a decision they can defend.

Text Note 2–9. Questions To Ask About Scope and Complexity

Is this risk assessment mandated, required by a court decision, or providing guidance to a community?

Will decisions be 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 information is 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, 1993b, 1994e). Shortcomings consistently 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

Throughout problem formulation, risk assessors consider what is known and not known about a problem and its setting. Each product of problem formulation contains uncertainty. 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).

Text Note 3–3. Initiating a Risk Assessment: What's Different When Stressors, Effects, or Values Drive the Process?

The reasons for initiating a risk assessment influence when risk assessors generate products in problem formulation. When the assessment is initiated because of concerns about stressors, risk assessors use what is known about the stressor and its source to focus the assessment. Objectives for the assessment are based on determining how the stressor is likely to come in contact with and affect possible receptors. 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. Frequently, the affected ecological entities and their response form the basis for defining assessment endpoints. 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 by goals for the ecological values 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 the assessment endpoints and describing the diversity of potential effects. This information is then captured in the conceptual model(s).

Text Note 3–4. Assessing Available Information: Questions to Ask Concerning Source, Stressor, and Exposure Characteristics, Ecosystem Characteristics, and Effects (derived in part from Barnthouse and Brown, 1994)

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 3–5. 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 should 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 (relevance to management goals). ''Salmon reproduction and population recruitment'' is a good assessment endpoint for this risk assessment. In addition, 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 foster a 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 entity's response becomes a stressor to another entity. Secondary effects are often 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 blackbirds, alteration of wetland hydrology that changes spawning habitat for fish, and so forth.

Text Note 3–7. Identifying Susceptibility

Often it is possible to identify ecological entities most likely to be susceptible to a stressor. However, in some cases where stressors are not known at the initiation of a risk assessment, or specific effects have not been identified, the most susceptible entities may not be known. Where this occurs, professional judgment may be required to make initial selections of potential endpoints.

Once done, available information on potential stressors in the system can be evaluated to determine which of the endpoints are most likely susceptible to identified stressors. If an assessment endpoint is selected for a risk assessment that directly supports management goals and is ultimately found not susceptible to stressors in the system, then a conclusion of no risk is appropriate. However, where there are multiple possible assessment endpoints that address management goals and only some of those are susceptible to a stressor, the susceptible endpoints should be selected. If the susceptible endpoints are not initially selected for an assessment, an additional iteration of the risk assessment with alternative assessment endpoints may be needed to determine risk.

Text Note 3–8. 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, risk is caused by the absence of exposure to a critical resource.

Text Note 3–9. 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 on 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 §§ [c][5] and 3[c][6]); using cost-benefit considerations. Goal was to have no regularly repeated bird kills.	Individual bird survival.
Modeling Future Losses of Bottomland Forest Wetlands (Brody et al., 1993).	National Environment 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).	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 (U.S. EPA, 1996b).	Clean Water Act—wetlands protection; water quality criteria—pesticides; endangered species. National Estuarine Research Reserve, Massachusetts, Area of Critical Environment 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 to 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 3–10. 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., emergence of midges can be used to evaluate an assessment endpoint for fish feeding behavior).
- Ecological entity may not be as sensitive to the stressor (e.g., catfish versus salmon for sedimentation).
- Ecological entity is not exposed to the stressor (e.g., using insectivorous birds for avian risk of pesticide application to seeds).
- Ecological entities are irrelevant to the assessment (e.g., lake fish in salmon stream).
- Importance of a species or attributes of an ecosystem are not fully considered (e.g., mussel-fish connection, see text note 3–8).
- Attribute is not sufficiently sensitive for detecting important effects (e.g., survival compared with recruitment for endangered species).

Text Note 3–11. What Are the Benefits of Developing Conceptual Models?

- The process of creating a conceptual model is a powerful learning tool.
- Conceptual models are easily modified as knowledge increases.
- Conceptual models highlight what is known and not known and can be used to plan future work.
- Conceptual models can be a powerful communication tool. They provide an explicit expression of the 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 3–12. What Are Risk Hypotheses, and Why Are They Important?

Risk hypotheses are proposed answers to questions risk assessors have about what responses assessment endpoints will show when they are exposed to stressors and how exposure will occur. Risk hypotheses clarify and articulate relationships that are posited through the consideration of available data, information from scientific literature, and the best professional judgment of 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 3–13. 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. PMN chemical A has a K_{ow} of 5.5 and molecular structure similar to 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 on 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 finfish. Large mats of macroalgae clog the estuary, most of the eelgrass has died, and the scallops are gone.

Hypotheses: Nutrient loading from septic systems, air pollution, and lawn fertilizers causes 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 from excess algal growth and low dissolved oxygen.

Text Note 3–14. Uncertainty in Problem Formulation

Uncertainties in problem formulation are manifested in the quality of conceptual models. To address uncertainty:

- Be explicit in defining assessment endpoints; include both an entity and its 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 3–15. Why Was Measurement Endpoint Changed?

The original definition of measurement endpoint was ''a measurable characteristic that is related to the valued characteristic chosen as the assessment endpoint'' (Suter, 1989; U.S. EPA, 1992a). The definition refers specifically to the response of an assessment endpoint to a stressor. It does not include measures of ecosystem characteristics, life-history considerations, exposure, or other measures. Because measurement endpoint does not encompass these other important measures and there was confusion about its meaning, the term was replaced with measures of effect and supplemented by two other categories of measures.

Text Note 3–16. Examples of a Management Goal, Assessment Endpoint, and Measures

Goal: Viable, self-sustaining coho salmon population that supports a subsistence and sport fishery.

Assessment Endpoint: Coho salmon breeding success, fry survival, and adult return rates.

Measures of Effects

- Egg and fry response to low dissolved oxygen.
- Adult behavior in response to obstacles.
- Spawning behavior and egg survival with changes in 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 breeding behavior.
- Natural reproduction, growth, and mortality rates.

Measures of Exposure

- Number of hydroelectric dams and associated ease of fish passage.
- Toxic chemical concentrations in water, sediment, and fish tissue.
- Nutrient and dissolved oxygen levels in ambient waters.
- Riparian cover, sediment loading, and water temperature.

Text Note 3–17. How Do Water Quality Criteria Relate to Assessment Endpoints?

Water quality criteria (U.S. EPA, 1986b) 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, management decisions, assessment endpoints, and measures.

Regulatory Goal

- Clean Water Act, § 101: Protect the chemical, physical, and biological integrity of the Nation's waters.

Program Management Decisions

- 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 no-observed-adverse-effect levels (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 3–18. The Data Quality Objectives Process

The data quality objectives (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 data are collected or the assessor (in consultation with the risk manager) 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) recognize several areas that are important to ensuring that environmental data will meet study objectives, including:

- Planning and scoping.
- Designing data collection operations.
- Implementing and monitoring planned operations.
- Assessing and verifying data usability.

Text Note 4–3. Questions for Evaluating a Study's Utility for Risk Assessment

Are the study objectives relevant to the risk assessment?

Are the variables and conditions the study represents comparable with those important to the risk assessment?

Is the study design adequate to meet its objectives?

Was the study conducted properly?

How are variability and uncertainty treated and reported?

Text Note 4–4. 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 or 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	Collect needed data	Discuss rationale for using a factor of 10 to extrapolate between a lowest-observed-adverse-effect level (LOAEL) and a NOAEL.
	Describe approaches used for bridging gaps and their rationales.	
	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.	
	Collect additional data.	
	Verify location of samples or other spatial features	Ground-truth remote sensing data.
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.	
Uncertainty about a model's form (empirical models).	Evaluate whether alternative models should be combined formally or treated separately.	Present results obtained using alternative models.
	Compare model predictions with data collected in the system of interest.	Compare results of a plant uptake model with data collected in the field.

Text Note 4–5. 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 flux rates.

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.

3. Disaggregate models only insofar as required by the goals of the model to facilitate testing.

Text Note 4–6. Questions for Source Description

Where does the stressor originate?

What environmental media first receive 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 4–7. 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 4–8. 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 4–9. 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 4–10. 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 kg food/kg body-weight-day).

m=Number of contaminated food types

Note: A similar equation can be used to calculate uptake by adding an absorption factor that accounts for the fraction of the chemical in the kth food type that is absorbed into the organism. The choice of potential dose or uptake depends on the form of the stressor-response relationship. Source: U.S. EPA, 1993a.

Text Note 4–11. Measuring Internal Dose Using Biomarkers and Tissue Residues

Biomarkers and tissue residues are particularly useful when exposure across many pathways must be integrated and when site-specific factors influence bioavailability. They can also be very useful when metabolism and accumulation kinetics are important, although these factors can make interpretation of results more difficult (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 residue or biomarker (van Gestel and van Brummelen, 1996). Standard analytical methods are generally available for tissue residues, making them more readily usable for routine assessments than biomarkers. Readers are referred to the review in Ecotoxicology (Vol. 3, Issue 3, 1994), Huggett et al. (1992), and the debate in Human Health and Ecological Risk Assessment (Vol. 2, Issue 2, 1996).

Text Note 4–12. 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 4–13. 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?

Will analyses be used as input to a process model?

Text Note 4–14. 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 4–15. 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 hours). Because these tests seldom exceed 96 hours, 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 4–16. 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 level for which effects are not statistically different from the controls (the no-observed-adverse-effect level, NOAEL) and the lowest level at which effects were statistically significant from the control (the lowest-observed-adverse-effect level, LOAEL). The range between the NOAEL and the LOAEL is sometimes called the maximum acceptable toxicant concentration, or MATC. The MATC, which can also be reported as the geometric mean of the NOAEL and the LOAEL (i.e., GMATC), 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 4–17. 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 4–18. 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 4–19. Examples of Extrapolations To Link Measures of Effect to Assessment Endpoints

Every risk assessment has data gaps that should 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 time frame to longer-term effects.

Text Note 4–20. 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 4–21. 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 affect 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 4–22. 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. An Example of Field Methods Used for Risk Estimation

Along with quotients comparing field measures of exposure with laboratory acute toxicity data (see text note 5–3), EPA evaluated the risks of granular carbofuran to birds based on incidents of bird kills following carbofuran applications. More than 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 5–2. 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 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 5–3. 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 factors before 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 5–4. 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 5–5. 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 for different species (e.g., HCN, 1993; Cardwell et al., 1993; Baker et al., 1994; Solomon et al., 1996). Figure 5–

5 shows a distribution of exposure concentrations of an herbicide compared with single-species toxicity data for algae (and one vascular plant species) 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 centile 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 5–6. 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 5–7. What Are Statistically Significant Effects?

Statistical testing is the ''statistical procedure or decision rule that 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 intertreatment variance exceeds intratreatment 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.
- Discuss the degree of scientific consensus in key areas of uncertainty.

′ Identify major data gaps and, where appropriate, indicate whether gathering additional data would add significantly to the overall confidence in the assessment results.

′ Discuss science policy judgments or default assumptions used to bridge information gaps and the basis for these assumptions.

′ Discuss how the elements of quantitative uncertainty analysis are embedded in the estimate of risk.

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 stressors 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, 1993c)

Questions Principally for Risk Assessors To Ask Risk Managers

- 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 Risk Assessors

- 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 the results of the risk management decision?

Text Note 6–2. Risk Communication Considerations for Risk Managers (U.S. EPA, 1995b)

- 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, 1992b) (i.e., with exposure defined as ''contact of a chemical, physical, or biological agent''). The 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, 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, rectangles are used to designate inputs, hexagons indicate actions, and circles represent outputs. There have been some minor changes in the wording for the boxes outside of the risk assessment process (planning; communicating results to the risk manager; acquire data, iterate process, monitor results). ''Iterate process'' was added to emphasize the iterative (and frequently tiered) nature of risk assessment. The term ''interested parties'' was added to the planning and risk management boxes to indicate their increasing role in the risk assessment process (Commission on Risk Assessment and Risk Management, 1997). The new diagram of problem formulation contains several changes. The hexagon emphasizes the importance of integrating available 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.

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. It is important that evaluation of these two aspects of analysis is an interactive process to ensure compatible outputs that can be integrated in risk characterization. The dotted line and hexagon that include 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.

A.2.1. Endpoint Terminology

The Framework Report uses the assessment and measurement endpoint terminology of Suter (1990), but offers no specific terms for measures of stressor levels or ecosystem characteristics. Experience has demonstrated that measures unrelated to effects are sometimes inappropriately called measurement endpoints, which were defined by Suter (1990) as ''measurable responses to a stressor that are related to the valued characteristic chosen as assessment endpoints.'' These Guidelines replace measurement endpoint with measure of effect, which is ''a change in an attribute of an assessment endpoint or its surrogate in response to a stressor to which it is exposed.'' An assessment endpoint is an explicit expression of the environmental value to be protected, operationally defined by an entity and its attributes. 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 to mean ''subjected to some action or influence.'' 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 entity 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).

A.2.4. Lines of Evidence

The Framework Report used the phrase weight of evidence to describe the process of evaluating multiple lines of evidence in risk characterization. These Guidelines use the phrase lines of evidence instead to de-emphasize the balancing of opposing factors based on assignment of quantitative values to reach a conclusion about a ''weight'' in favor of a more inclusive approach, which evaluates all available information, even evidence that may be qualitative in nature.

Appendix B—Key Terms (Adapted From U.S. EPA, 1992a)

Adverse ecological effects—Changes that are considered undesirable because they alter valued structural or functional characteristics of ecosystems or their components. An evaluation of adversity may consider the type, intensity, and scale of the effect as well as the potential for recovery.

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, operationally defined by an ecological entity and its attributes. For example, salmon are valued ecological entities; reproduction and age class structure are some of their important attributes. Together ''salmon reproduction and age class structure'' form an assessment endpoint.

Attribute—A quality or characteristic of an ecological entity. An attribute is one component of an assessment endpoint.

Characterization of ecological effects—A portion of the analysis phase of ecological risk assessment that evaluates the ability of a stressor(s) 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 a professional judgment approach to evaluate the relative magnitude of effects and set priorities among a wide range of environmental problems (e.g., U.S. EPA, 1993d). 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 professional judgment and an ecological risk assessment approach to analyze future ecological risk scenarios and risk management alternatives (U.S. EPA, 1995e).

Conceptual model—A conceptual model in problem formulation is a written description and visual representation of predicted relationships between ecological entities and the stressors to which they may be exposed.

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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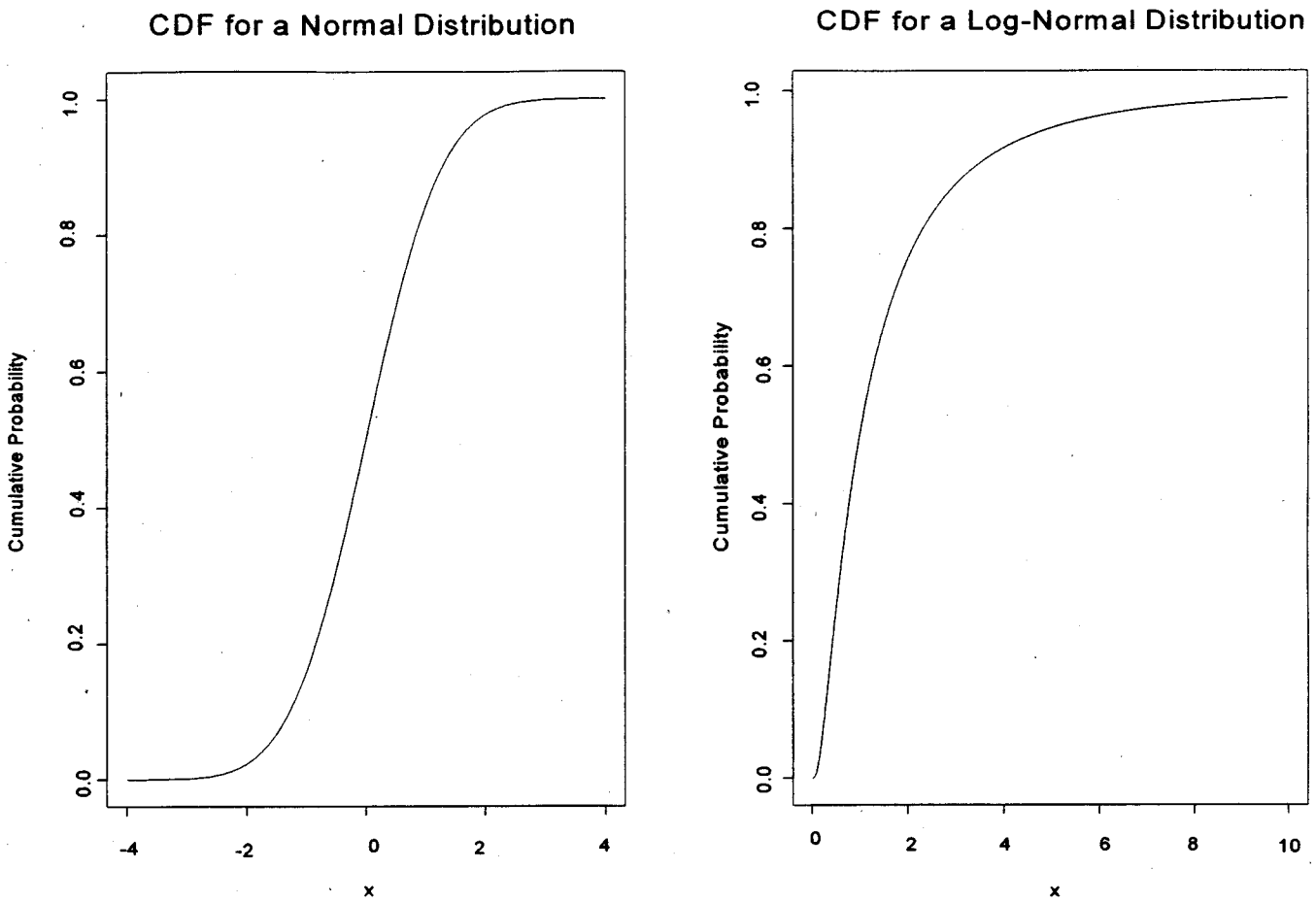

Figure B-1. Plots of cumulative distribution function (CDF).

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Cumulative ecological risk assessment—A process that involves consideration of the aggregate ecological risk to the target entity caused by the accumulation of risk from multiple stressors.

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).

EC_{50}—A statistically or graphically estimated concentration that is expected to cause one or more specified effects in 50% of a group of organisms under specified conditions (ASTM, 1996).

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 is one component of an assessment endpoint.

Ecological relevance—One of the three criteria for assessment endpoint selection. Ecologically relevant endpoints reflect important characteristics of the system and are functionally related to other endpoints.

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 (EIS)—Environmental impact statements are prepared under the National Environmental Policy Act by Federal agencies as they evaluate the environmental consequences of proposed actions. EISs describe baseline environmental conditions; the purpose of, need for, and consequences of a proposed action; the no-action alternative; and the consequences of a reasonable range of alternative actions. A separate risk assessment could be prepared for each alternative, or a comparative risk assessment might be developed. However, risk assessment is not the only approach used in EISs.

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).

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, 1996).

Lines of evidence—Information derived from different sources or by different techniques that can be used to describe and interpret risk estimates. Unlike 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. The geometric mean is also known as the chronic value.

Measure of ecosystem and receptor characteristics—Measures that influence the behavior and location of ecological entities of the assessment endpoint, the distribution of a stressor, and life-history characteristics of the assessment endpoint or its surrogate that may affect exposure or response to the stressor.

Measure of effect—A change in an attribute of an assessment endpoint or its surrogate in response to a stressor to which it is exposed.

Measure of exposure—A measure of stressor existence and movement in the environment and its contact or co-occurrence with the assessment endpoint.

Measurement endpoint—See ''measure of effect.''

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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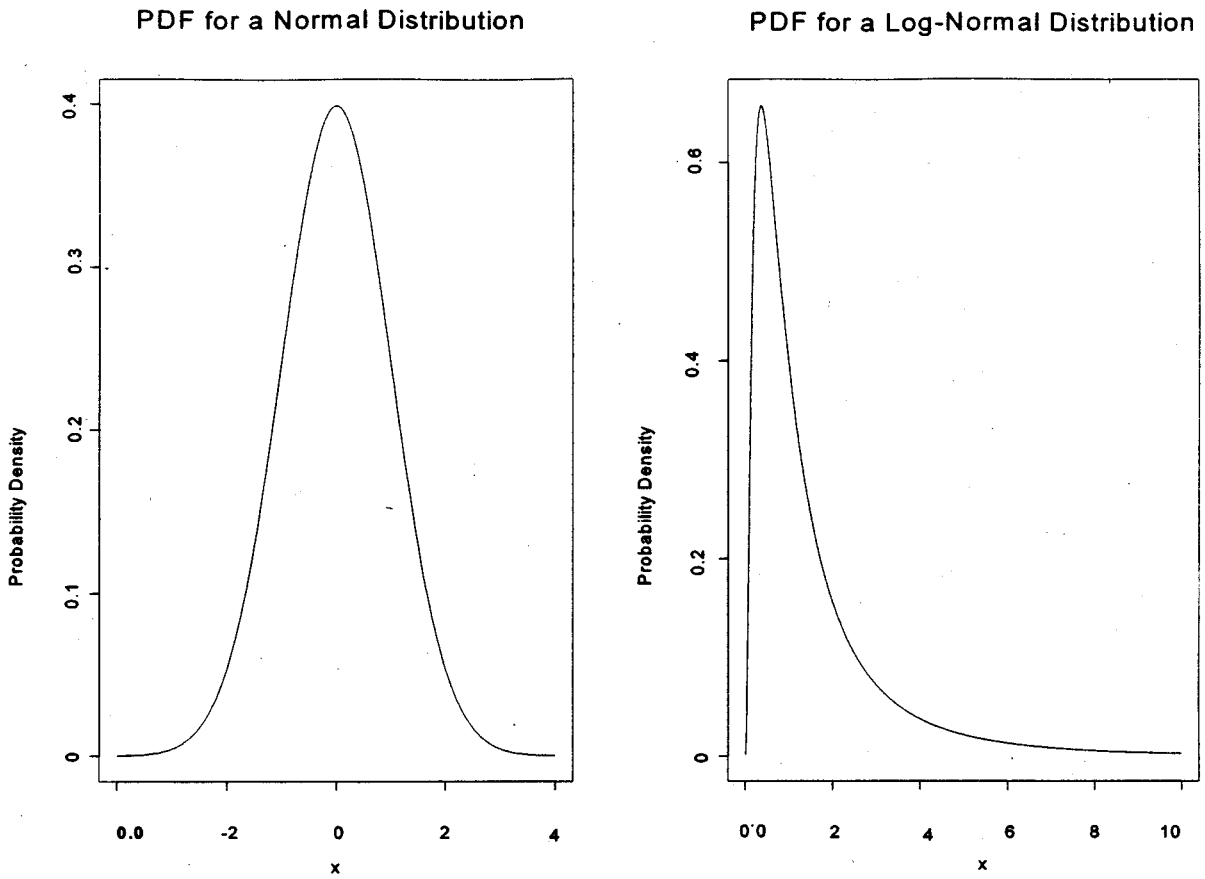

Figure B-2. Plots of probability density functions (PDF).

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Prospective risk assessment—An evaluation of the future risks of a stressor(s) not yet released into the environment or of future conditions resulting from an existing stressor(s).

Receptor—The ecological entity exposed to the stressor.

Recovery—The rate and extent of return of a population or community to some aspect(s) of its previous condition. Because of the dynamic nature of ecological systems, the attributes of a ''recovered'' system should 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 professional judgment. Others do not make this distinction.

Retrospective risk assessment—An evaluation of the causal linkages between observed ecological effects and stressor(s) in the environment.

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. Lines of evidence and the adversity of effects are discussed.

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.

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.

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).

Trophic levels—A functional classification of taxa within a community that is based on feeding relationships (e.g., aquatic and terrestrial green plants make up the first trophic level and herbivores make up 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, or 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, it is helpful to use distinct and consistent shapes to distinguish between 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, and the level of complexity may vary considerably depending on the assessment. Pictorial representations of the processes of an ecosystem can be more effective (e.g., Bradley and Smith, 1989).

