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Title 3—

The President

Proclamation 7544 of April 19, 2002

National Organ and Tissue Donor Awareness Week, 2002

By the President of the United States of America

A Proclamation

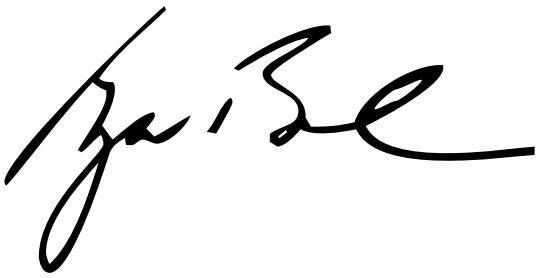
Our Nation's organ and tissue donor program is an important part of our healthcare system. Through the organ donor program, Americans can provide hope to those who face difficult and often life-threatening conditions caused by the failure of vital organs. The selfless generosity of organ and tissue donors helps meet a significant and growing need in our country.

Statistics show that approximately 60 Americans receive a transplant every day. However, at the same time, another 15 people die because not enough organs are available. There are more than 79,500 patients waiting for an organ transplant, and another person joins the waiting list every 13 minutes.

My Administration is committed to expanding the organ and tissue program to close this gap. Last year, Secretary of Health and Human Services (HHS) Tommy Thompson assumed leadership of this effort through the ''Gift of Life Donation Initiative.'' This Initiative involves collaboration among businesses and employees to make organ donation information more available. It also includes the development of a national forum on donor registries, a new model donor card, and increased cooperation between HHS, other Federal agencies, and State governments to promote donor awareness.

Every day, Americans across our Nation provide help for those in need in countless ways. During this week, we renew our efforts to foster this compassion and to help save lives by promoting organ and tissue donation.

NOW, THEREFORE, I, GEORGE W. BUSH, President of the United States of America, by virtue of the authority vested in me by the Constitution and laws of the United States, do hereby proclaim April 21 through April 27, 2002, as National Organ and Tissue Donor Awareness Week. I call upon all medical professionals, educators, volunteers, government agencies, and private organizations to join me in raising awareness of the need for organ donors in communities throughout our Nation. IN WITNESS WHEREOF, I have hereunto set my hand this nineteenth day of April, in the year of our Lord two thousand two, and of the Independence of the United States of America the two hundred and twenty-sixth.



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Presidential Documents

Title 3—

The President

Proclamation 7545 of April 19, 2002

National Volunteer Week, 2002

By the President of the United States of America

A Proclamation

Citizen service has always been a cornerstone of our democracy. Since our founding, Americans have stepped forward to serve the needs of others, strengthen our communities, and defend the freedoms we treasure.

Our country and the world continue to see the compassion, strength, and generosity of Americans in the aftermath of the attacks of September 11, 2001. Volunteers from across the Nation united to help meet the needs of those harmed by the tragic attacks, volunteering their time, their financial resources, and their kindness.

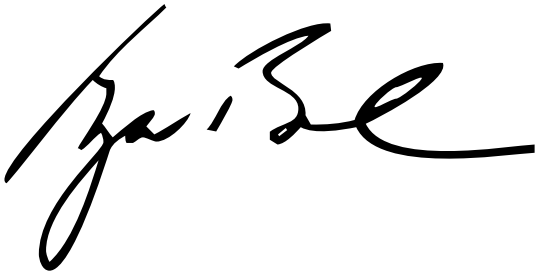
The spirit that guided our response to the attacks is still evident in Americans of every age group and background who volunteer their time to enhance the lives of others. These compassionate people work through a broad range of organizations that reflect the diversity of our country, including private charities, faith-based organizations, schools, neighborhood groups, volunteer centers, service clubs, and Federal service programs. The efforts of millions of Americans help solve some of our most pressing problems and build bonds of trust among people.

To tap further into our Nation's vast resources of compassion and strength, I recently created the USA Freedom Corps (USAFC). And I have called on all Americans to give at least 2 years—or 4,000 hours—during their lives in service to others. This service is essential to forging a united response to overcoming the challenges that face our Nation.

The USAFC will help unleash our armies of compassion, enhance homeland security, provide additional service and volunteer opportunities in our communities, and help people in America and around the world to meet important needs. Many Americans are already answering the call, volunteering a few hours each week or a few days each month to aid a local school, by mentoring or tutoring a child. Citizens are also donating their time to support a place of worship, to offer their expertise to a neighborhood association, or to strengthen a local service organization. Others are serving our country full time in the military or in programs such as AmeriCorps, Senior Corps, and the Peace Corps. I urge citizens to keep a record of their service experiences in a journal that will enable them to share them with their children and grand children, inspiring new generations to engage in community service.

The spirit exemplified by America's volunteers will help create a culture of responsibility and caring that will inspire us to achieve greatness as a Nation. During National Volunteer Week, I encourage all Americans to learn more about how they can serve, to volunteer to help those in need, and to encourage the volunteers across the country who are answering the call to service. Americans looking for a way to serve can contact the USA Freedom Corps web site at www.usafreedomcorps.gov or call, toll-free, 1-877-USA-CORPS (872-2677).

NOW, THEREFORE, I, GEORGE W. BUSH, President of the United States of America, by virtue of the authority vested in me by the Constitution and laws of the United States, do hereby proclaim April 21 through April 27, 2002, as National Volunteer Week. I call on all Americans to join together to celebrate the vital work that volunteers perform every day across our country. IN WITNESS WHEREOF, I have hereunto set my hand this nineteenth day of April, in the year of our Lord two thousand two, and of the Independence of the United States of America the two hundred and twenty-sixth.



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Rules and Regulations

Federal Register

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

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OFFICE OF PERSONNEL MANAGEMENT

5 CFR Part 532

RIN 3206–AJ60

Prevailing Rate Systems; Change in the Survey Cycle for the Portland, OR, Appropriated Fund Wage Area

AGENCY: Office of Personnel Management.

ACTION: Interim rule with request for comments.

SUMMARY: The Office of Personnel Management is issuing an interim rule to change the timing of local wage surveys in the Portland, Oregon, appropriated fund Federal Wage System (FWS) wage area. This change will help the Department of Defense better balance its FWS wage survey workload. DOD will conduct full-scale wage surveys in the Portland wage area in August of each even-numbered fiscal year beginning in August 2002.

EFFECTIVE DATE: This interim rule is effective on April 24, 2002. Comments must be received on or before May 24, 2002.

ADDRESSES: Send or deliver comments to Donald J. Winstead, Assistant Director for Compensation Administration, Workforce Compensation and Performance Service, Office of Personnel Management, Room 7H31, 1900 E Street NW., Washington, DC 20415–8200, or FAX: (202) 606–4264.

FOR FURTHER INFORMATION CONTACT: Chenty I. Carpenter at (202) 606–2838; by FAX at (202) 606–4264; or by e-mail at cicarpen@opm.gov.

SUPPLEMENTARY INFORMATION: The Department of Defense (DOD) requested that the Office of Personnel Management (OPM) change the timing of local wage surveys in the Portland, Oregon, appropriated fund Federal Wage System (FWS) wage area. Full-scale wage surveys currently begin in August of each odd-numbered fiscal year. Full-scale wage surveys will begin in the future in August of each even-numbered fiscal year. Under section 532.207 of title 5, Code of Federal Regulations, the scheduling of wage surveys takes into consideration the best timing in relation to wage adjustments in the principal local private enterprise establishments, a reasonable distribution of the workload of the lead agency, the timing of surveys for nearby wage areas, and scheduling relationships with other pay surveys.

DOD asked OPM to change the starting time for local wage surveys in the Portland, Oregon, wage area to August of even-numbered fiscal years to balance the overall workload of its survey office. DOD conducted a full scale survey in August of 2001 and will conduct another full-scale wage survey in Portland in August 2002.

The Federal Prevailing Rate Advisory Committee, the national labor-management committee responsible for advising OPM on matters concerning the pay of FWS employees, recommended by consensus that we change the full-scale survey cycle for the Portland wage area from August of each odd-numbered fiscal year to August of each even-numbered fiscal year.

Regulatory Flexibility Act

I certify that this regulation will not have a significant economic impact on a substantial number of small entities because it will affect only Federal agencies and employees.

List of Subjects in 5 CFR Part 532

Administrative practice and procedure, Freedom of information, Government employees, Reporting and recordkeeping requirements, Wages.

Office of Personnel Management.

Kay Coles James,

Director.

Accordingly, the Office of Personnel Management amends 5 CFR part 532 as follows:

PART 532—PREVAILING RATE SYSTEMS

1. The authority citation for part 532 continues to read as follows:

Authority: 5 U.S.C. 5343, 5346; § 532.707 also issued under 5 U.S.C. 552.

Appendix A to Subpart B of Part 532 [Amended]

2. Appendix A to subpart B of Part 532 is amended by revising ''odd'' to ''even'' under the heading Fiscal year of full-scale survey under the State of Oregon for the Portland appropriated fund wage area.

[FR Doc. 02–9958 Filed 4–23–02; 8:45 am]

BILLING CODE 6325–39–M

DEPARTMENT OF AGRICULTURE

Food Safety and Inspection Service

9 CFR Part 390

[Docket No. 99–029F]

RIN 0583–AC75

Sharing Recall Distribution Lists With State and Other Federal Government Agencies

AGENCY: Food Safety and Inspection Service, USDA.

ACTION: Final rule.

SUMMARY: The Food Safety and Inspection Service (FSIS) is adding regulations concerning sharing distribution lists from a firm that is recalling meat or poultry products with State and other Federal agencies. This rule will permit FSIS to share with officials of State governments and of other Federal agencies, distribution lists without being compelled to disclose the information to the public under the Freedom of Information Act (FOIA). This action is necessary for improved public health protection and will facilitate cooperation among regulatory agencies.

EFFECTIVE DATE: This rule is effective July 31, 2002.

FOR FURTHER INFORMATION CONTACT: Ralph Stafko, Senior Policy Manager, Federal, State and Local Government Relations Staff, OPPDE, FSIS, U.S. Department of Agriculture, Washington, DC 20250, (202) 418–8900. FSIS has drafted a Memorandum of Understanding (MOU) for use by FSIS and State agencies in implementing this rule. For information on the MOU, contact Ralph Stafko at the telephone number above.

SUPPLEMENTARY INFORMATION:

Background

Overview of Recalls of Meat and Poultry Products

FSIS is responsible for ensuring that meat and poultry products are safe, wholesome, and accurately labeled. FSIS enforces the Federal Meat Inspection Act (FMIA) and the Poultry Products Inspection Act (PPIA), which require Federal inspection and regulation of meat and poultry products prepared for distribution in commerce for use as human food. When there is reason to believe that meat or poultry products in commerce are adulterated or misbranded, FSIS will request that the firms that introduced the products into commerce recall them.

Recalls are voluntary actions taken by manufacturers or distributors in cooperation with Federal and State agencies. Although the product is marked ''inspected and passed,'' FSIS may determine, based on information that becomes available to the Agency after the product is shipped, that there is reason to believe that the product is not eligible to bear the mark of inspection.

FSIS does not have statutory authority to order recalls. Recall actions are initiated by a firm, either on its own initiative or at the request of FSIS. If a firm does not agree to initiate a recall, FSIS may detain or seize the product wherever it is located.

Sharing Recall Distribution Lists With State and Federal Agencies

This final rule delineates the circumstances in which FSIS will share the distribution lists of a firm involved in a recall with State and other Federal agencies. Distribution lists are records that show where and when the product was shipped. Sharing these lists will contribute to improved public health protection by allowing for more effective and timely verification that products are removed from commerce. It will also have the effect of enhancing cooperation and effective communication with other agencies.

Historically, FSIS' communications with State agencies had the same status as communication with any member of the public. Under the FOIA at 5 U.S.C. 552(a)(3)(A), any record of the Agency that is disclosed in an authorized manner to any member of the public is available for disclosure to all members of the public.

Thus, FSIS was unwilling to share distribution information with the States. Distribution information is confidential commercial information that is valuable to a firm and to its competitors. FSIS recognized that if it made the information regularly available to the public, firms would be unwilling to voluntarily share this information with the Agency. The Agency's ability to verify that recalls were proceeding effectively would be significantly hampered as a result, and the public health would consequently suffer.

Beginning in 1996, however, with the publication of the Pathogen Reduction; Hazard Analysis and Critical Control Point (HACCP) Systems final rule, FSIS has pointed out the need for a farm-to-table approach to food safety. The Agency has also pointed out that this approach needs to be supported by a seamless food safety system. As a result, FSIS has begun to work more and more closely with other Federal and State agencies. One type of situation in which FSIS has come to see cooperation as particularly important is that involving outbreaks of foodborne illness and the recall of meat and poultry products to protect the public health. To enhance cooperation with State and other Federal government agencies, FSIS needs the ability, in some circumstances, to disclose certain confidential commercial information to other agencies while still protecting the confidentiality of the information in all other respects.

Therefore, on September 19, 2000 (65 FR 56503), FSIS proposed to amend 9 CFR part 390 by adding a new section that would enable FSIS to share with State agencies and other Federal agencies certain confidential commercial information, specifically, distribution lists from the firm recalling a meat or poultry product, which are protected from mandatory public disclosure by exemption 4 of the FOIA (5 U.S.C. 552(b)(4)).

FSIS modeled its proposed rule, in part, on two Food and Drug Administration (FDA) regulations, 21 CFR 20.85 and 20.88, which permit FDA to disclose certain nonpublic information to State governments and other Federal officials without requiring FDA to make the information or documents available to the public.

In response to the proposed rule, FSIS received 18 comments. After carefully analyzing the comments, FSIS has decided to adopt the proposed rule.

Under 9 CFR 390.9, the Administrator or his/her designee may share distribution lists that have been obtained by FSIS with State and other Federal government agencies as part of a cooperative effort between agencies, in accordance with the following conditions.

The State government officials will provide a written statement establishing their authority to protect distribution lists from public disclosure and a written commitment not to disclose such information without the submitter's written permission or written confirmation from FSIS that the information is no longer confidential.

Officials of other Federal agencies will need to provide a similar written commitment not to disclose the information and must refer any request for distribution lists to FSIS for response.

FSIS intends that the disclosure of information to other agencies will be for the purpose of recalls of meat and poultry products. The regulatory text of this rule limits the sharing of information to recalls.

Under this final rule, 9 CFR 390.9 also provides that these government officials are not members of the public for purposes of disclosure of distribution lists submitted to FSIS, and that such disclosures will not invoke the requirements in 9 CFR part 390 for uniform access to records. Disclosure of distribution lists to government agencies as specified in this rule will be an authorized disclosure.

This rule will do nothing to diminish public access to Agency records. The purpose of this rule is not to reduce the number or types of records that will be available to the public from FSIS but to enhance the Agency's ability to engage in information exchanges with Federal and State agencies.

This regulation also is related to a Memorandum of Understanding (MOU) between FSIS and the Food and Drug Administration (FDA) signed in February 1999, which was intended to facilitate sharing of information. This MOU has been limited in effect by FSIS' inability to provide proprietary information on recalls to FDA. This regulation will remedy this limitation.

Comments and Responses

As stated above, FSIS received eighteen comments on the proposed rule from trade and professional associations, consumer advocacy groups, a State Department of Health, and a Federal government agency. The regulatory text of this final rule incorporates changes made in response to these comments.

General Comments

Most of the commenters expressed general support for sharing distribution lists with State and other Federal government agencies without being compelled to disclose the information to the public under the FOIA. Many of

these commenters, however, did recommend revisions of specific provisions in the rule. One commenter generally opposed the proposed rule.

FSIS responses to all of the relevant comments follow.

Comment: Most of the commenters stated that FSIS should specify what ''confidential commercial information'' and ''proprietary information'' may be shared with State and Federal agencies.

Response: FSIS agrees with the comment. The Agency's intent in the proposed rule was to share certain confidential commercial information, i.e., distribution lists, from firms with Federal and State agencies. Distribution lists are records of where and when product was shipped from the firm recalling the product. Distribution lists also include lists from the establishment's secondary and tertiary distributors. Therefore, FSIS has modified the final regulation and the phrases ''confidential commercial information'' and ''proprietary information'' have been removed wherever they appear and replaced with the term ''distribution lists.''

Comment: Several commenters asserted that sharing recall information should be permitted only when there is a Class I recall. Class I recalls involve a health hazard situation where there is a reasonable probability that the use of the product will cause serious, adverse health consequences or death.

Response: FSIS disagrees with this comment. A Class II recall involves a remote chance of an adverse health consequence but still involves a potential health hazard. Therefore, in the interest of public health protection, distribution lists should, and will, be shared in the event of a Class II recall.

However, because § 390.9(a)(2) requires that the disclosure be in the interest of public health, FSIS will not share information in Class III recall instances, where the use of a product will not cause adverse health consequences.

Comment: Most commenters urged that information be limited to those other Federal or State agencies that are responsible for enforcing food safety statutes and that can assist FSIS in verifying the removal of products.

Response: FSIS agrees with the comment. This rule specifically addresses food recall activities. The Agency has modified the rule to state that distribution lists will be distributed to agencies that are involved in food safety to assist FSIS in recall verification activities.

Comment: Numerous commenters said that confidential commercial information should not be released to any State that does not have a confidentiality statute that protects the state from releasing confidential commercial information to the public.

The commenters went on to say that, even though FSIS will only disclose confidential commercial information provided that the State government officials give a written statement to establish their authority to protect the information from public disclosure, it is only acceptable if the State has protective laws in place that disallow sharing such information with the public.

Related comments asked that FSIS enter into Memorandums of Understanding (MOUs) or cooperative agreements with State and Federal agencies with whom FSIS plans to share information. The comments said that these agreements would ensure that the receiving agency understands exactly which information must be kept confidential, and that the agency agrees to do so.

Response: FSIS agrees. As the proposed rule stated, State and Federal government agencies must provide a written statement establishing their authority to protect confidential commercial information from public disclosure.

FSIS intends to enter into MOUs, cooperative agreements, or other appropriate documents with State and other Federal agencies that are interested in receiving distribution lists, on the condition that FSIS expects that the agencies report back to FSIS the results of the use of the distribution list information.

Comment: Several commenters requested that when FSIS receives a request for confidential commercial information belonging to a firm, that the Agency notify the firm immediately, as provided by 7 CFR 1.11.

Response: FSIS will, of course, comply with existing Departmental regulatory requirements and will notify the firm that provided the information to FSIS.

Comment: Some commenters requested that FSIS make even more clear in the preamble to the final rule just what the consequences or penalties will be should a State or Federal employee who had been the recipient of shared confidential commercial information accidentally or purposefully release this information without authorization.

Response: The penalty for an unauthorized disclosure is that FSIS will not share information with the agency involved and will cancel the MOU or agreement with it. Also, a firm can pursue its legal remedies in the case of unauthorized disclosures of its distribution lists.

Comment: Two commenters said that as written, proposed section 390.9(a)(1) appears to be misworded and suggested revised wording. The proposed section 390.9(a)(1) stated ''Federal government agencies must provide a written commitment not to disclose the information, but to refer the confidential commercial information to FSIS in order for FSIS to respond to the request for information.''

Response: FSIS agrees that the section appears to be misworded and has revised § 390.9(a)(1) to be more clear. The sentence will read as follows:

> Federal government agencies must provide a written commitment not to disclose the information and to refer any request for distribution lists to FSIS for response.

Comment: One commenter questioned the meaning and effect of the review under Executive Order 12988, Civil Justice Reform, as it states that ''This rule: (1) Preempts State and local laws and regulations that are inconsistent with this rule.'' The commenter wanted to know if the proposed rule preempts sunshine or open records laws which many states have and which give the public a right of access to governmental records.

Response: This final rule has no preemptive effect. Therefore, agencies must follow the edicts of their State law. A State agency in a State with such a law would not be able to enter into an MOU with FSIS that would violate such a law.

Comment: A commenter stated that FSIS should address its concerns about whether information released as a result of this rule could hurt the marketing ability of small establishments, by raising the danger of disclosure of confidential sales lists to competing establishments and businesses.

Response: These concerns are not warranted. This rule has been developed to protect the confidentiality of such information.

FSIS has built mechanisms into the regulation to protect information by requiring written commitments not to disclose information and written assurances that the State agencies and other Federal agencies that receive the information have the means and the intent to protect the confidentiality of the information. FSIS has every confidence that they will do so.

Comment: One commenter stated that FSIS should work with each State government to develop a list of authorities that should receive information, e.g., the State's health department and State agencies that run

State-operated institutions (prisons, schools, hospitals, etc.).

Response: FSIS disagrees. With the MOU, it is unnecessary to specify the agencies. However, the only agencies that need the list are those that assist FSIS in recall effectiveness checks. State agencies understand the sensitivity of the information. State schools, hospitals, or prisons, while they may need to know of the recall, have no need for the distribution lists. Schools, prisons, hospitals, as well as any other recipients of recalled product, are notified directly by the recalling firm.

General Opposition

Comment: One commenter generally opposed the proposed rule for two key reasons:

1. The proposed rule would substantially weaken Freedom of Information (FOIA) protections relating to certain types of confidential information by authorizing FSIS to share this information with State government agencies; and

2. The proposed rule does not clearly identify the scope of information that may be shared, or the circumstances under which information may be shared.

Response: FSIS stated in the proposal that it would share confidential commercial information with other government entities in conjunction with a recall. This broad statement satisfied any legal notice requirement. However, in the final rule, FSIS is specifying the information it intends to disclose. As mentioned previously, FSIS will share distribution lists with Federal and State agencies and has modified this final regulation to reflect this clarification.

FSIS disagrees that this rule would weaken Freedom of Information (FOIA) protections relating to confidential information by authorizing FSIS to share this information with States. FSIS will maintain the confidentiality of distribution lists and will only share this information with agencies that agree to partner with FSIS to effectively determine recalled product removal.

Further, FSIS has required that safeguards be in place in any State with which the information is to be shared, so that the confidentiality of the information can, and will, be protected. The Agency will deny a request for distribution lists if the government officials are unable to assure FSIS of their ability and willingness to protect the information.

Compliance With Executive Order 12866 and the Regulatory Flexibility Act of 1996

This rule has been determined to be not significant for the purposes of Executive Order 12866 and, therefore, has not been reviewed by the Office of Management and Budget.

The Administrator, FSIS, has determined that this action will not have a significant economic impact on a substantial number of small entities as defined by the Regulatory Flexibility Act (5 U.S.C. 601) because this rule promotes cooperation between FSIS and other Federal and State agencies.

Economic Impact

Impacts/Net Benefits Associated with this Action

This action is new. No significant changes in recall activities are expected as a result of this action.

1. Net benefits are likely to include increased public health protection.

2. Net benefits are likely also to include enhanced communications and cooperation between FSIS and State and other Federal agencies.

Expected Benefits

During a meat or poultry recall, FSIS will be able to share distribution lists with State agencies and other Federal agencies without having to disclose this information to the general public or media under the Freedom of Information Act. Doing so will help FSIS to verify that adulterated, unhealthful products are removed from consumer channels quickly and efficiently and to protect the public health.

Because of this rule, the sharing of recall information will help all the government agencies to work cooperatively to enhance public health and provide consumer protection from foodborne illnesses. The State agencies will provide a written agreement not to disclose such information without the submitter's written permission or written confirmation from FSIS. Federal agencies must agree not to release the information but to refer any request for the information to FSIS for response to the requestor. This will ensure that the other government agencies do not inadvertently share this information with the public. Increased consumer protection and public health and efficiency in government will be the basic benefits of this rule.

Expected Costs

There are minimal costs associated with sharing recall information with State and other Federal agencies. Costs will consist of the labor it takes to draft and agree to Memorandum of Understandings, and the labor it takes for FSIS to share the information with these agencies. These costs are already absorbed by the labor cost of these officials.

There are no costs to industry.

Expected Effects on Small Entities

No disproportionate significant economic impact will be experienced by small entities. FSIS will share with State and other Federal government officials confidential and proprietary information (distribution lists) of both large and small entities, if the recall warrants it.

Additional Public Notification

Public awareness of all segments of rulemaking and policy development is important. Consequently, in an effort to better ensure that minorities, women, and persons with disabilities are aware of this rule, FSIS will announce it and provide copies of this **Federal Register** publication in the FSIS Constituent Update. FSIS provides a weekly FSIS Constituent Update, which is communicated via fax to over 300 organizations and individuals. In addition, the update is available on line through the FSIS web page located at *http://www.fsis.usda.gov.* The update is used to provide information regarding FSIS policies, procedures, regulations, **Federal Register** notices, FSIS public meetings, recalls, and any other types of information that could affect or would be of interest to our constituents/stakeholders. The constituent fax list consists of industry, trade, and farm groups, consumer interest groups, allied health professionals, scientific professionals, and other individuals that have requested to be included. Through these various channels, FSIS is able to provide information to a much broader, more diverse audience. For more information and to be added to the constituent fax list, fax your request to the Congressional and Public Affairs Office, at (202) 720–5704.

Executive Order 12898

Pursuant to Executive Order 12898 (59 FR 7629, February 16, 1994), ''Federal Actions to Address Environmental Justice in Minority Populations and Low-Income Populations,'' FSIS has considered potential impacts of this rule on environmental and health conditions in low-income and minority communities.

Sharing recall information with other agencies will benefit FSIS, the regulated industry, and consumers. Thus, this regulation does not adversely affect the

public health or environment in low-income and minority communities.

Executive Order 12988

This rule has been reviewed under Executive Order 12988, Civil Justice Reform. This rule: (1) Will not preempt State and local laws and regulations that are inconsistent with this rule; (2) has no retroactive effect; and (3) does not require administrative proceedings before parties may file suit in court challenging this rule. However, the administrative procedures specified in 9 CFR 390.7 must be exhausted prior to any judicial challenge of the application of the provisions of this rule, if the challenge involves any decision of an FSIS employee relating to a denial of access of information.

Paperwork Requirements

There are no paperwork or recordkeeping requirements associated with this rule under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3520).

List of Subjects in 9 CFR Part 390

Confidential business information, Freedom of information, Government employees.

For the reasons set forth in the preamble, 9 CFR part 390 is amended to read as follows:

1. The heading of 9 CFR part 390 is revised to read as follows:

PART 390—FREEDOM OF INFORMATION AND PUBLIC INFORMATION

2. The authority citation for part 390 continues to read as follows:

Authority: 5 U.S.C. 301, 552; 7 CFR 1.3, 2.7.

3. Section 390.9 is added to read as follows:

§ 390.9 Communications with State and other Federal government agencies.

(a) The Administrator of the Food Safety and Inspection Service (FSIS), or designee, may authorize the disclosure of distribution lists (records that show where and when product was shipped) obtained from a firm recalling products, or incorporated into agency-prepared records, to State and other Federal government agencies to verify the removal of the recalled product, provided that:

(1) The State agency has provided both a written statement establishing its authority to protect confidential distribution lists from public disclosure and a written commitment not to disclose any information provided by FSIS, without the written permission of the submitter of the information or written confirmation by FSIS that the information no longer has confidential status. Federal government agencies must provide a written commitment not to disclose the information and to refer any request for distribution lists to FSIS for response; and

(2) The Administrator of FSIS or designee determines that disclosure would be in the interest of public health.

(b) This provision does not authorize the disclosure to State or other Federal government agencies of trade secret information, unless otherwise provided by law or pursuant to an express written authorization provided by the submitter of the information.

(c) Information disclosed under this section is not a disclosure of information to the public. Disclosures made under this section do not waive any FOIA exemption protection.

Done in Washington, DC, on: April 15, 2002.

Margaret O'K. Glavin,

Acting Administrator.

[FR Doc. 02–9840 Filed 4–23–02; 8:45 am]

BILLING CODE 3410–DM–P

NATIONAL CREDIT UNION ADMINISTRATION

12 CFR Part 701

Organization and Operations of Federal Credit Unions

AGENCY: National Credit Union Administration (NCUA).

ACTION: Final rule.