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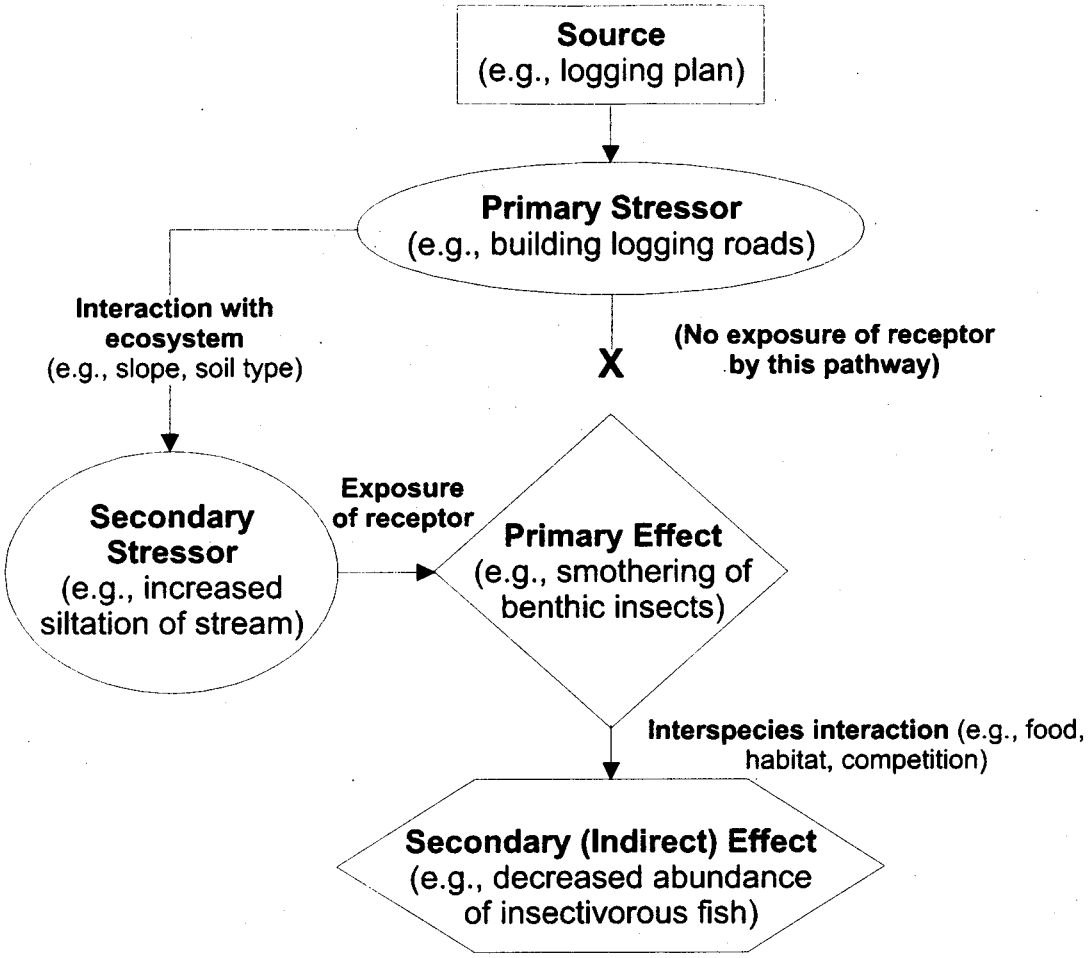

Figure C-1. Conceptual model for logging.

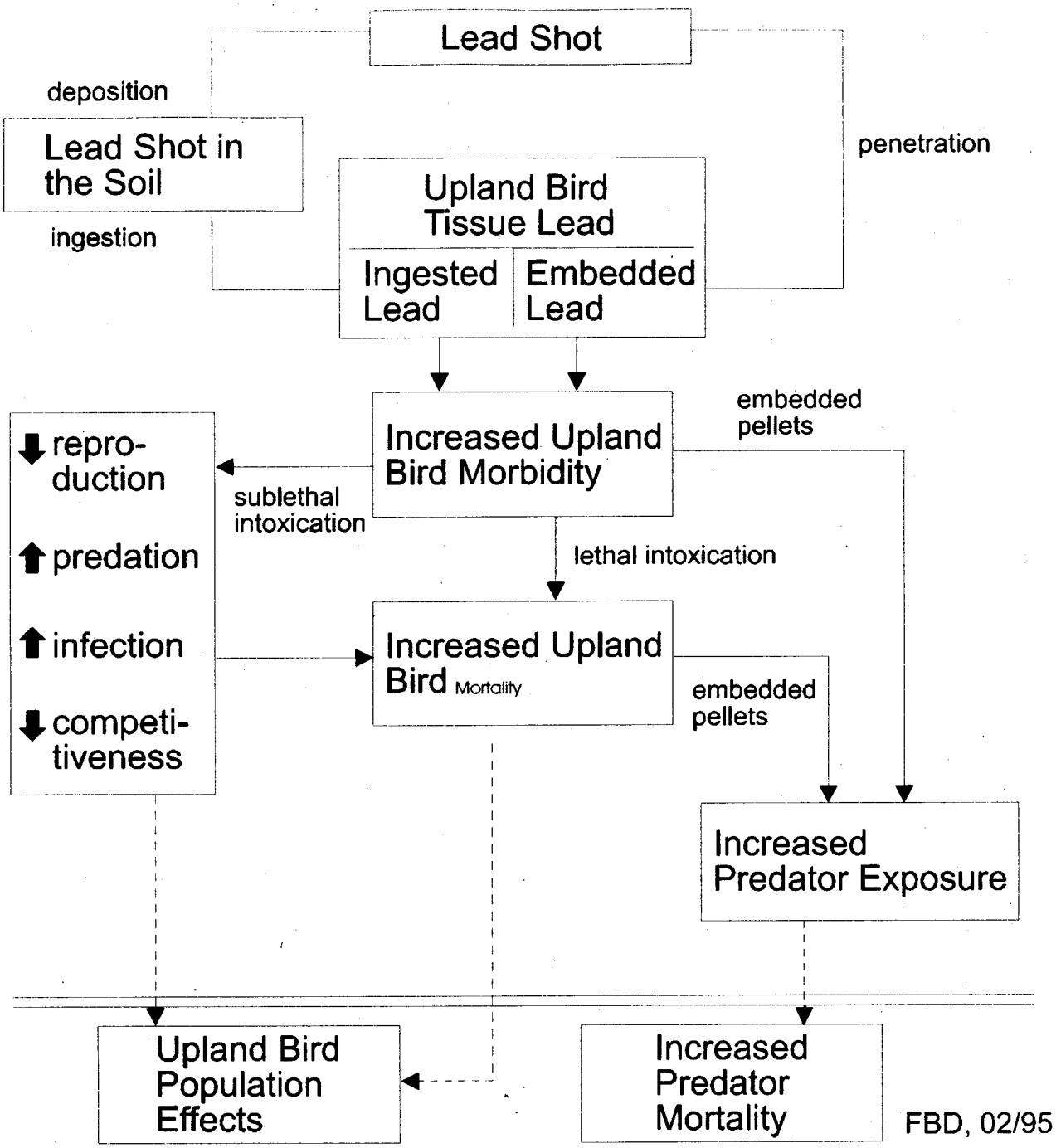

Figure C-2. Conceptual model for tracking stress associated with lead shot through upland ecosystems. Reprinted from *Environmental Toxicology and Chemistry* by Kendall et al. (1996) with permission of the Society of Environmental Toxicology and Chemistry (copyright 1996).

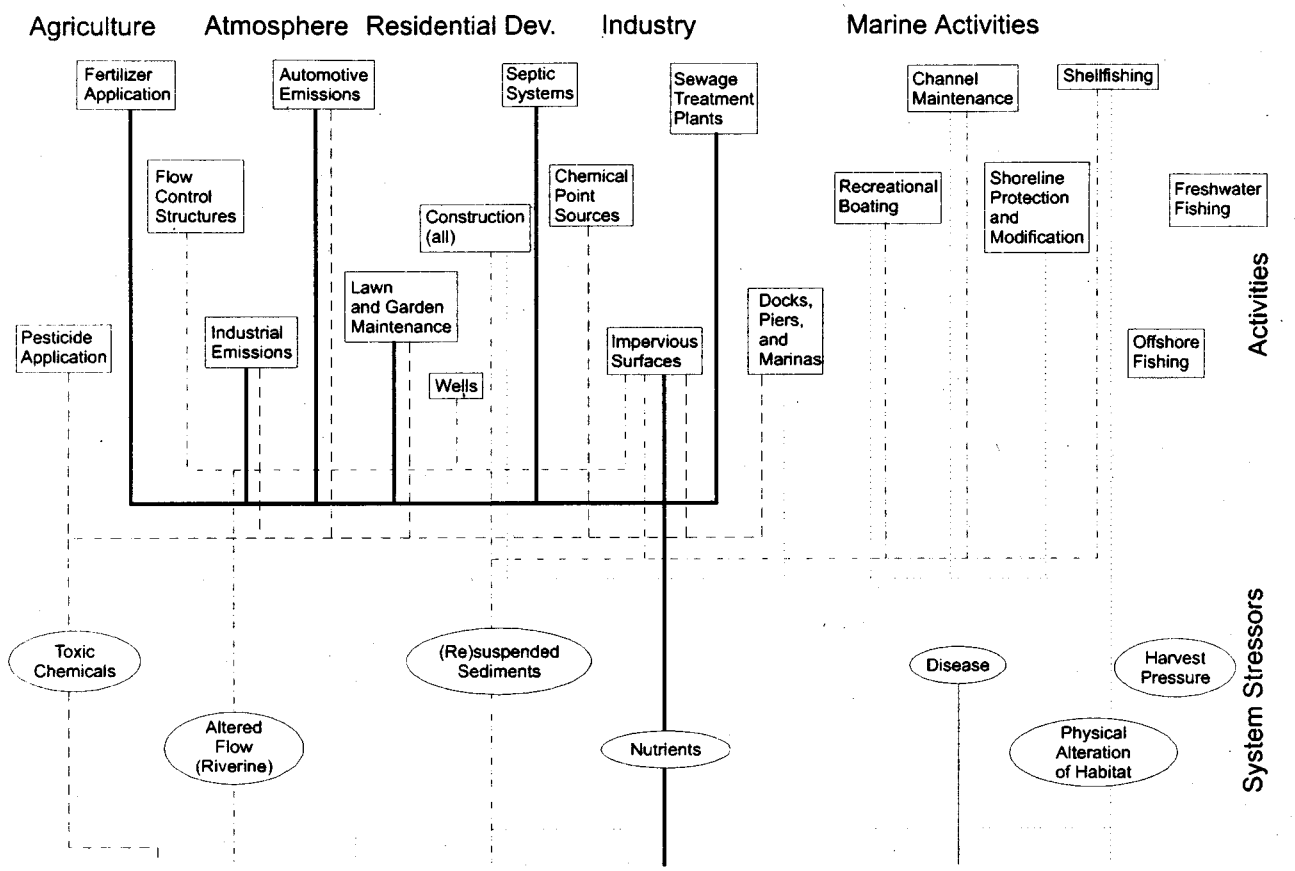

Figure C-3. Waquoit Bay watershed conceptual model.

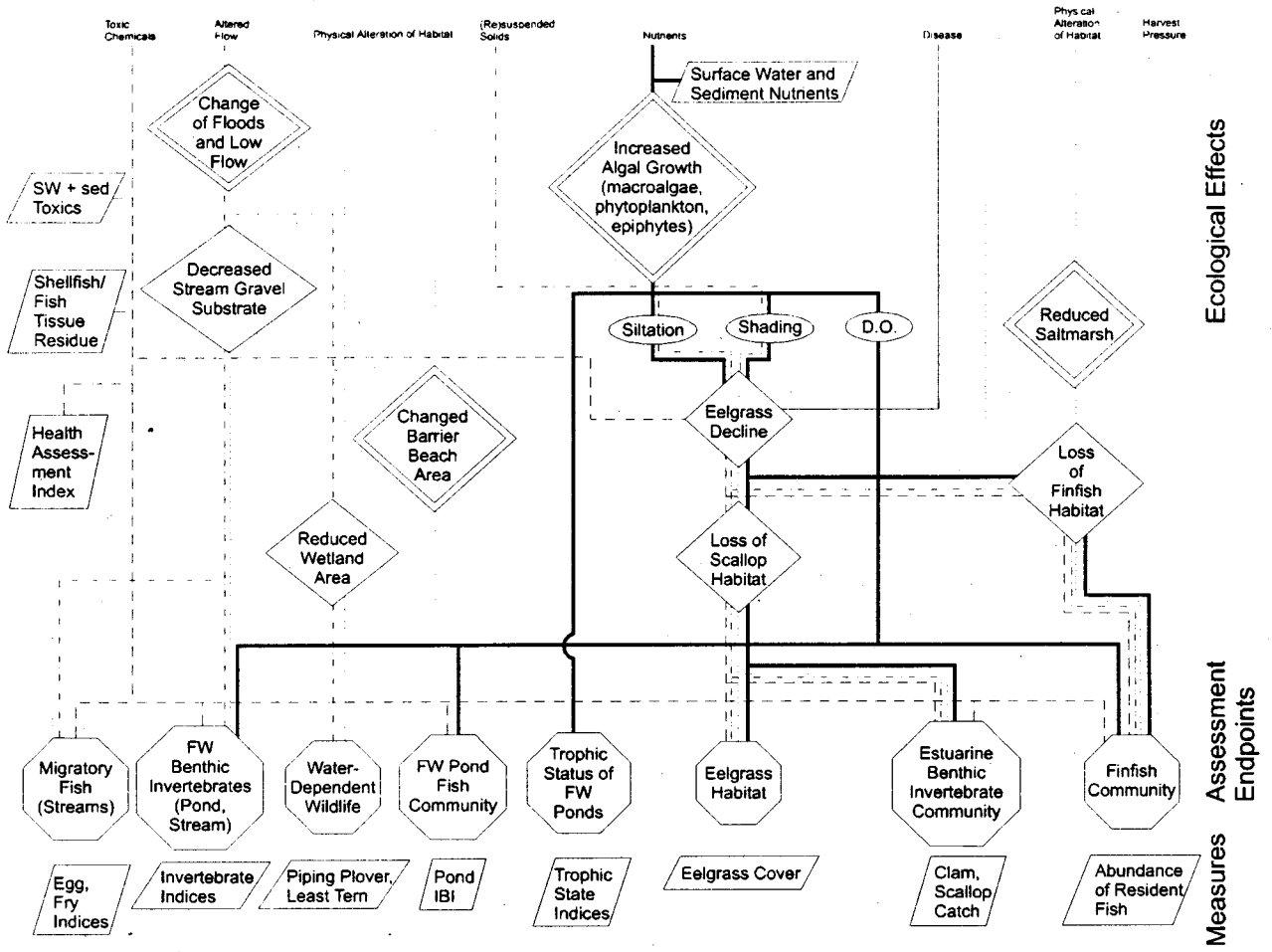

Figure C-3. Waquoit Bay watershed conceptual model (continued).

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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 the effect of 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, because of hypothesized exposure of predators to lead, to increased 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 they 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 pine seed orchards. The assessment endpoint was survival of birds that forage in agricultural areas where carbofuran is applied.

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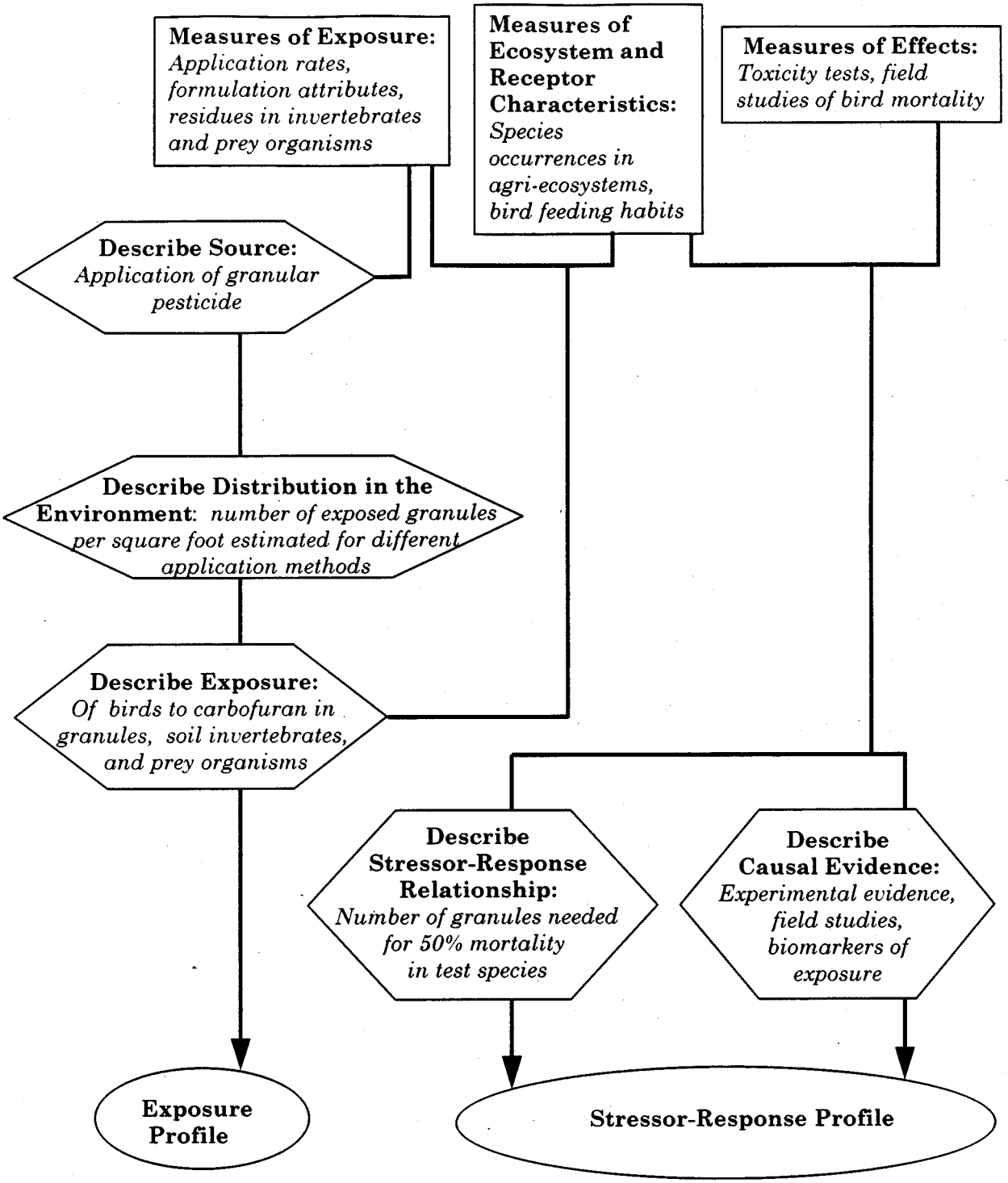

Figure D-1. Example of the analysis phase process: special review of carbofuran. Rectangles indicate inputs, hexagons indicate actions, and circles indicate outputs.

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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 on the basis of the application rate. The number of exposed granules was estimated from literature data. On the basis of 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 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; Conner 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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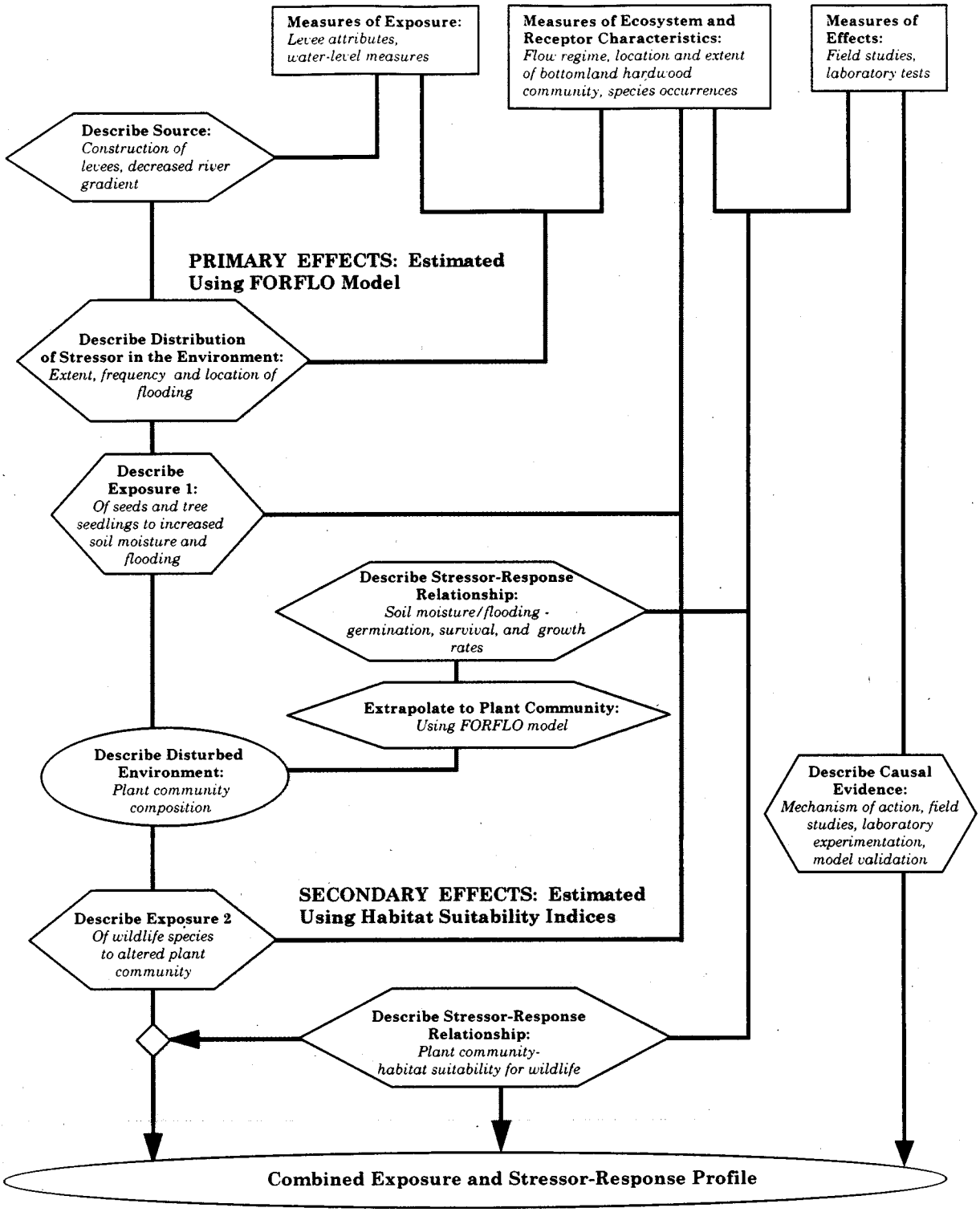

Figure D-2. Example of the analysis phase process: modeling losses of bottomland hardwoods. Rectangles indicate inputs, hexagons indicate actions, and circles indicate outputs.

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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. Measures of ecosystem and receptor characteristics included location and extent of bottomland-hardwood communities, plant species occurrences within these communities, and information on historic flow regimes. Measures of effects 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 into a GIS along with the hydrological information. The changes projected by FORFLO were then 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) was 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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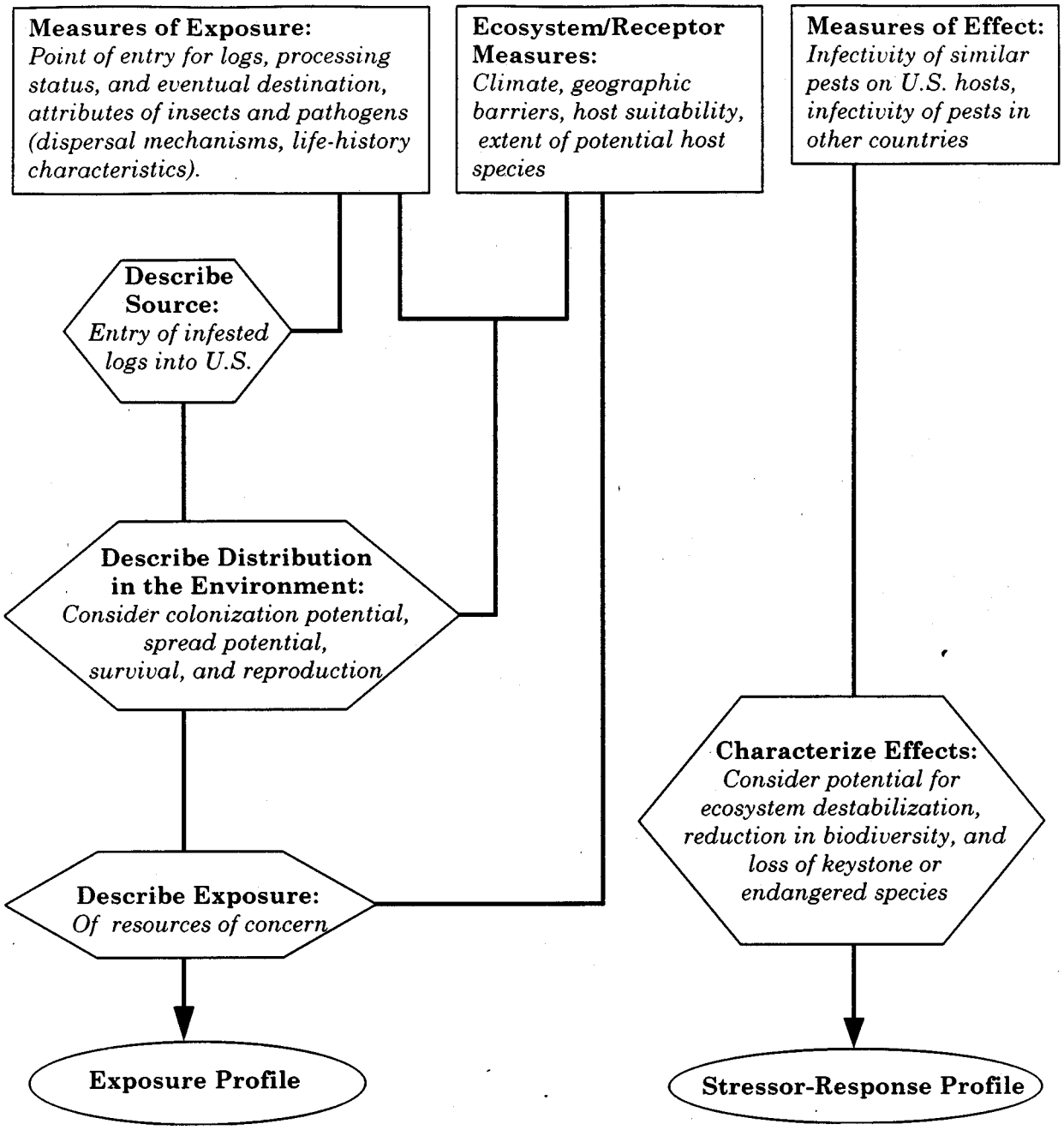

Figure D-3. Example of the analysis phase process: pest risk assessment of the importation of logs from Chile. Rectangles indicate inputs, hexagons indicate actions, and circles indicate outputs.

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The analysis phase was carried out by eliciting professional opinions from a team of experts. Measures of exposure 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. Measures of ecosystem and receptor characteristics included the climate of the United States, location of geographic barriers, knowledge of host suitability, and ranges of potential host species. Measures of effect 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 organism's given entry was evaluated by considering the potential for colonization and spread beyond the point of entry as well as the likelihood of the 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 on the basis of 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, for the purposes of these Guidelines, those factors are considered 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) [1]

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 determines that if no action is taken, significant risks to the communities will result. Additional risk assessments are 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 (fish larvae), 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 intensity 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, which 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. On the basis of 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. There should not be a long recovery period for ichthyoplankton, since 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.

[1] This example is simplified for illustrative purposes. In other situations, it may be considerably more difficult to draw clear conclusions regarding relative ecological adversity.

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Part B: Response to Science Advisory Board and Public Comments

1. Introduction

This section summarizes the major issues raised in public comments and by EPA's Science Advisory Board (SAB) on the previous draft of these Guidelines (the Proposed Guidelines for Ecological Risk Assessment, hereafter ''Proposed Guidelines''). A notice of availability for public comment of the Proposed Guidelines was published September 9, 1996 (61 FR 47552–47631). Forty-four responses were received. The Ecological Processes and Effects Committee of the SAB reviewed the Proposed Guidelines on September 19–20, 1996, and provided comments in January 1997 (EPA–SAB–EPEC–97–002).

The SAB and public comments were diverse, reflecting the different perspectives of the reviewers. Many of the comments were favorable, expressing agreement with the overall approach to ecological risk assessment. Many comments were beyond the scope of the Guidelines, including requests for guidance on risk management issues (such as considering social or economic impacts in decision making). Major issues raised by reviewers are summarized below. In addition to providing general comments (section 2), reviewers were asked to comment on seven specific questions (section 3).

2. Response to General Comments

Probably the most common request was for greater detail in specific areas. In some cases, additional discussion was added (for example, on the use of tiering and iteration and the respective roles of risk assessors, risk managers, and interested parties throughout the process). In other areas, topics for additional discussion were included in a list of potential areas for further development (see response to question 2, below). Still other topics are more appropriately addressed by regional or program offices within the context of a certain regulation or issue, and are deferred to those sources.

A few reviewers felt that since ecological risk assessment is a relatively young science, it is premature to issue guidelines at this time. The Agency feels that it is appropriate to issue guidance at this time, especially since the Guidelines contain major principles but refrain from recommending specific methodologies that might become rapidly outdated. To help ensure the continued relevance of the Guidelines, the Agency intends to develop documents addressing specific topics (see response to question 2 below) and will revise these Guidelines as experience and scientific consensus evolve.

Some reviewers asked whether the Guidelines would be applied to previous or ongoing ecological risk assessments, and whether existing regional or program office guidance would be superseded in conducting ecological risk assessments. As described in section 1.3 (Scope and Intended Audience), the Guidelines are principles, and are not regulatory in nature. It is anticipated that guidance from program and regional offices will evolve to implement the principles set forth in these Guidelines. Similarly, some reviewers requested that assessments require a comparison of the risks of alternative scenarios (including background or baseline conditions) or an assignment of particular levels of ecological significance to habitats. These decisions would be most appropriately made on a case-by-case basis, or by a program office in response to program-specific needs.

Several Native American groups noted a lack of acknowledgment of tribal governments in the document. This Agency oversight was corrected by including tribal governments at points in the Guidelines where other governmental organizations are mentioned.

Several reviewers noted that the Proposed Guidelines mentioned the need for ''expert judgment'' in several places and asked how the Agency defined ''expert'' and what qualifications such an individual should have. At present, there is no standard set of qualifications for an ecological risk assessor, and such a standard would be very difficult to produce, since ecological assessments are frequently done by teams of individuals with expertise in many areas. To avoid this problem, the Guidelines now use the term ''professional judgment,'' and note that it is important to document the rationale for important decisions.

Some reviewers felt that the Guidelines should address effects only at the population level and above. The Guidelines do not make this restriction for several reasons. First, some assessments, such as those involving endangered species, do involve considerations of individual effects. Second, the decision as to which ecological entity to protect should be the result, on a case-by-case basis, of the planning process involving risk assessors, risk managers, and interested parties, if appropriate. Some suggestions have been proposed (U.S. EPA, 1997a). Finally, there appears to be some confusion among reviewers between conducting an assessment concerned with population-level effects, and using data from studies of effects on individuals (e.g., toxicity test results) to infer population-level effects. These inferences are commonly used (and generally accepted) in chemical screening programs, such as the Office of Pollution Prevention and Toxics Premanufacturing Notification program (U.S. EPA, 1994e).

The use of environmental indices received a number of comments. Some reviewers wanted the Guidelines to do more to encourage the use of indices, while others felt that the disadvantages of indices should receive greater emphasis. The Guidelines discuss both the advantages and limitations of using indices to guide risk assessors in their proper use.

Other reviewers requested that the Guidelines take a more definitive position on the use of ''realistic exposure assumptions,'' such as those proposed in the Agency's exposure guidelines (U.S. EPA, 1992b). Although the exposure guidelines offer many useful suggestions that are applicable to human health risk assessment, it was not possible to generalize the concepts to ecological risk assessment, given the various permutations of the exposure concept for different types of stressors or levels of biological organization. The Guidelines emphasize the importance of documenting major assumptions (including exposure assumptions) used in an assessment.

Several reviewers requested more guidance and examples using nonchemical stressors, i.e., physical or biological stressors. This topic has been included in the list of potential subjects for future detailed treatment (see response to question 2, below).

3. Response to Comments on Specific Questions

Both the Proposed Guidelines and the charge to the SAB for its review contained a set of seven questions asked by the Agency. These questions, along with the Agency's response to comments received, are listed below.

(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 in 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 among risk assessors, risk managers, and other interested parties?

Most reviewers felt there was general compatibility between the Proposed Guidelines and the NRC report, although some emphasized the need for continued interactions among risk assessors, risk managers, and interested parties (or stakeholders) throughout the ecological risk assessment process and asked that the Guidelines provide additional details concerning such interactions. To give greater emphasis to these interactions, the ecological risk assessment diagram was modified to include ''interested parties'' in the planning box at the beginning of the process and ''communicating with interested parties'' in the risk management box following the risk assessment. Some additional discussion concerning interactions among risk assessors, risk managers, and interested parties was added, particularly to section 2 (planning). However, although risk assessor/risk manager interrelationships are discussed, too great an emphasis in this area is inconsistent with the scope of the Guidelines, which focus on the interface between risk assessors and risk managers, not on providing risk management guidance.

(2) The Proposed Guidelines are intended to provide a starting point for Agency programs 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?

Reviewers recommended numerous topics for further development. Examples include:

- Landscape ecology.
- Data sources and quality.
- Physical and biological stressors.
- Multiple stressors.
- Defining reference areas for field studies.
- Ecotoxicity thresholds.
- The role of biological and other types of indicators.
- Bioavailability, bioaccumulation, and bioconcentration.
- Uncertainty factors.
- Stressor-response relationships (e.g., threshold vs. continuous).
- Risk characterization techniques.
- Risk communication to the public.
- Public participation.
- Comparative ecological risk.
- Screening and tiering assessments.
- Identifying and selecting assessment endpoints.

These suggestions will be included in a listing of possible topics proposed to the Agency's Risk Assessment Forum for future development.

(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?

In response to a number of comments, the discussion of field data in the

Guidelines was expanded, especially in section 4.1. Nevertheless, many suggested topics requested a level of detail that was inconsistent with the scope of the Guidelines. Some areas may be covered through the development of future Risk Assessment Forum documents.

(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?

Landscape ecology is critical to many aspects of ecological risk assessment, especially assessments conducted at larger spatial scales. However, given the general nature of these Guidelines and the responses received to this question, the Guidelines could not be expanded substantially at this time. This topic has been added to the list of potential subjects for future development.

(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 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 general approaches for evaluating causality of an observed effect. What additional principles can be added?

Few additional principles were provided that could be included in the Guidelines. To further progress in evaluating multiple stressors, EPA cosponsored a workshop on this issue, held by the Society of Environmental Toxicology and Chemistry in September 1997. In addition, evaluating multiple stressors is one of the proposed topics for further development.

(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?

Many reviewers emphasized the importance of tiered assessments, and in response the discussion of tiered assessments was significantly expanded in the planning phase of ecological risk assessment. Including more detailed information (such as specific decision criteria to proceed from one tier to the next) would require a particular context for an assessment. Such specific guidance is left to the EPA program offices and regions.

(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 attribute 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?

Reviewer reaction was quite evenly divided between those who felt strongly that decision criteria should be defined in problem formulation and those who felt just as strongly that such decisions should be delayed until risk characterization. Although the Guidelines contain more discussion of this topic, they still take the position that assessment endpoints need not contain specific decision criteria.

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Part III

Environmental Protection Agency

Guidelines For Neurotoxicity Risk Assessment; Notice

ENVIRONMENTAL PROTECTION AGENCY

[FRL–6011–3]

RIN 2080–AA08

Guidelines for Neurotoxicity Risk Assessment

AGENCY: Environmental Protection Agency.

ACTION: Notice of availability of final Guidelines for Neurotoxicity Risk Assessment.

SUMMARY: The U.S. Environmental Protection Agency (EPA) is today publishing in final form a document entitled *Guidelines for Neurotoxicity Risk Assessment* (hereafter ''Guidelines''). These Guidelines were developed as part of an interoffice guidelines development program by a Technical Panel of the Risk Assessment Forum. The Panel was composed of scientists from throughout the Agency, and selected drafts were peer-reviewed internally and by experts from universities, environmental groups, industry, and other governmental agencies. The Guidelines are based, in part, on recommendations derived from various scientific meetings and workshops on neurotoxicology, from public comments, and from recommendations of the Science Advisory Board. An earlier draft underwent external peer review in a workshop held on June 2–3, 1992, and received internal review by the Risk Assessment Forum. The Risk Assessment Subcommittee of the Committee on the Environment and Natural Resources of Office of Science and Technology Policy reviewed the proposed Guidelines during a meeting held on August 15, 1995. The Guidelines were revised and proposed for public comment on October 4, 1995 (60 FR 52032–52056). The proposed Guidelines were reviewed by the Science Advisory Board on July 18, 1996. EPA appreciates the efforts of all participants in the process, and has tried to address their recommendations in these Guidelines.

This notice describes the scientific basis for concern about exposure to agents that cause neurotoxicity, outlines the general process for assessing potential risk to humans because of environmental contaminants, and addresses Science Advisory Board and public comments on the 1995 *Proposed Guidelines for Neurotoxicity Risk Assessment* (60 FR:52032–52056). These Guidelines are intended to guide Agency evaluation of agents that are suspected to cause neurotoxicity, in line with the policies and procedures established in the statutes administered by the Agency.

DATES: The Guidelines will be effective on April 30, 1998.

ADDRESSES: The Guidelines will be made available in several ways:

(1) The electronic version will be accessible from EPA's National Center for Environmental Assessment home page on the Internet at http://www.epa.gov/ncea.

(2) 3½″ high-density computer diskettes in WordPerfect format will be available from ORD Publications, Technology Transfer and Support Division, National Risk Management Research Laboratory, Cincinnati, OH; Tel: 513–569–7562; Fax: 513–569–7566. Please provide the EPA No.: EPA/630/R–95/001Fa when ordering.

(3) This notice contains the full document. Copies of the Guidelines 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 PB No. (PB98–117831) when ordering.

FOR FURTHER INFORMATION CONTACT: Dr. Hugh A. Tilson, Neurotoxicology Division, National Health and Environmental Effects Research Laboratory, U.S. Environmental Protection Agency, Research Triangle Park, NC 27711, Tel: 919–541–2671; Fax: 919–541–4849; E-mail: tilson.hugh@epamail.epa.gov.

SUPPLEMENTARY INFORMATION: In its 1983 book *Risk Assessment in the Federal Government: Managing the Process*, the National Academy of Sciences recommended that Federal regulatory agencies establish ''inference guidelines'' to promote consistency and technical quality in risk assessment, and to ensure that the risk assessment process is maintained as a scientific effort separate from risk management. A task force within EPA accepted that recommendation and requested that Agency scientists begin to develop such guidelines. In 1984, EPA scientists began work on risk assessment guidelines for carcinogenicity, mutagenicity, suspect developmental toxicants, chemical mixtures, and exposure assessment. Following extensive scientific and public review, these first five guidelines were issued on September 24, 1986 (51 FR 33992–34054). Since 1986, additional risk assessment guidelines have been proposed, revised, reproposed, and finalized. These guidelines continue the process initiated in 1984. As with other EPA guidelines (e.g., 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 evolve.

These Guidelines set forth principles and procedures to guide EPA scientists in the conduct of Agency risk assessments and to inform Agency decision makers and the public about these procedures. Policies in this document are intended as internal guidance for EPA. Risk assessors and risk managers at EPA are the primary audience, although these Guidelines may be useful to others outside the Agency. In particular, the Guidelines emphasize that risk assessments will be conducted on a case-by-case basis, giving full consideration to all relevant scientific information. This approach means that Agency experts study scientific information on each chemical under review and use the most scientifically appropriate interpretation to assess risk. The Guidelines also stress that this information will be fully presented in Agency risk assessment documents, and that Agency scientists will identify the strengths and weaknesses of each assessment by describing uncertainties, assumptions, and limitations, as well as the scientific basis and rationale for each assessment. The Guidelines are formulated in part to bridge gaps in risk assessment methodology and data. By identifying these gaps and the importance of the missing information to the risk assessment process, EPA wishes to encourage research and analysis that will lead to new risk assessment methods and data.

Dated: April 30, 1998.

Carol M. Browner,

Administrator.

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Part A: Guidelines for Neurotoxicity Risk Assessment

1. Introduction

These Guidelines describe the principles, concepts, and procedures that the U.S. Environmental Protection Agency (EPA) will follow in evaluating data on potential neurotoxicity associated with exposure to environmental toxicants. The Agency's authority to regulate substances that have the potential to interfere with human health is derived from a number of statutes that are implemented through multiple offices within EPA. The procedures outlined here are intended to help develop a sound scientific basis for neurotoxicity risk assessment, promote consistency in the Agency's assessment of toxic effects on the nervous system, and inform others of the approaches used by the Agency in those assessments. This document is not a regulation and is not intended for EPA regulations. The Guidelines set forth current scientific thinking and approaches for conducting and evaluating neurotoxic risk assessments. They are not intended, nor can they be relied upon, to create any rights enforceable by any party in litigation with the United States.

1.1. Organization of These Guidelines

This introduction (section 1) summarizes the purpose of these Guidelines within the overall framework of risk assessment at EPA. It also outlines the organization of the guidance and describes several default assumptions to be used in the risk assessment process, as discussed in the recent National Research Council report ''Science and Judgment in Risk Assessment'' (NRC, 1994).

Section 2 sets forth definitions of particular terms widely used in the field of neurotoxicology. These include ''neurotoxicity'' and ''behavioral alterations.'' Also included in this section are discussions concerning reversible and irreversible effects and direct versus indirect effects.

Risk assessment is the process by which scientific judgments are made concerning the potential for toxicity in humans. The National Research Council (NRC, 1983) has defined risk assessment as including some or all of the following components (paradigm): hazard identification, dose-response assessment, exposure assessment, and risk characterization. In its 1994 report ''Science and Judgment in Risk Assessment'' the NRC extended its view of the paradigm to include characterization of each component (NRC, 1994). In addition, it noted the importance of an approach that is less fragmented and more holistic, less linear and more interactive, and that deals with recurring conceptual issues that cut across all stages of risk assessment. These Guidelines describe a more interactive approach by organizing the process around the qualitative evaluation of the toxicity data (hazard characterization), the quantitative dose-response analysis, the exposure assessment, and the risk characterization. In these Guidelines, hazard characterization includes deciding whether a chemical has an effect by means of qualitative consideration of dose-response relationships, route, and duration of exposure. Determining a hazard often depends on whether a dose-response relationship is present (Kimmel et al., 1990). This approach combines the information important in comparing the toxicity of a chemical with potential human exposure scenarios (section 3). In addition, it avoids the potential for labeling chemicals as ''neurotoxicants'' on a purely qualitative basis. This organization of the risk assessment process is similar to that discussed in the Guidelines for Developmental Toxicity Risk Assessment (56 FR 63798), the main difference being that the quantitative dose-response analysis is discussed under a separate section in these Guidelines.

Hazard characterization involves examining all available experimental animal and human data and the associated doses, routes, timing, and durations of exposure to determine qualitatively if an agent causes neurotoxicity in that species and under what conditions. From the hazard characterization and criteria provided in these Guidelines, the health-related database can be characterized as sufficient or insufficient for use in risk assessment (section 3.3). Combining hazard identification and some aspects of dose-response evaluation into hazard characterization does not preclude the evaluation and use of data for other purposes when quantitative information for setting reference doses (RfDs) and reference concentrations (RfCs) is not available.

The next step in the dose-response analysis (section 4) is the quantitative analysis, which includes determining the no-observed-adverse-effect-level (NOAEL) and/or the lowest-observed-adverse-effect-level (LOAEL) for each study and type of effect. Because of the limitations associated with the use of the NOAEL, the Agency is beginning to use an additional approach, the benchmark dose approach (BMD) (Crump, 1984; U.S. EPA, 1995a), for

more quantitative dose-response evaluation when sufficient data are available. The benchmark dose approach takes into account the variability in the data and the slope of the dose-response curve, and provides a more consistent basis for calculation of the RfD or RfC. If data are considered sufficient for risk assessment, and if neurotoxicity is the effect occurring at the lowest dose level (i.e., the critical effect), an oral or dermal RfD or an inhalation RfC, based on neurotoxic effects, is then derived. This RfD or RfC is derived using the NOAEL or benchmark dose divided by uncertainty factors to account for interspecies differences in response, intraspecies variability, and other factors of study design or the database. A statement of the potential for human risk and the consequences of exposure can come only from integrating the hazard characterization and dose-response analysis with the human exposure estimates in the final risk characterization.

The section on exposure assessment (section 5) identifies human populations exposed or potentially exposed to an agent, describes their composition and size, and presents the types, magnitudes, frequencies, and durations of exposure to the agent. The exposure assessment provides an estimate of human exposure levels for particular populations from all potential sources.

In risk characterization (section 6), the hazard characterization, dose-response analysis, and exposure assessment for given populations are combined to estimate some measure of the risk for neurotoxicity. As part of risk characterization, a summary of the strengths and weaknesses of each component of the risk assessment is given, along with major assumptions, scientific judgments and, to the extent possible, qualitative and quantitative estimates of the uncertainties. This characterization of the health-related database is always presented in conjunction with information on the dose, route, duration, and timing of exposure as well as the dose-response analysis including the RfD or RfC. If human exposure estimates are available, the exposure basis used for the risk assessment is clearly described, e.g., highly exposed individuals or highly sensitive or susceptible individuals. The NOAEL may be compared to the various estimates of human exposure to calculate the margin(s) of exposure (MOE). The considerations for judging the acceptability of the MOE are similar to those for determining the appropriate size of the uncertainty factor for calculating the RfD or RfC.

The Agency recently issued a policy statement and associated guidance for risk characterization (U.S. EPA, 1995b, 1995c), which is currently being implemented throughout EPA. This statement is designed to ensure that critical information from each stage of a risk assessment is used in forming conclusions about risk and that this information is communicated from risk assessors to risk managers (policy makers), from middle to upper management, and from the Agency to the public. Additionally, the policy provides a basis for greater clarity, transparency, reasonableness, and consistency in risk assessments across Agency programs.

Final neurotoxicity risk assessment guidelines may reflect additional changes in risk characterization practices resulting from implementation activities. Risk assessment is just one component of the regulatory process and defines the potential adverse health consequences of exposure to a toxic agent. The other component, risk management, combines risk assessment with statutory directives regarding socioeconomic, technical, political, and other considerations in order to decide whether to control future exposure to the suspected toxic agent and, if so, the nature and level of control. One major objective of these Guidelines is to help the risk assessor determine whether the experimental animal or human data indicate the potential for a neurotoxic effect. Such information can then be used to categorize evidence that will identify and characterize neurotoxic hazards, as described in section 3.3, Characterization of the Health-Related Database, and Table 8 of these Guidelines. Risk management is not dealt with directly in these Guidelines because the basis for decision making goes beyond scientific considerations alone, but the use of scientific information in this process is discussed. For example, the acceptability of the MOE is a risk management decision, but the scientific bases for establishing this value are discussed here.

1.2. The Role of Environmental Agents in Neurotoxicity

Chemicals are an integral part of life, with the capacity to improve as well as endanger health. The general population is exposed to chemicals in air, water, foods, cosmetics, household products, and drugs used therapeutically or illicitly. During daily life, a person experiences a multitude of exposures to potentially neuroactive substances, singly and in combination, both synthetic and natural. Levels of exposure vary and may or may not pose a hazard, depending on dose, route, and duration of exposure.

A link between human exposure to some chemical substances and neurotoxicity has been firmly established (Anger, 1986; OTA, 1990). Because many natural and synthetic chemicals are present in today's environment, there is growing scientific and regulatory interest in the potential for risks to humans from exposure to neurotoxic agents. If sufficient exposure occurs, the effects resulting from such exposures can have a significant adverse impact on human health. It is not known how many chemicals may be neurotoxic in humans (Reiter, 1987). EPA's TSCA inventory of chemical substances manufactured, imported, or processed in the United States includes more than 65,000 substances and is increasing yearly. An overwhelming majority of the materials in commercial use have not been tested for neurotoxic potential (NRC, 1984).