SUMMARY: The NCUA Board is amending its chartering and field of membership manual to make four changes to ease regulatory burden. First, applicants need not submit documentation to establish a community area that is the same as one the NCUA has previously determined to be a well-defined local community, neighborhood or rural district. Second, the Board is deleting the category of common characteristics and background of residents from the examples of acceptable documentation because this category has proven to generate documentation of limited relevance. Third, an existing community charter need not document in writing how it plans on serving the entire community. Fourth, the Board is updating the definition of an investment area because of the release of new census data and updated Community Development Financial Institution Fund standards.

EFFECTIVE DATE: May 24, 2002.

ADDRESSES: National Credit Union Administration, 1775 Duke Street, Alexandria, Virginia 22314–3428.

FOR FURTHER INFORMATION CONTACT: Michael J. McKenna, Chairman, Field of Membership Task Force, 1775 Duke Street, Alexandria, Virginia 22314 or telephone (703) 518–6540 or Regina Metz, Staff Attorney, Office of General Counsel, 1775 Duke Street, Alexandria, Virginia 22314 or telephone (703) 518–6540 or Lynn Markgraf, Program Officer, Office of Examination and Insurance, 1775 Duke Street, Alexandria, Virginia 22314 or telephone (703) 518–6396.

SUPPLEMENTARY INFORMATION:

Background

NCUA's chartering and field of membership policy is set out in Interpretive Ruling and Policy Statement 99–1, Chartering and Field of Membership Policy (IRPS 99–1), as amended by IRPS 00–01. The policy is incorporated by reference in NCUA's regulations at 12 CFR 701.1. It is also published as NCUA's Chartering and Field of Membership Manual (Chartering Manual), which is the document most interested parties use and to which references in the following discussion are made.

In 2001, the NCUA Board issued two interim final rules on chartering and field of membership. In this document the Board is finalizing both rules as IRPS 02–2. Each rule and each amendment is discussed separately below.

March Interim Final Rule

On March 8, 2001, the NCUA Board issued IRPS 01–1, an interim final rule with a sixty-day comment period, amending the Chartering Manual. 66 FR 15619 (March 20, 2001). The comment period ended on May 21, 2001. Nine comments were received. Comments were received from two Federal credit unions, four state credit union leagues, one national credit union trade association and two bank trade associations. Almost all of the commenters supported both of the interim final rule's field of membership changes. Most of these commenters believe these amendments will reduce documentation requirements and save Federal credit unions time and funds in converting to a community charter.

1. Previously Established Communities

The Chartering Manual requires community charter applicants to establish that an area is a ''well-defined local community, neighborhood, or rural district.'' Chartering Manual, Chapter 2, V.A.1. It provides that an applicant may submit

a letter describing how the area meets the standards for interaction or common interest for certain geographic and population sizes, namely, a single political jurisdiction such as a county with 300,000 or fewer people, or multiple, contiguous political jurisdictions with 200,000 or fewer people. Applicants must submit maps and information about the area's population and political jurisdiction.

For larger areas in terms of population and geographic size, the Chartering Manual provides for applicants to submit a narrative summary and documentation supporting the finding of interaction and common interests in the proposed community. The Chartering Manual provides examples of the type of documentation that an applicant may submit but does not require or specify particular documentation.

In the interim final rule, the NCUA Board stated that applicants need not submit documentation to establish a community area that is the same as one the NCUA has previously determined to be a well-defined local community, neighborhood or rural district. Eight commenters fully supported this amendment. One commenter did not understand the amendment. The Board believes this amendment provides a common sense approach for documentation requirements by eliminating redundant proof by subsequent applicants for the same geographic area that either it or a regional director has already addressed. Therefore, the NCUA Board is adopting this interim final amendment without change.

Applicants need only identify in their applications the fact of the prior approval and their reliance on the summary and documentation already part of the agency's records. The community area must be identical to a previously approved application. No variance is allowed. Nevertheless, applicants may be required to submit their own summary and documents if the agency has reason to believe that the documents on file from previous applications are no longer accurate or are insufficient.

Two commenters stated that this policy should be revisited periodically since the community aspect of a geographic area may change over time. One commenter suggested five years and another suggested ten years. Another commenter asked that the agency provide further guidance on when the agency might require applicants to submit their own summary and other documents if the agency has reason to believe the documents on file from previous applicants are no longer accurate or are insufficient. Basically, the agency will require more information if there has been a significant and quantifiable change in a community's characteristics. The NCUA Board believes that communities may change over time and will revisit the time frame for action when necessary.

One commenter requested that NCUA consider permitting a credit union converting to a community charter to add new members from their groups that are located outside the community boundaries. This comment is unrelated to the interim final rule but the NCUA Board has decided to continue its current policy on groups outside the community.

2. Documentation Requirements

The Chartering Manual provides examples of documentation that applicants may consider using to support the area as a community, neighborhood, or rural district. One of these examples was: ''common characteristics and background of residents (for example, income, religious beliefs, primary ethnic groups, similarity of occupations, household types, primary age, group, etc.).'' *Id.* at 2–46. This documentation has proven to be of limited relevance in determining whether the area meets the community requirements. Therefore, in the interim final rule the Board deleted the category of common characteristics and background of residents from the examples of acceptable documentation because it has proven to generate documentation of limited relevance. Eight commenters approved of this amendment, although one commenter believes this type of information can be useful in showing interaction or common interests. For the reasons stated above, the Board is adopting this amendment in final.

These two final amendments will help reduce the time involved in the community application process, reduce costs for credit unions seeking to serve a previously approved community, and reduce regional and Board staff time and preparation.

The Board wants to note that these amendments only apply to required documentation to support the proposed area as a community. They do not eliminate any of the remaining requirements necessary to process a community application, such as addressing safety and soundness concerns and the requirement for business and marketing plans.

December Interim Final Rule

On December 13, 2001, the NCUA Board issued an interim final rule with a sixty-day comment period amending the Chartering Manual. 66 FR 65625 (December 20, 2001). The comment period ended on February 19, 2002.

Although the Board actually received 494 comment letters or e-mail messages, NCUA staff has credited multiple comment letters from the same credit union or the same source as one comment, for a total of 428 comments. Comments were received from 260 Federal credit unions, 120 state chartered credit unions, 4 national credit union trade associations, 23 state credit union leagues, 2 bank trade associations, 2 community groups, 1 financial group and 16 members or otherwise unidentified persons.

1. The Provision Commonly Referred to as the Community Action Plan (CAP)

In October 2000, the NCUA Board required an existing community charter to address, in either its marketing or business plan or other appropriate separate documentation, how it plans on serving the entire community, including how the credit union will market to the community and what products and services the credit union will offer to assist underserved members in the communities. Some in the credit union community refer to this as the ''community action plan'' requirement or as ''CAP'', though the final rule did not use that term. The NCUA Board stated in the preamble to the final rule that ''existing credit unions will have until December 31, 2001, to have a plan in place addressing how the credit union will serve the entire community.'' 65 FR 64512, 64518 (October 27, 2000). The Board implemented this rule even while recognizing that there was no tangible evidence that credit unions were not planning on serving their entire community. In fact, the NCUA Board stated that, based ''on the comments of community credit unions and the submissions some of them provided, many community credit unions already have adopted plans and offer products and services designed to serve the entire community.'' 65 FR 64512, 64517 (October 27, 2000).

The NCUA Board issued an interim final rule on December 13, 2001, eliminating this regulatory requirement, known as CAP. Four hundred and fifteen commenters supported the elimination of the regulatory requirement. Most of the commenters applauded the Board's decision to repeal this unnecessary regulatory burden because they believe it is

something credit unions are already doing. The commenters who supported the Board's action primarily made the following points: (1) Credit unions do not need a regulation requiring them to serve their members; (2) credit unions are serving low-income people by adding underserved areas to their fields of membership; (3) community charters naturally serve their entire communities; (4) Congress specifically rejected similar requirements in the Credit Union Membership Access Act; (5) there is no evidence that community credit unions are not serving their entire fields of membership adequately; (6) the rule is not directly related to safety and soundness; (7) the rule was costly and burdensome to implement; (8) the rule was similar to Community Reinvestment Act requirements.

Many commenters discussed how credit unions reach out and serve low-income members. Many commenters stated that ''continued improvements in NCUA's membership application process are more appropriate than a CAP rule and will do more to ensure all individuals, including disadvantaged groups, are eligible for credit union service.'' The Board believes this comment addresses the fact that the agency has streamlined its SEG approval process and underserved area approval process. The Board will continue to study methods to streamline the field of membership process.

Twelve commenters opposed the repeal of CAP and requested that it be reinstated. One additional commenter, a credit union, was not sure of its position on this issue. The primary contentions of commenters opposing the repeal of CAP were that CAP is good for credit unions and its burden is minimal. They believe CAP is a simple requirement to help ensure that credit unions serve their entire communities. A few commenters objected to the process of using an interim final rule to repeal CAP. A few commenters did not understand the rule and believe that, under CAP, a credit union would make its written plan available to the public.

In general, the Board agrees with the commenters who supported the repeal of CAP. Therefore, the Board is adopting this amendment as a final rule because the Board continues to believe that it is an unreasonable practice to require only certain credit unions to adopt specific written policies addressing service to the entire community, without any evidence these credit unions are failing to serve their entire communities. In addition, this regulatory requirement addresses few, if any, safety and soundness concerns.

This Board believes that a regulation that does not address a substantiated safety and soundness concern or a potential problem is unnecessary. In this case, the Board believes it is prudent to eliminate this regulatory requirement because there is no evidence that community charters are not marketing their services to their entire communities.

2. Underserved Areas

The addition of underserved areas, as defined in Chapter 3 of the Chartering Manual, to the field of membership of operating credit unions is a continuing priority of the NCUA Board. A Federal credit union seeking to add to its field of membership an underserved area first must meet a three-prong test. First, the area must be a local community. Second, the area must also be classified as an investment area as defined in section 103(16) of the Community Development Banking and Financial Institutions Act of 1994, 12 U.S.C. 4703(16). Third, the credit union adding the underserved area must establish and maintain an office or facility in the area, or have a preexisting office within close proximity.

In October 2000, the NCUA Board made it less burdensome for federal credit unions to add underserved areas. 65 FR 64512 (October 27, 2000). Because of these changes and the credit union community's greater interest, the number of underserved areas added to Federal credit union's field of membership increased from 50 in the year 2000 to 281 in 2001.

The Chartering Manual provides examples of an ''investment area'' for the purpose of adding an underserved area. The Federal Credit Union Act defines an ''underserved area'' as a ''local community, neighborhood, or rural district'' that is an ''investment area'' as defined in Section 103(16) of the Community Development Banking and Financial Institutions Act of 1994. The 1994 law permits the Community Development Financial Institutions Fund of the United States Department of the Treasury (CDFI Fund) to further define investment areas. In the interim final rule, the Board updated the definition of an investment area in chapter three of the Chartering Manual by incorporating 2000 census data and the CDFI Fund's updated definition of an investment area.

Fifty-nine commenters generally favored NCUA's underserved area policies. Twelve additional commenters specifically favored updating the definition of an investment area. Most of these commenters believe this amendment will promote greater participation in serving underserved areas. Two commenters opposed the amendment. Both of these commenters appeared to misunderstand the statutory authority of NCUA to allow credit unions to serve underserved areas.

The NCUA Board is adopting the interim final rule in final with a minor modification. This final rule makes the Chartering Manual consistent with 2000 census data and the CDFI Fund's modifications. If the 2000 census data is not readily available for a particular category, the latest information from the Census Bureau may be used. In addition, the Board is permitting credit unions to submit other government data to demonstrate that an area is an investment area if this information is more readily available than census data. This alternative data must be issued after the year 2000. This one additional change along with the original amendments will ultimately make it easier for credit unions to add underserved areas and thus serve more members of modest means.

Regulatory Procedures

Regulatory Flexibility Act

The Regulatory Flexibility Act requires NCUA to prepare an analysis to describe any significant economic impact a regulation may have on a substantial number of small credit unions (those under one million dollars in assets). These final amendments will not have a significant economic impact on a substantial number of small credit unions and, therefore, a regulatory flexibility analysis is not required.

Paperwork Reduction Act

The NCUA Board has determined that this interim final rule does not increase, and will in fact reduce, paperwork requirements under the Paperwork Reduction Act and regulations of the Office of Management and Budget.

Small Business Regulatory Enforcement Fairness Act

The Small Business Regulatory Enforcement Fairness Act of 1996 (Public Law 104–121) provides generally for congressional review of agency rules. A reporting requirement is triggered in instances where NCUA issues a final rule as defined by Section 551 of the Administrative Procedures Act. 5 U.S.C. 551. The Office of Management and Budget has determined that the provisions contained in IRPS 02–1 do not constitute a major rule.

Executive Order 13132

Executive Order 13132 encourages independent regulatory agencies to

consider the impact of their regulatory actions on state and local interests. In adherence to fundamental federalism principles, NCUA, an independent regulatory agency as defined in 44 U.S.C. 3502(5), voluntarily complies with the executive order. This rule does not apply to state-chartered credit unions and will not have substantial direct effect on the states, on the relationship between the national government and the states, or on the distribution of power and responsibilities among the various levels of government. NCUA has determined that this final rule does not constitute a policy that has federalism implications for purposes of the executive order.

List of Subjects in 12 CFR Part 701

Credit, Credit unions, Reporting and recordkeeping requirements.

By the National Credit Union Administration Board on April 18, 2002.

Becky Baker,

Secretary of the Board.

Accordingly, NCUA amends 12 CFR part 701 as follows:

PART 701—ORGANIZATION AND OPERATION OF FEDERAL CREDIT UNIONS

1. The authority citation for part 701 continues to read as follows:

Authority: 12 U.S.C. 1752(5), 1755, 1756, 1757, 1759, 1761a, 1761b, 1766, 1767, 1782, 1784, 1787, 1789. Section 701.6 is also authorized by 15 U.S.C. 3717. Section 701.31 is also authorized by 15 U.S.C. 1601 et seq.; 42 U.S.C. 1981 and 3601–3610. Section 701.35 is also authorized by 42 U.S.C. 4311–4312.

2. Section 701.1 is revised to read as follows:

§ 701.1 Federal credit union chartering, field of membership modifications, and conversions.

National Credit Union Administration policies concerning chartering, field of membership modifications, and conversions are set forth in Interpretive Ruling and Policy Statement 99–1, Chartering and Field of Membership Policy (IRPS 99–1), as amended by IRPS 00–1 and IRPS 02–2. Copies may be obtained by contacting NCUA at the address found in § 792.2(g)(1) of this chapter. The combined IRPS are incorporated into this section.

(Approved by the Office of Management and Budget under control number 3133–0015.)

Note: The text of the Interpretive Ruling and Policy Statement (IRPS 99–1) does not, and the following amendments will not, appear in the Code of Federal Regulations.

3. In IRPS 99–1, Chapter 2, Section V.A.2 is revised to read as follows:

In addition to the documentation requirements set forth in Chapter 1 to charter a credit union, a community credit union applicant must provide additional documentation addressing the proposed area to be served and community service policies.

A community credit union is unique in that it must meet the statutory requirements that the proposed community area is (1) well-defined, and (2) a local community, neighborhood, or rural district.

''Well-defined'' means the proposed area has specific geographic boundaries. Geographic boundaries may include a city, township, county (or its political equivalent), or clearly identifiable neighborhood. Although congressional districts or other political boundaries which are subject to occasional change, and state boundaries are well-defined areas, they do not meet the second requirement that the proposed area be a local community, neighborhood, or rural district.

The meaning of local community, neighborhood, or rural district includes a variety of factors. Most prominent is the requirement that the residents of the proposed community area interact or have common interests. In determining interaction and/or common interests, a number of factors become relevant. For example, the existence of a single major trade area, shared governmental or civic facilities, or area newspaper is significant evidence of community interaction and/or common interests. Conversely, numerous trade areas, multiple taxing authorities, and multiple political jurisdictions, tend to diminish the characteristics of a local area.

Population and geographic size are also significant factors in determining whether the area is local in nature. A large population in a small geographic area or a small population in a large geographic area may meet NCUA community chartering requirements. For example, an ethnic neighborhood, a rural area, a city, and a county with 300,000 or less residents will generally have sufficient interaction and/or common interests to meet community charter requirements. While this may most often be true, it does not preclude community charters consisting of multiple counties or local areas with populations of any size from meeting community charter requirements.

Conversely, a larger population in a large geographic area may not meet NCUA community chartering requirements. It is more difficult for a major metropolitan city, a densely populated county, or an area covering multiple counties with significant population to have sufficient interaction and/or common interests, and to therefore demonstrate that these areas meet the requirement of being ''local.'' In such cases, documentation supporting the interaction and/or common interests will be greater than the evidence necessary for a smaller and less densely populated area.

In most cases, the ''well-defined local community, neighborhood, or rural district'' requirement will be met if (1) the area to be served is in a recognized single political jurisdiction, i.e., a county or its political equivalent or any contiguous political subdivisions contained therein, and if the population of the requested well-defined area does not exceed 300,000, or (2) the area to be served is in multiple contiguous political jurisdictions, i.e. a county or its political equivalent or any political subdivisions contained therein and if the population of the requested well-defined area does not exceed 200,000. If the proposed area meets either of these criteria, the credit union must only submit a letter describing how the area meets the standards for community interaction or common interests.

If NCUA does not find sufficient evidence of community interaction or common interests, more detailed documentation will be necessary to support that the proposed area is a well-defined community. The credit union must also provide evidence of the political jurisdiction(s) and population. Evidence of the political jurisdiction(s) should include maps designating the area to be served. One map must be a regional or state map with the proposed community outlined. The other map must outline the proposed community and the identifying geographic characteristics of the surrounding areas.

If the area to be served does not meet the political jurisdiction(s) and population requirements of the preceding paragraph, or if required by NCUA, the application must include documentation to support that it is a well-defined local community, neighborhood, or rural district. It is the applicant's responsibility to demonstrate the relevance of the documentation provided in support of the application. This must be provided in a narrative summary. The narrative summary must explain how the documentation demonstrates interaction or common interests. For example, simply listing newspapers and organizations in the area is not sufficient to demonstrate that the area is a local community, neighborhood, or rural district.

Examples of acceptable documentation may include:

- The defined political jurisdictions;
- Major trade areas (shopping patterns and traffic flows);
- Shared/common facilities (for example, educational, medical, police and fire protection, school district, water, etc.);
- Organizations and clubs within the community area;
- Newspapers or other periodicals published for and about the area;
- Maps designating the area to be served. One map must be a regional or state map with the proposed community outlined. The other map must outline the proposed community and the identifying geographic characteristics of the surrounding areas;
- Other documentation that demonstrates that the area is a community where individuals have common interests or interact.

An applicant need not submit a narrative summary or documentation to support a proposed community charter, amendment or conversion as a well-defined local community, neighborhood, or rural district if the NCUA has previously determined that the same exact geographic area meets that requirement in connection with consideration of a prior application. Applicants may contact the appropriate regional office to find out if the area they are interested in has already been determined to meet the community requirements. If the area is the same as a previously approved area, an applicant need only include a statement to that effect in the application. Applicants may be required to submit their own summary and documentation regarding the community requirements if NCUA has reason to believe that prior submissions are not sufficient or are no longer accurate.

A community credit union is frequently more susceptible to competition from other local financial institutions and generally does not have substantial support from any single sponsoring company or association. As a result, a community credit union will often encounter financial and operational factors that differ from an occupational or associational charter. Its diverse membership may require special marketing programs targeted to different segments of the community. For example, the lack of payroll deduction creates special challenges in the development of savings promotional programs and in the collection of loans.

Accordingly, it is essential for the proposed community credit union to develop a detailed and practical business and marketing plan to serve the entire community for at least the first two years of operation. The proposed credit union must not only address the documentation requirements set forth in Chapter 1, but also focus on the accomplishment of the unique financial and operational factors of a community charter.

Community credit unions will be expected to regularly review and to follow, to the fullest extent economically possible, the marketing and business plan submitted with their application.

4. In IRPS 99–1, Chapter 3, Section III is revised to read as follows:

All federal credit unions may include in their fields of membership, without regard to location, communities satisfying the definition for serving underserved areas in the Federal Credit Union Act. More than one federal credit union can serve the same underserved area. The Federal Credit Union Act defines an underserved area as a local community, neighborhood, or rural district that is an ''investment area'' as defined in Section 103(16) of the Community Development Banking and Financial Institutions Act of 1994.

The ''well-defined local community, neighborhood, or rural district'' requirement will be met if (1) the area to be served is in a recognized single political jurisdiction, i.e., a county or its political equivalent or any contiguous political subdivisions contained therein, and if the population of the requested well-defined area does not exceed 300,000 or (2) the area to be served is in multiple contiguous political jurisdictions, i.e., a county or its political equivalent or any political subdivisions contained therein and if the population of the requested well-defined area does not exceed 200,000. If the proposed area meets either of these criteria and meets the definition of an investment area that is underserved, then it is presumed to be a local community, neighborhood, or rural district.

An investment area includes any of the following (as reported in the most recently completed decennial census or equivalent government data):

- An area encompassed or located in an Empowerment Zone or Enterprise Community designated under section 1391 of the Internal Revenue Code of 1996 (26 U.S.C. 1391);
- An area where the percentage of the population living in poverty is at least 20 percent;
- An area in a Metropolitan Area where the median family income is at or below 80 percent of the Metropolitan Area median family income or the national Metropolitan Area median family income, whichever is greater;
- An area outside of a Metropolitan Area, where the median family income is at or below 80 percent of the statewide non-Metropolitan Area median family income or the national non-Metropolitan Area median family income, whichever is greater;
- An area where the unemployment rate is at least 1.5 times the national average;
- An area where the percentage of occupied distressed housing (as indicated by lack of complete plumbing and occupancy of more than one person per room) is at least 20 percent;
- An area located outside of a Metropolitan Area with a county population loss between the most recent decennial census and the previous decennial census of at least 10 percent;
- An area located outside of a Metropolitan Area with a county net migration loss (out-migration minus in-migration) over the five-year period preceding the most recent decennial census of at least 5 percent;
- An area meeting the criteria for economic distress that may be established by the Community Development Financial Institutions Fund (CDFI) of the United States Department of the Treasury.

In addition, the local community, neighborhood, or rural district must be underserved, based on data considered by the NCUA Board and the Federal banking agencies.

Once an underserved area has been added to a federal credit union's field of membership, the credit union must establish and maintain an office or facility in the community within two years. A service facility is defined as a place where shares are accepted for members' accounts, loan applications are accepted and loans are disbursed. This definition includes a credit union owned branch, a shared branch, a mobile branch, an office operated on a regularly scheduled weekly basis, or a credit union owned electronic facility that meets, at a minimum, these requirements. This definition does not include an ATM.

If a credit union has a preexisting office within close proximity to the underserved area, then it will not be required to maintain an office or facility within the underserved area. Close proximity will be determined on a case-by-case basis, but the office must be readily accessible to the residents and the distance from the underserved area will not be an impediment to a majority of the residents to transact credit union business.

The federal credit union adding the underserved community must document that the community meets the definition for serving underserved areas in the Federal Credit Union Act. The charter type of a federal credit union adding such a community will not change and therefore the credit union will not be able to receive the benefits afforded to low-income designated credit unions, such as expanded use of non member deposits and access to the Community Development Revolving Loan Program for Credit Unions.

A federal credit union that desires to include an underserved community in its field of membership must first develop a business plan specifying how it will serve the community. The business plan, at a minimum, must identify the credit and depository needs of the community and detail how the credit union plans to serve those needs. The credit union will be expected to regularly review the business plan, to determine if the community is being adequately served. The regional director may require periodic service status reports from a credit union about the underserved area to ensure that the needs of the underserved area are being met as well as requiring such reports before NCUA allows a federal credit union to add an additional underserved area.

[FR Doc. 02–9971 Filed 4–23–02; 8:45 am]

BILLING CODE 7535–01–U

SOCIAL SECURITY ADMINISTRATION

20 CFR Part 404

[Regulations No. 4 and 16]

RIN 0960–AE99

Technical Revisions to Medical Criteria for Determinations of Disability

AGENCY: Social Security Administration (SSA).

ACTION: Final rules.

SUMMARY: These final rules make a number of technical revisions to the Listing of Impairments (the listings). We use the listings when you claim benefits based on disability under titles II and XVI of the Social Security Act (the Act). We are making these revisions to reflect advances in medical knowledge, treatment and terminology, to clarify certain criteria in the listings, to remove listings that we rarely use, and to add new listings consistent with current medical practice. We are making these individual technical revisions in order to improve our medical listings and make them easier to understand and use.

DATES: These final regulations are effective May 24, 2002.

FOR FURTHER INFORMATION CONTACT: Carolyn Kiefer, Social Insurance Specialist, Office of Disability, Social Security Administration, 3–B–9 Operations Building, 6401 Security Boulevard, Baltimore, Maryland 21235–6401, (410) 965–9104 or TTY 1–800–966–5609 for information about these rules. For information on eligibility, filing for benefits, or coverage of earnings, call our national toll-free number, 1–800–772–1213 or TTY (410) 966–5609, or visit our Internet web site, Social Security Online, at *http://www.sss.gov.*

SUPPLEMENTARY INFORMATION: We are revising and making final the rules we proposed in the Notice of Proposed Rulemaking (NPRM) published in the **Federal Register** on February 11, 2000 (65 FR 6932).

Background

Under title II of the Act, we provide for the payment of disability benefits if you are disabled and belong to one of the following three groups:

- Workers insured under the Act;
- Children of insured workers; and
- Widows, widowers, and surviving divorced spouses (see 20 CFR 404.336) of insured workers.

Under title XVI of the Act, we provide for Supplemental Security Income (SSI) payments on the basis of disability if you have limited income and resources.

Under both title II and title XVI programs, disability must be the result of any medically determinable physical or mental impairment or combination of impairments that can be expected to result in death or that has lasted or can be expected to last for a continuous period of at least 12 months.

Our definitions of disability are shown in the following table:

If you file a claim under * * *	And you are * * *	Disability means you have a medically determinable impairment(s) that meets the statutory duration requirement and results in * * *
Title II	An adult or a child	The inability to do any substantial gainful activity (SGA).
Title XVI	An adult	The inability to do any SGA.
Title XVI	A child	Marked and severe functional limitations.

We use a sequential evaluation process, set out in §§ 404.1520 and 416.920 of our regulations, when we evaluate a claim for disability benefits if you are an adult. We use a separate sequential evaluation process described in § 416.924 of our regulations if you are a child claiming SSI payments based on disability. At step three of both sequential evaluation processes, we determine whether you have an impairment(s) that meets or medically equals the listings. If you are a child applying for SSI payments based on disability, we also determine if your impairment(s) functionally equals the listings.

The listings describe, for each of the major body systems, impairments that we consider severe enough to prevent you from doing any gainful activity. In the case of a child applying for SSI payments based on disability, the listings describe impairments that we consider severe enough to result in marked and severe functional limitations.

The listings are divided into Part A and Part B. We apply the medical criteria in Part A when we assess your claim if you are an adult (i.e., a person age 18 or over). If you are a child, we first use the criteria in Part B. If the criteria in Part B do not apply, and the specific disease process(es) has a similar effect on adults and children, we then use the criteria in Part A (see §§ 404.1525, 404.1526, 416.925, and 416.926).

The changes we are making in these final rules are not intended to be a comprehensive update and revision of the listings. We continue to review each of the body system listings to determine appropriate substantive revisions and updates. If we determine that more substantive revisions are necessary, we will publish notices of proposed rulemaking in the **Federal Register** describing those proposed revisions and requesting public comments.

Explanation of Revisions

We are revising language throughout the listings to incorporate imaging techniques other than x-rays alone. This revised language was incorporated in the following listing sections: 2.00B2; 5.03; 5.04; 5.05; 6.02(C)(1); 7.16; and 9.03. This is being done by adding language allowing for ''appropriate medically acceptable imaging'' to be used when imaging evidence is called for as part of the medical documentation. Since x-rays are incorporated in the phrase ''appropriate medically acceptable imaging,'' we have removed the specific mention of ''x-rays'' when we refer to appropriate medically acceptable imaging throughout the listings addressed in this rulemaking.