Estimates of the number of chemicals with neurotoxic properties have been made for subsets of substances. For instance, a large percentage of the more than 500 registered active pesticide ingredients affect the nervous system of the target species to varying degrees. Of 588 chemicals listed by the American Conference of Governmental Industrial Hygienists, 167 affected the nervous system or behavior at some exposure level (Anger, 1984). Anger (1990) estimated that of the approximately 200 chemicals to which 1 million or more American workers are exposed, more than one-third may have adverse effects on the nervous system if sufficient exposure occurs. Anger (1984) also recognized neurotoxic effects as one of the 10 leading workplace disorders. A number of therapeutic substances, including some anticancer and antiviral agents and abused drugs, can cause adverse or neurotoxicological side effects at therapeutic levels (OTA, 1990). The number of chemicals with neurotoxic potential has been estimated to range from 3% to 28% of all chemicals (OTA, 1990). Thus, estimating the risks of exposure to chemicals with neurotoxic potential is of concern with regard to their overall impact on human health.

1.3. Neurotoxicity Risk Assessment

In addition to its primary role in psychological functions, the nervous system controls most, if not all, other bodily processes. It is sensitive to perturbation from various sources and has limited ability to regenerate. There is evidence that even small anatomical, biochemical, or physiological insults to the nervous system may result in

adverse effects on human health. Therefore, there is a need for consistent guidance on how to evaluate data on neurotoxic substances and assess their potential to cause transient or persistent and direct or indirect effects on human health.

These Guidelines develop principles and concepts in several areas. They outline the scientific basis for evaluating effects due to exposure to neurotoxicants and discuss principles and methods for evaluating data from human and animal studies on behavior, neurochemistry, neurophysiology, and neuropathology. They also discuss adverse effects on neurological development and function in infants and children following prenatal and perinatal exposure to chemical agents. They outline the methods for calculating reference doses or reference concentrations when neurotoxicity is the critical effect, discuss the availability of alternative mathematical approaches to dose-response analyses, characterize the health-related database for neurotoxicity risk assessment, and discuss the integration of exposure information with results of the dose-response assessment to characterize risks. These Guidelines do not advocate developing reference doses specific for neurotoxicity, but rather support the use of neurotoxicity as one possible endpoint to develop reference doses. EPA offices have published guidelines for neurotoxicity testing in animals (U.S. EPA, 1986, 1987, 1988a, 1991a). The testing guidelines address the development of new data for use in risk assessment.

These neurotoxicity risk assessment guidelines provide the Agency's first comprehensive guidance on the use and interpretation of neurotoxicity data, and are part of the Agency's risk assessment guidelines development process, which was initiated in 1984. As part of its neurotoxicity guidelines development program, EPA has sponsored or participated in several conferences on relevant issues (Tilson, 1990); these and other sources (see references) provide the scientific basis for these Guidelines.

This guidance is intended for use by Agency risk assessors and is separate and distinct from the recently published document on principles of neurotoxicity risk assessment (U.S. EPA, 1994). The document on principles was prepared under the auspices of the Subcommittee on Risk Assessment of the Federal Coordinating Council for Science, Engineering, and Technology and was not intended to provide specific directives for how neurotoxicity risk assessment should be performed. It is expected that, like other EPA risk assessment guidelines for noncancer endpoints (U.S. EPA, 1991b), this document will encourage research and analysis leading to new risk assessment methods and data, which in turn would be used to revise and improve the Guidelines and better guide Agency risk assessors.

1.4. Assumptions

There are a number of unknowns in the extrapolation of data from animal studies to humans. Therefore, a number of default assumptions are made that are generally applied in the absence of data on the relevance of effects to potential human risk. Default assumptions should not be applied indiscriminately. First, all available mechanistic and pharmacokinetic data should be considered. If these data indicate that an alternative assumption is appropriate or if they obviate the need for applying an assumption, such information should be used in risk assessment. For example, research in rats may determine that the neurotoxicity of a chemical is caused by a metabolite. If subsequent research finds that the chemical is metabolized to a lesser degree or not at all in humans, then this information should be used in formulating the default assumptions. The following default assumptions form the basis of the approaches taken in these Guidelines:

(1) It is assumed that an agent that produces detectable adverse neurotoxic effects in experimental animal studies will pose a potential hazard to humans. This assumption is based on the comparisons of data for known human neurotoxicants (Anger, 1990; Kimmel et al., 1990; Spencer and Schaumburg, 1980), which indicate that experimental animal data are frequently predictive of a neurotoxic effect in humans.

(2) It is assumed that behavioral, neurophysiological, neurochemical, and neuroanatomical manifestations are of concern. In the past, the tendency has been to consider only neuropathological changes as endpoints of concern. Based on data on agents that are known human neurotoxicants (Anger, 1990; Kimmel et al., 1990; Spencer and Schaumberg, 1980), there is usually at least one experimental species that mimics the types of effects seen in humans, but in other species tested, the neurotoxic effect may be different or absent. For example, certain organophosphate compounds produce a delayed-onset neuropathy in hens similar to that seen in humans, whereas rodents are characteristically insensitive to these compounds. A biologically significant increase in any of the manifestations is considered indicative of an agent's potential for disrupting the structure or function of the human nervous system.

(3) It is assumed that the neurotoxic effects seen in animal studies may not always be the same as those produced in humans. Therefore, it may be difficult to determine the most appropriate species in terms of predicting specific effects in humans. The fact that every species may not react in the same way is probably due to species-specific differences in maturation of the nervous system, differences in timing of exposure, metabolism, or mechanisms of action.

(4) It is also assumed that, in the absence of data to the contrary, the most sensitive species is used to estimate human risk. This is based on the assumption that humans are as sensitive as the most sensitive animal species tested. This provides a conservative estimate of sensitivity for added protection to the public. As with other noncancer endpoints, it is assumed that there is a nonlinear dose-response relationship for neurotoxicants. Although there may be a threshold for neurotoxic effects, these are often difficult to determine empirically. Therefore, a nonlinear relationship is assumed to exist for neurotoxicants.

These assumptions are ''plausibly conservative'' (NRC, 1994) in that they are protective of public health and are also well founded in scientific knowledge about the effects of concern.

2. Definitions and Critical Concepts

This section defines the key terms and concepts that EPA will use in the identification and evaluation of neurotoxicity. The various health effects that fall within the broad classification of neurotoxicity are described and examples are provided. Adverse effects include alterations from baseline or normal conditions that diminish an organism's ability to survive, reproduce, or adapt to the environment. Neurotoxicity is an adverse change in the structure or function of the central and/or peripheral nervous system following exposure to a chemical, physical, or biological agent (Tilson, 1990). Functional neurotoxic effects include adverse changes in somatic/autonomic, sensory, motor, and/or cognitive function. Structural neurotoxic effects are defined as neuroanatomical changes occurring at any level of nervous system organization; functional changes are defined as neurochemical, neurophysiological, or behavioral effects. Chemicals can also be categorized into four classes: Those that act on the central nervous system, the peripheral nerve fibers, the peripheral

nerve endings, or muscles or other tissues (Albert, 1973). Changes in function can result from toxicity to other specific organ systems, and these indirect changes may be considered adverse. For example, exposure to a high dose of a chemical may cause damage to the liver, resulting in general sickness and a decrease in a functional endpoint such as motor activity. In this case, the change in motor activity could be considered as adverse, but not necessarily neurotoxic. A discussion concerning problems associated with risk assessment of high doses of chemicals in the context of drinking water and health was published by the National Research Council (1986).

The risk assessor should also know that there are different levels of concern based on the magnitude of effect, duration of exposure, and reversibility of some neurotoxic effects. Neurotoxic effects may be irreversible (the organism cannot return to the state prior to exposure, resulting in a permanent change) or reversible (the organism can return to the pre-exposure condition). Clear or demonstrable irreversible change in either the structure or function of the nervous system causes greater concern than do reversible changes. If neurotoxic effects are observed at some time during the lifespan of the organism but are slowly reversible, the concern is also high. There is lesser concern for effects that are rapidly reversible or ''transient,'' i.e., measured in minutes, hours, or days, and that appear to be associated with the pharmacokinetics of the causal agent and its presence in the body. Reversible changes that occur in the occupational setting or environment, however, may be of high concern if, for example, exposure to a short-acting solvent interferes with operation of heavy equipment in an industrial plant. The context of the exposure should be considered in evaluating reversible effects. Setting of exposure limits is not always associated with the determination of a reference dose, which is based on chronic dosing. Data from acute or subacute dosing can be used for health advisories or in studies involving developmental exposures.

It should also be noted that the nervous system is known for its reserve capacity (Tilson and Mitchell, 1983). That is, repeated insult to the nervous system could lead to an adaptation. There are, however, limits to this capacity, and when these limits are exceeded, further exposure could lead to frank manifestations of neurotoxicity at the structural or functional level. The risk assessor should be aware that once damaged, neurons, particularly in the central nervous system, have a limited capacity for regeneration. Reversibility of effects resulting from cell death or from the destruction of cell processes may represent an activation of repair capacity, decreasing future potential adaptability. Therefore, even reversible neurotoxic changes should be of concern. Evidence of progressive effects (those that continue to worsen even after the causal agent has been removed), delayed-onset effects (those that occur at a time distant from the last contact with the causal agent), residual effects (those that persist beyond a recovery period), or latent effects (those that become evident only after an environmental challenge or aging) have a high level of concern.

Environmental challenges can include stress, increased physical or cognitive workload, pharmacological manipulations, and nutritional deficiency or excess. Evidence for reversibility may depend on the region of the nervous system affected, the chemical involved, and organismic factors such as the age of the exposed population. Some regions of the nervous system, such as peripheral nerves, have a high capacity for regeneration, while regions in the brain such as the hippocampus are known for their ability to compensate or adapt to neurotoxic insult. For example, compensation is likely to be seen with solvents (e.g., n-hexane) that produce peripheral neuropathy because of the repair capacity of the peripheral nerve. In addition, tolerance to some cholinergic effects of cholinesterase-inhibiting compounds may be due to compensatory down-regulation of muscarinic receptors. Younger individuals may have more capacity to adapt than older individuals, suggesting that the aged may be at greater risk to neurotoxic exposure.

Neurotoxic effects can be observed at various levels of organization of the nervous system, including neurochemical, anatomical, physiological, or behavioral. At the neurochemical level, for example, an agent that causes neurotoxicity might inhibit macromolecule or transmitter synthesis, alter the flow of ions across cellular membranes, or prevent release of neurotransmitter from the nerve terminals. Anatomical changes may include alterations of the cell body, the axon, or the myelin sheath. At the physiological level, a chemical might change the thresholds for neural activation or reduce the speed of neurotransmission. Behavioral alterations can include significant changes in sensations of sight, hearing, or touch; alterations in simple or complex reflexes and motor functions; alterations in cognitive functions such as learning, memory, or attention; and changes in mood, such as fear or rage, disorientation as to person, time, or place, or distortions of thinking and feeling, such as delusions and hallucinations. At present, relatively few neurotoxic syndromes have been thoroughly characterized in terms of the initial neurochemical change, structural alterations, physiological consequence, and behavioral effects. Knowledge of exact mechanisms of action is not, however, necessary to conclude that a chemically induced change is a neurotoxic effect.

Neurotoxic effects can be produced by chemicals that do not require metabolism prior to interacting with their sites in the nervous system (primary neurotoxic agents) or those that require metabolism prior to interacting with their sites (secondary neurotoxic agents). Chemically induced neurotoxic effects can be direct (due to an agent or its metabolites acting directly on sites in the nervous system) or indirect (due to agents or metabolites that produce their effects primarily by interacting with sites outside the nervous system). For example, excitatory amino acids such as domoic acid damage specific neurons directly by activating excitatory amino acid receptors in the nervous system, whereas carbon monoxide decreases oxygen availability, which can indirectly kill neurons. Other examples of indirect effects include cadmium-induced spasms in blood vessels supplying the nervous system, dichloroacetate-induced perturbation of metabolic pathways, and chemically induced alterations in skeletomuscular function or structure and effects on the endocrine system. Professional judgment may be required in making determinations about direct versus indirect effects.

The interpretation of data as indicative of a potential neurotoxic effect involves the evaluation of the validity of the database. This approach and these terms have been adapted from the literature on human psychological testing (Sette, 1987; Sette and MacPhail, 1992), where they have long been used to evaluate the level of confidence in different measures of intelligence or other abilities, aptitudes, or feelings. There are four principal questions that should be addressed: whether the effects result from exposure (content validity); whether the effects are adverse or toxicologically significant (construct validity); whether there are correlative measures among behavioral, physiological, neurochemical, and

morphological endpoints (concurrent validity); and whether the effects are predictive of what will happen under various conditions (predictive validity). Addressing these issues can provide a useful framework for evaluating either human or animal studies or the weight of evidence for a chemical (Sette, 1987; Sette and MacPhail, 1992). The next sections indicate the extent to which chemically induced changes can be interpreted as providing evidence of neurotoxicity.

3. Hazard Characterization

3.1. Neurotoxicological Studies: Endpoints and Their Interpretation

The qualitative characterization of neurotoxic hazard can be based on either human or animal data (Anger, 1984; Reiter, 1987; U.S. EPA, 1994). Such data can result from accidental, inappropriate, or controlled experimental exposures. This section describes many of the general and some of the specific characteristics of human studies and reports of neurotoxicity. It then describes some features of animal studies of neuroanatomical, neurochemical, neurophysiological, and behavioral effects relevant to risk assessment. The process of characterizing the sufficiency or insufficiency of neurotoxic effects for risk assessment is described in section 3.3. Additional sources of information relevant to hazard characterization, such as comparisons of molecular structure among compounds and in vitro screening methods, are also discussed.

The hazard characterization should:

a. Identify strengths and limitations of the database:

- Epidemiological studies (case reports, cross-sectional, case-control, cohort, or human laboratory exposure studies);
- Animal studies (including structural or neuropathological, neurochemical, neurophysiological, behavioral or neurological, or developmental endpoints).

b. Evaluate the validity of the database:

- Content validity (effects result from exposure);
- Construct validity (effects are adverse or toxicologically significant);
- Concurrent validity (correlative measures among behavioral, physiological, neurochemical, or morphological endpoints);
- Predictive validity (effects are predictive of what will happen under various conditions).

c. Identify and describe key toxicological studies.

d. Describe the type of effects:

- Structural (neuroanatomical alternations);
- Functional (neurochemical, neurophysiological, behavioral alterations).

e. Describe the nature of the effects (irreversible, reversible, transient, progressive, delayed, residual, or latent).

f. Describe how much is known about how (through what biological mechanism) the chemical produces adverse effects.

g. Discuss other health endpoints of concern.

h. Comment on any nonpositive data in humans or animals.

I. Discuss the dose-response data (epidemiological or animal) available for further dose-response analysis.

j. Discuss the route, level, timing, and duration of exposure in studies demonstrating neurotoxicity as compared to expected human exposures.

k. Summarize the hazard characterization:

- Confidence in conclusions;
- Alternative conclusions also supported by the data;
- Significant data gaps; and
- Highlights of major assumptions.

3.1.1. Human Studies

It is well established that information from the evaluation of human exposure can identify neurotoxic hazards (Anger and Johnson, 1985; Anger, 1990). Prominent among historical episodes of neurotoxicity in human populations are the outbreaks of methylmercury poisoning in Japan and Iraq and the neurotoxicity seen in miners of metals, including mercury, manganese, and lead (Carson et al., 1987; Silbergeld and Percival, 1987; OTA, 1990). In the past decade, lead poisoning in children has been a prominent issue of concern (Silbergeld and Percival, 1987). Neurotoxicity in humans has been studied and reviewed for many pesticides (Hayes, 1982; NRDC, 1989; Ecobichon and Joy, 1982; Ecobichon et al., 1990). Organochlorines, organophosphates, carbamates, pyrethroids, certain fungicides, and some fumigants are all known neurotoxicants. They may pose occupational risks to manufacturing and formulation workers, pesticide applicators and farm workers, and consumers through home application or consumption of residues in foods. Families of workers may also be exposed by transport into the home from workers' clothing. Data on humans can come from a number of sources, including clinical evaluations, case reports, epidemiologic studies, and human laboratory exposure studies. A more extensive description of issues concerning human neurotoxicology and risk assessment has been published elsewhere (U.S. EPA, 1993). A review of the types of tests used to assess cognitive and neurological function in children, in addition to a discussion of methodological issues in the design of prospective, longitudinal studies of developmental neurotoxicity in humans, has recently been published (Jacobson and Jacobson, 1996). Stanton and Spear (1990) reviewed assessment measures used in developmental neurotoxicology for their comparability in humans and laboratory animals and their ability to detect comparable adverse effects across species. At the level of the various functional assessments for sensory, motivational, cognitive and motor function, and social behavior, there was good agreement across species among the neurotoxic agents reviewed.

3.1.1.1. Clinical Evaluations

Clinical methods are used extensively in neurology and neuropsychology to evaluate patients suspected of having neurotoxicity. An array of examiner-administered and paper-and-pencil tasks are used to assess sensory, motor, cognitive, and affective functions and personality states/traits. Neurobehavioral data are synthesized with information from neurophysiological studies and medical history to derive a working diagnosis. Brain functional imaging techniques based on magnetic resonance imaging or emission tomography may also be useful in helping diagnose neurodegenerative disorders following chemical exposures in humans (Omerand et al., 1994; Callender et al., 1994). Clinical diagnostic approaches have provided a rich conceptual framework for understanding the functions (and malfunctions) of the central and peripheral nervous systems and have formed the basis for the development of methods for measuring the behavioral expression of nervous system disorders. Human neurobehavioral toxicology has borrowed heavily from neurology and neuropsychology for concepts of nervous system impairment and functional assessment methods. Neurobehavioral toxicology has adopted the neurologic/neuropsychologic model, using adverse changes in behavioral function to assist in identifying chemical-or drug-induced changes in nervous system processes.

Neurological and neuropsychological methods have long been employed to identify the adverse health effects of environmental workplace exposures (Sterman and Schaumburg, 1980).

Peripheral neuropathies (with sensory and motor disturbances), encephalopathies, organic brain syndromes, extrapyramidal syndromes, demyelination, autonomic changes, and dementia are well-characterized consequences of acute and chronic exposure to chemical agents. The range of exposure conditions that produce clinical signs of neurotoxicity also has been defined by these clinical methods. It is very important to make external/internal dose measurements in humans to determine the actual dose(s) that can cause unwanted effects.

Aspects of the neurological examination approach limit its usefulness for neurotoxicological risk assessment. Information obtained from the neurological exam is mostly qualitative and descriptive rather than quantitative. Estimates of the severity of functional impairment can be reliably placed into only three or four categories (for example, mild, moderate, severe). Much of the assessment depends on the subjective judgment of the examiner. For example, the magnitude and symmetry of muscle strength are often judged by having the patient push against the resistance of the examiner's hands. The endpoints are therefore the absolute and relative amount of muscle load sensed by the examiner in his or her arms.

Compared with other methods, the neurological exam may be less sensitive in detecting early neurotoxicity in peripheral sensory and motor nerves. While clinicians' judgments are equal in sensitivity to quantitative methods in assessing the amplitude of tremor, tremor frequency is poorly quantified by clinicians. Thus, important aspects of the clinical neurologic exam may be insufficiently quantified and lack sufficient sensitivity for detecting early neurobehavioral toxicity produced by environmental or workplace exposure conditions. However, a neurological evaluation of persons with documented neurobehavioral impairment would be helpful for identifying nonchemical causes of neurotoxicity, such as diabetes and cardiovascular insufficiency.

Administration of a neuropsychological battery also requires a trained technician, and interpretation requires a trained and experienced neuropsychologist. Depending on the capabilities of the patient, 2 to 4 hours may be needed to administer a full battery; 1 hour may be needed for the shorter screening versions. These practical considerations may limit the usefulness of neuropsychological assessment in large field studies of suspected neurotoxicity.

In addition to logistical problems in administration and interpretation, neuropsychological batteries and neurological exams share two disadvantages with respect to neurotoxicity risk assessment. First, neurological exams and neuropsychological test batteries are designed to confirm and classify functional problems in individuals selected on the basis of signs and symptoms identified by the patient, family, or other health professionals. Their usefulness in detecting low base-rate impairment in workers or the general population is generally thought to be limited, decreasing the usefulness of clinical assessment approaches for epidemiologic risk assessment.

Second, neurological exams and neuropsychological test batteries were developed to assess the functional correlates of the most common forms of nervous system dysfunction: brain trauma, focal lesions, and degenerative conditions. The clinical tests were validated against these neurological disease states. With a few notable exceptions, chemicals are not believed to produce impairment similar to that from trauma or lesions; neurotoxic effects are more similar to the effects of degenerative disease. There has been insufficient research to demonstrate which tests designed to assess functional expression of neurologic disease are useful in characterizing the modes of central nervous system impairment produced by chemical agents and drugs.

It should be noted that alternative approaches are available that avoid many of the limitations of clinical and neurological and traditional neuropsychological methods. Computerized behavioral assessment systems designed for field testing of populations exposed to chemicals in the community or workplace have been developed during the past decade. The most widely used system is the Neurobehavioral Evaluation System (NES) developed by Baker et al. (1985). Advantages of computerized tests include (1) standardized administration to eliminate intertester variability and minimize subject-experimenter interaction; (2) automated data collection and scoring, which is faster, easier, and less error-prone than traditional methods; and (3) test administration requires minimal training and experience. NES tests have proven sensitive to a variety of solvents, metals, and pesticides (Otto, 1992). Computerized systems available for human neurotoxicity testing are critically reviewed in Anger et al. (1996).

3.1.1.2. Case Reports

The first type of human data available is often the case report or case series, which can identify cases of a disease and are reported by clinicians or discerned through active or passive surveillance, usually in the workplace. However, case reports involving a single neurotoxic agent, although informative, are rare in the literature; for example, farmers are likely to be exposed to a wide variety of potentially neurotoxic pesticides. Careful case histories assist in identifying common risk factors, especially when the association between the exposure and disease is strong, the mode of action of the agent is biologically plausible, and clusters occur in a limited period of time.

Case reports can be obtained more quickly than more complex studies. Case reports of acute high-level exposure to a toxicant can be useful for identifying signs and symptoms that may also apply to lower exposure. Case reports can also be useful when corroborating epidemiological data are available.

3.1.1.3. Epidemiologic Studies

Epidemiology has been defined as ''the study of the distributions and determinants of disease and injuries in human populations'' (Mausner and Kramer, 1985). Knowing the frequency of illness in groups and the factors that influence the distribution is the tool of epidemiology that allows the evaluation of causal inference with the goal of prevention and cure of disease (Friedlander and Hearn, 1980). Epidemiologic studies are a useful means of evaluating the effects of neurotoxic substances on human populations, particularly if effects of exposure are cumulative or exposures are repeated. Such studies are less useful in cases of acute exposure, where the effects are short-term. Frequently, determining the precise dose or exposure concentration in epidemiological studies can be difficult.

3.1.1.3.1. Cross-Sectional Studies.

In cross-sectional studies or surveys, both the disease and suspected risk factors are ascertained at the same time, and the findings are useful in generating hypotheses. A group of people are interviewed, examined, and tested at a single point in time to ascertain a relationship between a disease and a neurotoxic exposure. This study design does not allow the investigator to determine whether the disease or the exposure came first, rendering it less useful in estimating risk. These studies are intermediate in cost and time

required to complete compared with case reports and more complex analytical studies, but should be augmented with additional data.

3.1.1.3.2. Case-Control (Retrospective) Studies.

Last (1986) defines a case-control study as one that ''starts with the identification of persons with the disease (or other outcome variable) of interest, and a suitable control population (comparison, reference group) of persons without the disease.'' He states that the relationship of an ''attribute'' to the disease is measured by comparing the diseased with the nondiseased with regard to how frequently the attribute is present in each of the groups. The cases are assembled from a population of persons with and without exposure, and the comparison group is selected from the same population; the relative distribution of the potential risk factor (exposure) in both groups is evaluated by computing an odds ratio that serves as an estimate of the strength of the association between the disease and the potential risk factor. The statistical significance of the ratio is determined by calculating a p-value and is used to approximate relative risk.

The case-control approach to the study of potential neurotoxicants in the environment provides a great deal of useful information for the risk assessor. In his textbook, Valciukas (1991) notes that the case-control approach is the strategy of choice when no other environmental or biological indicator of neurotoxic exposure is available. He further states: ''Considering the fact that for the vast majority of neurotoxic chemical compounds, no objective biological indicators of exposure are available (or if they are, their half-life is too short to be of any practical value), the case-control paradigm is a widely accepted strategy for the assessment of toxic causation.'' The case-control study design, however, can be very susceptible to bias. The potential sources of bias are numerous and can be specific to a particular study. Many of these biases also can be present in cross-sectional studies. For example, recall bias or faulty recall of information by study subjects in a questionnaire-based study can distort the results. Analysis of the case-comparison study design assumes that the selected cases are representative persons with the disease—either all cases with the disease or a representative sample of them have been ascertained. It further assumes that the control or comparison group is representative of the nonexposed population (or that the prevalence of the characteristic under study is the same in the control group as in the general population). Failure to satisfy these assumptions may result in selection bias that may invalidate study results.

An additional source of bias in case-control studies is the presence of confounding variables, i.e., factors known to be associated with the exposure and causally related to the disease under study. These should be controlled, either in the design of the study by matching cases to controls on the basis of the confounding factor, or in the analysis of the data by using statistical techniques such as stratification or regression. Matching requires time to identify an adequate number of potential controls to distinguish those with the proper characteristics, while statistical control of confounding factors requires a larger study.

The definition of exposure is critical in epidemiologic studies. In occupational settings, exposure assessment often is based on the job assignment of the study subjects, but can be more precise if detailed company records allow the development of exposure profiles. Positive results from a properly controlled retrospective study should weigh heavily in the risk assessment process.

3.1.1.3.3. Cohort (Prospective, Follow-Up) Studies.

In a prospective study design, a healthy group of people is assembled and followed forward in time and observed for the development of dysfunction. Such studies are invaluable for determining the time course for development of dysfunction (e.g., follow-up studies performed in various cities on the effects of lead on child development). This approach allows the direct estimate of risks attributed to a particular exposure, since toxic incidence rates in the cohort can be determined. Prospective study designs also allow the study of chronic effects of exposure. One major strength of the cohort design is that it allows the calculation of rates to determine the excess risk associated with an exposure. Also, biases are reduced by obtaining information before the disease develops. This approach, however, can be very time-consuming and costly.

In cohort studies information bias can be introduced when individuals provide distorted information about their health because they know their exposure status and may have been told of the expected health effects of the exposure under study. More credence should be given to those studies in which both observer and subject bias are carefully controlled (e.g., double-blind studies).

A special type of cohort study is the retrospective cohort study, in which the investigator goes back in time to select the study groups and traces them over time, often to the present. The studies usually involve specially exposed groups and have provided much assistance in estimating risks due to occupational exposures. Occupational retrospective cohort studies rely on company records of past and current employees that include information on the dates of employment, age at employment, date of departure, and whether diseased (or dead in the case of mortality studies). Workers can then be classified by duration and degree of exposure. Positive or negative results from a properly controlled prospective study should weigh heavily in the risk assessment process.

3.1.1.4. Human Laboratory Exposure Studies

Neurotoxicity assessment has an advantage not afforded to the evaluation of other toxic endpoints, such as cancer or reproductive toxicity, in that the effects of some chemicals are short in duration and reversible. This makes it ethically possible to perform human laboratory exposure studies and obtain data relevant to the risk assessment process. Information from experimental human exposure studies has been used to set occupational exposure limits, mostly for organic solvents that can be inhaled. Laboratory exposure studies have contributed to risk assessment and the setting of exposure limits for several solvents and other chemicals with acute reversible effects.

Human exposure studies sometimes offer advantages over epidemiologic field studies. Combined with appropriate sampling of biological fluids (urine or blood), it is possible to calculate body concentrations, examine toxicokinetics, and identify metabolites. Bioavailability, elimination, dose-related changes in metabolic pathways, individual variability, time course of effects, interactions between chemicals, and interactions between chemical and environmental/biobehavioral processes (stressors, workload/respiratory rate) are factors that are generally easier to collect under controlled conditions.

Other goals of laboratory studies include the in-depth characterization of effects, the development of new assessment methods, and the examination of the sensitivity, specificity, and reliability of neurobehavioral assessment methods across chemical classes. The laboratory is the most appropriate setting for the

study of environmental and biobehavioral variables that affect the action of chemical agents. The effects of ambient temperature, task difficulty, rate of ongoing behavior, conditioning variables, tolerance/sensitization, sleep deprivation, motivation, and so forth are sometimes studied.

From a methodological standpoint, human laboratory studies can be divided into two categories: between-subjects and within-subjects designs. In the former, the neurobehavioral performance of exposed volunteers is compared with that of nonexposed participants. In the latter, preexposure performance is compared with neurobehavioral function under the influence of the chemical or drug. Within-subjects designs have the advantage of requiring fewer participants, eliminating individual differences as a source of variability, and controlling for chronic mediating variables, such as caffeine use and educational achievement. A disadvantage of the within-subjects design is that neurobehavioral tests must be administered more than once. Practice on many neurobehavioral tests often leads to improved performance that may confound the effect of the chemical/drug. There should be a sufficient number of test sessions in the pre-exposure phase to allow performance on all tests to achieve a relatively stable baseline level.

Participants in laboratory exposure studies may have been recruited from populations of persons already exposed to the chemical/drug or from chemical-naive populations. Although the use of exposed volunteers has ethical advantages, can mitigate against novelty effects, and allows evaluation of tolerance/sensitization, finding an accessible exposed population in reasonable proximity to the laboratory can be difficult. Chemical-naive participants are more easily recruited but may differ significantly in important characteristics from a representative sample of exposed persons. Chemical-naive volunteers are often younger, healthier, and better educated than the populations exposed environmentally, in the workplace, or pharmacotherapeutically.

Compared with workplace and environmental exposures, laboratory exposure conditions can be controlled more precisely, but exposure periods are much shorter. Generally only one or two relatively pure chemicals are studied for several hours, whereas the population of interest may be exposed to multiple chemicals containing impurities for months or years. Laboratory studies are therefore better at identifying and characterizing effects with acute onset and the selective effects of pure agents. In all cases, the potential for participant bias should be as carefully controlled for as possible. Even the consent form can lead to participant bias, as toxic effects have been reported in some individuals who were warned of such effects in an informed consent form. In addition, double-blind studies have been shown to provide some control for observer bias that may occur in single-blind studies. More credence should be given to those studies in which both observer and subject bias are carefully controlled (Benignus, 1993).

A test battery that examines multiple neurobehavioral functions may be more useful for screening and the initial characterization of acute effects. Selected neurobehavioral tests that measure a limited number of functions in multiple ways may be more useful for elucidating mechanisms or validating specific effects.

Both chemical and behavioral control procedures are valuable for examining the specificity of the effects. A concordant effect among different measures of the same neurobehavioral function (e.g., reaction time) and a lack of effect on some other measures of psychomotor function (e.g., untimed manual dexterity) would increase the confidence in a selective effect on motor speed and not on attention or another nonspecific motor function. Likewise, finding concordant effects among similar chemical or drug classes along with different effects from dissimilar classes would support the specificity of chemical effect. For example, finding that the effects of a solvent were similar to those of ethanol but not caffeine would support the specificity of solvent effects on a given measure of neurotoxicity.

3.1.2. Animal Studies

This section provides an overview of the major types of endpoints that may be evaluated in animal neurotoxicity studies, describes the kinds of effects that may be observed and some of the tests used to detect and quantify these effects, and provides guidance for interpreting data. Compared with human studies, animal studies are more often available for specific chemicals, provide more precise exposure information, and control environmental factors better (Anger, 1984). For these reasons, risk assessments tend to rely heavily on animal studies.

Many tests that can measure some aspect of neurotoxicity have been used in the field of neurobiology in the past 50 years. The Office of Prevention, Pesticides and Toxic Substances (OPPTS) has published animal testing guidelines that were developed in cooperation with the Office of Research and Development (U.S. EPA, 1991a). While the test endpoints included in the 1991 document serve as a convenient focus for this section, there are many other endpoints for which there are no current EPA guidelines. The goal of the current document is to provide a framework for interpreting data collected in tests frequently used by neurotoxicologists.

Five categories of endpoints will be described: structural or neuropathological, neurophysiological, neurochemical, behavioral, and developmental. Table 1 lists a number of endpoints in each of these categories. It is imperative for the risk assessor to understand that the interpretation of the indicators listed in Table 1 as neurotoxic effects is dependent on the dose at which such changes occur and the possibility that damage to other organ systems may contribute to or cause such changes indirectly.

TABLE 1.—EXAMPLES OF POSSIBLE INDICATORS OF A NEUROTOXIC EFFECT

Structural or neuropathological endpoints:
Gross changes in morphology, including brain weight.
Histologic changes in neurons or glia (neuronopathy, axonopathy, myelinopathy).
Neurochemical endpoints:
Alterations in synthesis, release, uptake, degradation of neurotransmitters.
Alterations in second-messenger-associated signal transduction.
Alterations in membrane-bound enzymes regulating neuronal activity.
Inhibition and aging of neuropathy enzyme.
Increases in glial fibrillary acidic protein in adults.
Neurophysiological endpoints:
Change in velocity, amplitude, or refractory period of nerve conduction.

TABLE 1.—EXAMPLES OF POSSIBLE INDICATORS OF A NEUROTOXIC EFFECT—Continued

Change in latency or amplitude of sensory-evoked potential.
Change in electroencephalographic pattern.
Behavioral and neurological endpoints:
Increases or decreases in motor activity.
Changes in touch, sight, sound, taste, or smell sensations.
Changes in motor coordination, weakness, paralysis, abnormal movement or posture, tremor, ongoing performance.
Absence or decreased occurrence, magnitude, or latency of sensorimotor reflex.
Altered magnitude of neurological measurement, including grip strength, hindlimb splay.
Seizures.
Changes in rate or temporal patterning of schedule-controlled behavior.
Changes in learning, memory, and attention.
Developmental endpoints:
Chemically induced changes in the time of appearance of behaviors during development.
Chemically induced changes in the growth or organization of structural or neurochemical elements.

3.1.2.1. Structural Endpoints of Neurotoxicity

Structural endpoints are typically defined as neuropathological changes evident by gross observation or light microscopy, although most neurotoxic changes will be detectable only at the light microscopic level. Gross changes in morphology can include discrete or widespread lesions in nerve tissue. A change in brain weight is considered to be a biologically significant effect. This is true regardless of changes in body weight, because brain weight is generally protected during undernutrition or weight loss, unlike many other organs or tissues. It is inappropriate to express brain weight changes as a ratio of body weight and thereby dismiss changes in absolute brain weight. Changes in brain weight are a more reliable indicator of alteration in brain structure than are measurements of length or width in fresh brain, because there is little historical data in the toxicology literature.

Neurons are composed of a neuronal body, axon, and dendritic processes. Various types of neuropathological lesions may be classified according to the site where they occur (Spencer and Schaumburg, 1980; WHO, 1986; Krinke, 1989; Griffin, 1990). Neurotoxicant-induced lesions in the central or peripheral nervous system may be classified as a neuronopathy (changes in the neuronal cell body), axonopathy (changes in the axons), myelinopathy (changes in the myelin sheaths), or nerve terminal degeneration. Nerve terminal degeneration represents a very subtle change that may not be detected by routine histopathology, but requires detection by special procedures such as silver staining or neurotransmitter-specific immunohistochemistry. For axonopathies, a more precise location of the changes may also be described (i.e., proximal, central, or distal axonopathy). In the case of some developmental exposures, a neurotoxic chemical might delay or accelerate the differentiation or proliferation of cells or cell types. Alteration in the axonal termination site might also occur with exposure. In an aged population, exposure to some neurotoxicants might accelerate the normal loss of neurons associated with aging (Reuhl, 1991). In rare cases, neurotoxic agents have been reported to produce neuropathic conditions resembling neurodegenerative disorders, such as Parkinson's disease, in humans (WHO, 1986). Table 2 lists examples of such neurotoxic chemicals, their putative site of action, the type of neuropathology produced, and the disorder or condition that each typifies. Inclusion of any chemical in any of the following tables is for illustrative purposes, i.e., it has been reported that the chemical will produce a neurotoxic effect at some dose; any individual chemical listed may also adversely affect other organs at lower doses. It is important that the severity of each structural union be graded objectively and the grading criteria reported.

TABLE 2.—NEUROTOXICANTS AND DISORDERS WITH SPECIFIC NEUROLOGICAL TARGETS

Site of action	Neurotoxic change	Neurotoxic chemical	Corresponding neurodegenerative disorder
Neuron cell body	Neuronopathy	Methylmercury	Minamata disease.
		Quinolinic acid	Huntington's disease.
		3-Acetylpyridine	Cerebellar ataxia.
Nerve terminal	Terminal destruction	1-Methyl-4-phenyl 1,2, 3,6-tetrahydro- pyridine (MPTP) (dopaminergic)	Parkinson's disease.
Schwann cell myelin	Myelinopathy	Hexachlorophene	Congenital hypomyelinogenesis.
Centra-peripheral distal axon	Distal axonopathy	Acrylamide, carbon disulfide, n-hexane.	Peripheral neuropathy.
Central axons	Central axonopathy	Clioquinol	Subacute myeloopticoneuro-pathy.
Proximal axon	Proximal axonopathy	B,B′-Iminodipropionitrile	Motor neuron disease.

Alterations in the structure of the nervous system (i.e., neuronopathy, axonopathy, myelinopathy, terminal degeneration) are regarded as evidence of a neurotoxic effect. The risk assessor should note that pathological changes in many cases require time for the perturbation to become observable, especially with evaluation at the light microscopic level. Neuropathological studies should control for potential differences in the area(s) and section(s) of the nervous system sampled; in the age, sex, and body weight of the subject; and in fixation artifacts (WHO, 1986). Concern for the structural integrity of nervous system tissues derives from

their functional specialization and lack of regenerative capacity.

Within general class of nervous system structural alteration, there are various histological changes that can result after exposure to neurotoxicants. For example, specific changes in nerve cell bodies include chromatolysis, vacuolization, and cell death. Axons can undergo swelling, degeneration, and atrophy, while myelin sheath changes include folding, edematous splitting, and demyelination. Although terminal degeneration does occur, it is not readily detectable by light microscopy. Many of these changes are a result of complex effects at specific subcellular organelles, such as the axonal swelling that occurs as a result of neurofilament accumulation in acrylamide toxicity. Other changes may be associated with regenerative or adaptive processes that occur after neurotoxicant exposure.

3.1.2.2. Neurophysiological Endpoints of Neurotoxicity

Neurophysiological studies measure the electrical activity of the nervous system. The term ''neurophysiology'' is often used synonymously with ''electrophysiology'' (Dyer, 1987). Neurophysiological techniques provide information on the integrity of defined portions of the nervous system. Several neurophysiological procedures are available for application to neurotoxicological studies. Examples are listed in Table 3. They range in scale from procedures that employ microelectrodes to study the function of single nerve cells or restricted portions of them, to procedures that employ macroelectrodes to perform simultaneous recordings of the summed activity of many cells. Microelectrode procedures typically are used to study mechanisms of action and are frequently performed in vitro. Macroelectrode procedures are generally used in studies to detect or characterize the potential neurotoxic effects of agents of interest because of potential environmental exposure. The present discussion concentrates on macroelectrode neurophysiological procedures because it is more likely that they will be the focus of decisions regarding critical effects in risk assessment. All of the procedures described below for use in animals also have been used in humans to determine chemically induced alterations in neurophysiological function.

TABLE 3.—EXAMPLES OF NEUROPHYSIOLOGICAL MEASURES OF NEUROTOXICITY

System/function	Procedure	Representative agents
Retina	Electroretinography (ERG)	Developmental lead.
Visual pathway	Flash-evoked potential (FEP)	Carbon disulfide.
Visual function	Pattern-evoked potential (PEP) (pattern size and contrast).	Carbon disulfide.
Auditory pathway	Brain stem auditory evoked potential (BAER) (clicks).	Aminoglycoside, antibiotics, toluene, styrene.
Auditory function	BAER (tones)	Aminoglycoside, antibiotics, toluene, styrene.
Somatosensory pathway	Somatosensory provoked	Acrylamide, n-hexane.
Somatosensory function	Sensory-evoked potential (SEP) (tactile)	Acrylamide, n-hexane.
Spinocerebellar pathway	SEP recorded from cerebellum	Acrylamide, n-hexane.
Mixed nerve	Peripheral nerve compound action potential (PNAP).	Triethyltin.
Motor axons	PNAP isolate motor components	Triethyltin.
Sensory axons	PNAP isolate sensory components	Triethyltin.
Neuromuscular	Electromyography (EMG)	Dithiobiuret.
General central nervous system/level of arousal.	Electroencephalography (EEG)	Toluene.

3.1.2.2.1. Nerve Conduction Studies. Nerve conduction studies, generally performed on peripheral nerves, can be useful in investigations of possible peripheral neuropathy. Most peripheral nerves contain mixtures of individual sensory and motor nerve fibers, which may or may not be differentially sensitive to neurotoxicants. It is possible to distinguish sensory from motor effects in peripheral nerve studies by measuring activity in sensory nerves or by measuring the muscle response evoked by nerve stimulation to measure motor effects. While a number of endpoints can be recorded, the most critical variables are nerve conduction velocity, response amplitude, and refractory period. It is important to recognize that damage to nerve fibers may not be reflected in changes in these endpoints if the damage is not sufficiently extensive. Thus, the interpretation of data from such studies may be enhanced if evaluations such as nerve pathology and/or other structural measures are also included.

Nerve conduction measurements are influenced by a number of factors, the most important of which is temperature. An adequate nerve conduction study will either measure the temperature of the limb under study and mathematically adjust the results according to well-established temperature factors or will control limb temperature within narrow limits. Studies that measure peripheral nerve function without regard for temperature are not adequate for risk assessment.

In well-controlled studies, statistically significant decreases in nerve conduction velocity are indicative of a neurotoxic effect. While a decrease in nerve conduction velocity is indicative of demyelination, it frequently occurs later in the course of axonal degradation because normal conduction velocity may be maintained for some time in the face of axonal degeneration. For this reason, a measurement of normal nerve conduction velocity does not rule out peripheral axonal degeneration if other signs of peripheral nerve dysfunction are present.

Decreases in response amplitude reflect a loss of active nerve fibers and may occur prior to decreases in conduction velocity in the course of peripheral neuropathy. Hence, changes in response amplitude may be more sensitive measurements of axonal degeneration than is conduction velocity. Measurements of response amplitude, however, can be more variable and require careful application of experimental techniques, a larger sample size, and greater statistical power than measurements of velocity to detect changes. The refractory period refers to the time required after stimulation before a nerve can fire again and reflects the functional status of nerve membrane ion channels. Chemically induced changes in

refractory periods in a well-controlled study indicate a neurotoxic effect.

In summary, alterations in peripheral nerve response amplitude and refractory period in studies that are well controlled for temperature are indicative of a neurotoxic effect. Alterations in peripheral nerve function are frequently associated with clinical signs such as numbness, tingling, or burning sensations or with motor impairments such as weakness. Examples of compounds that alter peripheral nerve function in humans or experimental animals include acrylamide, carbon disulfide, n-hexane, lead, and some organophosphates.

3.1.2.2.2. Sensory, Motor, and Other Evoked Potentials. Evoked potential studies are electrophysiological procedures that measure the response elicited from a defined stimulus such as a tone, a light, or a brief electrical pulse. Evoked potentials reflect the function of the system under study, including visual, auditory, or somatosensory; motor, involving motor nerves and innervated muscles; or other neural pathways in the central or peripheral nervous system (Rebert, 1983; Dyer, 1985; Mattsson and Albee, 1988; Mattsson et al., 1992; Boyes, 1992, 1993). Evoked potential studies should be interpreted with respect to the known or presumed neural generators of the responses, and their likely relationships with behavioral outcomes, when such information is available. Such correlative information strengthens the confidence in electrophysiological outcomes. In the absence of such supportive information, the extent to which evoked potential studies provide convincing evidence of neurotoxicity is a matter of professional judgment on a case-by-case basis. Judgments should consider the nature, magnitude, and duration of such effects, along with other factors discussed elsewhere in this document.

Data are in the form of a voltage record collected over time and can be quantified in several ways. Commonly, the latency (time from stimulus onset) and amplitude (voltage) of the positive and negative voltage peaks are identified and measured. Alternative measurement schemes may involve substitution of spectral phase or template shifts for peak latency and spectral power, spectral amplitude, root-mean-square, or integrated area under the curve for peak amplitude. Latency measurements are dependent on both the velocity of nerve conduction and the time of synaptic transmission. Both of these factors depend on temperature, as discussed in regard to nerve conduction, and similar caveats apply for sensory evoked potential studies. In studies that are well controlled for temperature, increases in latencies or related measures can reflect deficits in nerve conduction, including demyelination or delayed synaptic transmission, and are indicators of a neurotoxic effect.

Decreases in peak latencies, like increases in nerve conduction velocity, are unusual, but the neural systems under study in sensory evoked potentials are complex, and situations that might cause a peak measurement to occur earlier are conceivable. Two such situations are a reduced threshold for spatial or temporal summation of afferent neural transmission and a selective loss of cells responding late in the peak, thus making the measured peak occur earlier. Decreases in peak latency should not be dismissed outright as experimental or statistical error, but should be examined carefully and perhaps replicated to assess possible neurotoxicity. A decrease in latency is not conclusive evidence of a neurotoxic effect.

Changes in peak amplitudes or equivalent measures reflect changes in the magnitude of the neural population responsive to stimulation. Both increases and decreases in amplitude are possible following exposure to chemicals. Whether excitatory or inhibitory neural activity is translated into a positive or negative deflection in the sensory evoked potential is dependent on the physical orientation of the electrode with respect to the tissue generating the response, which is frequently unknown. Comparisons should be based on the absolute change in amplitude. Therefore, either increases or decreases in amplitude may be indicative of a neurotoxic effect.

Within any given sensory system, the neural circuits that generate various evoked potential peaks differ as a function of peak latency. In general, early latency peaks reflect the transmission of afferent sensory information. Changes in either the latency or amplitude of these peaks are considered convincing evidence of a neurotoxic effect that is likely to be reflected in deficits in sensory perception. The later-latency peaks, in general, reflect not only the sensory input but also the more nonspecific factors such as the behavioral state of the subject, including such factors as arousal level, habituation, or sensitization (Dyer, 1987). Thus, changes in later-latency evoked potential peaks should be interpreted in light of the behavioral status of the subject and would generally be considered evidence of a neurotoxic effect.

3.1.2.2.3. Seizures/Convulsions. Some neurotoxicants (e.g., lindane, pyrethroids, trimethyltin, dichlorodiphenyltrichloroethane [DDT]) produce observable convulsions. When convulsionlike behaviors are observed, as described in the behavioral section on convulsions, neurophysiological recordings can provide additional information to help interpret the results. Recordings of brain electrical activity that demonstrate seizurelike activity are indicative of a neurotoxic effect.

In addition to producing seizures directly, chemicals may also alter the frequency, severity, duration, or threshold for eliciting seizures through other means by a phenomenon known as ''kindling.'' Such alterations can occur after acute exposure or after repeated exposure to dose levels below the acute threshold. In experiments demonstrating changes in sensitivity following repeated exposures to the test compound, information regarding possible changes in the pharmacokinetic distribution of the compound is required before the seizure susceptibility changes can be interpreted as evidence of neurotoxicity. Increases in susceptibility to seizures are considered adverse.

3.1.2.2.4. Electroencephalography (EEG). EEG analysis is used widely in clinical settings for the diagnosis of neurological disorders, and less often for the detection of subtle toxicant-induced dysfunction (WHO, 1986; Eccles, 1988). The basis for using EEG in either setting is the relationship between specific patterns of EEG waveforms and specific behavioral states. Because states of alertness and stages of sleep are associated with distinct patterns of electrical activity in the brain, it is generally thought that arousal level can be evaluated by monitoring the EEG. Dissociation of EEG activity and behavior can, however, occur after exposure to certain chemicals. Normal patterns of transition between sleep stages or between sleeping and waking states are known to remain disturbed for prolonged periods of time after exposure to some chemicals. Changes in the pattern of the EEG can be elicited by anesthetic drugs and stimuli producing arousal (e.g., lights, sounds). In studies with toxicants, changes in EEG pattern can sometimes precede alterations in other objective signs of neurotoxicity (Dyer, 1987).

EEG studies should be done under highly controlled conditions, and the data should be considered on a case-by-case basis. Chemically induced seizure activity detected in the EEG pattern is evidence of a neurotoxic effect.

3.1.2.3. Neurochemical Endpoints of Neurotoxicity

Many different neurochemical endpoints have been measured in neurotoxicological studies, and some have proven useful in advancing the understanding of mechanisms of action of neurotoxic chemicals (Bondy, 1986; Mailman, 1987; Morell and Mailman, 1987; Costa, 1988; Silbergeld, 1993). Normal functioning of the nervous system depends on the synthesis and release of specific neurotransmitters and activation of their receptors at specific presynaptic and postsynaptic sites. Chemicals can interfere with the ionic balance of a neuron, act as a cytotoxicant after transport into a nerve terminal, block reuptake of neurotransmitters and their precursors, act as a metabolic poison, overstimulate receptors, block transmitter release, and inhibit transmitter synthetic or catabolic enzymes. Table 4 lists several chemicals that produce neurotoxic effects at the neurochemical level (Bondy, 1986; Mailman, 1987; Morell and Mailman, 1987; Costa, 1988).