We made a revision to our proposed rulemaking language in the prefaces of the listings for the body systems affected by this change. We added language to explain that appropriate medically acceptable imaging includes, but is not limited to, x-ray imaging, computerized axial tomography (CAT scan) or magnetic resonance imaging (MRI), with or without contrast material, myelography, and radionuclear bone scans. To further clarify what we mean by ''appropriate,'' we added a sentence to these prefaces that states ''Appropriate means that the technique used is the proper one to support the evaluation and diagnosis of the impairment.''

We made a number of revisions to the listings for the Special Senses and Speech body systems, 2.00 and 102.00. We substituted the heading ''Disorders of Vision'' in 2.00A for ''Ophthalmology'' to make clear that these listings deal with visual disorders, rather than the branch of medicine dealing with the anatomy, physiology, and pathology of the eye. We also removed the word ''central'' when referring to visual acuity in the preface sections 2.00A1, 2.00A2, 2.00A5, 2.00A6, 102.00A, listings 2.02 and 102.02, and in Table No. 1, because the word is redundant. It is the loss of visual acuity in itself (be it central or peripheral) that results in the inability to distinguish detail, and thereby prevents reading and fine work. We further clarify this in a revision to section 2.00A2 which states that ''Loss of visual acuity may result in impaired distant vision or near vision, or both.'' We also clarified listing 2.04 by replacing the phrase ''central visual efficiency'' with the phrase ''visual acuity efficiency.'' We removed listing 2.05, *Complete homonymous hemianopsia,* as a separate listing since it merely directs evaluation to listing 2.04, which we are not substantively changing. Listing 2.04 will permit evaluation of this disorder.

We also removed the word ''organic'' in section 2.00B3 and in listing 2.09 because the cause of the loss of speech is not material to its evaluation under this body system. We also clarified listing 2.09 to make it clear that the inability to produce by any means speech that can be heard, understood, or sustained is sufficient to meet this listing; all three of these factors do not need to be present to meet the listing.

For the respiratory system listings for adults and children, 3.00 and 103.00, we changed some of the technical testing requirements to be simpler and to be consistent with standard laboratory practices. If the spirogram is generated by any means other than direct pen linkage to a mechanical displacement-type spirometer, we will no longer require separate calibration tracings to be performed at the time each pulmonary function test is performed. Rather, a single daily calibration of the testing device will suffice. For direct pen linkage spirometry equipment, the tracing is directly generated and inherently accurate so that no mechanically generated calibrations are required. We also revised listing section 3.00F so that we no longer require that the algorithm used to calculate the test for diffusing capacity of the lungs for carbon monoxide be provided as part of the documentation for this test. Rather, the source of the predicted equation should be provided. This information is sufficient to verify that the test was performed adequately.

We added a new listing for both adults and children to cover lung transplants, listings 3.11 and 103.05, respectively. These listings provide that we will consider an individual to be disabled for 12 months following the date of surgery. After that time, we will evaluate any residual impairment.

In order to correct a possible misinterpretation in our intent, we revised listing sections 4.00A and 104.00A. We now state that we will ''consider'' (rather than ''make'') a medical equivalence finding for an adult, and a medical or functional equivalence finding for a child seeking SSI payments, in situations where the individual has either a medically determinable impairment that is not listed, or has a combination of impairments, no one of which meets a listing. We have always intended that we consider whether the impairment or combination of impairments medically equals a listing (or, as appropriate, medically or functionally equals a listing). The use of the word ''make'' may have given the erroneous impression that we would automatically find medical equivalence in all cases where the impairment(s) was severe but did not meet the exact requirements of a listing.

For the digestive body systems listings for adults and children, 5.00 and 105.00, we added new listings to address liver transplantation, listings 5.09 and 105.09, respectively. Under these listings, we will consider the individual to be disabled for 12 months following the date of the liver transplant surgery. After that period, we will evaluate any residual impairment.

For the hemic and lymphatic body system listings, for adults and children, we added T-cell lymphoblastic lymphoma to listings 7.11 and 107.11, respectively. These listings currently address acute leukemia only. We also included a discussion of T-cell lymphoblastic lymphoma in the sections 7.00E and 107.00C of the preface to the listings. Because T-cell lymphoblastic lymphoma follows the same course and requires the same treatment as acute leukemia, we believe it will simplify adjudication by naming this particular lymphoma in the listings. We also added stem cell transplantation as a new medical technique comparable to bone marrow transplantation in listing 7.17.

In the skin body system listing, we corrected a spelling error in listing 8.06.

In the endocrine body system listing for adults, we removed paragraph A of listing 9.02. This listing, which addresses progressive exophthalmos as measured by exophthalmometry, is a rare complication in light of today's medical treatments for thyroid disease.

In the neurological body system listings for adults and children, 11.00 and 111.00, we made a number of changes to reflect current medical terminology (convulsive and nonconvulsive epilepsy), and to modify the documentation requirement for an electroencephalogram (EEG). With the exception of nonconvulsive epilepsy in children, we will no longer require that an EEG be part of the documentation needed to support the presence of epilepsy. An EEG is a definitive diagnostic tool in cases of nonconvulsive epilepsy in children, but it is rare for an EEG to confirm epilepsy in its other forms for either adults or children. In listings 11.02 and 11.03, we changed the terminology to reflect convulsive and nonconvulsive epilepsy, and we made comparable changes to the childhood epilepsy listings. We also changed references to ''anticonvulsive''

treatment to ''antiepileptic'' treatment and ''antiepileptic'' drugs. These changes are consistent with current medical usage.

We changed listing 111.02B3 to refer to a ''Significant mental disorder'' for consistency with other listing terminology, for example, that of listings 111.07B3 and 4, and to clarify that we require a defined mental impairment in order to fulfill this listing criteria for convulsive epilepsy.

We eliminated current listing 11.15 for tabes dorsalis because this disease is rarely seen today, given the availability of effective medical screening and treatment for syphilis. With this deletion, we also amended listing 11.17 by removing the reference to listing 11.15B currently in listing 11.17A. The current reference to listing 11.04B contained in listing 11.17 adequately addresses the disorganization of motor function that is needed to evaluate the effects of these degenerative diseases on an individual's gait.

In the neoplastic diseases body system listings for adults, 13.00, we amended listing 13.08 to add the criterion, ''Anaplastic (undifferentiated) carcinoma of the thyroid,'' and designated it as listing 13.08A. This is a distinct type of thyroid carcinoma with a poor prognosis, and it is of the same level of severity as the current thyroid listing. By identifying this type of carcinoma specifically, we believe we will simplify adjudication for these types of cases.

For clarity, we refer to the changes we are making here as the ''final'' rules and to the rules that will be changed by these final rules as the ''current'' rules. However, these final rules do not go into effect until 30 days after the date of this publication. Therefore, the ''current'' rules will still be in effect until that date.

Public Comments

On February 11, 2000, we published a notice of proposed rulemaking (NPRM) in the **Federal Register** (65 FR 6929) proposing to make a number of technical revisions to our listings. We gave interested persons 60 days within which to submit written comments on the proposed rules; the comment period closed on April 11, 2000. We received 90 comments from the public. Most of the comments came from disabled individuals. Other comments came from State agencies that make disability determinations for us, advocacy organizations, and professional organizations whose members have interests and responsibilities that require them to have some expertise in the evaluation of disability claims.

Several commenters simply expressed agreement with the proposed changes, believed that they would be beneficial, and stated that the language was improved so that it was easier to understand. Along this line, some of these commenters specifically supported our proposal to update the language in our listings concerning imaging techniques to include other appropriate medically acceptable imaging techniques in addition to x-rays. These commenters believed this was an improvement that would be beneficial for both claimants and adjudicators.

A few commenters, however, stated that the proposed revisions to the listings were difficult to read and understand. These commenters recommended that the listings be written to be understandable to lay people, rather than to doctors. Since the listings summarize required medical signs, laboratory findings, and symptoms, we often find it necessary to retain appropriate medical terms and language in the listings. To the extent possible, we write our regulations in plain language. We intend to incorporate as much plain language as possible as we review and revise each individual body system listing, and we wrote these proposed revisions as simply as possible within the context of the listing being revised.

The following are summaries of comments that directly related to the proposed rules, or related to areas that were discussed in the proposed rules, along with our responses. Because some of the comments were lengthy, we have condensed, summarized and paraphrased them. We have tried, however, to summarize the commenters' views accurately, and to respond to all of the significant issues raised by the commenters that were within the scope of these rules. Many of the comments, however, pertained to matters that were not within the scope of these proposed rules. We referred those comments to the appropriate components of the Social Security Administration and do not address them in this preamble.

Musculoskeletal Body System

Comment: Two commenters requested that we make additional changes to the listings on the evaluation of osteomyelitis (listings 1.08 and 101.08). One commenter recommended that we include the spinal manifestations of the disorder in the listings. The other commenter suggested that we clarify the reference to a ''major joint of an upper or lower extremity'' in listing 1.08, since osteomyelitis involves bones, not joints. The first commenter also expressed concern that chronic osteomyelitis was not listed because she knew of situations in which treatment did not eliminate the infection.

Response: We have not adopted these comments. We have not included any technical revisions to the musculoskeletal body system listings in these final rules. On November 19, 2001, we published final rules in the **Federal Register** revising the medical criteria we use for evaluating musculoskeletal impairments in adults and children. In those final rules, we noted that we removed listings 1.08 and 101.08, osteomyelitis or septic arthitis, because fundamental advances in antibiotic therapy has meant that, when they do occur, these conditions are not usually expected to last for one year. Therefore, we will evaluate claims involving these impairments on a case-by-case basis to determine whether they medically equal (or, as appropriate, functionally equal) the listings (66 FR 58010).

Comment: One commenter suggested that we make an additional change to listing 1.11, fracture of the femur, tibia, tarsal bone, or pelvis, to include the non-union of the distal fibula.

Response: This listing, which is now listing 1.06 as a result of the final rules that we published on November 19, 2001, addresses the major bones of the lower extremities that are usually involved in weight bearing. While we did not specifically include reference to situations involving non-union of the distal fibula, a case of this type that fulfilled the overall severity requirements of listing 1.06 could be found to medically equal this listing.

Special Senses and Speech

Comment: One commenter recommended that we make changes to listing 2.09 in addition to the ones we proposed. This commenter first suggested that we clarify the term ''sustained'' in listing 2.09. This commenter also expressed concern that, if the term ''organic'' was deleted from listing 2.09, the rules should also clarify whether all known means to produce speech must have been tried and failed. Finally, the commenter recommended that we include language from the preamble to the NPRM in the final rules, either in listing 2.09 or in the introductory section of the listing, section 2.00B3. The commenter stated that we should include in the regulatory text the statement that, ''We believe that any one of these factors is sufficient to establish that an individual has a listing-level impairment.''

Response: We have not adopted these comments. Revised listing 2.09 makes

clear that the inability to produce speech linked to any of the three factors (can be heard, can be understood, or can be sustained) will satisfy the requirements of the listing. We do not believe that adding the sentence from the preamble to the proposed rules, as the commenter suggested, clarifies the rule any further. The other issues raised by this commenter will require more extensive revisions to the special senses and speech listings than were intended under this rulemaking proceeding. We will consider more detailed clarifications as part of our review of the special senses and speech body system listings.

Comment: Some commenters expressed concern about the changes we proposed to listing section 2.00, on the evaluation of vision disorders. One commenter recommended that section 2.00A1 not be revised to remove the word ''central'' when referring to vision and visual acuity because the terms ''central vision'' and ''visual acuity'' are not medically synonymous. The commenter noted that it is possible to have a small island of usable vision in the center of a dense central field loss. This could result in measurable but unusable central visual acuity. This could potentially occur in cases involving impairments such as macular degeneration, diabetic retinopathy, end-stage glaucoma, end-stage retinitis pigmentosa, and ischemic vision loss. The commenter also stated that the term ''peripheral fields'' was unclear. The second commenter, an ophthalmologist, expressed similar concerns. He commented that we were not using accurate terminology when we proposed to use the terms ''visual acuity'' and ''peripheral fields.''

Response: We have not adopted these comments. While we understand the commenters' concerns, our use of the terms we proposed in this section of the preface is consistent with common definitions which satisfy our needs for purposes of disability adjudication. We agree that vision physiologists might prefer to use more sophisticated terminology in accordance with their professional needs to discern complex distinctions. However, for purposes of disability adjudication, our use of the terms ''visual acuity'' and ''peripheral fields'' are familiar and defined concepts. We believe, based on our program experience, that they adequately satisfy our needs in evaluating disability claims of individuals with visual impairments. However, we will consider these comments when we review and revise the special senses and speech body system listings.

Comment: One commenter recommended that we continue to use the term ''Ophthalmology'' instead of our proposed revision, ''Disorders of Vision,'' for the heading of listing section 2.00A. Similarly, another commenter thought we should use the term ''Visual Impairment'' rather than ''Disorders of Vision.'' This commenter stated that this was consistent with terminology used by schools and most rehabilitation facilities.

Response: We have not adopted these comments. As we noted above, we believe our use of more common terminology is suitable for our purposes. We also believe that changing our heading of listing section 2.00A to ''Disorders of Vision'' is appropriate to convey our identification of the material in this section of the listings.

Comment: One commenter stated that we should revise our measurement assessment tools for the peripheral field and for central visual function, and eliminate the use of the Goldmann perimeter and the Snellen visual acuity tests. Another commenter agreed that we should revise our rules on the use of the Goldmann perimeter in light of our emphasis on changes in the listings to reflect advances in medical knowledge.

Response: We have not adopted these comments. These comments raise issues that are outside the scope of this rulemaking proceeding. We will consider the concerns the commenters expressed as we consider more substantive revisions to the special senses and speech body system listings.

Digestive System

Comment: One commenter suggested that we include other diagnostic techniques, such as a CAT scan or ultrasound, as acceptable confirmation of liver disease, in addition to a liver biopsy, under listing 5.05F.

Response: We have not adopted this comment because it is beyond the scope of this rulemaking proceeding. We will, however, consider the comment as part of our comprehensive review of the digestive system listings.

Neurological

Comment: One commenter recommended that we revise the preface to the listing to reflect the deletion of listing 11.15, for tabes dorsalis.

Response: We have not adopted this comment. Listing 11.15 is not discussed in the preface to the current neurological listings, and we see no need to add a discussion regarding its deletion. Tabes dorsalis is rarely seen in modern medicine. If we had to evaluate this condition, it would be appropriate to consider whether the condition medically equaled other neurological listings. For example, sensory deficits associated with tabes dorsalis could be evaluated under listing 11.04A, or visual limitations associated with this condition could be evaluated using listing 11.09B.

Comment: One commenter, from an advocacy organization on behalf of individuals with epilepsy, commended the proposed change of wording to use ''antiepileptic'' in place of ''anticonvulsant.'' Another commenter, however, stated that the change would limit the listing, because convulsive disorders other than epilepsy would no longer fall under this listing section. The first commenter also supported the elimination of the requirement for an electroencephalogram (EEG) in all diagnoses of epilepsy. However, this commenter also expressed concern that we did not change some other outdated terminology contained in the epilepsy listings, and recommended that we make additional changes to the listings.

Response: We agree with the commenter about the need to make additional revisions to the listings for epilepsy in order to further update them. We are in the process of reviewing and revising the neurological body system listings and expect to issue proposed rules as part of that revision. We expect that any future revisions will address the commenter's concerns. Because the changes the commmenter suggested are more detailed and substantive, we do not believe that these suggested changes are within the scope of this rulemaking proceeding. In regard to the concern that these proposed changes would limit the usefulness of the seizure listings, the primary disorder being addressed here is in fact epilepsy. Other convulsive disorders or similarly disruptive disorders can still be evaluated under these epilepsy listings by using medical equivalence, as has been done in the past with such disorders as narcolepsy and pseudoseizures.

Comment: One commenter stated that we should use the terms ''partial'' seizures and ''generalized'' seizures in the listings, rather than ''convulsive epilepsy'' (listing 11.02) and ''nonconvulsive epilepsy'' (listing 11.03).

Response: As noted above, we are currently reviewing the entire neurological body system to identify further appropriate revisions. As part of this process, we anticipate some restructuring of listings using broader impairment categories, as well as additional changes in the listings dealing with epilepsy and terminology related to epilepsy. We will consider the

commenter's recommendations during the review of the entire neurological body system listings.

Comment: One commenter expressed concern that we were removing myasthenia gravis from the listings as a listed impairment.

Response: We did not propose removing this impairment as a listed impairment in our regulations. Myasthenia gravis is evaluated under listing 11.12.

Comment: One commenter questioned when we would recognize post-polio syndrome as a disabling impairment, since the neuromuscular effects result in additional functional loss and are usually permanent and slowly progressive.

Response: The late effects of polio, also referred to as post-polio syndrome or sequelae, are recognized as a potentially disabling impairment and are evaluated under our current listing 11.11, Anterior poliomyelitis. Under listing 11.11, we evaluate your overall motor function. If the impairment is not found to meet or equal a listed impairment, we consider the impact of the impairment and any related symptoms in determining your residual functional capacity and we proceed to evaluate your impairment under our sequential evaluation procedures in accordance with § 404.1545.

Mental

Comment: One commenter recommended that we use the definition of mental retardation (MR) found in the Diagnostic and Statistical Manual of Mental Disorders (4th ed. 1994) (DSM–IV), published by the American Psychiatric Association, as the definition of MR in listing 12.05 and 112.05.

Response: We did not adopt the comment. The definition of MR we use in our listings is consistent with, if not identical to, the definitions of MR used by the leading professional organizations. The four major professional organizations in the United States that deal with MR have each established their own definition of MR. While all the definitions require significant deficits in intellectual functioning, as evidenced by IQ scores of approximately 70 or below, age of onset and the method of measuring the required deficits in adaptive functioning differ among the organizations.

For example, the definition of MR used in the DSM–IV is predominantly based on (but not identical to) the revised definition of MR promulgated by the American Association on Mental Retardation (AAMR) in 1993. The DSM–IV states: ''The essential feature of mental retardation is significantly subaverage general intellectual functioning (further defined as an IQ standard score of approximately 70 or below), that is accompanied by significant limitations in at least two of the following skill areas: communication, self-care, home living, social/interpersonal skills, use of community resources, self-direction, functional academic skills, work, leisure, health, and safety. The onset must occur before age 18 years.''

Following publication of this new definition of MR by the AAMR, the American Psychological Association published its own ''Manual of Diagnosis and Professional Practice in Mental Retardation, 1996.'' It states: ''Mental retardation refers to (a) significant limitations in general intellectual functioning; (b) significant limitations in adaptive functioning, which exist concurrently; and (c) onset of intellectual and adaptive limitations before the age of 22 years.'' In its definition, (a) is defined as ''* * * an IQ or comparable normed score that is two or more standard deviations below the population mean for the measure;'' and for (b), ''* * * the criterion of significance is a summary index score that is two or more standard deviations below the mean * * *.''

The definition of MR used by SSA in the listings is not restricted to diagnostic uses alone, nor does it seek to endorse the methodology of one professional organization over another. While capturing the essence of the definitions used by the professional organizations, it also is used to determine eligibility for disability benefits. SSA's definition establishes the necessary elements, while allowing use of any of the measurement methods recognized and endorsed by the professional organizations.

Neoplastic Diseases—Malignant

Comment: One commenter requested that we add ''undifferentiated'' carcinoma of the thyroid to the listing 13.08. The commenter noted that this would be the same as the proposed anaplastic carcinoma of the thyroid, but the inclusion of both terms would better clarify the rules.

Response: We have adopted this comment and have made the change in listing 13.08.

General

Comment: A professional organization representing disability adjudicators at the state level generally agreed with the proposed revisions. However, the comments expressed concern about the proposed deletion of listing 2.05 for complete homonymous hemianopsia and listing 11.15 for tabes dorsalis, and the removal of the reference in listing 9.02 to ''progressive exophthalmos as measured by exophthalmometry.'' The commenter agreed that these conditions were rarely seen, but remained concerned that their removal may lead to these conditions being overlooked. The commenter recommended that any revisions to these listings be done as we revise individual body system listings.

Response: We have not adopted these comments. We believe it is appropriate to delete listings 2.05 and 11.15 and to remove the reference to progressive exophthalmos in listing 9.02 as part of these final rules. All of these conditions are extremely rare and are amenable to treatment, given modern medical practices. The listings are intended to identify commonly occurring and frequently seen impairments that are considered severe enough to preclude any gainful activity in adults (or that result in ''marked and severe functional limitations'' in children). We do not believe there is any benefit in waiting to delete these listings until we revise the specific body system listings.

Comment: A number of commenters requested that other specific impairments be included in the listings. The commenters suggested that we add a number of impairments that are not now included in the listings, such as Lyme disease, trigeminal neuralgia, chronic fatigue syndrome (CFS), fibromyalgia, systemic mastocytosis, migraines, vestibular disorders, reflex sympathetic dystrophy syndrome, narcolepsy, arachnoiditis, porphyria, and hepatitis A, B, and C. The commenters believe that these impairments are medically severe and result in substantial functional loss due to the illnesses themselves as well as the associated symptoms and side effects from various treatments. They requested that specific listing criteria be included in our listings so that individuals with these disorders could be found disabled as appropriate and would not be overlooked solely due to the fact that their specific impairments were not named in the listings.

Response: We did not adopt these comments, which are outside the scope of this rulemaking proceeding. In proposing these revisions, we intended primarily to address existing listings and to update or clarify the medical terminology used in some listings. We explained in the NPRM that more substantive changes to the listings would be addressed when we reviewed the listing criteria for each individual body system (65 FR 6929). We will consider including new criteria for

specific impairments, such as those mentioned above, as we review the appropriate respective body systems.

However, we emphasize that if you have an impairment(s) that is not included in the listings, you may still be found disabled at the third step of the sequential evaluation processes for adults and children if your impairment(s) medically equals a listing. This longstanding policy is explained in §§ 404.1526 and 416.926 of our regulations. If you are a child under age 18, we may also find that an impairment or combination of impairments functionally equals the listings, as explained in § 416.926a of our regulations. In addition, if you are an adult, we can find you disabled at a later step in the sequential evaluation process, as explained in §§ 404.1545–404.1568 and 416.945–416.968 of our regulations. With respect to the specific impairments noted by the commenters, a Social Security Ruling (SSR), SSR 99–2p (64 FR 23380), provides detailed guidance on how we evaluate claims involving CFS.

Comment: Several commenters suggested that we make specific changes to listings that we did not propose changing in the proposed rules.

Response: We did not adopt these comments, which are also outside the scope of this rulemaking proceeding. However, we will consider the commenters' proposed changes as we revise individual body system listings.

Comment: A few commenters were concerned that individuals would lose their benefits based on the proposed technical changes to the listings.

Response: No individual's disability benefits will be ceased solely on the basis of these technical revisions to the listings. We conduct periodic reviews of individuals receiving benefits to determine whether they are still disabled. These reviews are known as continuing disability reviews (CDRs). However, when we conduct CDRs, we do not find that your disability has ended based on a change in a listing. In most cases, we must show that your impairment(s) has medically improved and that this improvement is ''related to the ability to work.'' If your impairment(s) has not medically improved, we will generally find that you are still disabled. Even if the impairment(s) has medically improved, our regulations provide that the improvement is not ''related to the ability to work'' if the impairment(s) continues to meet or equal the ''same listing section used to make our most recent favorable decision.'' This is true even if we have deleted or revised the listing section that we used to make the most recent favorable decision. See §§ 404.1594(c)(3)(i) and 416.994(b)(2)(iv)(A) of our regulations. A similar provision for CDRs for children eligible for SSI based on disability appears in § 416.994a(b)(2) of our regulations.

As we noted in the effective date section of this preamble, these final rules will be effective on May 24, 2002. Our current rules will continue to apply until the effective date of these final rules. When these final rules become effective, we will apply them to new applications filed on or after the effective date of the rules. We will also apply them to the entire period at issue for claims that are pending at any stage of our administrative review process, including claims that are pending administrative review after remand from a Federal court.

With respect to claims in which we have made a final decision, and that are pending judicial review in Federal court, we expect that the court's review of the Commissioner's final decision would be made in accordance with the rules in effect at the time of the final decision. If the court determines that the Commissioner's final decision is not supported by substantial evidence, or contains an error of law, we would expect that the court would reverse the final decision, and remand the case for further administrative proceedings pursuant to the fourth sentence of section 205(g) of the Act, except in those few instances where the court determines that it is appropriate to reverse the final decision and award benefits, without remanding the case for further administrative proceedings. In those cases decided by a court after the effective date of the rules, where the court reverses the Commissioner's final decision and remands the case for further administrative proceedings, on remand, we will apply the provisions of these final rules to the entire period at issue in the claim.

Comment: One commenter felt that these proposed revisions were structured to take disability benefits away from individuals who were stabilized by medications. This individual felt that medications had masked the severity of his liver disease and this had adversely affected his ability to receive a transplant.

Response: These proposed revisions are not in any way intended to change the way we evaluate the impairment(s) of individuals who benefit from prescribed medication(s). In evaluating any medical impairment, we must consider the impact of any treatments and medications that you are taking, both from the standpoint of how they benefit you as well as any adverse side effects you may experience. We evaluate your impairment in light of the medications or treatments that you have been provided by your medical sources. We do not judge the appropriateness of such medications or treatments.

Other Changes

We proposed several changes to the listings that we are not making in these final rules. The NPRM contained a drafting error in reference to section 11.02 addressing epilepsy. We proposed to revise the heading to be more consistent with current medical technology, but we had not intended to change the frequency criterion for the number of seizures required to meet this listing. The proposed rules incorrectly stated the frequency as ''occurring more frequently than once weekly.'' (65 FR 6935). We did not intend to change the existing frequency criterion, which continues to read, ''occurring more frequently than once a month.'' We have revised the final rules consistent with our original intent.

Second, the NPRM proposed revising § 416.926a(d) to remove subparagraphs (8) and (9) of this section and revise the numbering accordingly. On June 14, 2000, we published a notice of intent to issue regulations and request for comments that asked experts in growth impairments in children, and other interested members of the public, for comments on how we should revise the childhood growth impairment listings (65 FR 37321). We will consider whether and how we should revise these examples of growth impairments, which we consider to functionally equal the listings, in the context of that rulemaking proceeding. As a result, we are not making any changes to § 416.926a in these final rules. Former § 416.926a(d)(8) and (9) were redesignated as § 416.926a(m)(7) and (m)(8), respectively, in the final childhood disability rules that we published on September 11, 2000 (65 FR 54747). Those final rules were effective on January 2, 2001.

Third, we have not included the technical revisions involving the adult mental disorders body system listings (section 12.00) in these final rules. On August 21, 2000, we published final rules revising the medical criteria we use for evaluating mental disorders and traumatic brain injury in adults (65 FR 50746). In those final rules, we made several revisions to listing 12.05, including a revision to the capsule definition to the listing. Consequently, there is no need to include any additional changes to that listing in these final rules.

Fourth, we did not include the technical revisions involving the musculoskeletal body system listings (section 1.00 and 101.00) for adults and children in these final rules. On November 19, 2001, we published final rules revising the medical criteria we use for evaluating musculoskeletal disorders in adults and children (66 FR 58010). In those final rules, we made the revisions we had proposed in this rulemaking proceeding.

However, the language we used in the final rules revising the musculoskeletal listings to describe what we mean by appropriate medically acceptable imaging techniques should also be included in the preface of other body systems that refer to imaging techniques. Accordingly, we added this language to the prefaces of those body systems that we address in this rulemaking proceeding as part of these final rules. We will also add it as needed to other body system listings as we revise them in the future. The addition of this language allows us to delete the specific references to ''x-rays'' in listing sections 2.00B2 and 113.00A, and to delete the phrase ''x-ray imaging'' previously included in listings 5.03, 5.04, 5.05, and 105.05.

Aside from those changes noted above, we are not making any other changes to the proposed revisions.