TABLE 4.—EXAMPLES OF NEUROTOXICANTS WITH KNOWN NEUROCHEMICAL MECHANISMS

Site of action	Examples
Neurotoxicants acting on ionic balance:	
Inhibit sodium entry	Tetrodotoxin.
Block closing of sodium channel	p,p′-DDT, pyrethroids.
Increase permeability to sodium	Batrachotoxin.
Increase intracellular calcium	Chlorodecone.
Synaptic neurotoxicants	MPTP.
Uptake blockers	Hemicholinium.
Metabolic poisons	Cyanide.
Hyperactivation of receptors	Domoic acid.
Blocks transmitter release	Botulinum toxin.
Inhibition of transmitter degradation	Pesticides of the organophosphate and carbamate classes.
Blocks axonal transport	Acrylamide.

As stated previously, any neurochemical change is potentially neurotoxic. Persistent or irreversible chemically induced neurochemical changes are indicative of neurotoxicity. Because the ultimate functional significance of some biochemical changes is not known at this time, neurochemical studies should be interpreted with reference to the presumed neurotoxic consequence(s) of the neurochemical changes. For example, many neuroactive agents can increase or decrease neurotransmitter levels, but such changes are not indicative of a neurotoxic effect. If, however, these neurochemical changes may be expected to have neurophysiological, neuropathological, or neurobehavioral correlates, then the neurochemical changes could be classified as neurotoxic effects.

Some neurotoxicants, such as the organophosphate and carbamate pesticides, are known to inhibit the activity of a specific enzyme, acetylcholinesterase (for a review see Costa, 1988), which hydrolyzes the neurotransmitter acetylcholine. Inhibition of the enzyme in either the central or peripheral nervous system prolongs the action of the acetylcholine at the neuron's synaptic receptors and is thought to be responsible for the range of effects these chemicals produce, although it is possible that these compounds have other modes of action (Eldefrawi et al., 1992; Greenfield et al., 1984; Small, 1990).

There is agreement that objective clinical measures of cholinergic overstimulation (e.g., salivation, sweating, muscle weakness, tremor, blurred vision) can be used to evaluate dose-response and dose-effect relationships and define the presence and absence of effects. A given depression in peripheral and central cholinesterase activity may or may not be accompanied by clinical manifestations. A depression in RBC and/or plasma cholinesterase activity may or may not be accompanied by clinical manifestations. It should be noted, however, that reduction in cholinesterase activity, even if the anticholinesterase exposure is not severe enough to precipitate clinical signs or symptoms, may impair the organism's ability to adapt to additional exposures to anticholinesterase compounds. Inhibition of RBC and/or plasma cholinesterase activity is a biomarker of exposure, as well as a reflection of cholinesterase inhibition in other peripheral tissues (e.g., neuromuscular junction, peripheral nerve, or ganglia) (Maxwell et al., 1987; Nagymajtenyi et al., 1988; Padilla et al., 1994), thereby contributing to the overall hazard identification of cholinesterase-inhibiting compounds.

The risk assessor should also be aware that tolerance to the cholinergic overstimulation may be observed following repeated exposure to cholinesterase-inhibiting chemicals. It has been reported, however, that although tolerance can develop to some effects of cholinesterase inhibition, the cellular mechanisms responsible for the development of tolerance may also lead to the development of other effects, i.e., cognitive dysfunction, not present at the time of initial exposure (Bushnell et al., 1991). These adaptive biochemical changes in the tolerant animal may render it supersensitive to subsequent exposure to cholinergically active compounds (Pope et al., 1992).

In general, the risk assessor should understand that assessment of cholinesterase-inhibiting chemicals should be done on a case-by-case basis using a weight-of evidence approach in which all of the available data (e.g., brain, blood, and other tissue cholinesterase activity, as well as the presence or absence of clinical signs) is considered in the evaluation. Generally, the toxic effects of anticholinesterase compounds are viewed as reversible, but there is human and experimental animal evidence indicating that there may be residual, if not permanent, effects of exposure to these compounds (Steenland et al., 1994; Tandon et al., 1994; Stephens et al., 1995).

A subset of organophosphate agents also produces organophosphate-induced delayed neuropathy (OPIDN) after acute or repeated exposure. Inhibition and aging of neurotoxic esterase (or neuropathy enzymes) are associated with agents that produce OPIDN (Johnson, 1990; Richardson, 1995). The conclusion that a chemical may produce OPIDN should be based on at least two of three factors: (1) Evidence of a clinical syndrome, (2) pathological lesions, and (3) neurotoxic esterase (NTE) inhibition. NTE inhibition is necessary, but not sufficient, evidence

of the potential to produce OPIDN when there is at least 55%–70% inhibition after acute exposure (Ehrich et al., 1995) and at least 45% inhibition following repeated exposure.

Chemically induced injury to the central nervous system may be accompanied by hypertrophy of astrocytes. In some cases, these astrocytic changes can be seen light microscopically with immunohistochemical stains for glial fibrillary acidic protein (GFAP), the major intermediate filament protein in astrocytes. In addition, GFAP can be quantified by an immunoassay, which has been proposed as a marker of astrocyte reactivity (O'Callaghan, 1988). Immunohistochemical stains have the advantage of better localization of GFAP increases, whereas immunoassay evaluations are superior at detecting and quantifying changes in GFAP levels and establishing dose-response relationships. The ability to detect and quantify changes in GFAP by immunoassay is improved by dissecting and analyzing multiple brain regions. The interpretation of a chemical-induced change in GFAP is facilitated by corroborative data from the neuropathology or neuroanatomy evaluation. A number of chemicals known to injure the central nervous system, including trimethyltin, methylmercury, cadmium, 3-acetylpyridine, and methylphenyltetrahydropyridine (MPTP), have been shown to increase levels of GFAP. Measures of GFAP are now included as an optional test in the Neurotoxicity Screening Battery (U.S. EPA, 1991a).

Increases in GFAP above control levels may be seen at dosages below those necessary to produce damage seen by standard microscopic or histopathological techniques. Because increases in GFAP reflect an astrocyte response in adults, treatment-related increases in GFAP are considered to be evidence that a neurotoxic effect has occurred. There is less agreement as to how to interpret decreases in GFAP relative to an appropriate control group. The absence of a change in GFAP following exposure does not mean that the chemical is devoid of neurotoxic potential. Known neurotoxicants such as cholinesterase-inhibiting pesticides, for example, would not be expected to increase brain levels of GFAP. Interpretation of GFAP changes prior to weaning may be confounded by the possibility that chemically induced increases in GFAP could be masked by changes in the concentration of this protein associated with maturation of the central nervous system, and these data may be difficult to interpret.

3.1.2.4. Behavioral Endpoints of Neurotoxicity

Behavior reflects the integration of the various functional components of the nervous system. Changes in behavior can arise from a direct effect of a toxicant on the nervous system, or indirectly from its effects on other physiological systems. Understanding the interrelationship between systemic toxicity and behavioral changes (e.g., the relationship between liver damage and motor activity) is extremely important. The presence of systemic toxicity may complicate, but does not preclude, interpretation of behavioral changes as evidence of neurotoxicity. In addition, a number of behaviors (e.g., schedule-controlled behavior) may require a motivational component for successful completion of the task. In such cases, experimental paradigms designed to assess the motivation of an animal during behavior might be necessary to interpret the meaning of some chemical-induced changes in behavior.

EPA's testing guidelines developed for the Toxic Substances Control Act and the Federal Insecticide, Fungicide and Rodenticide Act describe the use of functional observational batteries (FOB), motor activity, and schedule-controlled behavior for assessing neurotoxic potential (U.S. EPA, 1991a). Examples of measures obtained in a typical FOB are presented in Table 5. There are many other measures of behavior, including specialized tests of motor and sensory function and of learning and memory (Tilson, 1987; Anger, 1984).

TABLE 5.—EXAMPLES OF MEASURES IN A REPRESENTATIVE FUNCTIONAL OBSERVATIONAL BATTERY

Home cage and open field	Manipulative	Physiological
Arousal	Approach response.	Body temperature.
Autonomic signs.	Click response.	Body weight.
Convulsions, tremors.	Foot splay.	
Gait	Grip strength	
Mobility	Righting reflex.	
Posture	Tail pinch response.	
Rearing.		
Stereotypy.		
Touch response.		

TABLE 6.—EXAMPLES OF SPECIALIZED BEHAVIORAL TESTS TO MEASURE NEUROTOXICITY

Function	Procedure	Representative agents
Motor Function		
Weakness	Grip strength, swimming endurance, suspension rod, discriminative motor function.	n-Hexane, methyl. n-Butylketone, carbaryl.
Incoordination	Rotorod, gait assessments, righting reflex	3-Acetylpyridine, ethanol.
Tremor	Rating scale, spectral analysis	Chlordecone, Type I. pyrethroids, DDT.
Myoclonic spasms	Rating scale	DDT, Type II pyrethroids.
Sensory Function		
Auditory	Discrimination conditioning Reflex modification.	Toluene, trimethyltin.
Visual	Discrimination conditioning	Methylmercury.
Somatosensory	Discrimination conditioning	Acrylamide.
Pain sensitivity	Discrimination conditioning	Parathion.
Olfactory	Discrimination conditioning	3-Methylindole, methylbromide.
Cognitive Function		
Habituation	Startle reflex	Diisopropylfluorophosphate. Pre/neonatal methylmercury.

TABLE 6.—EXAMPLES OF SPECIALIZED BEHAVIORAL TESTS TO MEASURE NEUROTOXICITY—Continued

Function	Procedure	Representative agents
Classical conditioning	Nictitating membrane	Aluminum.
	Conditioned flavor	Carbaryl.
	aversion	Trimethyltin, IDPN.
	Passive avoidance	Neonatal trimethyltin.
	Olfactory conditioning.	
Instrumental conditioning	One-way avoidance	Chlordecone.
	Two-way avoidance	Pre/neonatal lead.
	Y-maze avoidance	Hypervitaminosis A.
	Biel water maze	Styrene.
	Morris water maze	DFP.
	Radial arm maze	Trimethyltin.
	Delayed matching to sample	DFP.
	Repeated acquisition	Carbaryl.

At the present time, there is no clear consensus concerning the use of specific behavioral tests to assess chemical-induced sensory, motor, or cognitive dysfunction in animal models. The risk assessor should also know that the literature is clear that a number of other behaviors besides those listed in Tables 1, 5, and 6 could be affected by chemical exposure. For example, alterations in food and water intake, reproduction, sleep, temperature regulation, and circadian rhythmicity are controlled by specific regions of the brain, and chemical-induced alterations in these behaviors could be indicative of neurotoxicity. It is reasonable to assume that an NOAEL or LOAEL could be based on one or more of these endpoints.

The following sections describe, in general, behavioral tests and their uses and offer guidance on interpreting data.

3.1.2.4.1. Functional Observational Battery (FOB). An FOB is designed to detect and quantify major overt behavioral, physiological, and neurological signs (Gad, 1982; O'Donoghue, 1989; Moser, 1989). A number of batteries have been developed, each consisting of tests generally intended to evaluate various aspects of sensorimotor function (Tilson and Moser, 1992). Many FOB tests are essentially clinical neurological examinations that rate the presence or absence, and in many cases the severity, of specific neurological signs. Some FOBs in animals are similar to clinical neurological examinations used with human patients. Most FOBs have several components or tests. A typical FOB is summarized in Table 5 and evaluates several functional domains, including neuromuscular (i.e., weakness, incoordination, gait, and tremor), sensory (i.e., audition, vision, and somatosensory), and autonomic (i.e., pupil response and salivation) function.

The relevance of statistically significant test results from an FOB is judged according to the number of signs affected, the dose(s) at which effects are observed, and the nature, severity, and persistence of the effects and their incidence in relation to control animals. In general, if only a few unrelated measures in the FOB are affected, or the effects are unrelated to dose, the results may not be considered evidence of a neurotoxic effect. If several neurological signs are affected, but only at the high dose and in conjunction with other overt signs of toxicity, including systemic toxicity, large decreases in body weight, decreases in body temperature, or debilitation, there is less persuasive evidence of a direct neurotoxic effect. In cases where several related measures in a battery of tests are affected and the effects appear to be dose dependent, the data are considered to be evidence of a neurotoxic effect, especially in the absence of systemic toxicity. The risk assessor should be aware of the potential for a number of false positive statistical findings in these studies because of the large number of endpoints customarily included in the FOB.

FOB data can be grouped into one or more of several neurobiological domains, including neuromuscular (i.e., weakness, incoordination, abnormal movements, gait), sensory (i.e., auditory, visual, somatosensory), and autonomic functions (Tilson and Moser, 1992). This statistical technique may be useful when separating changes that occur on the basis of chance or in conjunction with systemic toxicity from those treatment-related changes indicative of neurotoxic effects. In the case of the developing organism, chemicals may alter the maturation or appearance of sensorimotor reflexes. Significant alterations in or delay of such reflexes is evidence of a neurotoxic effect.

Examples of chemicals that affect neuromuscular function are 3-acetylpyridine, acrylamide, and triethyltin. Organophosphate and carbamate insecticides produce autonomic dysfunction, while organochlorine and pyrethroid insecticides increase sensorimotor sensitivity, produce tremors and, in some cases, cause seizures and convulsions (Spencer and Schaumburg, 1980).

3.1.2.4.2. Motor Activity. Motor activity represents a broad class of behaviors involving coordinated participation of sensory, motor, and integrative processes. Assessment of motor activity is noninvasive and has been used to evaluate the effects of acute and repeated exposure to neurotoxicants (MacPhail et al., 1989). An organism's level of activity can, however, be affected by many different types of environmental agents, including non-neurotoxic agents. Motor activity measurements also have been used in humans to evaluate disease states, including disorders of the nervous system (Goldstein and Stein, 1985).

Motor activity is usually quantified as the frequency of movements over a period of time. The total counts generated during a test period will depend on the recording mechanism and the size and configuration of the testing apparatus. Effects of agents on motor activity can be expressed as absolute activity counts or as a percentage of control values. In some cases, a transformation (e.g., square root) may be used to achieve a normal distribution of the data. In these cases, the transformed data and not raw data should be used for risk assessment purposes. The frequency of motor activity within a session usually decreases and is reported as the average number of counts occurring in each successive block of time. The EPA's

Office of Prevention, Pesticides and Toxic Substances guidelines (U.S. EPA, 1991a), for example, call for test sessions of sufficient duration to allow motor activity to approach steady-state levels during the last 20 percent of the session for control animals. A sum of the counts in each epoch will add up to the total number of counts per session.

Motor activity can be altered by a number of experimental factors, including neurotoxic chemicals. Decreases in activity could occur following high doses of non-neurotoxic agents (Kotsonis and Klaassen, 1977; Landauer et al., 1984). Examples of neurotoxic agents that decrease motor activity include many pesticides (e.g., carbamates, chlorinated hydrocarbons, organophosphates, and pyrethroids), heavy metals (lead, tin, and mercury), and other agents (3-acetylpyridine, acrylamide, and 2,4-dithiobiuret). Some neurotoxicants (e.g., toluene, xylene, triadimefon) produce transient increases in activity by presumably stimulating neurotransmitter release, while others (e.g., trimethyltin) produce persistent increases in motor activity by destroying specific regions of the brain (e.g., hippocampus).

Following developmental exposures, neurotoxic effects are often observed as a change in the ontogenetic profile or maturation of motor activity patterns. Frequently, developmental exposure to neurotoxic agents will produce an increase in motor activity that persists into adulthood or that results in changes in other behaviors. This is evidence of a neurotoxic effect. Like other organ systems, the nervous system may be differentially sensitive to toxicants in groups such as the young. For example, toxicants introduced to the developing nervous system may kill stem cells and thus cause profound effects on adult structure and function. Moreover, toxicants may have greater access to the developing nervous system before the blood-brain barrier is completely formed or before metabolic detoxifying systems are functional.

Motor activity measurements are typically used with other tests (e.g., FOB) to help detect neurotoxic effects. Agent-induced changes in motor activity associated with other overt signs of toxicity (e.g., loss of body weight, systemic toxicity) or occurring in non-dose-related fashion are of less concern than changes that are dose dependent, are related to structural or other functional changes in the nervous system, or occur in the absence of life-threatening toxicity.

13.1.2.4.3. Schedule-Controlled Operant Behavior. Schedule-controlled operant behavior (SCOB) involves the maintenance of behavior (e.g., performance of a lever-press or key-peck response) by reinforcement. Different rates and patterns of responding are controlled by the relationship between response and subsequent reinforcement. SCOB provides a measure of performance of a learned behavior (e.g., lever press or key peck) and involves training and motivational variables that should be considered in evaluating the data. Agents may interact with sensory processing, motor output, motivational variables (i.e., related to reinforcement), training history, and baseline characteristics (Rice, 1988; Cory-Slechta, 1989). Qualitatively, rates and patterns of SCOB display cross-species generality, but the quantitative measures of rate and pattern of performance can vary within and between species.

In laboratory animals, SCOB has been used to study a wide range of neurotoxicants, including methylmercury, many pesticides, organic and inorganic lead, triethyltin, and trimethyltin (MacPhail, 1985; Tilson, 1987; Rice, 1988). The primary SCOB endpoints for evaluation are response rate and the temporal pattern of responding. These endpoints may vary as a function of the contingency between responding and reinforcement presentation (i.e., schedule of reinforcement). Schedules of reinforcement that have been used in toxicology studies include fixed ratio and fixed interval schedules. Fixed ratio schedules engender high rates of responding and a characteristic pause after delivery of each reinforcement. Fixed interval schedules engender a relatively low rate of responding during the initial portion of the interval and progressively higher rates near the end of the interval. For some schedules of reinforcement, the temporal pattern of responding may play a more important role in defining the performance characteristics than the rate of responding. For other schedules, the reverse may be true. For example, the temporal pattern of responding may be more important than rate of responding for defining performance on a fixed interval schedule. For a fixed ratio schedule, more importance might be placed on the rate of responding than on the post-reinforcement pause.

The overall qualitative patterns are important properties of the behavior. Substantial qualitative changes in operant performance, such as elimination of characteristic response patterns, can be evidence of an adverse effect. Most chemicals, however, can disrupt operant behavior at some dose, and such adverse effects may be due either to neurotoxic or non-neurotoxic mechanisms. Unlike large qualitative changes in operant performance, small quantitative changes are not adverse. Some changes may actually represent an improvement, e.g., an increase in the index of curvature with a decrease in fixed interval rate of responding. Assessing the toxicological importance of these effects requires considerable professional judgment and evaluation of converging evidence from other types of toxicological endpoints. While most chemicals decrease the efficiency of responding at some dose, some agents may increase response efficiency on schedules requiring high response rates because of a stimulant effect or an increase in central nervous system excitability. Agent-induced changes in responding between reinforcements (i.e., the temporal pattern of responding) may occur independently of changes in the overall rate of responding. Chemicals may also affect the reaction time to respond following presentation of a stimulus. Agent-induced changes in response rate or temporal patterning associated with other overt signs of toxicity (e.g., body weight loss, systemic toxicity, or occurring in a non-dose-related fashion) are of less concern than changes that are dose dependent, related to structural or other functional changes in the nervous system, or occur in the absence of life-threatening toxicity.

3.1.2.4.4. Convulsions. Observable convulsions in animals are indicative of an adverse effect. These events can reflect central nervous system activity comparable to that of epilepsy in humans and could be defined as neurotoxicity. Occasionally, other toxic actions of compounds, such as direct effects on muscle, might mimic some convulsionlike behaviors. In some cases, convulsions or convulsionlike behaviors may be observed in animals that are otherwise severely compromised, moribund, or near death. In such cases, convulsions might reflect an indirect effect of systemic toxicity and are less clearly indicative of neurotoxicity. As discussed in the section on neurophysiological measures, electrical recordings of brain activity could be used to determine specificity of effects on the nervous system.

3.1.2.4.5. Specialized Tests for Neurotoxicity. Several procedures have been developed to measure agent-induced changes in specific neurobehavioral functions such as motor, sensory, or cognitive function (Tilson, 1987; Cory-Slechta, 1989). Table 6 lists several behavioral tests, the neurobehavioral functions they were designed to assess, and agents known to affect the response. Many of these tests in animals have been designed to assess neural functions in humans using similar testing procedures.

A statistically or biologically significant chemically induced change

in any measure in Table 6 may be evidence of an adverse effect. However, judgments of neurotoxicity may involve not only the analysis of changes seen but the structure and class of the chemical and other available neurochemical, neurophysiological, and neuropathological evidence. In general, behavioral changes seen across broader dose ranges indicate more specific actions on the systems underlying those changes, i.e., the nervous system. Changes that are not dose dependent or that are confounded with body weight changes and/or other systemic toxicity may be more difficult to interpret as neurotoxic effects.

3.1.2.4.5.1. Motor Function. Neurotoxicants commonly affect motor function. These effects can be categorized generally into (1) weakness or decreased strength, (2) tremor, (3) incoordination, and (4) spasms, myoclonia, or abnormal motor movements (Tilson, 1987; Cory-Slechta, 1989). Specialized tests used to assess strength include measures of grip strength, swimming endurance, suspension from a hanging rod, and discriminative motor function. Rotorod and gait assessments are used to measure coordination, while rating scales and spectral analysis techniques can be used to quantify tremor and other abnormal movements.

3.1.2.4.5.2. Sensory Function. Gross perturbations of sensory function can be observed in simple neurological assessments such as the hot plate or tail flick test. However, these tests may not be sufficiently sensitive to detect subtle sensory changes. Psychophysical procedures that study the relationship between a physical dimension (e.g., intensity, frequency) of a stimulus and behavior may be necessary to quantify agent-induced alterations in sensory function. Examples of psychophysical procedures include discriminated conditioning and startle reflex modification.

3.1.2.4.5.3. Cognitive Function. Alterations in learning and memory in experimental animals should be inferred from changes in behavior following exposure when compared with that seen prior to exposure or with a nonexposed control group. Learning is defined as a relatively lasting change in behavior due to experience, and memory is defined as the persistence of a learned behavior over time. Table 6 lists several examples of learning and memory tests and representative neurotoxicants known to affect these tests. Measurement of changes in learning and memory should be separated from other changes in behavior that do not involve cognitive or associative processes (i.e., motor function, sensory capabilities, motivational factors). In addition, any apparent toxicant-induced change in learning or memory should ideally be demonstrated over a range of stimulus and response conditions and testing conditions. In developmental exposures, it should be shown that the animals have matured enough to perform the specified task. Developmental neurotoxicants can accelerate or delay the ability to learn a response or may interfere with cognitive function at the time of testing. Older animals frequently perform poorly on some types of tests, and it should be demonstrated that control animals in this population are capable of performing the procedure. Neurotoxicants might accelerate age-related dysfunction or alter motivational variables that are important for learning to occur. Further, it is not the case that a decrease in responding on a learning task is adverse while an increase in performance on a learning task is not. It is well known that lesions in certain regions of the brain can facilitate the acquisition of certain types of behaviors by removing preexisting response tendencies (e.g., inhibitory responses due to stress) that moderate the rate of learning under normal circumstances.

Apparent improvement in performance is not either adverse or beneficial until demonstrated to be so by converging evidence with a variety of experimental methods. Examples of procedures to assess cognitive function include simple habituation, classical conditioning, and operant (or instrumental) conditioning, including tests for spatial learning and memory.

3.1.2.4.5.4. Developmental Neurotoxicity. Although the previous discussion of various neurotoxicity endpoints and tests applies to studies in which developmental exposures are used, there are particular issues of importance in the evaluation of developmental neurotoxicity studies. This section underscores the importance of detecting neurotoxic effects following developmental exposure because an NRC (1993) report has indicated that infants and children may be differentially sensitive to environmental chemicals such as pesticides. Exposure to chemicals during development can result in a spectrum of effects, including death, structural abnormalities, altered growth, and functional deficits (U.S. EPA, 1991b). A number of agents have been shown to cause developmental neurotoxicity when exposure occurred during the period between conception and sexual maturity (e.g., Riley and Vorhees, 1986; Vorhees, 1987).

Table 7 lists several examples of agents known to produce developmental neurotoxicity in experimental animals. Animal models of developmental neurotoxicity have been shown to be sensitive to several environmental agents known to produce developmental neurotoxicity in humans, including lead, ethanol, x-irradiation, methylmercury, and polychlorinated biphenyls (PCBs) (Kimmel et al., 1990; Needleman, 1990; Jacobson et al., 1985; Needleman, 1986). In many of these cases, functional deficits are observed at dose levels below those at which other indicators of developmental toxicity are evident or at minimally toxic doses in adults. Such effects may be transient, but generally are considered adverse. Developmental exposure to a chemical could result in transient or reversible effects observed during early development that could reemerge as the individual ages (Barone et al., 1995).

TABLE 7.—EXAMPLES OF COMPOUNDS OR TREATMENTS PRODUCING DEVELOPMENTAL NEUROTOXICITY

Alcohols	Methanol, ethanol.
Antimitotics	X-radiation, azacytidine.
Insecticides	DDT, chlordecone.
Metals	Lead, methylmercury, cadmium.
Polyhalogenated hydrocarbons.	PCBs, PBBs.

Testing for developmental neurotoxicity has not been required routinely by regulatory agencies in the United States, but is required by EPA when other information indicates the potential for developmental neurotoxicity (U.S. EPA, 1986, 1988a, 1988b, 1989, 1991a, 1991b). Useful data for decision making may be derived from well-conducted adult neurotoxicity studies, standard developmental toxicity studies, and multigeneration studies, although the dose levels used in the latter may be lower than those in studies with shorter term exposure.

Important design issues to be evaluated for developmental neurotoxicity studies are similar to those for standard developmental toxicity studies (e.g., a dose-response approach with the highest dose producing minimal overt maternal or perinatal toxicity, with number of litters large enough for adequate statistical power, with randomization of animals to dose groups and test groups, with litter generally considered as the statistical unit). In addition, the use of a replicate study design provides added confidence in the interpretation of data. A pharmacological/physiological challenge may also be valuable in

evaluating neurological function and ''unmasking'' effects not otherwise detectable. For example, a challenge with a psychomotor stimulant such as d-amphetamine may unmask latent developmental neurotoxicity (Hughes and Sparber, 1978; Adams and Buelke-Sam, 1981; Buelke-Sam et al., 1985).

Direct extrapolation of developmental neurotoxicity to humans is limited in the same way as for other endpoints of toxicity, i.e., by the lack of knowledge about underlying toxicological mechanisms and their significance (U.S. EPA, 1991b). However, comparisons of human and animal data for several agents known to cause developmental neurotoxicity in humans showed many similarities in effects (Kimmel et al., 1990). As evidenced primarily by observations in laboratory animals, comparisons at the level of functional category (sensory, motivational, cognitive, motor function, and social behavior) showed close agreement across species for the agents evaluated, even though the specific endpoints used to assess these functions varied considerably across species (Stanton and Spear, 1990). Thus, it can be assumed that developmental neurotoxicity effects in animal studies indicate the potential for altered neurobehavioral development in humans, although the specific types of developmental effects seen in experimental animal studies will not be the same as those that may be produced in humans. Therefore, when data suggesting adverse effects in developmental neurotoxicity studies are encountered for particular agents, they should be considered in the risk assessment process.

Functional tests with a moderate degree of background variability (e.g., a coefficient of variability of 20% or less) may be more sensitive to the effects of an agent on behavioral endpoints than are tests with low variability that may be impossible to disrupt without using life-threatening doses. A battery of functional tests, in contrast to a single test, is usually needed to evaluate the full complement of nervous system functions in an animal. Likewise, a series of tests conducted in animals in several age groups may provide more information about maturational changes and their persistence than tests conducted at a single age.

It is a well-established principle that there are critical developmental periods for the disruption of functional competence, which include both the prenatal and postnatal periods to the time of sexual maturation, and the effect of a toxicant is likely to vary depending on the time and degree of exposure (Rodier, 1978, 1990). It is also important to consider the data from studies in which postnatal exposure is included, as there may be an interaction of the agent with maternal behavior, milk composition, or pup suckling behavior, as well as possible direct exposure of pups via dosed food or water (Kimmel et al., 1992).

Agents that produce developmental neurotoxicity at a dose that is not toxic to the maternal animal are of special concern. However, adverse developmental effects are often produced at doses that cause mild maternal toxicity (e.g., 10%-20% reduction in weight gain during gestation and lactation). At doses causing moderate maternal toxicity (i.e., 20% or more reduction in weight gain during gestation and lactation), interpretation of developmental effects may be confounded. Current information is inadequate to assume that developmental effects at doses causing minimal maternal toxicity result only from maternal toxicity; rather, it may be that the mother and developing organism are equally sensitive to that dose level. Moreover, whether developmental effects are secondary to maternal toxicity or not, the maternal effects may be reversible while the effects on the offspring may be permanent. These are important considerations for agents to which humans may be exposed at minimally toxic levels either voluntarily or involuntarily, because several agents (e.g., alcohol) are known to produce adverse developmental effects at minimally toxic doses in adult humans (Coles et al., 1991).

Although interpretation of developmental neurotoxicity data may be limited, it is clear that functional effects should be evaluated in light of other toxicity data, including other forms of developmental toxicity (e.g., structural abnormalities, perinatal death, and growth retardation). For example, alterations in motor performance may be due to a skeletal malformation rather than nervous system change. Changes in learning tasks that require a visual cue might be influenced by structural abnormalities in the eye. The level of confidence that an agent produces an adverse effect may be as important as the type of change seen, and confidence may be increased by such factors as reproducibility of the effect, either in another study of the same function or by convergence of data from tests that purport to measure similar functions. A dose-response relationship is an extremely important measure of a chemical's effect; in the case of developmental neurotoxicity both monotonic and biphasic dose-response curves are likely, depending on the function being tested. The EPA Guidelines for Developmental Toxicity Risk Assessment (U.S. EPA, 1991b) may be consulted for more information on interpreting developmental toxicity studies. The endpoints frequently used to assess developmental neurotoxicity in exposed children have been reviewed by Winneke (1995).

3.1.3. Other Considerations

3.1.3.1. Pharmacokinetics

Extrapolation of test results between species can be aided considerably by data on the pharmacokinetics of a particular agent in the species tested and, if possible, in humans. Information on a toxicant's half-life, metabolism, absorption, excretion, and distribution to the peripheral and central nervous system may be useful in predicting risk. Of particular importance for the pharmacokinetics of neurotoxicants is the blood-brain barrier. The vast majority of the central nervous system is served by blood vessels with blood-brain barrier properties, which exclude most ionic and nonlipid-soluble chemicals from the brain and spinal cord. The brain contains several structures called circumventricular organs (CVOs) that are served by blood vessels lacking blood-brain barrier properties. Brain regions adjacent to these CVOs are thus exposed to relatively high levels of many neurotoxicants. Pharmacokinetic data may be helpful in defining the dose-response curve, developing a more accurate basis for comparing species sensitivity (including that of humans), determining dosimetry at sites, and comparing pharmacokinetic profiles for various dosing regimens or routes of administration. The correlation of pharmacokinetic parameters and neurotoxicity data may be useful in determining the contribution of specific pharmacokinetic processes to the effects observed.

3.1.3.2. Comparisons of Molecular Structure

Comparisons of the chemical or physical properties of an agent with those of known neurotoxicants may provide some indication of the potential for neurotoxicity. Such information may be helpful for evaluating potential toxicity when only minimal data are available. The structure-activity relationships (SAR) of some chemical classes have been studied, including hexacarbons, organophosphates, carbamates, and pyrethroids. Therefore, class relationships or SAR may help

predict neurotoxicity or interpret data from neurotoxicological studies. Under certain circumstances (e.g., in the case of new chemicals), this procedure is one of the primary methods used to evaluate the potential for toxicity when little or no empirical toxicity data are available. It should be recognized, however, that effects of chemicals in the same class can vary widely. Moser (1995), for example, reported that the behavioral effects of prototypic cholinesterase-inhibiting pesticides differed qualitatively in a battery of behavioral tests.

3.1.3.3. Statistical Considerations

Properly designed studies on the neurotoxic effects of compounds will include appropriate statistical tests of significance. In general, the likelihood of obtaining a significant effect will depend jointly on the magnitude of the effect and the variability obtained in control and treated groups. The risk assessor should be aware that some neurotoxicants may induce a greater variability in biologic response, rather than a clear shift in mean or other parameters (Laties and Evans, 1980; Glowa and MacPhail, 1995). A number of texts are available on standard statistical tests (e.g., Siegel, 1956; Winer, 1971; Sokal and Rohlf, 1969; Salsburg, 1986; Gad and Weil, 1988).

Neurotoxicity data present some unique features that should be considered in selecting statistical tests for analysis. Data may involve several different measurement scales, including categorical (affected or not), rank (more or less affected), and interval and ratio scales of measurement (affected by some percentage). For example, convulsions are usually recorded as being present or absent (categorical), whereas neuropathological changes are frequently described in terms of the degree of damage (rank). Many tests of neurotoxicity involve interval or ratio measurements (e.g., frequency of photocell interruptions or amplitude of an evoked potential), which are the most powerful and sensitive scales of measurement. In addition, measurements are frequently made repeatedly in control and treated subjects, especially in the case of behavioral and neurophysiological endpoints. For example, OPPTS guidelines for FOB assessment call for evaluations before exposure and at several times during exposure in a subchronic study (U.S. EPA, 1991a).

Descriptive data (categorical) and rank order data can be analyzed using standard nonparametric techniques (Siegel, 1956). In some cases, if it is determined that the data fit the linear model, the categorical modeling procedure can be used for weighted least-squares estimation of parameters for a wide range of general linear models, including repeated-measures analyses. The weighted least-squares approach to categorical and rank data allows computation of statistics for testing the significance of sources of variation as reflected by the model. In the case of studies assessing effects in the same animals at several time points, univariate analyses can be carried out at each time point when the overall dose effect or the dose-by-time interaction is significant.

Continuous data (e.g., magnitude, rate, amplitude), if found to be normally distributed, can be analyzed with general linear models using a grouping factor of dose and, if necessary, repeated measures across time (Winer, 1971). Univariate analyses of dose, comparing dose groups to the control group at each time point, can be performed when there is a significant overall dose effect or a dose-by-time interaction. Post hoc comparisons between control and treatment groups can be made following tests for overall significance. In the case of multiple endpoints within a series of evaluations, some type of correction for multiple observations is warranted (Winer, 1971).

3.1.3.4. In Vitro Data in Neurotoxicology

Methods and procedures that fall under the general heading of short-term tests include an array of in vitro tests that have been proposed as alternatives to whole-animal tests (Goldberg and Frazier, 1989). In vitro approaches use animal or human cells, tissues, or organs and maintain them in a nutritive medium. Various types of in vitro techniques, including primary cell cultures, cell lines, and cloned cells, produce data for evaluating potential and known neurotoxic substances. While such procedures are important in studying the mechanism of action of toxic agents, their use in hazard identification in human health risk assessment has not been explored to any great extent.

Data from in vitro procedures are generally based on simplified approaches that require less time to yield information than do many in vivo techniques. However, in vitro methods generally do not take into account the distribution of the toxicant in the body, the route of administration, or the metabolism of the substance. It also is difficult to extrapolate in vitro data to animal or human neurotoxicity endpoints, which include behavioral changes, motor disorders, sensory and perceptual disorders, lack of coordination, and learning deficits. In addition, data from in vitro tests cannot duplicate the complex neuronal circuitry characteristic of the intact animal.

Many in vitro systems are now being evaluated for their ability to predict the neurotoxicity of various agents seen in intact animals. This validation process requires considerations in study design, including defined endpoints of toxicity and an understanding of how a test agent would be handled in vitro as compared to the intact organism. Demonstrated neurotoxicity in vitro in the absence of in vivo data is suggestive but inadequate evidence of a neurotoxic effect. In vivo data supported by in vitro data enhance the reliability of the in vivo results.

3.1.3.5. Neuroendocrine Effects

Neuroendocrine dysfunction may occur because of a disturbance in the regulation and modulation of neuroendocrine feedback systems. One major indicator of neuroendocrine function is secretion of hormones from the pituitary. Hypothalamic control of anterior pituitary secretions is also involved in a number of important bodily functions. Many types of behaviors (e.g., reproductive behaviors, sexually dimorphic behaviors in animals) are dependent on the integrity of the hypothalamic-pituitary system, which could represent a potential site of neurotoxicity. Pituitary secretions arise from a number of different cell types in this gland, and neurotoxicants could affect these cells directly or indirectly. Morphological changes in cells mediating neuroendocrine secretions could be associated with adverse effects on the pituitary or hypothalamus and could ultimately affect behavior and the functioning of the nervous system. Biochemical changes in the hypothalamus may also be used as indicators of potential adverse effects on neuroendocrine function. Finally, the development of the nervous system is intimately associated with the presence of circulating hormones such as thyroid hormone (Porterfield, 1994). The nature of the nervous system deficit, which could include cognitive dysfunction, altered neurological development, or visual deficits, depends on the severity of the thyroid disturbance and the specific developmental period when exposure to the chemical occurred.

3.2. Dose-Response Evaluation

Dose-response evaluation is a critical part of the qualitative characterization of a chemical's potential to produce neurotoxicity and involves the description of the dose-response

relationship in the available data. Human studies covering a range of exposures are rarely available, and therefore animal data are typically used for estimating exposure levels likely to produce adverse effects in humans. Evidence for a dose-response relationship is an important criterion in establishing a neurotoxic effect, although this analysis may be limited when based on standard studies using three dose groups or fewer. The evaluation of dose-response relationships includes identifying effective dose levels as well as doses associated with no increase in adverse effects when compared with controls. The lack of a dose-response relationship in the data may suggest that the effect is not related to the putative neurotoxic effect or that the study was not appropriately controlled. Much of the focus is on identifying the critical effect(s) observed at the LOAEL and the NOAEL associated with that effect. The NOAEL is defined as the highest dose at which there is no statistically or biologically significant increase in the frequency of an adverse neurotoxic effect when compared with the appropriate control group in a database characterized as having sufficient evidence for use in a risk assessment (see section 3.3). The risk assessor should be aware of possible problems associated with estimating a NOAEL in studies involving a small number of test subjects and that have a poor dose-response relationship.

In addition to identifying the NOAEL/LOAEL or BMD, the dose-response evaluation defines the range of doses that are neurotoxic for a given agent, species, route of exposure, and duration of exposure. In addition to these considerations, pharmacokinetic factors and other aspects that might influence comparisons with human exposure scenarios should be taken into account. For example, dose-response curves may exhibit not only monotonic but also U-shaped or inverted U-shaped functions (Davis and Svendsgaard, 1990). Such curves are hypothesized to reflect multiple mechanisms of action, the presence of homeostatic mechanisms, and/or activation of compensatory or protective mechanisms. In addition to considering the shape of the dose-response curve, it should also be recognized that neurotoxic effects vary in terms of nature and severity across dose or exposure level. At high levels of exposure, frank lesions accompanied by severe functional impairment may be observed. Such effects are widely accepted as adverse. At progressively lower levels of exposure, however, the lesions may become less severe and the impairments less obvious. At levels of exposure near the NOAEL and LOAEL, the effects will often be mild, possibly reversible, and inconsistently found. In addition, the endpoints showing responses may be at levels of organization below the whole organism (e.g., neurochemical or electrophysiological endpoints). The adversity of such effects can be disputed (e.g., cholinesterase inhibition), yet it is such effects that are likely to be the focus of risk assessment decisions. To the extent possible, this document provides guidance on determining the adversity of neurotoxic effects. However, the identification of a critical adverse effect often requires considerable professional judgment and should consider factors such as the biological plausibility of the effect, the evidence of a dose-effect continuum, and the likelihood for progression of the effect with continued exposure.

3.3. Characterization of the Health-Related Database

This section describes a scheme for characterizing the sufficiency of evidence for neurotoxic effects. This scheme defines two broad categories: sufficient and insufficient (Table 8). Categorization is aimed at providing certain criteria for the Agency to use to define the minimum evidence necessary to define hazards and to conduct dose-response analyses. It does not address the issues related to characterization of risk, which requires analysis of potential human exposures and their relation to potential hazards in order to estimate the risks of those hazards from anticipated or estimated exposures. Several examples using a weight-of-evidence approach similar to that described in these Guidelines have been described elsewhere (Tilson et al., 1995; Tilson et al., 1996).

TABLE 8.—CHARACTERIZATION OF THE HEALTH-RELATED DATABASE

Sufficient evidence	The sufficient evidence category includes data that collectively provide enough information to judge whether or not a human neurotoxic hazard could exist. This category may include both human and experimental animal evidence.
Sufficient human evidence	This category includes agents for which there is sufficient evidence from epidemiologic studies, e.g., case control and cohort studies, to judge that some neurotoxic effect is associated with exposure. A case series in conjunction with other supporting evidence may also be judged ''sufficient evidence.'' Epidemiologic and clinical case studies should discuss whether the observed effects can be considered biologically plausible in relation to chemical exposure. (Historically, often much has been made of the notion of causality in epidemiologic studies. Causality is a more stringent criterion than association and has become a topic of scientific and philosophical debate. See Susser [1986], for example, for a discussion of inference in epidemiology.)
Sufficient experimental animal evidence/limited human data.	This category includes agents for which there is sufficient evidence from experimental animal studies and/or limited human data to judge whether a potential neurotoxic hazard may exist. Generally, agents that have been tested according to current test guidelines would be included in this category. The minimum evidence necessary to judge that a potential hazard exists would be data demonstrating an adverse neurotoxic effect in a single appropriate, well-executed study in a single experimental animal species. The minimum evidence needed to judge that a potential hazard does not exist would include data from an appropriate number of endpoints from more than one study and two species showing no adverse neurotoxic effects at doses that were minimally toxic in terms of producing an adverse effect. Information on pharmacokinetics, mechanisms, or known properties of the chemical class may also strengthen the evidence.

TABLE 8.—CHARACTERIZATION OF THE HEALTH-RELATED DATABASE—Continued

Insufficient evidence	This category includes agents for which there is less than the minimum evidence sufficient for identifying whether or not a neurotoxic hazard exists, such as agents for which there are no data on neurotoxicity or agents with databases from studies in animals or humans that are limited by study design or conduct (e.g., inadequate conduct or report of clinical signs). Many general toxicity studies, for example, are considered insufficient in terms of the conduct of clinical neurobehavioral observations or the number of samples taken for histopathology of the nervous system. Thus, a battery of negative toxicity studies with these shortcomings would be regarded as providing insufficient evidence of the lack of a neurotoxic effect of the test material. Further, most screening studies based on simple observations involving autonomic and motor function provide insufficient evaluation of many sensory or cognitive functions. Data, which by itself would likely fall in this category, would also include information on SAR or data from in vitro tests. Although such information would be insufficient by itself to proceed further in the assessment it could be used to support the need for additional testing.

Data from all potentially relevant studies, whether indicative of potential hazard or not, should be included in this characterization. The primary sources of data are human studies and case reports, experimental animal studies, other supporting data, and in vitro and/or SAR data. Because a complex interrelationship exists among study design, statistical analysis, and biological significance of the data, a great deal of scientific judgment, based on experience with neurotoxicity data and with the principles of study design and statistical analysis, is required to adequately evaluate the database on neurotoxicity. In many cases, interaction with scientists in specific disciplines either within or outside the field of neurotoxicology (e.g., epidemiology, statistics) may be appropriate.

The adverse nature of different neurotoxicity endpoints may be a complex judgment. In general, most neuropathological and many neurobehavioral changes are regarded as adverse. However, there are adverse behavioral effects that may not reflect a direct action on the nervous system. Neurochemical and electrophysiological changes may be regarded as adverse because of their known or presumed relation to neuropathological and/or neurobehavioral consequences. In the absence of supportive information, a professional judgment should be made regarding the adversity of such outcomes, considering factors such as the nature, magnitude, and duration of the effects reported. Thus, correlated measures of neurotoxicity strengthen the evidence for a hazard. Correlations between functional and morphological effects, such as the correlation between leg weakness and paralysis and peripheral nerve damage from exposure to tri-ortho-cresyl phosphate, are the most common and striking examples of this form of validity. Correlations support a coherent and logical link between behavioral effects and biochemical mechanisms. Replication of a finding also strengthens the evidence for a hazard. Some neurotoxicants cause similar effects across most species. Many chemicals shown to produce neurotoxicity in laboratory animals have similar effects in humans. Some neurological effects may be considered adverse even if they are small in magnitude, reversible, or the result of indirect mechanisms.

Because of the inherent difficulty in ''proving any negative,'' it is more difficult to document a finding of no apparent adverse effect than a finding of an adverse effect. Neurotoxic effects (and most kinds of toxicity) can be observed at many different levels, so only a single endpoint needs to be found to demonstrate a hazard, but many endpoints need to be examined to demonstrate no effect. For example, to judge that a hazard for neurotoxicity could exist for a given agent, the minimum evidence sufficient would be data on a single adverse endpoint from a well-conducted study. In contrast, to judge that an agent is unlikely to pose a hazard for neurotoxicity, the minimum evidence would include data from a host of endpoints that revealed no neurotoxic effects. This may include human data from appropriate studies that could support a conclusion of no evidence of a neurotoxic effect. With respect to clinical signs and symptoms, human exposures can reveal far more about the absence of effects than animal studies, which are confined to the signs examined.

In some cases, it may be that no individual study is judged sufficient to establish a hazard, but the total available data may support such a conclusion. Pharmacokinetic data and structure-activity considerations, data from other toxicity studies, or other factors may affect the strength of the evidence in these situations. For example, given that gamma diketones are known to cause motor system neurotoxicity, a marginal data set on a candidate gamma diketone, e.g., 1/10 animals affected, might be more likely to be judged sufficient than equivalent data from a member of a chemical class about which nothing is known.

A judgment that the toxicology database is sufficient to indicate a potential neurotoxic hazard is not the end of analysis. The circumstances of expression of the hazard are essential to describing human hazard potential. Thus, reporting should contain the details of the circumstances under which effects have been observed, e.g., ''long-term oral exposures of adult rodents to compound X at levels of roughly 1 mg/kg have been associated with ataxia and peripheral nerve damage.''

4. Quantitative Dose-Response Analysis

This section describes several approaches (including the LOAEL/NOAEL and BMD) for determining the reference dose (RfD) or reference concentration (RfC). The NOAEL or BMD/uncertainty factor approach results in an RfD or RfC, which is an estimate (with uncertainty spanning perhaps an order of magnitude) of a daily exposure to the human population (including sensitive subgroups) that is likely to be without an appreciable risk of deleterious effects during a lifetime.

The dose-response analysis characterization should:

- Describe how the RfD/RfC was calculated;
- Discuss the confidence in the estimates;
- Describe the assumptions or uncertainty factors used; and
- Discuss the route and level of exposure observed, as compared to expected human exposures.

4.1. LOAEL/NOAEL and BMD Determination

As indicated earlier, the LOAEL and NOAEL are determined for endpoints that are seen at the lowest dose level (so-called critical effect). Several limitations in the use of the NOAEL have been identified and described (e.g., Barnes and Dourson, 1988; Crump, 1984). For example, the NOAEL is derived from a single endpoint from a single study (the critical study) and

ignores both the slope of the dose-response function and baseline variability in the endpoint of concern. Because the baseline variability is not taken into account, the NOAEL from a study using small group sizes may be higher than the NOAEL from a similar study in the same species that uses larger group sizes. The NOAEL is also directly dependent on the dose spacing used in the study. Finally, and perhaps most importantly, use of the NOAEL does not allow estimates of risk or extrapolation of risk to lower dose levels. Because of these and other limitations in the NOAEL approach, it has been proposed that mathematical curve-fitting techniques (Crump, 1984; Gaylor and Slikker, 1990; Glowa, 1991; Glowa and MacPhail, 1995; U.S. EPA, 1995a) be compared with the NOAEL procedure in calculating the RfD or RfC. These techniques typically apply a mathematical function that describes the dose-response relationship and then interpolate to a level of exposure associated with a small increase in effect over that occurring in the control group or under baseline conditions. The BMD has been defined as a lower confidence limit on the effective dose associated with some defined level of effect, e.g., a 5% or 10% increase in response. These guidelines suggest that the use of the BMD should be explored in specific situations. The Agency is currently developing guidelines for the use of the BMD in risk assessment.