Regulatory Procedures

Executive Order 12866

The Office of Management and Budget (OMB) has reviewed these final rules in accordance with Executive Order (E.O.) 12866, as amended by E.O. 13258. We have also determined that these rules meet the plain language requirements of E.O. 12866.

Regulatory Flexibility Act

We certify that these final rules will not have a significant economic impact on a substantial number of small entities because these rules affect only individuals. Therefore, a regulatory flexibility analysis as provided in the Regulatory Flexibility Act, as amended, is not required.

Paperwork Reduction Act

These final rules contain reporting requirements at: 2.00B; 3.00F; 11.02; 11.03; 14.00B; 14.08M; 100.00B; 102.00A; 104.00E; 105.00B; 111.00A; and 113.00B; 114.00B; and 114.08N. The public reporting burden is accounted for in the Information Collection Requests for the various forms that the public uses to submit the information to SSA. Consequently, a 1-hour placeholder burden is being assigned to the specific reporting requirement(s) contained in these rules. We are seeking clearance of the burdens referenced in these rules because these rules were not considered during the clearance of the forms. An Information Collection Request has been submitted to OMB. While these rules will be effective 30 days from publication, these burdens will not be effective until cleared by OMB. We are soliciting comments on the burden estimate; the need for the information; its practical utility; ways to enhance its quality, utility and clarity; and on ways to minimize the burden on respondents, including the use of automated collection techniques or other forms of information technology. We will publish a notice in the **Federal Register** upon OMB approval of the information collection requirements. Comments should be submitted to the OMB desk officer for SSA within 30 days of publication of this final rule at the following address: Office of Management and Budget, Attn: Desk Officer for SSA, New Executive Office Building, Room 10235, 725 17th St., NW, Washington, DC 20503.

(Catalog of Federal Domestic Assistance Program Nos. 96.001, Social Security-Disability Insurance; 96.002, Social Security-Retirement Insurance; 96.004, Social Security-Survivors Insurance; 96.006, Supplemental Security Income)

List of Subjects in 20 CFR Part 404

Administrative practice and procedure, Blind, Disability benefits, Old-Age, Survivors and Disability Insurance, Reporting and recordkeeping requirements, Social Security.

Dated: February 12, 2002.

Jo Anne B. Barnhart,

Commissioner of Social Security.

For the reasons set forth in the preamble, part 404, subpart P of chapter III of title 20 of the Code of Federal Regulations is amended as follows:

PART 404—FEDERAL OLD–AGE, SURVIVORS AND DISABILITY INSURANCE (1950–)

Subpart P—Determining Disability and Blindness

1. The authority citation for subpart P of part 404 continues to read as follows:

Authority: Secs. 202, 205(a), (b), and (d)–(h), 216(i), 221(a) and (i), 222(c), 223, 225, and 702(a)(5) of the Social Security Act (42 U.S.C. 402, 405(a), (b), and (d)–(h), 416(i), 421(a) and (i), 422(c), 423, 425, and 902(a)(5)); sec. 211(b), Pub. L. 104–193, 110 Stat. 2105, 2189.

Appendix 1 to Subpart P of Part 404—[Amended]

2. Appendix 1 to subpart P of part 404 is amended as follows:

A. In part A:

1. Section 2.00 is amended:

a. By revising the heading of paragraph A;

b. By revising paragraph A1, the first two sentences of paragraph A2, and paragraph A5;

c. By amending the first, fourth, fifth, and sixth sentences of paragraph A6 to remove the word ''central'';

d. By revising the last sentence in the second undesignated paragraph of paragraph B2 and by amending the second undesignated paragraph of paragraph B2 to add two new sentences at the end of the paragraph;

e. By revising paragraph B3;

2. Section 2.02 is amended by removing the word ''central'' in the heading.

3. Section 2.04 is revised.

4. Section 2.05 is removed and reserved.

5. Section 2.09 is revised.

6. Table No. 1 following section 2.09 is amended by revising the heading to read: ''PERCENTAGE OF VISUAL ACUITY EFFICIENCY CORRESPONDING TO VISUAL ACUITY NOTATIONS FOR DISTANCE IN THE PHAKIC AND APHAKIC EYE (BETTER EYE)''; by revising the heading of the right column on the first line of the table to read, ''PERCENT VISUAL ACUITY EFFICIENCY''; and by amending footnotes 2 and 3 to Table No. 1 by removing the word ''central.''

7. Section 3.00 is amended by revising the last sentence in the second undesignated paragraph of paragraph E, and by amending paragraph F1 by revising the fourth and fifth sentences of the fourth undesignated paragraph.

8. Section 3.11 is added.

9. Section 4.00, paragraph A, is amended by revising the second sentence of the third undesignated paragraph, and paragraph C3 is amended by revising the third sentence of the paragraph and adding two new sentences.

10. Section 5.00, paragraph C, is amended by revising the fourth sentence and by adding two new sentences.

11. Section 5.03 is revised.

12. Section 5.04 is amended by revising the heading and by revising paragraph C.

13. Section 5.05 is amended by revising the first sentence in paragraph A.

14. Section 5.09 is added after the tables.

15. Section 6.00 is amended by adding two new sentences to paragraph A.

16. Section 6.02 is amended by revising paragraph C1.

17. Section 7.00 is amended by adding two new sentences to paragraph B.

18. Section 7.00 is amended by revising the first sentence of the first paragraph of paragraph E.

19. Section 7.11 is amended by revising the heading.

20. Section 7.16 is amended by revising the heading and by revising paragraph A.

21. Section 7.17 is amended by revising the heading and by revising the first sentence.

22. Section 8.06 is amended by revising the heading.

23. Section 9.00, the first paragraph, is amended by adding two new sentences.

24. In section 9.02, the word ''With:'' following the heading and paragraph A are removed and the paragraph designation ''B'' is removed from paragraph B.

25. Section 9.03, paragraph A, is revised.

26. Section 11.00 is amended in paragraph A:

a. By revising the heading;

b. By revising the first sentence in paragraph 11.00A;

c. By removing the first undesignated paragraph; and

d. By revising the first, second and third sentences in the second undesignated paragraph.

27. Section 11.02 is amended by revising the heading.

28. Section 11.03 is amended by revising the heading.

29. Section 11.15 is removed and reserved.

30. Section 11.17 is amended by revising paragraph A.

31. Section 13.08 is revised.

32. Section 14.00 is amended by revising the first sentence of the first undesignated paragraph of paragraph B and by adding two new sentences following this sentence.

33. Section 14.08 is amended by revising paragraph M6.

B. In part B:

1. Section 100.00, paragraph B, is revised.

2. Section 102.00 is amended by revising the first and second sentences of paragraph A.

3. Section 102.02 is amended by revising the heading.

4. Section 103.00, paragraph B, is amended by revising the last sentence of the second undesignated paragraph.

5. Section 103.00, paragraph D, is amended by adding a new first undesignated paragraph.

6. Section 103.00, paragraph E, is amended by revising the second sentence.

7. Section 103.04, paragraph B3, is revised.

8. Section 103.05 is added after Table III.

9. Section 104.00, paragraph A, is amended by revising the last sentence of the fifth undesignated paragraph, and paragraph E is amended by revising the first sentence of the second undesignated paragraph and adding a new sentence to the second undesignated paragraph.

10. Section 105.00 is amended by revising the first sentence in paragraph B and adding two new sentences.

11. Section 105.05 is amended by revising paragraphs A and C.

12. Section 105.09 is added.

13. Section 107.00, paragraph C, is amended by revising the heading and by revising the first sentence.

14. Section 107.11 is amended by revising the heading.

15. Section 111.00 paragraph A is revised and paragraph B is amended by revising the heading, and by removing the second sentence.

16. Section 111.02 is amended by revising the headings of paragraphs A and B; by revising the first sentence of the introductory text of paragraphs A and B; and by revising paragraph B3.

17. Section 111.03 is amended by revising the heading.

18. Section 113.00 is amended by revising the third sentence in paragraph B and by adding two new sentences to paragraph B.

19. Section 114.00 is amended by revising the first sentence of the second undesignated paragraph of paragraph B and by adding two new sentences following this sentence.

20. Section 114.08 is amended by revising paragraph N6.

The added and revised text is as follows:

Appendix 1 to Subpart P of Part 404–Listing of Impairments

* * * * *

2.00 Special Senses and Speech

A. Disorders of Vision

1. *Causes of impairment.* Diseases or injury of the eyes may produce loss of visual acuity or loss of the peripheral field. Loss of visual acuity results in inability to distinguish detail and prevents reading and fine work. Loss of the peripheral field restricts the ability of an individual to move about freely. The extent of impairment of sight should be determined by visual acuity and peripheral field testing.

2. *Visual acuity.* Loss of visual acuity may result in impaired distant vision or near vision, or both. However, for you to meet the level of severity described in 2.02 and 2.04, only the remaining visual acuity for distance of the better eye with best correction based on the Snellen test chart measurement may be used. * * *

* * * * *

5. *Visual efficiency.* Loss of visual efficiency may be caused by disease or injury resulting in reduction of visual acuity or visual field. The visual efficiency of one eye is the product of the percentage of visual acuity efficiency and the percentage of visual field efficiency. (See tables no. 1 and 2, following 2.09.)

* * * * *

B. * * *

2. * * *

* * * * *

* * * When polytomograms, contrast radiography, or other special tests have been performed, copies of the reports of these tests should be obtained in addition to appropriate medically acceptable imaging reports of the skull and temporal bone. Medically acceptable imaging includes, but is not limited to, x-ray imaging, computerized axial tomography (CAT scan) or magnetic resonance imaging (MRI), with or without contrast material, myelography, and radionuclear bone scans. ''Appropriate'' means that the technique used is the proper one to support the evaluation and diagnosis of the impairment.

3. *Loss of speech.* In evaluating the loss of speech, the ability to produce speech by any means includes the use of mechanical or electronic devices that improve voice or articulation. Impairments of speech may also be evaluated under the body system for the underlying disorder, such as neurological disorders, 11.00ff.

* * * * *

2.04 *Loss of visual efficiency.* The visual efficiency of the better eye after best correction is 20 percent or less. (The percent of remaining visual efficiency is equal to the product of the percent of remaining visual acuity efficiency and the percent of remaining visual field efficiency.)

2.05 [Reserved.]

* * * * *

2.09 *Loss of speech* due to any cause, with inability to produce by any means speech that can be heard, understood, or sustained.

* * * * *

3.00 Respiratory System

* * * * *

E. *Documentation of pulmonary function testing.*

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* * * If the spirogram was generated by any means other than direct pen linkage to a mechanical displacement-type spirometer, the testing device must have had a recorded calibration performed previously on the day of the spirometric measurement.

* * * * *

F. *Documentation of chronic impairment of gas exchange.*

1. * * *

* * * * *

* * * The percentage concentrations of inspired O_2 and inspired and expired CO and He for each of the maneuvers should be provided. Sufficient data must be provided, including documentation of the source of the predicted equation, to permit verification that the test was performed adequately, and that, if necessary, corrections for anemia or carboxyhemoglobin were made appropriately.

* * * * *

3.11 *Lung transplant.* Consider under a disability for 12 months following the date of surgery; thereafter, evaluate the residual impairment.

4.00 Cardiovascular System

A.* * *

* * * Therefore, in any case in which you have a medically determinable impairment that is not listed, or a combination of impairments no one of which meets a listing, we will consider a medical equivalence determination. * * *

* * * * *

C. * * *

3. * * * In selected cases, these tests may be purchased after a medical history and physical examination, report of appropriate medically acceptable imaging, ECGs, and other appropriate tests have been evaluated, preferably by a program physician with experience in the care of patients with cardiovascular disease. Medically acceptable imaging includes, but is not limited to, x-ray imaging, computerized axial tomography (CAT scan) or magnetic resonance imaging (MRI), with or without contrast material, myelography, and radionuclear bone scans. ''Appropriate'' means that the technique used is the proper one to support the evaluation and diagnosis of the impairment. * * *

* * * * *

5.00 Digestive System

* * * * *

C. * * * To be considered a severe impairment which will last for at least 12 months, a recurrent ulcer after definitive surgery must be demonstrated, despite therapy, by repeated appropriate medically acceptable imaging of the upper gastrointestinal tract or by gastroscopic examinations. Medically acceptable imaging includes, but is not limited to, x-ray imaging, computerized axial tomography (CAT scan) or magnetic resonance imaging (MRI), with or without contrast material, myelography, and radionuclear bone scans. ''Appropriate'' means that the technique used is the proper one to support the evaluation and diagnosis of the impairment. * * *

* * * * *

5.03 *Stricture, stenosis, or obstruction of the esophagus (demonstrated by endoscopy or other appropriate medically acceptable imaging)* with weight loss as described under listing 5.08.

5.04 *Peptic ulcer disease (demonstrated by endoscopy or other appropriate medically acceptable imaging).*

* * * * *

C. Recurrent obstruction demonstrated by endoscopy or other appropriate medically acceptable imaging; or,

* * * * *

5.05 *Chronic liver disease (e.g., portal, postnecrotic, or biliary cirrhosis; chronic active hepatitis; Wilson's disease).* With:

A. Esophageal varices (demonstrated by endoscopy or other appropriate medically acceptable imaging) with a documented history of massive hemorrhage attributable to these varices. * * *

* * * * *

5.09 *Liver transplant.* Consider under a disability for 12 months following the date of surgery; thereafter, evaluate the residual impairment(s).

6.00 Genito-Urinary System

A. * * * Medically acceptable imaging includes, but is not limited to, x-ray imaging, computerized axial tomography (CAT scan) or magnetic resonance imaging (MRI), with or without contrast material, myelography, and radionuclear bone scans. ''Appropriate'' means that the technique used is the proper one to support the evaluation and diagnosis of the impairment.

* * * * *

6.02 * * *

* * * * *

C. * * *

1. Renal osteodystrophy manifested by severe bone pain and abnormalities shown by appropriate medically acceptable imaging (e.g., osteitis fibrosa, marked osteoporosis, pathologic fractures); or

* * * * *

7.00 Hemic and Lymphatic System

* * * * *

B. * * * Medically acceptable imaging includes, but is not limited to, x-ray imaging, computerized axial tomography (CAT scan) or magnetic resonance imaging (MRI), with or without contrast material, myelography, and radionuclear bone scans. ''Appropriate'' means that the technique used is the proper one to support the evaluation and diagnosis of the impairment.

* * * * *

E. *Acute leukemia (including T-cell lymphoblastic lymphoma).* Initial diagnosis of acute leukemia or T-cell lymphoblastic lymphoma must be based upon definitive bone marrow pathologic evidence. * * *

* * * * *

7.11 *Acute leukemia (including T-cell lymphoblastic lymphoma).*

* * * * *

7.16 *Multiple myeloma (confirmed by appropriate serum or urine protein electrophoresis and bone marrow findings).* With:

A. Appropriate medically acceptable imaging evidence of bony involvement with intractable bone pain; or

* * * * *

7.17 *Aplastic anemias or hematologic malignancies (excluding acute leukemia and T-cell lymphoblastic lymphoma)*: With bone marrow or stem cell transplantation. * * *

* * * * *

8.06 *Hidradenitis suppurativa, acne conglobata.*

* * * * *

9.00 Endocrine System

* * * Medically acceptable imaging includes, but is not limited to, x-ray imaging, computerized axial tomography (CAT scan) or magnetic resonance imaging (MRI), with or without contrast material, myelography, and radionuclear bone scans. ''Appropriate'' means that the technique used is the proper one to support the evaluation and diagnosis of the impairment.

* * * * *

9.03 *Hyperparathyroidism.* With:

A. Generalized decalcification of bone on appropriate medically acceptable imaging study and elevation of plasma calcium to 11 mg. per deciliter (100 ml.) or greater; or

* * * * *

11.00 Neurological

A. *Epilepsy.* In epilepsy, regardless of etiology, degree of impairment will be determined according to type, frequency, duration, and sequelae of seizures. * * *

Under 11.02 and 11.03, the criteria can be applied only if the impairment persists despite the fact that the individual is following prescribed antiepileptic treatment. Adherence to prescribed antiepileptic therapy can ordinarily be determined from objective clinical findings in the report of the physician currently providing treatment for epilepsy. Determination of blood levels of phenytoin sodium or other antiepileptic drugs may serve to indicate whether the prescribed medication is being taken. * * *

* * * * *

11.02 *Epilepsy—convulsive epilepsy, (grand mal or psychomotor), documented by detailed description of a typical seizure pattern, including all associated phenomena; occurring more frequently than once a month in spite of at least 3 months of prescribed treatment.*

* * * * *

11.03 *Epilepsy—nonconvulsive epilepsy (petit mal, psychomotor, or focal), documented by detailed description of a typical seizure pattern, including all associated phenomena; occurring more frequently than once weekly in spite of at least 3 months of prescribed treatment.*

* * * * *

11.15 [Reserved.]

* * * * *

11.17 *Degenerative disease not listed elsewhere, such as Huntington's chorea, Friedreich's ataxia, and spino-cerebellar degeneration.* With:

A. Disorganization of motor function as described in 11.04B; or * * *

* * * * *

13.08 Thyroid gland:

A. Anaplastic (undifferentiated) carcinoma of the thyroid; or

B. Carcinoma with metastases beyond the regional lymph nodes, not controlled by prescribed therapy.

* * * * *

14.00 Immune System

* * * * *

B. * * *

The documentation needed to establish the existence of a connective tissue disorder is medical history, physical examination, selected laboratory studies, appropriate medically acceptable imaging, and, in some instances, tissue biopsy. Medically acceptable imaging includes, but is not limited to, x-ray imaging, computerized axial tomography (CAT scan) or magnetic resonance imaging (MRI), with or without contrast material, myelography, and radionuclear bone scans. ''Appropriate'' means that the technique used is the proper one to support the evaluation and diagnosis of the impairment. * * *

* * * * *

14.08 *Human immunodeficiency virus (HIV) infection.*

* * * * *

M. * * *

6. Sinusitis documented by appropriate medically acceptable imaging.

* * * * *

100.00 Growth Impairment

* * * * *

B. *Bone age determinations* should include a full descriptive report of medically acceptable imaging specifically obtained to determine bone age and must cite the standardization method used. Where appropriate medically acceptable imaging must be obtained currently as a basis for adjudication under 100.03, views or scans of the left hand and wrist should be ordered. In addition appropriate medically acceptable imaging of the knee and ankle should be obtained when cessation of growth is being evaluated in an older child at, or past, puberty. Medically acceptable imaging includes, but is not limited to, x-ray imaging, computerized axial tomography (CAT scan) or magnetic resonance imaging (MRI), with or without contrast material, myeolgraphy, and radionuclear bone scans. ''Appropriate'' means that the technique used is the proper one to support the evaluation and diagnosis of the impairment.

* * * * *

102.00 Special Senses and Speech

A. *Visual impairments in children.* Impairment of visual acuity should be determined with use of the standard Snellen test chart. Where this cannot be used, as in very young children, a complete description of the findings should be provided, using other appropriate methods of examination, along with a description of the techniques used for determining the visual acuity for distance. * * *

* * * * *

102.02 *Impairments of visual acuity.*

* * * * *

103.00 Respiratory System

* * * * *

B. * * *

* * * * *

* * * If the spirogram was generated by any means other than direct pen linkage to a mechanical displacement-type spirometer, the testing device must have had a recorded calibration performed previously on the day of the spirometric measurement.

* * * * *

D. * * *

Medically acceptable imaging includes, but is not limited to, x-ray imaging, computerized axial tomography (CAT scan) or magnetic resonance imaging (MRI), with or without contrast material, myelography, and radionuclear bone scans. ''Appropriate'' means that the technique used is the proper one to support the evaluation and diagnosis of the impairment.

E. * * *

The diagnosis is established by the requirement for continuous or nocturnal supplemental oxygen for more than 30 days, in association with characteristic changes on medically acceptable imaging and clinical signs of respiratory dysfunction, including retractions, rales, wheezing, and tachypnea.

* * * * *

103.04 *Cystic fibrosis.*

* * * * *

B. * * *

3. Appropriate medically acceptable imaging evidence of extensive disease, such as thickening of the proximal bronchial airways or persistence of bilateral peribronchial infiltrates;

* * * * *

103.05 *Lung transplant.* Consider under a disability for 12 months following the date of surgery; thereafter, evaluate the residual impairment(s).

104.00 Cardiovascular System

A. * * *

When you have a medically determinable impairment that is not listed, an impairment that does not meet the requirements of a listing, or a combination of impairments no one of which meets the requirements of a listing, we will consider a determination whether your impairment(s) medically equals or, as appropriate, functionally equals the listings. (See §§ 404.1526, 416.926, and 416.926a.)

* * * * *

E. * * *

Findings of cardiomegaly shown by appropriate medically acceptable imaging evidence must be accompanied by other evidence of chronic heart failure or ventricular dysfunction. ''Appropriate'' means that the imaging technique used is the proper one to support the evaluation and diagnosis of the impairment. * * *

* * * * *

105.00 Digestive System

* * * * *

B. *Documentation of gastrointestinal impairments* should include pertinent operative findings, appropriate medically acceptable imaging studies, endoscopy, and biopsy reports. Medically acceptable imaging includes, but is not limited to, x-ray imaging, computerized axial tomography (CAT scan) or magnetic resonance imaging (MRI), with or without contrast material, myelography, and radionuclear bone scans. ''Appropriate'' means that the technique used is the proper one to support the evaluation and diagnosis of the impairment. * * *

* * * * *

105.05 *Chronic liver disease.* * * *

A. Inoperable biliary atresia demonstrated by appropriate medically acceptable imaging or surgery; or

* * * * *

C. Esophageal varices (demonstrated by endoscopy or other appropriate medically acceptable imaging); or

* * * * *

105.09 *Liver transplant.* Consider under a disability for 12 months following the date of surgery; thereafter, evaluate the residual impairment.

* * * * *

107.00 Hemic and Lymphatic System

* * * * *

C. *Acute leukemia (including T-cell lymphoblastic lymphoma).* Initial diagnosis of acute leukemia or T-cell lymphoblastic lymphoma must be based upon definitive bone marrow pathologic evidence. * * *

* * * * *

107.11 *Acute leukemia (including T-cell lymphoblastic lymphoma).*

* * * * *

111.00 Neurological

A. *Convulsive epilepsy* must be substantiated by at least one detailed description of a typical seizure. Report of recent documentation should include a neurological examination with frequency of episodes and any associated phenomena substantiated.

Young children may have convulsions in association with febrile illnesses. Proper use of 111.02 and 111.03 requires that epilepsy be established. Although this does not exclude consideration of seizures occurring during febrile illnesses, it does require documentation of seizures during nonfebrile periods.

There is an expected delay in control of epilepsy when treatment is started, particularly when changes in the treatment regimen are necessary. Therefore, an epileptic disorder should not be considered to meet the requirements of 111.02 or 111.03 unless it is shown that convulsive episodes have persisted more than three months after prescribed therapy began.

B. *Nonconvulsive epilepsy.* * * *

* * * * *

111.02 *Major motor seizure disorder.*

A. *Convulsive epilepsy.* In a child with an established diagnosis of epilepsy, the occurrence of more than one major motor seizure per month despite at least three months of prescribed treatment. * * *

* * * * *

B. *Convulsive epilepsy syndrome.* In a child with an established diagnosis of epilepsy, the occurrence of at least one major motor seizure in the year prior to application despite at least three months of prescribed treatment. * * *

* * * * *

3. Significant mental disorder; or

* * * * *

111.03 *Nonconvulsive epilepsy.* * * *

* * * * *

113.00 Neoplastic Diseases, Malignant

* * * * *

B. *Documentation.* * * * If an operative procedure has been performed, the evidence should include a copy of the operative note and the report of the gross and microscopic examination of the surgical specimen, along with all pertinent laboratory reports or reports from appropriate medically acceptable imaging. Medically acceptable imaging includes, but is not limited to, x-ray imaging, computerized axial tomography (CAT scan) or magnetic resonance imaging (MRI), with or without contrast material, myelography, and radionuclear bone scans. ''Appropriate'' means that the technique used is the proper one to support the evaluation and diagnosis of the impairment. * * *

* * * * *

114.00 Immune System

* * * * *

B. * * *

* * * * *

The documentation needed to establish the existence of a connective tissue disorder is medical history, physical examination, selected laboratory studies, appropriate medically acceptable imaging, and, in some instances, tissue biopsy. Medically acceptable imaging includes, but is not limited to, x-ray imaging, computerized axial tomography (CAT scan) or magnetic resonance imaging (MRI), with or without contrast material, myelography, and radionuclear bone scans. ''Appropriate'' means that the technique used is the proper one to support the evaluation and diagnosis of the impairment. * * *

* * * * *

114.08 *Human immunodeficiency virus (HIV) infection.*

* * * * *

N. * * *

6. Sinusitis documented by appropriate medically acceptable imaging.

* * * * *

[FR Doc. 02–9737 Filed 4–23–02; 8:45 am]

BILLING CODE 4191–02–P

DEPARTMENT OF THE TREASURY

Internal Revenue Service

26 CFR Parts 1, 301 and 602

[TD 8989]

RIN 1545–AY56

Guidance Necessary To Facilitate Electronic Tax Administration

AGENCY: Internal Revenue Service (IRS), Treasury.

ACTION: Final and temporary regulations.

SUMMARY: This document contains regulations designed to eliminate regulatory impediments to the electronic filing of Form 1040, ''U.S. Individual Income Tax Return.'' These regulations generally affect taxpayers who file Form 1040 electronically and who are required to file any of the following forms: Form 56, ''Notice Concerning Fiduciary Relationship''; Form 2120, ''Multiple Support Declaration''; Form 2439, ''Notice to Shareholder of Undistributed Long-Term Capital Gains''; Form 3468, ''Investment Credit''; and Form T (Timber), ''Forest Activities Schedules.'' The text of the temporary regulations also serves as the text of the proposed regulations set forth in the notice of proposed rulemaking on this subject in the Proposed Rules section in this issue of the **Federal Register**.

EFFECTIVE DATE: These regulations are effective April 24, 2002.

FOR FURTHER INFORMATION CONTACT: James C. Gibbons, (202) 622–4910 (not a toll-free number).

SUPPLEMENTARY INFORMATION:

Paperwork Reduction Act

These regulations are being issued without prior notice and public procedure pursuant to the Administrative Procedure Act (5 U.S.C. 553). For this reason, the collections of information contained in these regulations have been reviewed and, pending receipt and evaluation of public comments, approved by the Office of Management and Budget under control number 1545–1783. Responses to these collections of information are mandatory.

An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless the collection of information displays a valid OMB control number.

For further information concerning these collections of information, and where to submit comments on the collections of information and the accuracy of the estimated burden, and suggestions for reducing this burden, please refer to the preamble to the cross-referencing notice of proposed rulemaking published in the Proposed Rules section of this issue of the **Federal Register**.

Books or records relating to a collection of information must be retained as long as their contents may become material in the administration of any internal revenue law. Generally, tax returns and tax return information are confidential, as required by 26 U.S.C. 6103.

Background

This document contains amendments to the Income Tax Regulations (26 CFR part 1) and the Procedure and Administration Regulations (26 CFR part 301) designed to eliminate regulatory impediments to the electronic filing of Form 1040.

In 1998, Congress enacted the Internal Revenue Service Restructuring and Reform Act of 1998 (RRA 1998), Public Law 105–206 (112 Stat. 685) (1998). Section 2001(a) of RRA 1998 states that the policy of Congress is that paperless filing should be the preferred and most convenient means of filing Federal tax returns. Section 2001(a) of RRA 1998 also sets a long-range goal for the IRS to have at least 80 percent of all Federal tax returns filed electronically by 2007. Section 2001(b) of RRA 1998 requires the IRS to establish a 10-year strategic plan to eliminate barriers to electronic filing. To the extent practicable, this plan is to provide for electronic filing of electronically prepared returns for taxable years beginning after 2001.

The temporary regulations amend the Procedure and Administration Regulations to provide a regulatory statement of IRS authority to prescribe what return information or documentation must be filed with a return, statement or other document required to be made under any provision of the internal revenue laws or regulations. The regulations give the IRS maximum flexibility in prescribing (1) what needs to be filed in support of a return or claim, and (2) the form of the filing, *e.g.,* electronic versus paper. The regulations permit the IRS to prescribe required return information in forms, instructions, or other appropriate guidance.