Many neurotoxic endpoints provide continuous measures of response, such as response speed, nerve conduction velocity, IQ score, degree of enzyme inhibition, or the accuracy of task performance. Although it is possible to impose a dichotomy on a continuous effects distribution and to classify some level of response as ''affected'' and the remainder as ''unaffected,'' it may be very difficult and inappropriate to establish such clear distinctions, because such a dichotomy would misrepresent the true nature of the neurotoxic response. The risk assessor should be aware of the importance of trying to reconcile findings from several studies that seem to report widely divergent results. Alternatively, quantitative models designed to analyze continuous effect variables may be preferable. Other techniques that allow this approach, with transformation of the information into estimates of the incidence or frequency of affected individuals in a population, have been proposed (Crump, 1984; Gaylor and Slikker, 1990; Glowa and MacPhail, 1995). Categorical regression analysis has been proposed because it can evaluate different types of data and derive estimates for short-term exposures (Rees and Hattis, 1994). Decisions about the most appropriate approach require professional judgment, taking into account the biological nature of the continuous effect variable and its distribution in the population under study.

Although dose-response functions in neurotoxicology are generally linear or monotonic, curvilinear functions, especially U-shaped or inverted U-shaped curves, have been reported as noted earlier (section 3.2). Dose-response analyses should consider the uncertainty that U-shaped dose-response functions might contribute to the estimate of the NOAEL/LOAEL or BMD. Typically, estimates of the NOAEL/LOAEL are taken from the lowest part of the dose-response curve associated with impaired function or adverse effect.

4.2. Determination of the Reference Dose or Reference Concentration

Since the availability of dose-response data in humans is limited, extrapolation of data from animals to humans usually involves the application of uncertainty factors to the NOAEL/LOAEL or BMD. The NOAEL or BMD/uncertainty factor approach results in an RfD or RfC, which is an estimate (with uncertainty spanning perhaps an order of magnitude) of a daily exposure to the human population (including sensitive subgroups) that is likely to be without an appreciable risk of deleterious effects during a lifetime. The oral RfD and inhalation RfC are applicable to chronic exposure situations and are based on an evaluation of all the noncancer health effects, including neurotoxicity data. RfDs and RfCs in the Integrated Risk Information System (IRIS–2) database for several agents are based on neurotoxicity endpoints and include a few cases in which the RfD or RfC is calculated using the BMD approach (e.g., methylmercury, carbon disulfide). The size of the final uncertainty factor used will vary from agent to agent and will require the exercise of scientific judgment, taking into account interspecies differences, the shape of the dose-response curve, and the neurotoxicity endpoints observed. Uncertainty factors are typically multiples of 10 and are used to compensate for human variability in sensitivity, the need to extrapolate from animals to humans, and the need to extrapolate from less than lifetime (e.g., subchronic) to lifetime exposures. An additional factor of up to 10 may be included when only a LOAEL (and not a NOAEL) is available from a study, or depending on the completeness of the database, a modifying factor of up to 10 may be applied, depending on the confidence one has in the database. Uncertainty factors of less than 10 can be used, depending upon the availability of relevant information. Barnes and Dourson (1988) provide a more complete description of the calculation, use, and significance of RfDs in setting exposure limits to toxic agents by the oral route. Jarabek et al. (1990) provide a more complete description of the calculation, use, and significance of RfCs in setting exposure limits to toxic agents in air. Neurotoxicity can result from acute, shorter term exposures, and it may be appropriate in some cases, e.g., for air pollutants or water contaminants, to set shorter term exposure limits for neurotoxicity as well as for other noncancer health effects.

5. Exposure Assessment

Exposure assessment describes the magnitude, duration, frequency, and routes of exposure to the agent of interest. This information may come from hypothetical values, models, or actual experimental values, including ambient environmental sampling results. Guidelines for exposure assessment have been published separately (U.S. EPA, 1992) and will, therefore, be discussed only briefly here.

The exposure assessment should include an exposure characterization that:

- Provides a statement of the purpose, scope, level of detail, and approach used in the exposure assessment;
- Presents the estimates of exposure and dose by pathway and route for individuals, population segments, and populations in a manner appropriate for the intended risk characterization;
- Provides an evaluation of the overall level of confidence in the estimate of exposure and dose and the conclusions drawn; and
- Communicates the results of the exposure assessment to the risk assessor, who can then use the exposure characterization, along with the hazard and dose/response characterizations, to develop a risk characterization.

A number of considerations are relevant to exposure assessment for neurotoxicants. An appropriate evaluation of exposure should consider the potential for exposure via ingestion, inhalation, and dermal penetration from relevant sources of exposure, including multiple avenues of intake from the same source.

In addition, neurotoxic effects may result from short-term (acute), high-concentration exposures as well as from

longer term (subchronic), lower level exposures. Neurotoxic effects may occur after a period of time following initial exposure or be obfuscated by repair mechanisms or apparent tolerance. The type and severity of effect may depend significantly on the pattern of exposure rather than on the average dose over a long period of time. For this reason, exposure assessments for neurotoxicants may be much more complicated than those for long-latency effects such as carcinogenicity. It is rare for sufficient data to be available to construct such patterns of exposure or dose, and professional judgment may be necessary to evaluate exposure to neurotoxic agents.

6. Risk Characterization

6.1. Overview

Risk characterization is the summarization step of the risk assessment process and consists of an integrative analysis and a summary. The integrative analysis (a) involves integration of the toxicity information from the hazard characterization and dose-response analysis with the human exposure estimates, (b) provides an evaluation of the overall quality of the assessment and the degree of confidence in the estimates of risk and conclusions drawn, and © describes risk in terms of the nature and extent of harm. The risk characterization summary communicates the results of the risk assessment to the risk manager in a complete, informative, and useful format.

This summary should include, but is not limited to, a discussion of the following elements:

- Quality of and confidence in the available data;
- Uncertainty analysis;
- Justification of defaults or assumptions;
- Related research recommendations;
- Contentious issues and extent of scientific consensus;
- Effect of reasonable alternative assumptions on conclusions and estimates;
- Highlights of reasonable plausible ranges;
- Reasonable alternative models; and
- Perspectives through analogy.

The risk manager can then use the derived risk to make public health decisions.

An effective risk characterization should fully, openly, and clearly characterize risks and disclose the scientific analyses, uncertainties, assumptions, and science policies that underlie decisions throughout the risk assessment and risk management processes. The risk characterization should feature values such as transparency in the decision-making process; clarity in communicating with the scientific community and the public regarding environmental risk and the uncertainties associated with assessments of environmental risk; and consistency across program offices in core assumptions and science policies, which are well grounded in science and reasonable. The following sections describe these four aspects of the risk characterization in more detail.

6.2. Integration of Hazard Characterization, Dose-Response Analysis, and Exposure Assessment

In developing the hazard characterization, dose-response analysis, and exposure portions of the risk assessment, the risk assessor should take into account many judgments concerning human relevance of the toxicity data, including the appropriateness of the various animal models for which data are available and the route, timing, and duration of exposure relative to expected human exposure. These judgments should be summarized at each stage of the risk assessment process (e.g., the biological relevance of anatomical variations may be established in the hazard characterization process, or the influence of species differences in metabolic patterns in the dose-response analysis). In integrating the information from the assessment, the risk assessor should determine if some of these judgments have implications for other portions of the assessment and whether the various components of the assessment are compatible.

The risk characterization should not only examine the judgments but also explain the constraints of available data and the state of knowledge about the phenomena studied in making them, including (1) the qualitative conclusions about the likelihood that the chemical may pose a specific hazard to human health, the nature of the observed effects, under what conditions (route, dose levels, time, and duration) of exposure these effects occur, and whether the health-related data are sufficient to use in a risk assessment; (2) a discussion of the dose-response characteristics of the critical effects, data such as the shapes and slopes of the dose-response curves for the various endpoints, the rationale behind the determination of the NOAEL and LOAEL and calculation of the benchmark dose, and the assumptions underlying the estimation of the RfD or RfC; and (3) the estimates of the magnitude of human exposure; the route, duration, and pattern of the exposure; relevant pharmacokinetics; and the number and characteristics of the population(s) exposed.

If data to be used in a risk characterization are from a route of exposure other than the expected human exposure, then pharmacokinetic data should be used, if available, to make extrapolations across routes of exposure. If such data are not available, the Agency makes certain assumptions concerning the amount of absorption likely or the applicability of the data from one route to another (U.S. EPA, 1992).

The level of confidence in the hazard characterization should be stated to the extent possible, including the appropriate category regarding sufficiency of the health-related data. A comprehensive risk assessment ideally includes information on a variety of endpoints that provide insight into the full spectrum of potential neurotoxicological responses. A profile that integrates both human and test species data and incorporates a broad range of potential adverse neurotoxic effects provides more confidence in a risk assessment for a given agent.

The ability to describe the nature of the potential human exposure is important in order to predict when certain outcomes can be anticipated and the likelihood of permanence or reversibility of the effect. An important part of this effort is a description of the nature of the exposed population and the potential for sensitive, highly susceptible, or highly exposed populations. For example, the consequences of exposure to the developing individual versus the adult can differ markedly and can influence whether the effects are transient or permanent. Other considerations relative to human exposures might include the likelihood of exposures to other agents, concurrent disease, and nutritional status.

The presentation of the integrated results of the assessment should draw from and highlight key points of the individual characterizations of component analyses performed under these Guidelines. The overall risk characterization represents the integration of these component characterizations. If relevant risk assessments on the agent or an analogous agent have been done by EPA or other Federal agencies, these should be described and the similarities and differences discussed.

6.3. Quality of the Database and Degree of Confidence in the Assessment

The risk characterization should summarize the kinds of data brought together in the analysis and the reasoning on which the assessment is based. The description should convey the major strengths and weaknesses of the assessment that arise from availability of data and the current limits of our understanding of the mechanisms of toxicity.

A health risk assessment is only as good as its component parts, i.e., hazard characterization, dose-response analysis, and exposure assessment. Confidence in the results of a risk assessment is thus a function of confidence in the results of the analysis of these elements. Each of these elements should have its own characterization as a part of the assessment. Within each characterization, the important uncertainties of the analysis and interpretation of data should be explained, and the risk manager should be given a clear picture of consensus or lack of consensus that exists about significant aspects of the assessment. Whenever more than one view is supported by the data and choosing between them is difficult, all views should be presented. If one has been selected over the others, the rationale should be given; if not, then all should be presented as plausible alternative results.

6.4. Descriptors of Neurotoxicity Risk

There are a number of ways to describe risks. Several relevant ways for neurotoxicity are as follows:

6.4.1. Estimation of the Number of Individuals

The RfD or RfC is taken to be a chronic exposure level at or below which no significant risk occurs. Therefore, presentation of the population in terms of those at or below the RfD or RfC (''not at risk'') and above the RfD or RfC (''may be at risk'') may be useful information for risk managers. This method is particularly useful to a risk manager considering possible actions to ameliorate risk for a population. If the number of persons in the at-risk category can be estimated, then the number of persons removed from the at-risk category after a contemplated action is taken can be used as an indication of the efficacy of the action.

6.4.2. Presentation of Specific Scenarios

Presenting specific scenarios in the form of ''what if?'' questions is particularly useful to give perspective to the risk manager, especially where criteria, tolerance limits, or media quality limits are being set. The question being asked in these cases is, at this proposed exposure limit, what would be the resulting risk for neurotoxicity above the RfD or RfC?

6.4.3. Risk Characterization for Highly Exposed Individuals

This measure is one example of the just-discussed descriptor. This measure describes the magnitude of concern at the upper end of the exposure distribution. This allows risk managers to evaluate whether certain individuals are at disproportionately high or unacceptably high risk.

The objective of looking at the upper end of the exposure distribution is to derive a realistic estimate of a relatively highly exposed individual or individuals. This measure could be addressed by identifying a specified upper percentile of exposure in the population and/or by estimating the exposure of the highest exposed individual(s). Whenever possible, it is important to express the number of individuals who comprise the selected highly exposed group and discuss the potential for exposure at still higher levels.

If population data are absent, it will often be possible to describe a scenario representing high-end exposures using upper percentile or judgment-based values for exposure variables. In these instances caution should be used in order not to compound a substantial number of high-end values for variables if a ''reasonable'' exposure estimate is to be achieved.

6.4.4. Risk Characterization for Highly Sensitive or Susceptible Individuals

This measure identifies populations sensitive or susceptible to the effect of concern. Sensitive or susceptible individuals are those within the exposed population at increased risk of expressing the toxic effect. All stages of nervous system maturation might be considered highly sensitive or susceptible, but certain subpopulations can sometimes be identified because of critical periods for exposure, for example, pregnant or lactating women, infants, or children. The aged population is considered to be at particular risk because of the limited ability of the nervous system to regenerate or compensate to neurotoxic insult.

In general, not enough is understood about the mechanisms of toxicity to identify sensitive subgroups for all agents, although factors such as nutrition (e.g., vitamin B), personal habits (e.g., smoking, alcohol consumption, illicit drug abuse), or preexisting disease (e.g., diabetes, neurological diseases, sexually transmitted diseases, polymorphisms for certain metabolic enzymes) may predispose some individuals to be more sensitive to the neurotoxic effects of specific agents. Gender-related differences in response to neurotoxicants have been noted, but these appear to be related to gender-dependent toxicodynamic or toxicokinetic factors.

In general, it is assumed that an uncertainty factor of 10 for intrapopulation variability will be able to accommodate differences in sensitivity among various subpopulations, including children and the elderly. However, in cases where it can be demonstrated that a factor of 10 does not afford adequate protection, another uncertainty factor may be considered in conducting the risk assessment.

6.4.5. Other Risk Descriptors

In risk characterization, dose-response information and the human exposure estimates may be combined either by comparing the RfD or RfC and the human exposure estimate or by calculating the margin of exposure (MOE). The MOE is the ratio of the NOAEL from the most appropriate or sensitive species to the estimated human exposure level. If a NOAEL is not available, a LOAEL may be used in calculating the MOE. Alternatively, a benchmark dose may be compared with the estimated human exposure level to obtain the MOE. Considerations for the evaluation of the MOE are similar to those for the uncertainty factor applied to the LOAEL/NOAEL or the benchmark dose. The MOE is presented along with a discussion of the adequacy of the database, including the nature and quality of the hazard and exposure data, the number of species affected, and the dose-response information.

The RfD or RfC comparison with the human exposure estimate and the calculation of the MOE are conceptually similar but are used in different regulatory situations. The choice of approach depends on several factors, including the statute involved, the situation being addressed, the database used, and the needs of the decision maker. The RfD or RfC and the MOE are considered along with other risk assessment and risk management issues in making risk management decisions, but the scientific issues that should be taken into account in establishing them have been addressed here.

If the MOE is equal to or more than the uncertainty factor multiplied by any modifying factor used as a basis for an RfD or RfC, then the need for regulatory concern is likely to be small. Although these methods of describing risk do not actually estimate risks per se, they give the risk manager some sense of how close the exposures are to levels of concern.

6.5. Communicating Results

Once the risk characterization is completed, the focus turns to communicating results to the risk manager. The risk manager uses the results of the risk characterization along with other technological, social, and economic considerations in reaching a regulatory decision. Because of the way in which these risk management factors may affect different cases, consistent but not necessarily identical risk management decisions should be made on a case-by-case basis. These Guidelines are not intended to give guidance on the nonscientific aspects of risk management decisions.

6.6. Summary and Research Needs

These Guidelines summarize the procedures that the U.S. Environmental Protection Agency would use in evaluating the potential for agents to cause neurotoxicity. These Guidelines discuss the general default assumptions that should be made in risk assessment for neurotoxicity because of gaps in our knowledge about underlying biological processes and how these compare across species. Research to improve the risk assessment process is needed in a number of areas. For example, research is needed to delineate the mechanisms of neurotoxicity and pathogenesis, provide comparative pharmacokinetic data, examine the validity of short-term in vivo and in vitro tests, elucidate the functional modalities that may be altered, develop improved animal models to examine the neurotoxic effects of exposure during the premating and early postmating periods and in neonates, further evaluate the relationship between maternal and developmental toxicity, provide insight into the concept of threshold, develop approaches for improved mathematical modeling of neurotoxic effects, improve animal models for examining the effects of agents given by various routes of exposure, determine the effects of recurrent exposures over prolonged periods of time, and address the synergistic or antagonistic effects of mixed exposures and neurotoxic response. Such research will aid in the evaluation and interpretation of data on neurotoxicity and should provide methods to assess risk more precisely. Additional research is needed to determine the most appropriate dose-response approach to be used in neurotoxicity risk assessments.

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Part B: Response to Science Advisory Board and Public Comments

1. Introduction

A notice of availability for public comments of these Guidelines was published in the **Federal Register** in October 1995. Twenty-five responses were received. These Guidelines were presented to the Environmental Health Committee of the Science Advisory Board (SAB) on July 18, 1996. The report of the SAB was provided to the Agency in April 1997. The SAB and public comments were diverse and represented varying perspectives. Many of the comments were favorable and expressed agreement with positions taken in the proposed Guidelines. Some comments addressed items that were more pertinent to testing guidance than risk assessment guidance or were otherwise beyond the scope of these Guidelines. Some of the comments concerned generic points that were not specific to neurotoxicity issues. Others

addressed topics that have not been developed sufficiently and should be viewed as research issues. There were conflicting views about the need to provide additional detailed guidance about decision making in the evaluation process as opposed to promoting extensive use of scientific judgment. Many public comments provided specific suggestions for clarification of details and corrections of factual material in the Guidelines.

2. Response to Science Advisory Board Comments

The SAB found the Guidelines ''* * * to be quite successful, and, all things considered, well suited to its intended task.'' However, recommendations were made to improve specific areas.

The SAB recommended that EPA keep hazard identification as an identifiable qualitative step in the risk assessment process and that steps should be taken to decouple the qualitative step of hazard identification from the more quantitatively rigorous steps of exposure evaluation and dose-response assessment. These Guidelines now include a hazard characterization step that clearly describes a qualitative evaluation of hazard within the context of the dose, route, timing and duration of exposure. This step is clearly differentiated from the quantitative dose-response analysis, which describes approaches for determining an RfD or RfC.

The SAB supported the presumption that what appears to be reversible neurotoxicity, especially when arising from gestational or neonatal exposure and observed before adulthood, should not be dismissed as of little practical consequence. They may be indices of silent toxicity that emerge later in life or may suggest more robust and enduring responses in aged individuals. These Guidelines explain the concept of functional reserve and advise caution in instances where reversibility is seen and in cases where exposure to a chemical may result in delayed-onset neurotoxicity. These Guidelines also indicate that reversibility may vary with the region of the nervous system damaged, the neurotoxic agent involved, and organismic factors such as age.

The SAB restated previous positions concerning cholinesterase-inhibiting chemicals. Agent-induced clinical signs of cholinergic dysfunction could be used to evaluate dose-response and dose-effect relationships and define the presence and absence of given effects in risk assessment. The SAB also indicated that inhibition of RBC and plasma cholinesterase activity could serve as a biomarker of exposure to cholinesterase-inhibiting agents and thereby corroborate observations concerning the presence of clinical effects associated with cholinesterase inhibition. The SAB also indicated that reduced brain cholinesterase activity should be assessed in the context of the biological consequences of the reduction. These Guidelines indicate that inhibition of cholinesterase in the nervous system reduces the organism's level of ''reserve'' cholinesterase and, therefore, limits the subsequent ability to respond successfully to additional exposures and that prolonged inhibition could lead to adverse functional changes associated with compensatory neurochemical mechanisms. In general, an attempt was made to coordinate these Guidelines with the views of a recently convened Scientific Advisory Panel regarding the risk assessment of cholinesterase-inhibiting pesticides (Office of Pesticide Programs, Science Policy on the Use of Cholinesterase Inhibition for Risk Assessments of Organophosphate and Carbamate Pesticides, 1997).

The SAB indicated that the Guidelines were inclusive of the major neurotoxicity endpoints of concern. No additional neurochemical, neurophysiological, or structural endpoints were suggested. Comments indicated that there was no need to consider endocrine disruptors differently from other potential neurotoxic agents.

The SAB found that the descriptions of the endpoints used in human and animal neurotoxicological assessments were thorough and well documented. Several sections, particularly concerning some of the neurochemical and neurobehavioral measures, were corrected for factual errors or supported with more detailed descriptions.

The SAB recommended that the use of the threshold assumption should occur after an evaluation of likely biological mechanisms and available data to provide evidence that linear responses would be expected. A strict threshold is not always clear in the human population because of the wide variation in background levels for some functions. Cumulative neurotoxicological effects might also alter the response of some individuals within a special population, which might allow the Agency to characterize the risk to the sensitive population. Although the SAB did not disagree with the Guidelines' assumption of a threshold as a default for neurotoxic effects, it was suggested that the term ''nonlinear dose-response curve for most neurotoxicants'' be substituted for the term ''threshold.'' The Neurotoxicity Risk Assessment Guidelines have been amended to harmonize their treatment of the issue of threshold with the presentation and position taken with other guidelines.

The SAB also recommended that the topic of susceptible populations be expanded to include the elderly and other groups. The elderly could be at increased risk of toxic effects for a number of reasons, including a decline in the reserve capacity with aging, changes in the ability to detoxify or excrete xenobiotics with age, and the potential to interact with medicines or other compounds that could synergize interactions with toxic chemicals. The SAB also indicated that other populations should be considered, including those with chronic and debilitating conditions, groups of workers with potential exposure to chemicals that may be neurotoxic, individuals with genetic polymorphisms that could affect responsiveness to certain neurotoxicants, and individuals that may experience differential exposure because of their proximity to chemicals in the environment or diet. The Guidelines have been modified to emphasize the possible presence of all of these susceptible populations. When specific information on differential risk is not available, the Agency will continue to apply a default uncertainty factor to account for potential differences in susceptibility.

The SAB recommended that the benchmark dose (BMD) was not ready for immediate incorporation into adjustment-factor-based safety assessment or to serve as a substitute or replacement for the more familiar NOAEL or LOAEL. The SAB also recommended that research and development on the BMD should be aggressively encouraged and actively supported. The BMD could be a replacement for the NOAEL or LOAEL after the appropriate research has been conducted.

3. Response to Public Comments

In addition to numerous supportive statements, several issues were indicated, although each issue was raised by only a few commentators. The public comment supported the SAB recommendation that there was no clear consensus concerning replacing the NOAEL approach with the BMD to calculate RfDs and RfCs for neurotoxicity endpoints. There was also support for ensuring that dose-response and other experimental design information be considered in interpreting the results of hazard identification studies before proceeding

to quantitative dose-response analysis. Public comment also supported the position that reversibility cannot be ignored in neurotoxicity risk assessment and that the risk assessor should exert caution in interpreting reversible effects, especially where an apparent transient effect is cited to support evidence for relatively benign effects. The public comment also supported the use of clinical signs in the risk assessment of cholinesterase-inhibiting compounds and the finding that inhibition of brain cholinesterase was an adverse effect. The Guidelines emphasize the importance of brain cholinesterase inhibition, particularly in cases of repeated exposure. The public comment agreed with the SAB that RBC and plasma cholinesterase activity are biomarkers of exposure. It was recommended that the Guidelines incorporate additional information addressing the neuroendocrine system as a potential target site, and a section has been added that defines the vulnerable components of the neuroendocrine system and the behavioral, hormonal, and physiological endpoints that may be indicative of a direct or indirect effect on the neuroendocrine system.

Public comment strongly endorsed the default assumption that there is a threshold for neurotoxic effects. The Guidelines, however, reflect the argument of the SAB that the term ''nonlinear dose-response curve for most neurotoxicants'' be substituted for ''threshold'' in order to be consistent with the presentation and positions taken by other risk assessment guidelines.

The public comments made a number of recommendations to improve the Guidelines with regard to consistency of language between text and tables, improve the clarity of some of the tables, and improve the description of some of the endpoints used in animal studies. A number of factual errors were corrected, including the description of the blood-brain barrier and the degree of inhibition of neurotoxic esterase associated with organophosphate-induced delayed-onset neuropathy. Therefore, a number of changes have been made in the Guidelines to clarify and correct specific passages, but every effort was made to maintain the original intent concerning the use and interpretation of results from various neurotoxicological endpoints. Finally, the public comment agreed with the SAB that factors such as nutrition, personal habits, age, or preexisting disease may predispose some individuals to be differentially sensitive to neurotoxic chemicals. The risk characterization section has been expanded to reflect these potentially sensitive subpopulations.

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H.J. Res. 102/P.L. 105–175

Expressing the sense of the Congress on the occasion of the 50th anniversary of the founding of the modern State of Israel and reaffirming the bonds of friendship and cooperation between the United States and Israel. (May 11, 1998; 112 Stat. 102)

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