In addition, the IRS identified five regulatory provisions that impede electronic filing by requiring the taxpayer to either include a third-party signature, or attach a document generated by a third party. The temporary regulations amend those provisions to eliminate the impediments.

Although the regulatory impediments to the electronic filing of Form 1040 are eliminated by the temporary regulations, the IRS may instruct a taxpayer who files Form 1040 on paper to attach a document that would not be required in the case of a Form 1040 filed electronically.

Explanation of Provisions

1. General Provision

Section 6001(a) of the Internal Revenue Code (Code) provides that every person liable for any tax, or for the collection thereof, will keep such records, render such statements, make such returns, and comply with such

rules and regulations as the Secretary may from time to time prescribe. The Secretary may require any person, by notice served upon such person or by regulations, to make such returns, render such statements, or keep such records, as the Secretary deems sufficient to show whether or not such person is liable for tax.

Section 6011(a) of the Code provides that any person liable for any tax, or for the collection thereof, will make a return or statement according to the forms and regulations prescribed by the Secretary. Every person required to make a return or statement shall include therein the information required by such forms and regulations.

The temporary regulations amend the general provisions under § 301.6011–1 of the Procedure and Administration Regulations to provide a regulatory statement of the Secretary's authority to prescribe in forms, instructions, or other appropriate guidance what information or documentation must be filed with any return or statement required to be made or other document required to be furnished under any provision of the internal revenue laws or regulations. Under this authority, the IRS may change forms and instructions to eliminate nonstatutory impediments, such as third-party signature or document requirements, to the electronic filing of Form 1040.

2. Form T (Timber): Forest Activities Schedules

Section 611 of the Code generally provides a reasonable allowance for depletion and for depreciation of improvements in computing taxable income from timber. See §§ 1.611–1(a) and 1.611–5(a) of the Income Tax Regulations. Section 1.611–3(h) provides that a taxpayer claiming a deduction for depletion of timber or for depreciation of plant and other improvements must attach to the taxpayer's income tax return a filled-out Form T for the taxable year covered by the income tax return. This section specifically provides that the information required by Form T will include a map, where necessary, to show clearly timber and land acquired, timber cut, and timber and land sold.

The attachment of a map to Form T is a regulatory impediment to the electronic filing of Form 1040 because it is a diagram not easily incorporated into an electronic return. It is also often generated by a third party. To enable the electronic filing of Form T, the temporary regulations remove the requirement that a taxpayer attach a map to substantiate the claimed depletion and depreciation. Instead, the temporary regulations require the taxpayer to be prepared to furnish a map, where necessary, to substantiate any claimed depletion or depreciation.

3. Form 56: Notice Concerning Fiduciary Relationship

Section 6903(b) of the Code requires a fiduciary to give notice of his or her qualification as a fiduciary to the IRS in accordance with regulations prescribed by the Secretary. Section 301.6903–1(b) of the Procedure and Administration Regulations provides that satisfactory evidence of the authority of the fiduciary to act for any other person in a fiduciary capacity must be filed with and made a part of the notice. Form 56, the notice concerning fiduciary relationship, requires a fiduciary to attach a certified copy of the document creating the fiduciary relationship. The attachment of evidence of fiduciary relationship is a regulatory impediment to the electronic filing of Form 56 because the evidence is a document generated by a third party.

To eliminate the barrier to electronic filing, Form 56 should be filed separately from Form 1040. Further, to enable the electronic filing of Form 56, the temporary regulations remove the requirement that the fiduciary attach the evidence of fiduciary relationship to Form 56. Instead, the temporary regulations require the fiduciary to be prepared to furnish the evidence to substantiate the fiduciary relationship.

4. Form 2120: Multiple Support Declaration

Section 152(c) of the Code provides that a taxpayer will be treated as having contributed over half of the support of an individual for a calendar year if: (1) No one person contributed over half of the individual's support; (2) each person in the group that collectively contributed more than half of the support of the individual would have been entitled to claim the individual as a dependent but for the fact that the person did not contribute over half of the individual's support; (3) the taxpayer claiming the individual as a dependent contributed more than 10 percent of the individual's support; and (4) every other person in the group who contributed more than 10 percent of the support files a written declaration that the person will not claim the individual as a dependent for any taxable year beginning in such calendar year. Section 1.152–3(a)(4) and (c) of the Income Tax Regulations requires that a taxpayer claiming an individual as a dependent attach to the taxpayer's income tax return a written declaration of waiver signed by the other persons described in section 152(c)(2). Form 2120 is used to make these waiver declarations.

Attaching the Form 2120 with third-party waiver declarations to Form 1040 is a regulatory impediment to the electronic filing of Form 1040 because third-party signatures are not easily incorporated into an electronic return. Therefore, the temporary regulations eliminate the requirement to attach the waiver declarations. Under the temporary regulations, a taxpayer claiming an individual as a dependent under a multiple support agreement is still required to obtain the waiver declarations but is no longer required to attach them to the taxpayer's income tax return. Instead, the temporary regulations require the taxpayer to attach a statement that (1) identifies the other persons described in section 152(c)(2) and (2) indicates that the taxpayer obtained waiver declarations from these persons. The temporary regulations will also require the taxpayer to retain the waiver declarations.

5. Form 2439: Notice to Shareholder of Undistributed Long-Term Capital Gains

Under § 1.852–4(b)(2) of the Income Tax Regulations, a person who is a shareholder of a regulated investment company at the close of the company's taxable year must include undistributed capital gain in long-term capital gain. Section 1.852–9(a)(1) requires the regulated investment company to give its shareholders notice of a designation of undistributed capital gains. The regulations provide that mailed copies of Form 2439 (copies B and C) constitute appropriate notice to shareholders. Section 1.852–9(c) requires the shareholder to attach copy B of Form 2439 to the shareholder's return for the taxable year in which the undistributed capital gain is includible in gross income.

Attaching copy B of Form 2439 to the shareholder's income tax return prevents electronic filing of Form 1040 because copy B is a document generated by a third party. Therefore, the temporary regulations remove the requirement that the shareholder attach a copy of Form 2439 to Form 1040 but require that the shareholder retain a copy of Form 2439.

A shareholder who files Form 1040 electronically will supply information from the shareholder's copy of the Form 2439. However, a shareholder who files Form 1040 on paper will continue to attach a copy of Form 2439 to the shareholder's paper Form 1040 in accordance with Form 2439 instructions.

6. Form 3468: Investment Credit

Section 47 of the Code generally provides a credit for rehabilitation expenditures incurred for a qualified rehabilitated building or a certified historic structure. Section 1.48–12(d)(7)(i) of the Income Tax Regulations provides that a taxpayer claiming the credit for rehabilitation of a certified historic structure must file Form 3468 with Form 1040. Form 3468 requires a copy of the final certification of completed work issued by the Secretary of the Interior. In addition, for returns filed after January 9, 1989, the taxpayer must submit evidence that the building is a certified historic structure. This status is evidenced by the final certification of completed work issued by the Secretary of the Interior. If the Secretary of the Interior has not issued a certification at the time the tax return is filed, § 1.48–12(d)(7)(ii) provides that the taxpayer must attach (1) a copy of the first page of the certification application, with an indication that it has been received by the Secretary of the Interior or designate, and (2) proof that the building is a certified historic structure (or that such status has been requested). In addition, the taxpayer is required to submit a copy of the certification as an attachment to Form 3468 accompanying the first income tax return filed after certification.

Attaching the certification impedes electronic filing of Form 3468 because it is a document generated by a third party. Therefore, the temporary regulations revise § 1.48–12(d)(7) to eliminate this requirement. For a return filed for a taxable year beginning after December 31, 2001, the taxpayer is required to provide on Form 3468 the NPS project number assigned by, and the date of the final certification of completed work received from, the Secretary of the Interior. For a taxpayer who has not received certification by the time the income tax return is filed for a year in which the credit is claimed, the current rules applicable to returns filed before receipt of the certification remain unchanged. However, the temporary regulations eliminate the requirement that the certification be attached to the first income tax return filed after its receipt. Instead, the taxpayer is required to provide the NPS project number assigned by, and the date of the final certification of completed work received from, the Secretary of the Interior on Form 3468 accompanying the first income tax return filed after certification.

Every taxpayer claiming the credit for rehabilitation of a certified historic structure must provide the required information on Form 3468 (or its successor) filed with the taxpayer's return and retain a copy of the certification. For a building owned by a pass-through entity (i.e., a partnership, S corporation, estate, or trust), only the pass-through entity, not the partner, shareholder or beneficiary, must provide on Form 3468 the NPS project number assigned by, and the date of the final certification of completed work received from, the Secretary of the Interior. However, each partner, shareholder, or beneficiary claiming a credit for qualified rehabilitation expenditures from a pass-through entity must provide the employer identification number of that entity on Form 3468 (or its successor).

Special Analyses

It has been determined that this Treasury decision is not a significant regulatory action as defined in Executive Order 12866. Therefore, a regulatory assessment is not required. It also has been determined that section 553(b) of the Administrative Procedure Act (5 U.S.C. chapter 5) does not apply to these regulations. It is hereby certified that the collection of information in these regulations will not have a significant economic impact on a substantial number of small entities. This certification is based upon the fact that the persons responsible for recordkeeping are principally individuals, and the burden is not significant as described earlier in the preamble. Therefore, a Regulatory Flexibility Analysis under the Regulatory Flexibility Act (5 U.S.C. chapter 6) is not required. Pursuant to section 7805(f) of the Internal Revenue Code, these temporary regulations will be submitted to the Chief Counsel for Advocacy of the Small Business Administration for comment on their impact on small business.

Drafting Information

The principal author of these regulations is Sara Paige Shepherd, Office of Associate Chief Counsel (Procedure and Administration), Administrative Provisions and Judicial Practice Division. However, other personnel from the IRS and the Treasury Department participated in the development of the regulations.

List of Subjects

26 CFR Part 1

Income taxes, Reporting and recordkeeping requirements.

26 CFR Part 301

Employment taxes, Estate taxes, Excise taxes, Gift taxes, Income taxes, Penalties, Reporting and recordkeeping requirements.

26 CFR Part 602

Reporting and recordkeeping requirements.

Adoption of Amendments to the Regulations

Accordingly, 26 CFR parts 1, 301 and 602 are amended as follows:

PART 1—INCOME TAXES

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

Authority: 26 U.S.C. 7805 * * *

2. In § 1.48–12, paragraph (d)(7)(iii) is added to read as follows:

§ 1.48–12 Qualified rehabilitated building; expenditures incurred after December 31, 1981.

* * * * *

(d) * * *

(7) * * *

(iii) *Effective dates.* Paragraph (d)(7)(i) of this section applies to returns for taxable years beginning before January 1, 2002. The requirement in the fourth sentence of paragraph (d)(7)(ii) of this section applies only if the first income tax return filed after receipt by the taxpayer of the certification is for a taxable year beginning before January 1, 2002. For rules applicable to returns for taxable years beginning after December 31, 2001, see § 1.48–12T(d)(7)(iii).

3. Section 1.48–12T is revised to read as follows:

§ 1.48–12T Qualified rehabilitated building; expenditures incurred after December 31, 1981 (temporary).

(a) through (d)(7)(ii) [Reserved] For further guidance, see § 1.48–12(a) through (d)(7)(ii).

(iii) *Returns for taxable years beginning after December 31, 2001—(A) In general.* Except as otherwise provided in § 1.48–12(d)(7)(ii) and this paragraph (d)(7)(iii), a taxpayer claiming the credit for rehabilitation of a certified historic structure (within the meaning of section 47(c)(3) and § 1.48–12(d)(1)) for a taxable year beginning after December 31, 2001, must provide with the return for the taxable year in which the credit is claimed, the NPS project number assigned by, and the date of the final certification of completed work received from, the Secretary of the Interior. If a credit (including a credit for a taxable year beginning before January 1, 2002) is claimed under the late certification procedures of § 1.48–12(d)(7)(ii) and the first income tax return filed by the taxpayer after receipt of the certification is for a taxable year beginning after

December 31, 2001, the taxpayer must provide the NPS project number assigned by, and the date of the final certification of completed work received from, the Secretary of the Interior with that return.

(B) *Reporting and recordkeeping requirements.* The information required under paragraph (d)(7)(iii)(A) of this section must be provided on Form 3468 (or its successor) filed with the taxpayer's return. In addition, the taxpayer must retain a copy of the final certification of completed work for as long as its contents may become material in the administration of any internal revenue law.

(C) *Passthrough entities.* In the case of a credit for qualified rehabilitation expenditures of a partnership, S corporation, estate, or trust, the requirements of this paragraph (d)(7)(iii) apply only to the entity. Each partner, shareholder or beneficiary claiming a credit for such qualified rehabilitation expenditures from a passthrough entity must, however, provide the employer identification number of the entity on Form 3468 (or its successor).

(D) *Effective dates.* This paragraph (d)(7)(iii) applies to returns and records for taxable years beginning after December 31, 2001. For rules applicable to returns and records for taxable years beginning before January 1, 2002, see § 1.48–12(d)(7)(i) and the fourth sentence of § 1.48–12(d)(7)(ii).

(e) through (f)(3) [Reserved]. For further guidance, see § 1.48–12(e) through (f)(3).

§ 1.152–3 [Amended]

4. In § 1.152–3, paragraph (c) is removed and reserved.

5. Section 1.152–3T is added to read as follows:

§ 1.152–3T Multiple support agreements (temporary).

(a) through (b) [Reserved]. For further guidance, see § 1.152–3(a) and (b).

(c)(1) The member of a group of contributors who claims an individual as a dependent for a taxable year beginning before January 1, 2002, under the multiple support agreement provisions of section 152(c) must attach to the member's income tax return for the year of the deduction a written declaration from each of the other persons who contributed more than 10 percent of the support of such individual and who, but for the failure to contribute more than half of the support of the individual, would have been entitled to claim the individual as a dependent.

(2) The taxpayer claiming an individual as a dependent for a taxable year beginning after December 31, 2001, under the multiple support agreement provisions of section 152(c) must provide with the income tax return for the year of the deduction—

(i) A statement identifying each of the other persons who contributed more than 10 percent of the support of the individual and who, but for the failure to contribute more than half of the support of the individual, would have been entitled to claim the individual as a dependent; and

(ii) A statement indicating that the taxpayer obtained a written declaration from each of the persons described in section 152(c)(2) waiving the right to claim the individual as a dependent.

(3) The taxpayer claiming the individual as a dependent for a taxable year beginning after December 31, 2001, must retain the waiver declarations and should be prepared to furnish the waiver declarations and any other information necessary to substantiate the claim of the taxpayer. Other information that will substantiate the dependency claim of the taxpayer may include a statement showing the names of all contributors (whether or not members of the group described in section 152(c)(2)) and the amount contributed by each to the support of the claimed dependent.

§ 1.611–3 [Amended]

6. In § 1.611–3, paragraph (h) is removed and reserved.

7. Section 1.611–3T is added to read as follows:

§ 1.611–3T Rules applicable to timber (temporary).

(a) through (g) [Reserved]. For further guidance, see § 1.611–3(a) through (g).

(h) *Reporting and recordkeeping requirements*—(1) *Taxable years beginning before January 1, 2002.* A taxpayer claiming a deduction for depletion of timber for a taxable year beginning before January 1, 2002, shall attach to the income tax return of the taxpayer a filled-out Form T (Timber) for the taxable year covered by the income tax return, including the following information—

(i) A map where necessary to show clearly timber and land acquired, timber cut, and timber and land sold;

(ii) Description of, cost of, and terms of purchase of timberland or timber, or cutting rights, including timber or timber rights acquired under any type of contract;

(iii) Profit or loss from sale of land, or timber, or both;

(iv) Description of timber with respect to which claim for loss, if any, is made;

(v) Record of timber cut;

(vi) Changes in each timber account as a result of purchase, sale, cutting, reestimate, or loss;

(vii) Changes in improvements accounts as the result of additions to or deductions from capital and depreciation, and computation of profit or loss on sale or other disposition of such improvements;

(viii) Operation data with respect to raw and finished material handled and inventoried;

(ix) Statement as to application of the election under section 631(a) and pertinent information in support of the fair market value claimed thereunder;

(x) Information with respect to land ownership and capital investment in timberland; and

(xi) Any other data which will be helpful in determining the reasonableness of the depletion or depreciation deductions claimed in the return.

(2) *Taxable years beginning after December 31, 2001.* A taxpayer claiming a deduction for depletion of timber on a return filed for a taxable year beginning after December 31, 2001, shall attach to the income tax return of the taxpayer a filled-out Form T (Timber) for the taxable year covered by the income tax return. In addition, the taxpayer must retain records sufficient to substantiate the right of the taxpayer to claim the deduction, including a map, where necessary, to show clearly timber and land acquired, timber cut, and timber and land sold for as long as their contents may become material in the administration of any internal revenue law.

§ 1.852–9 [Amended]

8. In § 1.852–9, paragraph (c)(1) is removed and reserved.

9. Section 1.852–9T is added to read as follows:

§ 1.852–9T Special procedural requirements applicable to designation under section 852(b)(3)(D) (temporary).

(a) through (b)(3) [Reserved]. For further guidance, see § 1.852–9(a) through (b)(3).

(c) *Shareholders*—(1)(i) *Return requirements for taxable years beginning before January 1, 2002.* For taxable years beginning before January 1, 2002, the copy B of Form 2439 furnished to a shareholder by the regulated investment company or by a nominee, as provided in § 1.852–9(a) or (b) shall be attached to the income tax return of the shareholder for the taxable year in which the amount of undistributed capital gains is includible in gross income as provided in § 1.852–4(b)(2).

(ii) *Recordkeeping requirements for taxable years beginning after December 31, 2001.* For taxable years beginning after December 31, 2001, the shareholder shall retain a copy of Form 2439 for as long as its contents may become material in the administration of any internal revenue law.

(c)(2) through (d) [Reserved] For further guidance, see § 1.852–9(c)(2) through (d) .

* * * * *

PART 301—PROCEDURE AND ADMINISTRATION

10. The authority citation for part 301 continues to read as follows:

Authority: 26 U.S.C. 7805 * * *

§ 301.6011–1 [Removed]

11. Section 301.6011–1 is removed.

12. Section 301.6011–1T is added to read as follows:

§ 301.6011–1T General requirement of return, statement or list (temporary).

(a) For provisions requiring returns, statements, or lists, see the regulations relating to the particular tax.

(b) The Secretary may prescribe in forms, instructions, or other appropriate guidance the information or documentation required to be included with any return or any statement required to be made or other document required to be furnished under any provision of the internal revenue laws or regulations.

§ 301.6903–1 [Amended]

13. In § 301.6903–1, paragraph (b) is removed and reserved.

14 Section 301.6903–1T is added to read as follows:

§ 301.6903–1T Notice of fiduciary (temporary).

(a) [Reserved] For further guidance, see § 301.6903–1(a).

(b) *Manner of notice*—(1) *Notices filed before April 24, 2002.* This paragraph (b)(1) applies to notices filed before April 24, 2002. The notice shall be signed by the fiduciary, and shall be filed with the Internal Revenue Service office where the return of the person for whom the fiduciary is acting is required to be filed. The notice must state the name and address of the person for whom the fiduciary is acting, and the nature of the liability of such person; that is, whether it is a liability for tax, and, if so, the type of tax, the year or years involved, or a liability at law or in equity of a transferee of property of a taxpayer, or a liability of a fiduciary under section 3467 of the Revised Statutes, as amended (31 U.S.C. 192) in respect of the payment of any tax from the estate of the taxpayer. Satisfactory evidence of the authority of the fiduciary to act for any other person in a fiduciary capacity must be filed with and made a part of the notice. If the fiduciary capacity exists by order of court, a certified copy of the order may be regarded as satisfactory evidence. When the fiduciary capacity has terminated, the fiduciary, in order to be relieved of any further duty or liability as such, must file with the Internal Revenue Service office with whom the notice of fiduciary relationship was filed written notice that the fiduciary capacity has terminated as to him, accompanied by satisfactory evidence of the termination of the fiduciary capacity. The notice of termination should state the name and address of the person, if any, who has been substituted as fiduciary. Any written notice disclosing a fiduciary relationship which has been filed with the Commissioner under the Internal Revenue Code of 1939 or any prior revenue law shall be considered as sufficient notice within the meaning of section 6903. Any satisfactory evidence of the authority of the fiduciary to act for another person already filed with the Commissioner or district director need not be resubmitted.

(2) *Notices filed on or after April 24, 2002.* This paragraph (b)(2) applies to notices filed on or after April 24, 2002. The notice shall be signed by the fiduciary, and shall be filed with the Internal Revenue Service Center where the return of the person for whom the fiduciary is acting is required to be filed. The notice must state the name and address of the person for whom the fiduciary is acting, and the nature of the liability of such person; that is, whether it is a liability for tax, and if so, the type of tax, the year or years involved, or a liability at law or in equity of a transferee of property of a taxpayer, or a liability of a fiduciary under 31 U.S.C. 3713(b), in respect of the payment of any tax from the estate of the taxpayer. The fiduciary must retain satisfactory evidence of his or her authority to act for any other person in a fiduciary capacity as long as the evidence may become material in the administration of any internal revenue law.

(c) through (e) [Reserved]. For further guidance, see § 301.6903–1(c) through (e).

PART 602—OMB CONTROL NUMBERS UNDER THE PAPERWORK REDUCTION ACT

15. The authority citation for part 602 continues to read as follows:

Authority: 26 U.S.C. 7805.

16. In § 602.101, paragraph (b) is amended by adding the following entries in numerical order to the table to read as follows:

§ 602.101 OMB Control numbers.

* * * * *

(b) * * *

CFR part or section where identified and described	Current OMB control No.
* * * * *	
1.48–12T	1545–0155 1545–1783
* * * * *	
1.152–3T	1545–0071 1545–1783
* * * * *	
1.611–3T	1545–0007 1545–0099, 1545–1784
* * * * *	
1.852–9T	1545–0074 1545–0123 1545–0144 1545–0145 1545–1783
* * * * *	
301.6903–1T	1545–0013 1545–1783
* * * * *	

Approved: March 22, 2002.

Robert E. Wenzel,

Deputy Commissioner of Internal Revenue.

Mark Weinberger,

Assistant Secretary of the Treasury (Tax Policy).

[FR Doc. 02–9819 Filed 4–23–02; 8:45 am]

BILLING CODE 4830–01–P

DEPARTMENT OF TRANSPORTATION

Coast Guard

33 CFR Part 117

[CGD13–02–004]

RIN 2115–AE47

Drawbridge Operations Regulations; Youngs Bay, OR

AGENCY: Coast Guard, DOT.

ACTION: Notice of temporary deviation from regulations.

SUMMARY: The Commander, Thirteenth Coast Guard District has issued a temporary deviation from the regulations governing the operation of the Old Youngs Bay Drawbridge across Youngs Bay, mile 2.4, at Astoria,

Oregon, to close the bascule span from 8 a.m. on June 17 to 6 p.m. on July 10, 2002. This temporary closure is necessary to allow the Oregon Department of Transportation (ODOT) to refurbish the bridge deck and install a pedestrian walkway in a timely manner. This course of action is intended to minimize disruption to highway traffic without significantly impacting navigation of the waterway.

EFFECTIVE DATE: This deviation is effective from 8 a.m. on June 17 to 6 p.m. on July 10, 2002.

ADDRESSES: Unless otherwise noted, documents referred to in this notice are available for inspection and copying at Commander (oan), Thirteenth Coast Guard District, 915 Second Avenue, Seattle, Washington 98174–1067, room 3510 between 7:45 a.m. and 4:15 p.m., Monday through Friday, except Federal holidays. The Bridge Section of the Aids to Navigation and Waterways Management Branch maintains the docket for this temporary deviation.

FOR FURTHER INFORMATION CONTACT: Austin Pratt, Chief, Bridge Section, Aids to Navigation and Waterways Management Branch, Telephone (206) 220–7282.

SUPPLEMENTARY INFORMATION: The Old Youngs Bay Bridge across Youngs Bay, mile 2.4, at Astoria, Oregon, provides 13 feet of vertical clearance above mean high water and 20 feet above mean low water. Navigation on the waterway consists mostly of small open vessels. In recent years, requests for openings have consistently decreased. In 2001, the bridge was opened only four times for the passage of vessels. Three of those openings were during the winter months. This deviation from the regulations in 33 CFR 117.899 will allow ODOT to complete their project faster, with less disruption to highway traffic and with a minimal impact on navigation.

Dated: April 12, 2002.

R.W. Wicklund,

Captain, U.S. Coast Guard Commander, Thirteenth Coast Guard District, Acting.

[FR Doc. 02–10034 Filed 4–23–02; 8:45 am]

BILLING CODE 4910–15–P

DEPARTMENT OF TRANSPORTATION

Coast Guard

33 CFR Part 117

[CGD01–01–182]

RIN 2115–AE47

Drawbridge Operation Regulations: Hutchinson River, Eastchester Creek, NY

AGENCY: Coast Guard, DOT.

ACTION: Temporary final rule; revision.

SUMMARY: The Coast Guard is revising the temporary final rule regulating the operation of the Pelham Parkway Bridge, mile 0.4, across the Hutchinson River in New York. The temporary rule, in effect from November 15, 2001 through May 12, 2002, requires the bridge to open on signal, after a one-hour advance notice is given, between 7 a.m. and 5 p.m., Monday through Friday. This revision provides that the draw need not open for vessel traffic from 6 a.m. to 7 p.m., on April 18, 19, 29, and 30, 2002. This action is necessary to facilitate necessary maintenance repairs at the bridge.

DATES: This temporary final rule is effective from November 15, 2001 through May 12, 2002.

ADDRESSES: Documents as indicated in this preamble are available for inspection or copying at the First Coast Guard District Office, 408 Atlantic Avenue, Boston, Massachusetts, 02110, 7 a.m. to 3 p.m., Monday through Friday, except Federal holidays. The telephone number is (617) 223–8364.

FOR FURTHER INFORMATION CONTACT: Mr. Joe Schmied, Project Officer, First Coast Guard District, at (212) 668–7165.

SUPPLEMENTARY INFORMATION:

Regulatory History

Pursuant to 5 U.S.C. 553, a notice of proposed rulemaking (NPRM) was not published for this regulation. Good cause exists for not publishing a Notice of proposed rulemaking in the **Federal Register**.

On October 17, 2001, we published a temporary final rule governing the operation of the Pelham Parkway Bridge (66 FR 52684). The temporary final rule required a one-hour advance notice for any bridge opening from November 15, 2001 through May 12, 2002. In the course of the ongoing rehabilitation of the bridge it was determined that certain work at the bridge required that it remain in the closed position for two two-day periods. After contacting all known waterway users to coordinate the closure dates, we decided to revise the temporary final rule to provide that the bridge remain closed on April 18, 19, 29, and 30, 2002.

Any delay encountered in this regulation's effective date would be unnecessary and contrary to the public interest since immediate action is needed to facilitate necessary electrical and mechanical maintenance at the bridge.

Background and Purpose

The Pelham Parkway Bridge has a vertical clearance of 13 feet at mean high water and 20 feet at mean low water in the closed position. The current operating regulations for the bridge, listed at 33 CFR 117.793, require the bridge to open on signal at all times.

The bridge owner, New York City Department of Transportation (NYCDOT), requested an additional temporary change to the operating regulations governing the Pelham Parkway Bridge to facilitate several bridge closures previously not anticipated in the original scope of work. As a result of the above information, we are revising the temporary final rule (66 FR 52684) we published on October 17, 2001, to add the additional closure dates to the rulemaking.

The additional work at the bridge will require the bridge to remain in the closed position on April 18, 19, 29, and 30, 2002.

The Coast Guard believes this additional temporary change to the drawbridge operation regulations is reasonable and will meet the present needs of navigation based upon coordination with the operators that use this waterway.

Regulatory Evaluation

This temporary final rule is not a significant regulatory action under section 3(f) of Executive Order 12866 and does not require an assessment of potential costs and benefits under section 6(a)(3) of that Order. It has not been reviewed by the Office of Management and Budget under that Order. It is not significant under the regulatory policies and procedures of the Department of Transportation (DOT) (44 FR 11040; Feb. 26, 1979). The Coast Guard expects the economic impact of this temporary final rule to be so minimal that a full Regulatory Evaluation under paragraph 10e of the regulatory policies and procedures of DOT is unnecessary. This conclusion is based on the fact that the additional bridge closures were coordinated with the mariners that normally use this waterway.

Small Entities

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

The Coast Guard certifies under 5 U.S.C. 605(b) that this rule will not have a significant economic impact on a substantial number of small entities. This conclusion is based on the fact that the additional bridge closures were coordinated with the mariners that normally use this waterway.

Collection of Information

This temporary final rule does not provide for a collection of information under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 *et seq.*).

Federalism

The Coast Guard has analyzed this temporary final rule in accordance with the principles and criteria contained in Executive Order 12612 and has determined that this temporary final rule does not have sufficient federalism implications to warrant the preparation of a Federalism Assessment.

Environment

The Coast Guard considered the environmental impact of this temporary final rule and concluded that, under Section 2.B.2., Figure 2–1, paragraph (32)(e), of Commandant Instruction M16475.1C, this temporary final rule is categorically excluded from further environmental documentation because promulgation of changes to drawbridge regulations have been found not to have a significant effect on the environment. A written ''Categorical Exclusion Determination'' is not required for this temporary final rule.

Indian Tribal Governments

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

Energy Effects

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

List of Subjects in 33 CFR Part 117

Bridges.

Regulations

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

PART 117—DRAWBRIDGE OPERATION REGULATIONS

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

Authority: 33 U.S.C. 499; 49 CFR 1.46; 33 CFR 1.05–1(g); section 117.255 also issued under the authority of Pub. L. 102–587, 106 Stat. 5039.

2. From November 15, 2001, through May 12, 2002, § 117.793(d) is revised to read as follows:

§ 117.793 Hutchinson River Eastchester Creek

* * * * *

(d) The Pelham Parkway Bridge, mile 0.4, shall open on signal; except that, from 7 a.m. to 5 p.m., Monday through Friday, the draw shall open on signal after at least a one-hour advance notice is given by calling the number posted at the bridge; except that, from 6 a.m. to 7 p.m., on April 18, 19, 29, and 30, 2002, the draw need not open for vessel traffic.

Dated: April 11, 2002.

G.N. Naccara,

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

[FR Doc. 02–10035 Filed 4–24–02; 8:45 am]

BILLING CODE 4910–15–M

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 52

[CA 262–0338c; FRL–7174–2]

Interim Final Determination That State Has Corrected the Rule Deficiencies and Stay of Sanctions in California, San Joaquin Valley Unified Air Pollution Control District

AGENCY: Environmental Protection Agency (EPA).

ACTION: Interim final determination.

SUMMARY: Elsewhere in today's **Federal Register**, EPA has proposed approval of revisions to the California State Implementation Plan (SIP). The revisions concern San Joaquin Valley Unified Air Pollution Control District (SJVUAPCD) Rule 4354. Based on the proposed approval, EPA is making an interim final determination that the State has corrected deficiencies in the rule for which a sanction clock began on October 2, 2000. This action will stay the imposition of the offset sanctions and defer the imposition of the highway sanctions. Although this action is effective upon publication, EPA will take comment and will publish a final rule taking into consideration any comments received on this interim final determination.

DATES: This interim final determination is effective April 24, 2002. Comments must be received by May 24, 2002.

ADDRESSES: Written comments must be submitted to Andrew Steckel, Rulemaking Section (AIR–4), Air Division, U.S. Environmental Protection Agency, Region IX, 75 Hawthorne Street, San Francisco, CA 94105.

Copies of the rule revisions and EPA's evaluation report for the rule are available for public inspection at EPA's Region IX office during normal business hours. Copies of the submitted rule revisions are available for inspection at the following locations:

Rulemaking Office (AIR–4), Air Division, U.S. Environmental Protection Agency, Region IX, 75 Hawthorne Street, San Francisco, CA 94105.

Environmental Protection Agency, Air Docket (6102), 401 ''M'' Street, SW., Washington, DC 20460.

California Air Resources Board, Stationary Source Division, Rule Evaluation Section, 1001 ''I'' Street, Sacramento, CA 95814.

San Joaquin Valley Unified Air Pollution Control District, 1990 E. Gettysburg Ave., Fresno, CA 93726.

FOR FURTHER INFORMATION CONTACT: Charnjit Bhullar, Rulemaking Office, AIR–4, Air Division, U.S. Environmental Protection Agency,

Region IX, 75 Hawthorne Street, San Francisco, CA 94105, Telephone: (415) 972–3960.

SUPPLEMENTARY INFORMATION:

I. Background

On September 29, 1998, the State submitted SJVUAPCD Rule 4354, for which EPA published a limited disapproval in the **Federal Register** on September 1, 2000 (65 FR 53181). The effective date of our limited disapproval was October 2, 2000. EPA's disapproval action started an 18-month clock for the imposition of one sanction (followed by a second sanction 6 months later) and a 24-month clock for promulgation of a Federal Implementation Plan (FIP). The State subsequently submitted a revised version of Rule 4354 on March 05, 2002. In the Proposed Rules section of today's **Federal Register**, EPA has proposed approval of the March 2002 submittal.

Based on the proposed approval, EPA believes that it is more likely than not that the State has corrected the original disapproval deficiencies. Therefore, EPA is taking this interim final rulemaking action finding that the State has corrected the deficiencies. However, EPA is also providing the public with an opportunity to comment on this interim final action. If, based on the comments on this action and the comments on EPA's proposed approval, EPA determines that the State's submittal is not approvable and this interim final action was inappropriate, EPA will either propose or take final action finding that the State has not corrected the original disapproval deficiencies. As appropriate, EPA will also issue an interim final determination that the deficiencies have not been corrected. Until EPA takes such action, the application of sanctions will continue to be stayed.

This action does not stop the sanctions clock that started for this area on October 2, 2000, the effective date of our disapproval. However, this action will stay the imposition of the offset sanction and will defer imposition of the highway sanction. See 40 CFR 52.31(d)(2)(ii). If EPA takes final action approving the State's submittal, such action will permanently stop the sanctions clock and will permanently lift any imposed, stayed or deferred sanctions. However, if at any time EPA determines that the State, in fact, did not correct the disapproval deficiencies, as appropriate, EPA either will withdraw this interim final determination or take final action finding that the State has not corrected the deficiencies. Such action will retrigger the sanctions consequences as described in 40 CFR 52.31.

II. EPA Action

EPA is taking interim final action finding that the State has corrected the disapproval deficiencies that started the sanctions clock. Based on this action, imposition of the offset sanction will be stayed and imposition of the highway sanction will be deferred until EPA takes final action fully approving the State's submittal or EPA takes action proposing or finally disapproving in whole or part the State submittal. If EPA takes final action approving the State's submittal, any deferral or stay of the sanctions clock will be permanently stopped and any imposed, stayed or deferred sanctions will be permanently lifted.

Because EPA has preliminarily determined that the State has an approvable plan, relief from sanctions should be provided as quickly as possible. Therefore, EPA is invoking the good cause exception to the 30-day notice requirement of the Administrative Procedure Act because the purpose of this document is to relieve a restriction. *See* 5 U.S.C. 553(d)(1).

III. Administrative Requirements

Under Executive Order 12866 (58 FR 51735, October 4, 1993), this action is not a ''significant regulatory action'' and therefore is not subject to review by the Office of Management and Budget. For this reason, this action is also not subject to Executive Order 32111, ''Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution, or Use'' (66 FR 28355, May 22, 2001). This action merely stays and defers federal sanctions. Accordingly, the Administrator certifies that this rule will not have a significant economic impact on a substantial number of small entities under the Regulatory Flexibility Act (5 U.S.C. 601 *et seq.*). Because this rule only stays an imposed sanction and defers the imposition of another, it does not contain any unfunded mandate or significantly or uniquely affect small governments, as described in the Unfunded Mandates Reform Act of 1995 (Pub. L. 104–4).

This rule also does not have tribal implications because it will not have a substantial direct effect on one or more Indian tribes, on the relationship between the Federal Government and Indian tribes, or on the distribution of power and responsibilities between the Federal Government and Indian tribes, as specified by Executive Order 13175 (65 FR 67249, November 9, 2000). This action also does not have Federalism implications because it does not have substantial direct effects on the States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government, as specified in Executive Order 13132 (64 FR 43255, August 10, 1999). This action merely stays a sanction and defers another one, and does not alter the relationship or the distribution of power and responsibilities established in the Clean Air Act. This rule also is not subject to Executive Order 13045, ''Protection of Children from Environmental Health Risks and Safety Risks'' (62 FR 19885, April 23, 1997), because it is not economically significant.

This rule does not contain technical standards; thus, the requirements of section 12(d) of the National Technology Transfer and Advancement Act of 1995 (15 U.S.C. 272 note) do not apply. As required by section 3 of Executive Order 12988 (61 FR 4729, February 7, 1996), in issuing this rule, EPA has taken the necessary steps to eliminate drafting errors and ambiguity, minimize potential litigation, and provide a clear legal standard for effected conduct. EPA has compiled with Executive Order 12630 (53 FR 8859, March 15, 1988) by examining the takings implications of the rule in accordance with the ''Attorney General's Supplemental Guidelines for the Evaluation of Risk and Avoidance of Unanticipated Takings'' issued under the executive order. This rule does not impose an information collection burden under the provisions of the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 *et seq.*).

The Congressional Review Act, 5 U.S.C. 801 *et seq.*, as added by the Small Business Regulatory Enforcement Fairness Act of 1996, generally provides that before a rule may take effect, the agency promulgating the rule must submit a rule report, which includes a copy of the rule, to each House of the Congress and to the Comptroller General of the United States. 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 impractible, 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 24, 2002. 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**. A major rule cannot take effect until 60 days after it is published in the **Federal Register**. This action is not a ''major rule'' as defined by 5 U.S.C. 804(2).

Under section 307(b)(1) of the Clean Air Act, petitions for judicial review of this action must be filed in the United States Court of Appeals for the appropriate circuit by June 24, 2002. 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 rules. This action may not be challenged later in proceedings to enforce its requirements. (See section 307(b)(2).)

List of Subjects in 40 CFR Part 52

Environmental protection, Air pollution control, Hydrocarbons, Intergovernmental relations, Ozone, Reporting and recordkeeping requirements, Volatile organic compounds.

Dated: April 10, 2002.

Nora L. McGee,

Acting Regional Administrator, Region IX.

[FR Doc. 02–9909 Filed 4–23–02; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 52

[MO 155–1155a; FRL–7175–3]

Approval and Promulgation of Implementation Plans; State of Missouri

AGENCY: Environmental Protection Agency (EPA).

ACTION: Direct final rule.

SUMMARY: EPA is taking final action to approve a set of volatile organic compound (VOC) rules applicable to the Missouri portion of the Kansas City maintenance area as a revision to the Missouri State Implementation Plan (SIP). These rules restrict VOC emissions from certain large stationary sources and area sources. The effect of this approval is to ensure Federal enforceability of the state air program rules and to maintain consistency between the state-adopted rules and the approved SIP. This action also determines that Missouri has met the condition of approval of its revised maintenance plan for Kansas City and rescinds the prior conditional approval of the revised maintenance plan.

DATES: This direct final rule will be effective June 24, 2002, unless EPA receives adverse comments by May 24, 2002. If adverse comments are received, EPA will publish a timely withdrawal of the direct final rule in the **Federal Register** informing the public that the rule will not take effect.

ADDRESSES: Comments may be mailed to Leland Daniels, Environmental Protection Agency, Air Planning and Development Branch, 901 North 5th Street, Kansas City, Kansas 66101.

Copies of documents relative to this action are available for public inspection during normal business hours at the above-listed Region 7 location. The interested persons wanting to examine these documents should make an appointment with the office at least 24 hours in advance.

FOR FURTHER INFORMATION CONTACT: Leland Daniels at (913) 551–7651.

SUPPLEMENTARY INFORMATION: Throughout this document whenever ''we,'' ''us,'' or ''our'' is used, we mean EPA. This section provides additional information by addressing the following questions:

What is a SIP?
What is the Federal approval process for a SIP?
What does Federal approval of a state regulation mean to me?
What is being addressed in this document?
Have the requirements for approval of a SIP revision been met?
What action is EPA taking?

What Is a SIP?

Section 110 of the Clean Air Act (CAA) requires states to develop air pollution regulations and control strategies to ensure that state air quality meets the national ambient air quality standards established by EPA. These ambient standards are established under section 109 of the CAA, and they currently address six criteria pollutants. These pollutants are: carbon monoxide, nitrogen dioxide, ozone, lead, particulate matter, and sulfur dioxide.

Each state must submit these regulations and control strategies to us for approval and incorporation into the Federally-enforceable SIP.

Each federally-approved SIP protects air quality primarily by addressing air pollution at its point of origin. These SIPs can be extensive, containing state regulations or other enforceable documents and supporting information such as emission inventories, monitoring networks, and modeling demonstrations.

What Is the Federal Approval Process for a SIP?

In order for state regulations to be incorporated into the federally-enforceable SIP, states must formally adopt the regulations and control strategies consistent with state and Federal requirements. This process generally includes a public notice, public hearing, public comment period, and a formal adoption by a state-authorized rulemaking body.

Once a state rule, regulation, or control strategy is adopted, the state submits it to us for inclusion into the SIP. We must provide public notice and seek additional public comment regarding the proposed Federal action on the state submission. If adverse comments are received, they must be addressed prior to any final Federal action by us.

All state regulations and supporting information approved by EPA under section 110 of the CAA are incorporated into the federally-approved SIP. Records of such SIP actions are maintained in the Code of Federal Regulations (CFR) at Title 40, part 52, entitled ''Approval and Promulgation of Implementation Plans.'' The actual state regulations which are approved are not reproduced in their entirety in the CFR outright but are ''incorporated by reference,'' which means that we have approved a given state regulation with a specific effective date.

What Does Federal Approval of a State Regulation Mean to Me?

Enforcement of the state regulation before and after it is incorporated into the federally-approved SIP is primarily a state responsibility. However, after the regulation is federally approved, we are authorized to take enforcement action against violators. Citizens are also offered legal recourse to address violations as described in section 304 of the CAA.

What Is Being Addressed in This Document?

Missouri has adopted and amended a set of regulations to control emission of VOCs from certain stationary sources and area sources located within the Missouri portion of the Kansas City ozone maintenance area, specifically Clay, Platte, and Jackson Counties. The rules we are approving include: Rule 10 Code of State Regulations (CSR) 10–2.205, Control of Emissions from Aerospace Manufacture and Rework Facilities (a new rule), Rule 10 CSR 10–2.210, Control of Emissions from Solvent Metal Cleaning (an amendment), Rule 10 CSR 10–2.215

Control of Emissions from Solvent Cleanup Operations (a new rule), and Rule 10 CSR 10–2.260, Control of Petroleum Liquid Storage, Loading and Transfer (amendment). Missouri, in a continuing effort to achieve additional needed emission reductions, has adopted these control regulations. Implementation of these rules is expected to reduce VOC emissions from both point and area sources by 1,978 tons per year. These new regulations were adopted by the Missouri Air Conservation Commission on December 7, 2000, May 24, 2001, February 6, 2001, and March 29, 2001, respectively, and became effective March 30, 2001, October 30, 2001, May 30, 2001, and July 30, 2001, respectively. Today, EPA is taking final action to approve rules 10 CSR 10–2.205, Control of Emissions from Aerospace Manufacture and Rework Facilities; rule 10 CSR 10–2.210, Control of Emissions from Solvent Metal Cleaning; rule 10 CSR 10–2.215 Control of Emissions from Solvent Cleanup Operations; and rule 10 CSR 10–2.260, Control of Petroleum Liquid Storage, Loading and Transfer a revision to the Missouri SIP.

In 1999 we conditionally approved (64 FR 28753, May 27, 1999) the new contingency measures in the maintenance plan and gave the State one year to opt-in to the RFG program or adopt equivalent emission reduction measures. By letter dated July 28, 1999, the Governor of Missouri filed an application to require RFG for the Kansas City, Missouri, area. The State's action to opt in to the RFG program fulfilled the condition we imposed upon the approval. Before EPA acted on the application to impose RFG, the Court of Appeals for the District of Columbia Circuit first stayed and later vacated an EPA rule which would have allowed former nonattainment areas (like Kansas City) and other areas to opt in to the RFG program (*American Petroleum Inst.* v. *U.S. Environmental Protection Agency*, 198 F. 3d 275 (D.C. Cir. 2000)). Subsequently, the State chose to implement a lower volatility gasoline measure (7.0 psi RVP). This measure was approved on February 2, 2002 (67 FR 6658, effective March 15, 2002).

In addition, Missouri has worked to establish control measures to provide the additional emissions reductions needed to fulfill the contingency measure requirement. As discussed above, during 2001 Missouri submitted four additional control measures to limit VOC emissions.

For these reasons, we are determining that Missouri has met the condition of the May 27, 1999, approval of the maintenance plan revision (64 FR 28753), and we are rescinding the prior conditional approval (40 CFR 52.1319) and providing full approval of the revision to the maintenance plan.

Have the Requirements for Approval of a SIP Revision Been Met?

The state submittal has met the public notice requirements for SIP submissions in accordance with 40 CFR 51.102. The submittal also satisfied the completeness criteria of 40 CFR part 51, appendix V. In addition, as explained above and in more detail in the technical support document which is part of this document, the revision meets the substantive SIP requirements of the CAA, including section 110 and implementing regulations.

What Action Is EPA Taking?

This action approves the four VOC rules (10 CSR 10–2.205, Control of Emissions from Aerospace Manufacture and Rework Facilities; 10 CSR 10–2.210, Control of Emissions from Solvent Metal Cleaning; 10 CSR 10–2.215 Control of Emissions from Solvent Cleanup Operations; and 10 CSR 10–2.260, Control of Petroleum Liquid Storage, Loading and Transfer) as a revision to Missouri's SIP for the Kansas City, Missouri, area. This action also provides full approval of the revision to the maintenance plan and also rescinds the prior conditional approval (40 CFR 52.1319).

We are processing this action as a final action because it adds noncontroversial regulations to the SIP and recognizes that an action previously taken by Missouri satisfied the prior conditional approval. We do not anticipate any adverse comments. Please note that if EPA receives adverse comment on an amendment, paragraph, or section of this rule and if that provision is severed from the remainder of the rule, EPA may adopt as final those provisions of the rule that are not the subject of an adverse comment.

Administrative Requirements

Under Executive Order 12866 (58 FR 51735, October 4, 1993), this action is not a ''significant regulatory action'' and therefore is not subject to review by the Office of Management and Budget. For this reason, this action is also not subject to Executive Order 13211, ''Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution, or Use'' (66 FR 28355, May 22, 2001). This action merely approves state law as meeting Federal requirements and imposes no additional requirements beyond those imposed by state law. Accordingly, the Administrator certifies that this rule will not have a significant economic impact on a substantial number of small entities under the Regulatory Flexibility Act (5 U.S.C. 601 *et seq.*). Because this rule approves pre-existing requirements under state law and does not impose any additional enforceable duty beyond that required by state law, it does not contain any unfunded mandate or significantly or uniquely affect small governments, as described in the Unfunded Mandates Reform Act of 1995 (Pub. L. 104–4).

This rule also does not have tribal implications because it will not have a substantial direct effect on one or more Indian tribes, on the relationship between the Federal Government and Indian tribes, or on the distribution of power and responsibilities between the Federal Government and Indian tribes, as specified by Executive Order 13175 (65 FR 67249, November 9, 2000). This action also does not have Federalism implications because it does not have substantial direct effects on the States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government, as specified in Executive Order 13132 (64 FR 43255, August 10, 1999). This action merely approves a state rule implementing a Federal standard, and does not alter the relationship or the distribution of power and responsibilities established in the CAA. This rule also is not subject to Executive Order 13045, ''Protection of Children from Environmental Health Risks and Safety Risks'' (62 FR 19885, April 23, 1997), because it is not economically significant.

In reviewing SIP submissions, EPA's role is to approve state choices, provided that they meet the criteria of the CAA. In this context, in the absence of a prior existing requirement for the State to use voluntary consensus standards (VCS), EPA has no authority to disapprove a SIP submission for failure to use VCS. It would thus be inconsistent with applicable law for EPA, when it reviews a SIP submission, to use VCS in place of a SIP submission that otherwise satisfies the provisions of the CAA. Thus, the requirements of section 12(d) of the National Technology Transfer and Advancement Act of 1995 (15 U.S.C. 272 note) do not apply. This rule does not impose an information collection burden under the provisions of the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 *et seq.*).

The Congressional Review Act, 5 U.S.C. 801 *et seq.,* as added by the Small Business Regulatory Enforcement Fairness Act of 1996, generally provides that before a rule may take effect, the agency promulgating the rule must

submit a rule report, which includes a copy of the rule, to each House of the Congress and to the Comptroller General of the United States. 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**. A major rule cannot take effect until 60 days after it is published in the **Federal Register**. This action is not a ''major rule'' as defined by 5 U.S.C. section 804(2).

Under section 307(b)(1) of the CAA, petitions for judicial review of this action must be filed in the United States Court of Appeals for the appropriate circuit by June 24, 2002. 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).)

List of Subjects 40 CFR Part 52

Environmental protection, Air pollution control, Carbon monoxide, Hydrocarbons, Incorporation by reference, Intergovernmental relations, Lead, Nitrogen dioxide, Ozone, Particulate matter, Reporting and recordkeeping requirements, Sulfur oxides.

Dated: April 11, 2002.

James B. Gulliford,

Regional Administrator, Region 7.

Chapter I, title 40 of the Code of Federal Regulations is amended as follows:

PART 52—[AMENDED]

1. The authority citation for part 52 continues to read as follows:

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

Subpart AA—Missouri

§ 52.1319 [Removed and Reserved]

2. Section 52.1319 is removed and reserved.

3. In § 52.1320(c), the table is amended under Chapter 2 by adding in numeric order entries 10–2.205 and 10–2.215, and by revising entries 10–2.210 and 10–2.260, to read as follows:

§ 52.1320 Identification of Plan.

* * * * *

(c) * * *

EPA-APPROVED MISSOURI REGULATIONS

Missouri citation	Title	State effective date	EPA approval date	Explanation
	Missouri Department of Natural Resources			
	Chapter 2—Air Quality Standards and Air Pollution Control Regulations for the Kansas City Metropolitan Area			
*	* * * *	*	*	*
10–2.205	Control of Emissions from Aerospace Manufacture and Rework Facilities.	3/30/01	4/24/02	
10–2.210	Control of Emissions from Solvent Metal Cleaning	10/30/01	4/24/02	
10–2.215	Control of Emissions from Solvent Cleanup Operations	5/30/01	4/24/02	
*	* * * *	*	*	*
10–2.260	Control of Petroleum Liquid Storage, Loading, and Transfer	7/30/01	4/24/02	
*	* * * *	*	*	*

* * * * *

[FR Doc. 02–9911 Filed 4–23–02; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 271

[FRL–7173–7]

Arkansas: Final Authorization of State Hazardous Waste Management Program Revisions

AGENCY: Environmental Protection Agency (EPA).

ACTION: Immediate final rule.

SUMMARY: The State of Arkansas has applied for Final authorization of its revisions to its Hazardous Waste Program under the Resource Conservation and Recovery Act (RCRA). The EPA has determined that these revisions satisfy all requirements needed to qualify for Final authorization, and is authorizing the State's revisions through this immediate final action. The EPA is publishing this rule to authorize the revisions without a prior proposal because we believe this action is not controversial and do not expect adverse comments. Unless we get adverse comments which oppose this authorization during the comment period, the decision to authorize the State of Arkansas Department of Environmental Quality's (ADEQ) revisions to their hazardous waste program will take effect. If adverse comments are received, we will publish a document in the **Federal Register** either; withdrawing this immediate final decision; or a notice containing a response to comments and which either affirms that the immediate final decision takes effect or reverses the decision.

DATES: This immediate final rule is effective on June 24, 2002, unless EPA receives adverse written comments by May 24, 2002. Should the EPA receive such comments, it will publish a timely document either: withdrawing the immediate final publication or affirming the publication and responding to comments.

ADDRESSES: Written comments referring to Docket Number AR–01–02, should be sent to Alima Patterson, Region 6, Regional Authorization Coordinator, Grants and Authorization Section (6PD-G), Multimedia Planning and Permitting Division, EPA Region 6, 1445 Ross Avenue, Dallas, Texas 75202–2733. Copies of the State of Arkansas program revision application and the materials which EPA used in evaluating the revision are available for inspection and copying from 8:30 a.m. to 4 p.m. Monday through Friday at the following addresses: EPA Region 6, 1445 Ross Avenue, Dallas, Texas 75202–2733,

(214) 665–8533: or Arkansas Department of Environmental Quality, 8101 Interstate 30, Little Rock, Arkansas 72219–8913, (501) 682–0876.

FOR FURTHER INFORMATION CONTACT: Alima Patterson (214) 665–8533.

SUPPLEMENTARY INFORMATION:

A. Why Are Revisions to State Programs Necessary?

States which have received final authorization from EPA under RCRA section 3006(b), 42 U.S.C. 6926(b), must maintain a hazardous waste program that is equivalent to, consistent with, and no less stringent than the Federal Hazardous Waste Program. As the Federal program changes, States must change their programs and ask EPA to authorize the changes. Changes to State programs may be necessary when Federal or State statutory or regulatory authority is modified or when certain other changes occur. Most commonly, States must change their programs because of changes to EPA's regulations in 40 CFR parts 124, 260 through 266, 268, 270, 273, and 279.

B. What Is the Effect of Today's Authorization Decision?

The effect of this decision is that a facility in Arkansas subject to RCRA will now have to comply with the authorized State requirements (in RCRA Clusters III-IX and Checklist 181 Universal Waste Rule, Specific Provisions for Hazardous Lamps in RCRA Cluster X listed in this document) instead of the equivalent Federal requirements in order to comply with RCRA. Arkansas has enforcement responsibilities under its state hazardous waste program for violations of such program, but EPA retains its authority under RCRA sections 3007, 3008, 3013, and 7003, which include, among others, authority to: (1) Do inspections, and require monitoring, tests, analyses or reports; (2) enforce RCRA requirements and suspend or revoke permits; and (3) take enforcement actions regardless of whether the State has taken its own actions. This action does not impose additional requirements on the regulated community because the regulations for which Arkansas is being authorized by today's action are already effective, and are not changed by today's action.

C. What Is the History of Arkansas' Final Authorization and It's Revisions?

Arkansas initially received final authorization on January 25, 1985, (50 FR 1513) to implement its Base Hazardous Waste Management program. Arkansas received authorization for revisions to its program at January 11, 1985 (50 FR 1513), effective January 25, 1985; March 27, 1990 (55 FR 11192) effective May 29, 1990; September 18, 1991 (56 FR 47153) effective November 18, 1991; October 5, 1992 (57 FR 45721) effective December 4, 1992; and October 7, 1994 (59 FR 51115) effective December 21, 1994. The authorized Arkansas RCRA program was incorporated by reference into the Code of Federal Regulations effective December 13, 1993 (58 FR 52674). On November 7, 2000, Arkansas submitted a final complete program revision application, seeking authorization of its program revisions in accordance with 40 CFR 271.21. The State of Arkansas also has adopted the regulations for Import and Export of Hazardous Waste. However, the requirements of the Import and Export regulations will be administered by the EPA and not the State, because the exercise of foreign relations and International Commerce powers is reserved to the Federal government under the United States Constitution. Therefore, the State of Arkansas is not seeking authorization for this rule.

On April 1994, Arkansas Department of Pollution Control and Ecology (ADPC&E), revised its Regulation Number 23 from one of ''incorporation by reference'' to the adoption and incorporation of a version of the full text of the Federal regulatory language. Modifications were made as necessary to provide for the appropriate State protocol or point of contact for federally authorized rules and regulations under the State waste management program, with additional or more stringent State requirements. The text of 40 CFR parts 260–266, 268, 270, 273 and 279 has been inserted into Chapter 2 of Regulation No 23, with the federal ''Parts'' redesignated as State ''Sections'', and federal ''Subparts'' redesignated as State ''Subsections''. Part, Subpart, and paragraph numbering and citations have been retained in the same format as in the federal regulations throughout the text. This restructuring makes it simpler for the regulated community to determine which specific rules are effective at any point in time under the State hazardous waste management program, and provides a single regulatory reference for most hazardous waste management situations within the State. The Consolidated Independent Counsel Statement submitted with Arkansas' application for final authorization addresses the revised program implementation requirements under RCRA as amended by The Hazardous and Solid Waste Amendments of 1984 (HSWA). The State is seeking authorization in this application for RCRA Clusters III, IV, V, VI, VII, VIII, IX and one rule in RCRA Cluster X (Universal Waste Rule, Specific Provisions for Hazardous Waste Lamps Checklist 181).

Reference to ''ARK'' ''Code Ann'' and ''A.C.A'' refer to the Arkansas Code of 1987 Annotated, as amended and effective in 2001. Reference to ''APC&E Reg. No. 23'' refers to the Arkansas of Pollution Control and Ecology Commission's Regulations Number 23 (Hazardous Waste Management) (formerly titled the Arkansas Hazardous Waste Management Code), amended on December 1, 1995, effective January 21, 1996, to adopt all rules promulgated by EPA through June 30, 1995, and last amended on February 25, 2000, to adopt all final rules promulgated by EPA through July 6, 1999 and became effective on May 20, 2000. Dates of enactment and adoption for other statutes or regulations are given when cited.

Arkansas Act 1219 of 1987 renamed the Arkansas Department of Pollution Control and Ecology (ADPC&E) as the ''Arkansas Department of Environmental Quality'' (hereafter referred to as the (ADEQ) with an effective date March 31, 1999. This name change was implemented in order to resolve public confusion concerning the respective functions and responsibilities of the Arkansas Department of Pollution Control and Ecology Commission and the Arkansas Department of Pollution Control and Ecology which arose because of the similarity in the names of these entities. The Arkansas Department of Environmental Quality succeeded to all the general powers and responsibilities previously assigned to the Department of Pollution Control and Ecology, and this name change in no way impaired or affected any of the powers and authorities of the ADPC&E, nor did it impair the continued effectiveness of any regulations, policies, or orders promulgated or issued by the Arkansas Pollution Control and Ecology Commission prior to the effective date of Act 1219. Likewise, references to Arkansas Department of Pollution Control and Ecology as it was referred to or empowered throughout the entire Arkansas Code, Annotated were changed to refer to the ''Arkansas Department of Environmental Quality''. The change in reference from the old to the name was codified in the Arkansas Code, Annotated, by Act 1164 of 1999. This administrative name change has been reflected throughout this application.

D. What Revisions Are We Approving With Today's Action?

On November 7, 2000, the State of Arkansas submitted a final complete program revision application, seeking authorization of their revisions in accordance with 40 CFR 271.21. We now make an immediate final decision, subject to receipt of adverse comments, that the State of Arkansas's hazardous waste program revision satisfies all the requirements necessary to qualify for Final authorization. Arkansas' revisions consist of regulations which specifically govern Federal Hazardous Waste promulgated from July 1, 1992, to June 30, 1999 (RCRA Clusters III-IX, and one rule in RCRA Cluster X Universal Waste Rule, promulgated July 6, 1999. Arkansas requirements are included in a chart with this document.

Federal citation	State analog
1. Used Oil Filter Exclusion; Technical Correction, [57 FR 29220] July 1, 1992. (Checklist 107).	Arkansas Code of 1987 Annotated (A.C.A.) as amended, effective 1995, Arkansas Pollution Control and Ecology (APC&E) Regulation Number 23, (Hazardous Waste Management) (HWM) A.C.A. § 8–7–209(a)(4), § 8–7–209(a)(5) introductory paragraph, § 8–7–203(6), § 8–7–202, Reg. No. 23 §§ 261.1 through 261.4, 261.1(b)(15), as amended December 1, 1995; effective January 21, 1996.
2. Toxicity Characteristics Revision; Technical Correction, [57 FR 30657] July 10, 1992. (Checklist 108).	A.C.A § 8–7–209(a)(4), APC&E Reg. No. 23 §§ 261.3(a)(2)(i) 261.4, 261.8, 261.24, 261.30(b), 261, Appendix II, 264.301(e)(1), 265.221(d)(1), 265.273(a), 265.301(d)(1) and 265, Appendix I, as amended December 1, 1995; effective January 21, 1996.
3. Land disposal Restrictions for Newly Listed Wastes and Hazardous Debris, [57 FR 37194–37282] August 18, 1992. (Checklist 109).	A.C.A § 8–7–209(a)(4), (5)(6), APC&E Reg. No. 23 §§ 261.3(f), 268.2, 268.5, 268.7, 268.14, 268.36, 268.40–43, 268.45, 270.13–14, 261.3(a)&(c), 268.9, 268.6, 260.10, 262.34, 264.110, 264.111, 264.112, 264.140, 264.142, 264 Subsection DD, 265.110–112, 265.140–2, 265.221, 265 Subsection DD, 268.50, 270.42, 270.72, as amended December 1, 1995; effective January 21, 1996.
4. Coke By-Product Listings, [57 FR 37284] August 18, 1992. (Checklist 110).	A.C.A § 8–7–209(a)(4), APC&E Reg. No. 23 §§ 261.4(a)(1), 261.31, 261.32, 261.33, 261, Appendix VIII, 264.572(a)(2), and 265.443(a)(2), as amended December 1, 1995; effective January 21, 1996.
5. Burning of Hazardous Waste in Boilers and Industrial Furnaces; Technical Amendment III, [57 FR 38558] August 25, 1992. (Checklist (111).	A.C.A. § 8–7–209(a)(4), (5), (6), § (8), (11) and (12), § 8–7–209(b), § 8–7–202 § 8–7–202(2), § 8–7–218(b)(2), § 8–7– 218(c), § 8–7–219, § 8–7–223, § 8–7–225(a), § 8–7–211, APC&E Reg. No. 23 §§ 260.10, 260.20(a), 261.2(d)(2), 261.2(e)(2)(iv), 261.4, 261.6, 260.10, 260.11, 260.20, 261.2, 261.33(b)(2), 264.1, 264.112, 264.340, 265.1, 265.112, 265.113, 265.340(a), 265.370, 264.1(g)(2), 265.1(c)(6), 266.100(a) and (f), 266.101(c)(1)(2), 266.103(b)(2)(ii)(iii), 266.103(b)(3)(ii)(B), 266.103(b)(3)(v), 266.103(c)(1), 266.103(c)(ii)(A), 266.103(c)(1)(ii)(A)(1), 266.103(c)(1)(ii)(A)(2), 266.103(c)(1)(ii)(C), 266.103(c)(1)(iii), 266.103(c)(vi), 266.103(c)(5), 266.103(c)(7)(ii)(B), 266.104(f)(1), 266.106(b)(7), 266.106(d)(1)(3)(5), 266.107(a), 266.108(c), 266.112(B)(2)(i), 3(b)(2) 266 Subsections H, 266 Appendices I–X, 270.22, 270.42, 270.66, 270.72, and 270.73, as amended December 1, 1995; effective January 21, 1996.
6. Recycled Used Oil Management Standards, [57 FR 41566–41626], September 10, 1992. (Checklist 112).	A.C.A. § 8–7–209(a)(4), § 8–7–209(a)(5), (6), and (11), APC&E Reg. No. 23 §§ 260.10, 261.3(a)(2), 261.5(j), 261.6(a)(2), (3), and (4), 266.40–266.44, 266.100(b), 279 and 30(b), as amended December 1, 1995; effective January 21, 1996.
7. Financial Responsibility for Third-Party Liability, Closure and post-closure, [57 FR 42832], September 16, 1992, Standards Applicable to Owners and Operators of Hazardous Waste Treatment, Storage, and Disposal Facilities; Liability Coverage, [53 FR 33938] September 1, 1988, Liability Requirements; Technical Amendments, [56 FR 30200] July 1, 1991. (Checklists 113, 113.1, and 113.2).	A.C.A. § 8–7–209(1), and (3), § 8–7–209(a) (5), (6), (8), (11) and (12), § 8–7–209(b), § 8–7–202(2), § 8–7– 218(b)(2), § 8–7–216(f), § 8–7–218(2)(b)(2), § 8–7–218(c), § 8–7–219, § 8–7–223, § 8–7–225(a), § 8–7–211, § 8–7–219(1)(2), 8–7–218, and 8–7–512, APC&E Reg. No. 23 §§ 264.141(h), 264.143(f)(10), 264.145(f)(11), 264.147(a)(2)–(7), 264.147(a)(7)(i)–(iii), 264.147(b)(2)–(7), 264.147(b)(7)(i)–(iii), 264.147(f)(6), 264.147(g),(1)(ii), 264.147(g)(2(i)–(ii), 264.147(h), (1)–(5), 264.147(i),(1)–(4), 264.147(i)(4)(i)–(ii), 264.147(j), 264.147(j)(1)–(4), 264.147(k), 264.151(i)–(ii) 264.151(b)(f)(g)(h)(1)–(2), 264.151(i)(2)(d), 264.151(j)(2)(d), 264.151(k), 264.151(1), 264.151(m)(1)–(2), 264.151(n)(1)–(2), 264.141(h), 265.143(e)(10) 265.141, 265.145(e)(11) and 265.147(f)(6), 264.147(a)(7), 264.147(b)(7), 265.134(E)(10)–(11), 265.147(a)(2)–(7)(i)–(iii), 265.147(b)(2)–(7)(i)–(iii), 265.147(f)(6), 265.147(g),(1)(ii), 265.147(g)(2)(i)–(ii), 265.147(h),(1)–(5), 265.147(i),(1)–(4)(i)–(ii), 265.147(j),(1)–(4), and 265.147(k), as amended December 1, 1995; effective January 21, 1996.
8. Burning of Hazardous Waste and Industrial Furnaces; Amendment IV, [57 FR 44999] September 30, 1992. (Checklist 114).	A.C.A. § 8–7–209(1), and (3), § 8–7–209(a) (5), (6), (8), (11) and (12), § 8–7–209(b), § 8–7–202(2), § 8–7–218(b)(2), § 8–7–218(c), § 8–7–219, § 8–7–223, § 8–7–225(a), § 8–7–211, APC&E Reg. No. 23 §§ 260.10, 260.20(a), 261.2(d)(2), 261.2(e)(2)(iv), 261.4, 261.6, 260.10, 260.11, 260.20, 261.2, 261.3, 261.4, 264.1, 264.112, 264.340, 265.1, 265.112, 265.113, 265.340(a), 265.370, 266 Subsection H, 266 Appendices I–X, 266.103(c)(1), 266.103(c)(1)(ii)(C), 266.103(c)(1)(iii), 266.103(c)(1)(vi), 266.103(c)(1)(vii)–(viii), 266.103(c)(1)(xi)(B), and 3(b)(2), as amended December 1, 1995; effective January 21, 1996.
9. Chlorinated Toluene Production and Waste Listing, [57 FR 47376] October 15, 1992. (Checklist 115).	A.C.A. § 8–7–209(a)(4), § 8–7–209(a)(5) introduction paragraph, and § 8–7–202, APC&E Reg. No. 23 §§ 261.4(b)(1), 261.31, 261.32, 261.33, 261, Appendices III, VII, and VIII, as amended December 1, 1995; effective January 21, 1996.

Federal citation	State analog
10. Hazardous Soil Case-by-Case Capacity Variance, [57 FR 47772] October 20, 1992. (Checklist 116).	A.C.A. § 8–7–209(a)(5), (11), § 8–7–202(2), § 8–7–218(b)(2), § 8–7–218(b)(c), § 8–7–303(c), § 8–7–303(1), § 8–7–308(4), and (6)8–7-APC&E Reg. No. 23 §§ 268.35(c)–(e), 268.35(e)(1)–(2), as amended December 1, 1995; effective January 21, 1996.
11. ''Mixture'' and ''Derived-From Rules; Response to Court Remand, [57 FR 7628] March 3, 1992. (CheckList 17A).	A.C.A. § 8–7–209(a)(4), APC&E Reg. No. 23 § 261.3 (a), (b), (c), and (d), as amended December 1, 1995; effective January 21, 1996.
12. ''Mixture'' and Derived-From Rules; Final Rule Correction, [57 23062] March 3, 1992. (Checklist 117A.1).	A.C.A. § 8–7–209(a)(4), APC&E Reg. No. 23 § 261.3 (a), (b), (c), and (d), as amended December 1, 1995; effective January 21, 1996.
13. ''Mixture'' and ''Derived-From'' Rules; Final Rule, [57 FR 49278] October 20, 1992. (Checklist 117.2).	A.C.A. § 8–7–209(a)(4), APC&E Reg. No. 23 § 261 (a), (b), (c), and (d), as amended December 1, 1995; effective January 21 1996.
14. Toxicity Characteristic Revisions, [57 FR 23062] June 1, 1992. (Checklist 117B).	A.C.A. § 8–7–209(a)(4), APC&E Reg. No. 23 §§ 261.3(a)(2)(i), 261.4, 261.8, 261.24, 261.30(b), 261, Appendix II, 264.301(e)(1), 265.221(d)(1), 265.273(a), 265.301(d)(1) and 265, Appendix I, as amended December 1, 1995; effective January 21, 1996.
15. Liquids in Landfills II, [57 FR 54452] November 18, 1992. (Checklist 118).	A.C.A. §§ 8–7–205(4), 8–7–209(a)(3), (4), (5)(B) and (5)(C), and (6), 8–7–218(a), 8–7–308(4), APC&E Reg. No. 23 §§ 260.10, 264.13(c)(3), 264.314, 264.316, 265.13(b)(c), 265.314, and 265.315, as amended December 1, 1995; effective January 21 1996.
16. Toxicity Characteristic Revisions; TCLP, [57 FR 55114] 1996. November 24, 1992]. (Checklist 119).	A.C.A. §§ 8–7205(4), APC&E Reg. No. 23 § 261, Appendix II, as amended December 1, 1995; effective January 21 1996.
17. Toxicity Characteristic Revisions; TCLP Correction, [58 FR 6854] February 2, 1993. (Checklist 119.1).	A.C.A. §§ 8–7205(4), APC&E Reg. No. 23 § 261, Appendix II, as amended December 1, 1995; effective January 21, 1996.
18. Wood Preserving; Amendments to Listings and Technical Requirements, [57 FR 61492] December 24, 1992. (Checklist 120).	A.C.A. § 8–7–209(a)(4), (5), (6), APC&E Reg. No. 23 §§ 264.1(a)(10), 261.31, 261.31, 261.32, 261.33, 261.4, 261.35, 261.34, Appendix VIII, 264.572(a)(2), 264.190, 264 Subsection W, 265 Subsection W, 264.570, 264.573, (a)(4), 265.440, and 265.443(a)(2), (4), (a), 270.22, and 270.26, as amended December 1, 1995; effective January 21, 1996.
19. Corrective Action Management Units and Temporary Units; Corrective Action Provisions Under Subtitle C, [58 FR 8658] February 16, 1993. (Checklist 121).	A.C.A. § 8–7–209(a)(5)(6) & (8), 8–7–508, 5–7–512, APC&E Reg. No. 23 §§ 260.10, 264.3, 264.101(b), 264, Subsection S, 265.1(b), 268.2(c), 270.2, & 270.42, as amended December 1, 1995; effective January 21, 1996.
20. Recycled Used Oil Management Standards; Technical Amendments and Corrections, [58 FR 26420] May 3, 1993. (Checklist 122).	A.C.A. § 8–7–209(a)(4), (5), (6) and (7), APC&E Reg. No. 23 §§ 260.10, 261.3(a)(2), 261.5(j), 261.6(a)(2), (3), and (4), 266.40–266.44, 266.100(b), 279, and 30.(b), as amended December 1, 1995; effective January 21, 1996.
21. Land Disposal Restrictions; Renewal of the Hazardous Waste Debris Case-by-Case Capacity Variance, [58 FR 28506–2811] May 14, 1993. (Checklist 123).	A.C.A. § 8–7–209(a)(5) and (6), APC&E Reg. No 23 § 268.35(c)–(e), as amended December 1, 1995; effective January 21, 1996.
22. Land Disposal Restrictions for Ignitable and Corrosive Characteristic Wastes Treatment Standards Were Vacated, [58 FR 29860–29887] May 24, 1993. (Checklist 124).	A.C.A. § 8–7–209(a)(5) and (6), APC&E Reg. No 23 § § 268.37, as amended December 1, 1995; effective January 21, 1996.
23. Boilers and Industrial Furnaces; Changes for Consistency with New Air Regulations, [58 FR 38816–38884] July 10, 1993. (Checklist 125).	A.C.A. § 8–7–209(a)(5) and (6), APC&E Reg. No. 23, §§ 260.11(a), 266.104(e), 266.106(h) and 266 Appendix X, as amended December 1, 1995; effective January 21, 1996.
24. Testing and Monitoring Activities, [58 FR 46040–46051] August 31, 1993, as amended September 19, 1994, at [59 FR 47980–4782]. (Checklist 126).	A.C.A. § 8–7–209(a)(5) and (6), APC&E Reg. No. 23 §§ 260.11(a), 260.22, 261.22(a), 261.24(a), 261, Appendices II, III and X, 264.190(a), 264.314(c), 264.314(d), 268.7(a), 268.40(a), 268.41(a), 268 Appendices I and IX, 270.6(a), 270.19(c), 270.62(b), 270.66(c), as amended December 1, 1995; effective January 21, 1996.
25. Boilers and Industrial Furnaces; Administrative Stay and Interim Standards for Bevill Residues, [58 FR 59598–59603], November 9, 1993. (Checklist 127).	A.C.A. § 8–7–209(a)(5) and (6), APC&E Reg. No. 23 §§ 266.112(b), and 266, Appendix VII, as amended December 1, 1995; effective January 21, 1996.
26. Hazardous Waste Management Systems; Identification and Listing of Hazardous Waste; Wastes from Wood Surface Protection, [59 FR 458] January 4,1994. (Checklist 128).	A.C.A. § 8–7–209(a)(4), and § 8–7–202, APC&E Reg. No. 23 §§ 260.11(a), and 261 Appendices VIII, as amended December 1, 1995; effective January 21, 1996.
27. Hazardous Waste Management Systems; Identification and Listing of Hazardous Waste; Treatability Studies Sample Exclusion, [59 FR 8362] February 18, 1994. (Checklist 129).	A.C.A. § 8–7–209(a)(4), § 8–7–209(a)(5) introductory paragraph, § 8–7–202, APC&E Reg. No. 23 § 261.4(e)(2)(i)–(ii), 261.4(e)(3), 261.4(e)(3)(i)–(iii), 261.4(e)(iii)(A)–(E), 261.4(f)(3), and 261.4(f)(4)–(5), as amended December 1, 1995; effective January 21, 1996.
28. Recycled Used Oil Management Standards; Technical Amendments and Corrections II, [59 FR 10550–10560], March 4, 1994. (Checklist 130).	A.C.A. § 8–7–209(a)(4), § 8–7–209(a)(5), (6), and (11), APC&E Reg. No. 23 §§ 260.10, 261.3(a)(2), 261.5(j), 261.6(a)(2), (3), and (4), 266.40–266.44 266.100(b), 279 and 30(b), as amended December 1, 1995; effective January 21, 1996.
29. Recordkeeping Instruction; [59 FR 13891] March 24, 1994. (Checklist 131).	A.C.A. § 8–6–1501–1504, § 8–7–209(a)(4), (5), (6), § 8–7–209(1), and (3), § 8–7–209(a)(5), (6), (8), (11) and (12), § 8–7–209(b), § 8–7–202(2), § 8–7–218(b)(2), § 8–7–218(c), § 8–7–219, § 8–7–223, § 8–7–225(a), § 8–7–211, APC&E Reg. No. 23 § 264 Appendix I, Tables 1 and § 265 Appendix I, Tables 2, as amended December 1, 1995; effective January 21, 1996.
30. Hazardous Waste Management System; Identification and Listing of Hazardous Wastes; Wastes from Wood Surface Protection; Correction, [59 FR 28484] June 2, 1994. (Checklist 132).	A.C.A. § 8–7–209(a)(4), (5), § 8–7–202, §§ 8–7–203(4)–(13), APC&E Reg. No. 23 §§ 260.11(a), and as amended December 1, 1995; effective January 21, 1996.

Federal citation	State analog
31. Standards Applicable to Owners and Operators of Hazardous Waste Treatment, Storage, and Disposal Facilities, Underground Storage Tanks, and Underground Injection Control Systems; Financial Assurance; Letter of Credit, [59 FR 29958] June 10, 1994. (Checklist 133).	A.C.A. § 8–7–209(a)(4), (5), (6), § 8–7–209(1), and (3), § 8–7–209(a)(5), (6), (8), (11) and (12), § 8–7–209(b), § 8–7–202(2), § 8–7–218(b)(2), § 8–7–218(c), § 8–7–219, § 8–7–223, § 8–7–225(a), § 8–7–211, APC&E Reg. No. 23 § 264.151(d) and (k), as amended December 1, 1995; effective January 21, 1996.
32. Hazardous Waste Management System; Correction of Listing of P015-Beryllium Power, [59 FR 31551], June 20, 1994. (Checklist 134).	A.C.A. § 8–7–209(a)(4), APC&E Reg. No. 23 §§ 261.4(a)(10), 261.31, 261.31, 261.32, 261.33, 261, Appendix VIII, 264.572(a)(2), and 265.443(a)(2), as amended December 1, 1995; effective January 21, 1996.
33. Recovered Oil Exclusion, [59 FR 38536–38545], July 28, 1994. (Checklist 135).	A.C.A. § 8–7–209(a)(4), APC&E Reg. No. 23 §§ 261.4, 261.6, and 266.100, A.C.A. § 8–7–209(a)(4), as amended December 1, 1995; effective January 21, 1996.
34. Removal of the Conditional Exemption for Certain Slag Residues, [59 FR 43496–43500], as amended August 24, 1994. (Checklist 136).	A.C.A. § 8–7–209(a)(4), (5), and (6), APC&E Reg. No. 23 §§ 266.20(c) and 268.41(a), as amended December 1, 1995; effective January 21, 1996.
35. Universal Treatment Standards and Treatment Standards for Organic Toxicity Characteristic Wastes and Newly Listed Wastes, [59 FR 47982–48110] September 19, 1994 as amended at [60 FR 242–302, January 3, 1995. (Checklist 137).	A.C.A. § 8–7–209(a)(2), (3), (4), (5), (11) and (b), A.C.A.§ 8–7–308(4) and (8), APC&E Reg. No. 23 §§ 260.30 260.30(b), 260.31(a)&(b), 260.32, 260.33(a)&(b), 266.100, 261.2(e)(1)(iii), 268.1, 268.7, 268.9, 268.38, 268.40, 268.41, 268.42, 268.43, 268.46, 268.48, and Appendices IV, V, and X, as amended December 1, 1995; effective January 21, 1996. State requirements are equivalent to those of the Federal program with the exception of the provisions of 40 CFR 268.7(a)(10), which provides an exemption for wastes managed under tolling arrangements as provided under 40 CFR 262.20(e). Arkansas does not allow the exemptions provided under this Federal rule, and thus does not exempt the wastes listed at 40 CFR 268.7(a)(10).
36. Testing and Monitoring Activities Amendment I, [60 FR 3089–3095], January 13, 1995. (Checklist 139).	A.C.A. § 8–7–209(a)(4), (5), and (11), APC&E Reg. No. 23 § 260.11, as amended December 1, 1995; effective January 21, 1996.
37. Carbamate Production Identification and Listing of Hazardous Waste, [60 FR 7824–7859], February 9, 1995, as amended at [60 FR 19165, April 17, 1995 and at [60 FR 25619], May 12, 1995. (Checklist 140).	A.C.A. § 8–7–209(a)(4), APC&E Reg. No. 23 § 261.3(a)(2)(iv)(G), and 261.3(c)(2)(ii)(D), 261.32, 261.33, and appendices VII and VIII, as amended December 1, 1995; effective January 21, 1996. The State had conducted an independent rulemaking, and the subsequent vacatur of the Federal rules in *Dihiocarbamate Task Force* v *EPA* did not immediately apply to the equivalent State's regulations. The State amended provision, in that they include the vacated waste streams are broader in scope than the equivalent Federal provisions. Arkansas has only one generator of that waste (Zeneca Ag Products), who subsequently applied to the Commission for a one-year variance from the State listing of those wastes. The Commission granted this variance, which expires February 28, 1998, pending further action by EPA to revise or re-promulgate its listing of the vacated waste streams. State requirements are broader in scope in comparison to the Federal program in that the State in that listings for K156, K157, and K158 include 3-iodo-2-propynyl n-butycarbamate (IPBC) as a hazardous constituent.
38. Testing and Monitoring Activities Amendment II, [60 FR 17001–17004], April 4, 1995. (Checklist 141).	A.C.A. § 8–7–209(a)(4), (5), and (11), APC&E Reg. No. 23 § 260.11, as amended December 1, 1995; effective January 21, 1996.
39. Universal Waste: General Provisions, [60 FR 25492–25551], May 11, 1995. (Checklist 142 A).	A.C.A. § 8–7–209(a)(2), (3), (4), (5), (11) and (b), APC&E Reg. No. 23 §§ 273, 260.10, 261.5 and 261.9, 262.10 and 262.11, 264.1(g)(11), and 265.1(c)(14), as amended December 1, 1995; effective January 21, 1996.
40. Universal Waste Rule: Specific Provisions for Batteries, [60 FR 25492–25551] May 11, 1995. (Checklist 142 B).	A.C.A. § 8–7–209(a)(2), (3), (4), (5), (11) and (b), 8– 10–301, (Act 952 of 1993, effective August 13, 1993), APC&E Reg. No. 23 §§ 260.10, 261.5 and 261.9, 262.10 and 262.11, 264.1(g)(11), 266, Subsection G and 273, 265.1(c)(14), as amended December 1, 1995; effective January 21, 1996.
41. Universal Waste Rule: Specific Provisions for Pesticides, [60 FR 25492–2551], May 11, 1995. (Checklist 142 C).	A.C.A. § 8–7–209(a)(2), (3), (4), (5), (11) and (b), APC&E Reg. No. 23 §§ 260.10, 261.5 and 261.9, 262.10 and 262.11, 264.1(g)(11), 266, and 273, 265.1(c)(14), as amended December 1, 1995; effective January 21, 1996.
42. Universal Waste Rule: Specific Provisions for Thermostats, [60 FR 25492–25551] May 11, 1995. (Checklist 142 D).	A.C.A. § 8–7–209(a)(2), (3), (4), (5), (11) and (b), APC&E Reg. No. 23 §§ 260.10, 261.5 and 261.9, 262.10 and Specific 262.11, 264.1(g)(11), 266, and 273, 265.1(c)(14), as amended December 1, 1995; effective January 21, 1996.
43. Universal Waste Rule: Petition Provisions to Add a New Universal Waste, [60 FR 25492–25551] May 11, 1995. (Checklist 142 E).	A.C.A. § 8–7–209(a)(2), (3), (4), (5), (11) and (b), APC&E 8 (Administrative Procedures), Reg. No. 23 §§ 260.20(a) and 260.23, 273.80 and 273.81, as amended December 1, 1995; effective January 21, 1996.
44. Removal of Legally Obsolete Rules, [60 FR 33912–33915] June 29, 1995. (Checklist 144).	A.C.A. §§ 8–7–205(4), 8–7–209(a); APC&E Reg. No. 23 §§ 261.31(a), 266.103(c)5, 266.104(f)–(h), 270.2, 270.10(e)(4), 270.10(f)(2), 270.10(g)(1) amended February 25, 2000 effective May 20, 2000.
45. Liquids in Landfills III, [60 FR 35703–35706] July 11, 1995 (Checklist 145).	A.C.A. §§ 8–7–205(4), 8–7–209(a)(3), (4), (5)(B), as amended and effective 1997; APC&E Reg. No. 23 §§ 264.314(e)(2)(ii)–(iii), and 265.314(f)(2)(ii)–(iii), as amended July 25, 1997, effective August 22, 1997.
46. RCRA Expanded Public Participation, [60 FR 63417–63434] December 11, 1995. (checklist 148).	A.C.A. §§ 8–4–203(b)–(h), 8–7–217, Reg. No. 8 § 2.1.2–10, No. 8 § 2.1.2–10, APC&E Reg. No. 23 §§ 3(b)(3), 270.7(d)(f), 270.2, 270.14(b)(22), 270.30(m), 270.61(b)(5), 270.62(b) & (d), 270.66(d) & (g), as amended July 25, 1997, effective August 22, 1997.
47. Amendments to the Definition of Solid Waste; Amendments II, [61 FR 13103–13106] March 26, 1996. (Checklist 150).	A.C.A. § 8–7–209(a)(4), APC&E Reg. No. 23 §§ 261.4(a)(12), as amended July 25, 1997, effective August 22, 1997.

Federal citation	State analog
48. Land Disposal Restrictions Phase III-Decharacterized Wastewaters, carbamate Waste, and Spent Potliners [61 FR 15566–15660] April 8, 1996, as amended April 8, 1996, at [61 FR 15660–15668] April 30, 1996, [61 FR 19117] June 28, 1996, [61 FR 33680–33690] July 10, 1996, [61 FR 36419–36421] August 26, 1996, [61 FR 43924–43931] February 19, 1997 [62 FR 7502–7600]. (Checklist 151).	A.C.A. § 8–7–209(a)(5) and (6), Reg. No. 23 §§ 268.35(c)–(e), 268.2(f), (i) and (j), 268.3(a)–(c)268.7(a) and (b), 268.8, 268.9(a) and (d), 268.39, 268(a), (e), (g), and Table 1, 268.(a), (e), (g), and Table TTS, 268.44(a), 268.48(a) and Table UTS, and 268 Appendix XI, as amended July 25, 1997, effective August 22, 1997.
49. Criteria for Classification of Solid Waste Disposal Facilities and Practices; Identification and Listing of Hazardous Waste; Requirements for Authorization of State Hazardous Waste Programs, [61 FR 34252] July 1, 1996. (Checklist 153).	A.C.A. § 8–7–209(a)(4), APC&EC Reg. 23 §§ 264.5(f)(3) and 264.5(g)(3); 261.5(f)(3)(i)–(iii) and (iv)–(vii), 261.5(g)(3) intro, 261.5(g)(3)(i)–(vii), as amended February 25, 2000 effective May 20, 2000.
50. Hazardous Waste Treatment, Storage, and Disposal Facilities and Hazardous Waste Generators; Organic Air Emission Standards for Tanks, Surface Impoundments, and Containers, [61 FR 59931] November 25, 1996, [59 FR 62896], December 6, 1994, [60 FR 26828] May 19, 1995, [60 FR 50426] September 29, 1995, [60 FR 56952] November 13, 1995, [61 FR 4903] February 9, 1996, [61 FR 28508] June 5, 1996. (Checklist 154, 154.1, 154.2, 154.3, 154.4, 154.5, and 154.6).	A.C.A. §§ 8–7–209(10), 8–7–209(b)(1), 8–7–209(b)(1)(F), 8–7–303(1) & (2), 8–7–310(a)(1), 8–7–310(a)(2), 8–7–209(b), 8–7–210(d), 8–7–218(c), 8–7–503(7), APC&E Reg. 23 §§ 23 260.11(a)–(b), 261.6(c)(1), and 262.34(d)(2), Reg. 23 §§ 270.4(a)(2)–(4), 270.14(b)(5), 270.15(e), 270.16(k), 270.17(j), 270.27(a), 270.27(a)(1)–(7), 262.20(f), 262.34(a)(1)(i) & (ii), 264 Subsection CC & 265 Subsection CC; amended February 25, 2000 effective May 20, 2000.
51. Land Disposal Restrictions Phase III—Emergency Extension of the K088 Capacity Variance, [62 FR 1992] January 14, 1997. (Checklist 155).	A.C.A. §§ 8–7–209(a)(5) and 6, APC&EC Regulation 23 § 262.39(c); amended February 25, 2000 effective May 20, 2000.
52. Military Munitions Rule: Hazardous Waste Identification and Management; Explosives Emergencies; Manifest Exemption for Transport of Hazardous Waste on Right-of-Ways on Contiguous Properties, [62 FR 6622] February 12, 1997. (Checklist 156).	A.C.A. §§ 8–7–209(a)(10), 8–7–209(b)(1), and 8–7–209(b)(1)(F), 8–7–209(a)(3), 8–7–209(a)(4) & 5, 8–7–224, APC&E Reg. 23 §§ 260.10 ''Military Munition'', 261.2(a)(iii)(iv), 262.10(i), 263.10(e) & (f), 264.1(g)(8)(i)(D), (iv), and (i), 264.70, 264 Subsection EE, 265.1(c)(11)(i)(D), (iv), & (f), 265.70, 266.201–203, 266.204–206, 270.1(c)(3)(i)(D), and (iii) 262.20(f), 266.205, 270.42(h) & (i), 265.1200, 265.1201(a), 265.1201(a)(1)–(5), 265.1201(b), 265.1201(b)(1)(i), 265.120(1)(ii)(A)–(C), 265.1201(b)(2)–(3), 265.1201(c)–(f), 265.1202(a)–(b), 266.200(a)–(b), and 270.42(h), 270.42(h)(1)–(3), and 270.42(i), as amended February 25, 2000 effective May 20, 2000.
53. Land Disposal Restrictions—Phase IV: Treatment Standards for Wood Preserving Wastes, Paperwork Reduction and Streamlining, Exemptions From RCRA for Certain Processed Materials; and Miscellaneous Hazardous Waste Provisions, [62 FR 25998] May 12, 1997. (Checklist 157).	A.C.A. §§ 8–7–209(a)(4)–(5), 8–7–209(6), 10, & 11, 8–7–202(2), 8–7–218(b)(2), 8–7–218(c), 8–7–303(1) & 8–7–308(4), APC&E Reg. 23 § 262.30(a)–(e), 268.1(e)(4), 268.4(a)(2)(iv), 268.4(a)(4), 268.7(a)–(c)(2), 268.9(a), 268.9(d)(1)(ii), 268.32, 268.34–268.37, 268.44(o), 268 Appendices I–III, VI, VIII & X, 268.42, Table 1, & 268.40; 261.1(c)(9)–(12), 261.2(c), Table 1, 261.4(a)(13)–(14), 261.4(14)(i)–(ii), 261.69(a)(3)(ii), 268.1(e) intro–(e)(3), 268.7(a)(1)–(3), 268.7(a)(i)–(ii), 268.7(a)(3)–(4), 268.7(a), table, 268.7(a)(5), 268.7(a)(5)(i)–(iii), 268.7(a)(6)–(9), 268.7(a)(9)(i)–(iv), 268.7(a)(10), 268.7(b), 268.7(b)(1)–(2), 268.7(b)(3) intro, 268.7(b)(3)(i)–(ii), 268.7(b)(3)(ii), table, 268.7(b)(4), 268.7(b)(4)(i)–(iii), 268.7(b)(4)–(6), 268.7(c)(1)–(2), as amended February 25, 2000 effective May 20, 2000.
54. Hazardous Waste Management; System; Testing and Monitoring Activities, [62 FR 32452] June 13, 1997. (Checklist 158).	A.C.A. §§ 8–7–209(a)(4), APC&E Reg. 23 §§ 260.11(a), 264.1034(d)(1)(iii) & (f), 264.1063(d)(2), 264 Appendix IX, 265.1034(d)(1)(iii) and (f), 265.1063(d)(2), 266.104(e)(1), 266.106(g)(1) & (2) 266.107(f) & 266 Appendix IX; amended February 25, 2000 effective May 20, 2000.
55. Hazardous Waste Management System; Carbamate Production, Identification and Listing of Hazardous Waste; Land Disposal Restrictions, [62 FR 32974] June 17, 1997. (Checklist 159).	A.C.A. §§ 8–7–209(a)(4), 8–7–211, APC&E Reg. 23 §§ 261.32, 261.33(f), 261 Appendices VII and VIII 268.39(a) and (d), 268.40; amended February 25, 2000 effective May 20, 2000.
56. Land Disposal Restrictions Phase III—Emergency Extension of the K088 National Capacity Variance, [62 FR 37694] July 14, 1997. (Checklist 160).	A.C.A. §§ 8–7–209(a)(5) and 6, APC&EC Reg. 23 § 262.39(c); amended February 25, 2000 effective May 20, 2000.
57. Second Emergency Revision of the Land Disposal Restrictions (LDR) Treatment Standards for Listed Hazardous Wastes From Carbamate Production, [62 FR 45568] August 28, 1997. (Checklist 161).	A.C.A. §§ 8–7–209(a)(5) and 6, APC&EC Reg. 23 § 268.40(g), 268.48(a); amended February 25, 2000 effective May 20, 2000.
58. Clarification of Standards for Hazardous Waste LDR Treatment Variances, [62 FR 64504] December 5, 1997. (Checklist 162).	A.C.A. §§ 8–7–209(a)(5)and 6, APC&EC Regulation 23 § 268.44(a), 268.44(h), & 268.44(m); amended February 25, 2000 effective May 20, 2000.
59. Organic Air Emission Standards for Tanks, Surface Impoundments, and Containers; Clarification and Technical Amendment, [62 FR 64636] December 8, 1997. (Checklist 163).	A.C.A. §§ 8–7–209(10), 8–7–209(b)(1), 8–7–209(b)(1)(F), 8–7–303(1) & (2), 8–7–310(a)(1) & 2, 8–7–209(b), 8–7–210(d), 8–7–218(c), 8–7–503(7), APC&E Regulation 23 §§ 262.34(a)(1)(i) & (ii), 264 Subsection CC & 265 Subsection CC; amended February 25, 2000 effective May 20, 2000.
60. Kraft Mill Steam Stripper Condensate Exclusion, [63 FR 18504] April 15, 1998. (Checklist 164).	A.C.A. §§ 8–7–209(a)(4), APC&EC Regulation 23 § 261.4(a)(15); amended February 25, 2000 effective May 20, 2000.
61. Recycled Used Oil Management Standards; Technical Correction and Clarification, [63 FR 24963] May 6, 1998. (Checklist 166).	A.C.A. §§ 8–7–204(b), 8–7–205(1), 8–7–207, 8–7–209(a)(1), (5), (6), (7), (8), (10), & (12), 8–7–209(b)(5) & (6), 8–7–210(b), 8–7–212, 8–7–213, 8–7–214, APC&EC Regulation 23 §§ 261.5(j), 261.6(a)(3)(iv)(A)–(C), 279; amended February 25, 2000 effective May 20, 2000.

Federal citation	State analog
62. Land Disposal Restrictions Phase IV—Treatment Standards for Metal Wastes and Mineral Processing Wastes, [63 FR 28556] May 26, 1998. (Checklist 167 A).	A.C.A. §§ 8–7–209(a)(5) and 8–7–209(a)(6), APC&EC Regulation 23 §§ 268.2(i), 268.3(d), 268.34, 268.40(e) & (h), 268 Table of Treatment Standards, & 268.48; amended February 25, 2000.
63. Land Disposal Restrictions Phase IV—Hazardous Soils Treatment Standards and Exclusions, [63 FR 28556] May 26, 1998. (Checklist 167 B).	A.C.A. §§ 8–7–209(b), 8–7–205(1), 8–7–207, 8–7–209(a)(1), (5), (6), (7), (8), (10), & (12), 8–7–209(b)(5) & (6), 8–7–210(b), 8–7–212, 8–7–213, 8–7–214, APC&EC Regulation 23 §§ 262.34(d)(4), 268.2(h) & (k), 268.7(a)(1)–(6), 268.7(b)(1)–(3), 268.7(b)(4) intro & 268.7(b)(iv), 268.7(e), 268.9(d)(2), 268.9(d)(2)(i), 268.44(h)(3)–(5) & 268.49; amended February 25, 2000.
64. Land Disposal Restrictions—Phase IV—Corrections, [63 FR 28556] May 26, 1998. (Checklist 167 C).	A.C.A. §§ 8–7–209(b), 8–7–205(1), 8–7–207, 8–7–209(a)(1), (5), (6), (7), (8), (10), & (12), 8–7–209(b)(5) & (6), 8–7–210(b), 8–7–212, 8–7–213, 8–7–214, APC&E Regulation 23 §§ 268.4(a)(2)(ii) & (iii), 268.7(a)(7), 268.7(b)(3)(ii) Table, 268.7(b)(4)(iv)(v), 268.7(b)(5) & (6), 268.40 Table, 268.40(e), 268.42(e), 268.42(a), 268.45(a), 268.45(d)(3) & (4), 268.48, & 268 Appendices VII & VIII; as amended February 25, 2000, effective May 20, 2000.
65. Bevill Exclusion Revisions and Clarification, [63 FR 28556] May 26, 1998. (Checklist 167 E).	A.C.A. §§ 8–7–209(a)(4), APC&E Regulation 23 §§ 261.4(a)(16)(iii) & 261.38; as amended February 25, 2000, effective May 20, 2000.
66. Exclusion of Recycled Wood Preserving Wastewaters, [63 FR 28556] May 26, 1998. (Checklist 167F).	A.C.A. §§ 8–7–209(a)(4), APC&E Regulation 23 §§ 261.4(a)(9)(iii); as amended February 25, 2000, effective May 20, 2000.
67. Hazardous Waste Combustors Revised Standards, [63 FR 33782] June 19, 1998. (Checklist 168).	A.C.A. §§ 8–7–209(a)(4), APC&E Regulation 23 §§ 261.4(a)(16)(iii) & 261.38; as amended February 25, 2000, effective May 20, 2000.
68. Petroleum Refining Process Waste, [63 FR 42110–42189] August 6, 1998. (Checklist 169).	A.C.A. §§ 8–7–209(a)(4), APC&E Regulation 23 §§ 261.3(c)(2)(ii)(B), 261.4(a)(12), 261.4(a)(18) & (19), 261.6(a)(3)(iv)(C) & (v), 261.31(a) & 266.100(b)(3); 261.3(a)(2)(iv)(C), 261.3(c)(2)(ii)(B), 261.3(c)(2)(ii)(E), 261.4(a)(12)(i), 261.4(12)(ii), 261.4(a)(18), 261.4(a)(18)(i)–(ii), 261.4(a)(19), 261.6(a)(3)(iv)(C), 261.6(a)(3)(v), 261.31(a), and 266.100(b)(3), as amended February 25, 2000, effective May 20, 2000.
69. Land Disposal Restrictions Process—Phase IV, [63 FR 46332] August 31, 1998. (Checklist 170).	A.C.A. §§ 8–7–209(a)(5)and 6, APC&EC Regulation 23 § 268.40(i); as amended February 25, 2000, effective May 20, 2000.
70. Emergency Revisions of LDR Treatment Standards, [63 FR 47409] September 4, 1998. (Checklist 171).	A.C.A. §§ 8–7–209(a)(5) and 8–7–209(a)(6), APC&EC Regulation 23 §§ 268.40(g)–(j), 268.40 Table, & 268.48(a) Table; as amended February 25, 2000, effective May 20, 2000.
71. Emergency Revisions of LDR Treatment Standards, [63 FR 48124] September 9, 1998. (Checklist 172).	A.C.A. §§ 8–7–209(a)(5)and 6, APC&EC Regulation 23 § 268.34(b); as amended February 25, 2000, effective May 20, 2000.
72. Land Disposal Restrictions Treatment Standards (Spent Potliners), [63 FR 51254] September 24, 1998. (Checklist 173).	A.C.A. §§ 8–7–209(a)(5) and 6, APC&EC Regulation 23 § 268.40, Table of Treatment Standards; as amended February 25, 2000, effective May 20, 2000.
73. Standards Applicable to Owners and Operators of Closed/Closing Facilities, [63 FR 56710] October 22, 1998. (Checklist 174).	A.C.A §§ 8–7–204(b), 8–7–205(1), 8–7–207, 8–7–209(a)(1), (5), (6), (7), (8), (9), (10), & (12), 8–7–209(b)(5) & (6), 8–7–210(b), 8–7–212–218, 8–7–220–222, APC&EC Regulation 23 §§ 270.14 & 270.28; as amended February 25, 2000, effective May 20, 2000.
74. Hazardous Remediation Waste Management Requirements (HWIR-Media), [63 FR 65874] November 30, 1998. (Checklist 175).	A.C.A. §§ 8–7–204(b), 8–7–205(1), 8–7–207, 8–7–209(a)(1), (5), (6), (7), (8), (10), & (12), 8–7–209(b)(5) & (6), 8–7–210(b), (5) & (6), 8–7–210(b), 8–7–212–218, 8–7–220–222, 8–7–505(3), 8–7–507, 8–7–508(a)(1) & (3), 8–7–5–11, APC&EC Regulation 23 §§ 260.10, 264.552(a), 264.553(a), 270.2, 270.11(d), 270.42, 270.68, 270.73(a) & 270. Subsection H (270.79–270.230,23 261.4(g)intro, 261.4(g)(1), 261.4(g)(2) intro, 261.4(g)(2)(ii)–(iii), 264.1(j)(2)–(3), 264.1(j)(3)(i)–(ii), 264.1(j)(4)–(17), 264.101, 264.554(b), 264.554(c) intro, 264.554(c)(1)–(3), 264.554(d) intro, 264.554(d)(1)(i)–(iii), 264.554(d)(2), 264.554(d)(2)(i)–vi), 264.554(e)intro, 264.554(e)(1)(i)–(ii), 264.554(e)(2), 264.554(f)intro, 264.554(f)(1)–(3), 264.554(g)–(h), 264.554(i)intro, 264.554(i)(1), 264.554(i)(1)((i)–(ii), 264.554(i)(2), 264.554(j) intro, 264.554(j)91), 264.554(j)(1)(i)–(iii), 264.554(j)(2)–(3), 264.554(k) intro, 264.554(k)(1),–(2), 264.554(1)–(2), 264.554(1) intro, 264.554(1)(1), 264.554(1)(i)–(ii), 264.554(1)(2)–(4), 264.554(m), as amended February 25, 2000, effective May 20, 2000.
75. Universal Waste Rule; Technical Amendment, [63 FR 71225] December 24, 1998. (Checklist 176).	A.C.A. §§ 8–7–204(b), 8–7–205(1), 8–7–207, 8–7–209(a)(1), (5), (6), (7), (8), (10), & (12), 8–7–209(b)(5) & (6), 8–7–212–214, APC&EC Regulation 23 §§ 260.10, 261.5(c), 261.5(f)((3)(vi), 261.5(g)((3)(vi), 261.9, 262.10(b), 262.11(d), 264.1(g)(11), 265,1(c)(14), 261.9(a), 264.1(g)(11)(i), 265.1(c)(14)(i), 266.80(a), 266.80(b), 268.1(f)(1), 270.1(c)(2)(viii)(A), 273.1(a)(1), 273.2, 268.1(f), 270.1(c)(2)(viii)–(A), 273.1(a)–(b), 273.5–6, 273.10–11–14, 273.13(a), 273.14(a), 273.15–273.31, 273.32(a)(1) & (2), 273.32(b), 273.33(a), 273.34, 273.34(a), 273.35–273.70; 264.1083(b)(1)(ii), 264.1084(h)(3), 264.1084(h)(3)(i)–(ii), 264.1086(e)(6), and 265.1080(b)(5), as amended February 25, 2000, effective May 20, 2000.
76. Organic Air Emission Standards, [64 FR 3381] January 21, 1999. (Checklist 177).	A.C.A. §§ 8–7–303(1) & (2), 8–7–310(a)(1) & (2), 8–7–310(a)(1) & (2), 8–7–209(b), 8–7–210(d), 8–7–218(c), 8–7–503(7), APC&EC Regulation 23 262.34(a)(1)(9)(i) & (ii),264, Subsection CC, & 265, Subsection, CC; 262.34(a)(1)(i)–(ii), as amended February 25, 2000, effective May 20, 2000.
77. Petroleum Refining Process Wastes, [64 FR 6806] February 11, 1999. (Checklist 178).	A.C.A. §§ 8–7–209(a)(4), APC&EC Regulation 23 § 261.4(b)(15); as amended February 25, 2000, effective May 20, 2000.

Federal citation	State analog
78. Land Disposal Restrictions Phase IV–Technical Corrections and Clarifications to Treatment Standards, [64 FR 25408] May 11, 1999. (Checklist 179).	A.C.A. §§ 8–7–209(b), 8–7–205(1), 8–7–207, 8–7–209(a)(1), (5), (6), (7), (8), (10), & (12), 8–7–209(b)(5) & (6), 8–7–210(b), 8–7–212, 8–7–213, 8–7–214, APC&EC Regulation 23 §§ 262.34(d)(4), 268.2(h) & (k), 268.7(a)(1)–(6), 268.7(b)(1)–(3), 268.7(b)(4) intro & (b)(iv), 268.7(e), 268.9(d)(2), 268.9(d)(2)(i), 268.44(h)(3)–(5) & 268.49; 268.4(a)(2)(ii)&(iii), 268.7(a)(7), 268.7(b)(3)(ii) Table, 268.7(b)(4)(iv)(v), 268.7(b)(5)&(6), 268.40 Table, 268.40(e), 268.42(e), 268.42(a), 268.45(a), 268.45(d)(3)&(4), 268.48, & 268 Appendices VII & VIII; as amended February 25, 2000.
79. Test procedures for the Analysis of Oil and Grease and Non-Polar Material, [64 FR 26315] May 14, 1999. (Checklist 180).	A.C.A. §§ 8–7–209(a)(4), APC&EC Regulation 23 § 260.11(a)(11) & 260.11(a)(16); as amended February 25, 2000, effective May 20, 2000.
80. Universal Waste Rule, [64 FR 36466] July 6, 1999. (Checklist 181).	A.C.A. §§ 8–7–209(b), 8–7–205(1), 8–7–207, 8–7–209(a)(1), (5)–(10) & (12), 8–7–209(b)(5) & (6), 8–7–210(b), 8–7–212–214, APC&EC Regulation 23 §§ 260.10, 261.9(b)(d), 264.1(g)(11)(ii)–(iv), 265.1(c)(14)(ii)–(iv), 268.1(f)(2)–(4), 273.1(a)(2)–(4), 270.1(c)(2)(viii)(B)–(D), 273.1(a)(2)–(4), 273.2(a)(1), 273.2(b)(2) & (3), 273.2(a), 273.4(a), 273.5–273.10, 273.13(d), 273.14(e) & 273.30; as amended February 25, 2000, effective May 20, 2000.

E. What Is the Relationship Between the Resource Conservation and Recovery Act and the Hazardous Waste Combustor MACT? How Does This Affect Delegation of This Standard to Arkansas Department of Environmental Quality's Authorization?

In this authorization document, the State of Arkansas is also seeking authorization for the Post-Closure Permit Requirement and Closure Process, (Checklist 174). On September 30, 1999, the EPA finalized the National Emission Standards for Hazardous Air Pollutants (NESHAP) for three categories waste combustors (HWCs): incinerators, cement kilns and light-weight aggregate kilns (64 FR 52828). The EPA promulgated this rule under joint authority of the Clean Air Act (CAA) and (RCRA). Before this rule went into effect, the air emissions from these three types of HWCs were primarily regulated under the authority of RCRA (see 40 CFR parts 264, 265, 266, and 270). However, with the release of the final HWC NESHAP (see 40 CFR part 63 subpart EEE), the air emissions from these sources are now regulated under RCRA and the CAA. Even though both statutes give us the authority to regulate these emissions, we determined that having emissions standards and permitting requirements in both sets of implementing regulations would be duplicative. For this reason, using the authority provided by section 1006(b) of RCRA, we deferred the RCRA requirements for HWC emission controls to the CAA requirements of 40 CFR part 63 subpart EEE.

Therefore, with today's authorization of the State of Arkansas for the RCRA provisions of the September 30, 1999, HWC NESHAP rule, the RCRA waste management standards for air emissions from these units will no longer apply after the facility has demonstrated compliance with 40 CFR part 63 subpart EEE. One notable exception concerns section 3005(c)(3) of RCRA, which requires that each RCRA permits contain the terms and conditions necessary to protect human health and the environment. Under this provision of RCRA, if a regulatory authority determines that more stringent conditions than the HWC NESHAP are necessary to protect human health and environment for a particular facility, then the regulatory authority may impose those conditions in the facility's RCRA permit. (See the HWC MACT rule preamble discussion on the interrelationship of the MACT rule with the RCRA Omnibus provision and site specific risk assessment at (64 FR 52828, pages 52839–52843, September 30, 1999, and RCRA Site-Specific Risk Assessment Policy for Hazardous Waste Combustion Facilities dated June, 2000, for more information.

F. What Decisions Have We Made?

We conclude that Arkansas' application to revise its authorized program meets all of the statutory and regulatory requirements established by RCRA. Therefore, Arkansas is granted final authorization to operate its hazardous waste program as revised, assuming no adverse comments are received as discussed above. Upon effective final approval, Arkansas will be responsible for permitting treatment, storage, and disposal facilities within its borders (except in Indian Country) and for carrying out the aspects of the RCRA program described in its revised program application, subject to the limitations of the Hazardous and Solid Waste Amendments of 1984 (HSWA). New Federal requirements and prohibitions imposed by Federal regulations that EPA promulgates under the authority of HSWA take effect in authorized States before they are authorized for the requirements. Thus, EPA will implement those requirements and prohibitions in Arkansas, including issuing permits, until the State is granted authorization to do so.

G. How Do the Revised State Rules Differ From the Federal Rules ?

On April 1994, Arkansas Department of Pollution Control and Ecology (ADPC&E), revised its Regulation Number 23 from one of ''incorporation by reference'' to the adoption and incorporation of a version of the full text of the Federal regulatory language. The last authorization that was granted to the State of Arkansas was RCRA Cluster II in 1994 which at that the State incorporated by reference. Since the verbatim adoption, the following regulations are different from the Federal regulations that were incorporated in the State's Program description submitted with clusters III through IX with one Checklist 181 in cluster X.

Areas Where the State program Is More Stringent

• Arkansas has enacted several requirements under its hazardous waste management program which are either in addition to, more stringent than, or broader in scope than the minimum standards of the Federal RCRA program set forth in 40 CFR Parts 260–279. These additional State requirements are set forth in the Arkansas Regulation No 23 Sections 1–6 and Sections 18–30, and appear in Sections 260–279 in italicized in Arkansas Reg No 23 are typed to distinguish them from the adopted Federal language. The following State requirements are more stringent than the corresponding Federal regulation. The reader is referred to the appropriate Statement of the Independent Legal Counsel in the authorization application for the specific Cluster for detailed

discussion of the significance of these differences.

• In the definition of ''*Existing hazardous waste management (HWM) facility*'', the deadline for the operation or construction of a facility to be included in this definition is 20 months earlier than the date set in the Federal regulations. Thus, more facilities are subject to the more stringent requirements for new facilities than is the case under the Federal requirements.

• Regulation No. 23 § 262.13(g) requires that all generators of hazardous wastes newly characterized as Toxicity Characteristic wastes must notify the Department even if they have previously notified the Department of other hazardous waste activity. The Federal program does not have an analogous requirement, making the State requirement more stringent.

• Arkansas does not have an analog to § 262.20(e) which allows generators under certain specified conditions (e.g., tolling arrangements) not to be subject to the manifest requirements. This difference makes the State provisions more stringent than their Federal counterparts.

• Regulation No. 23 § 262.21(d) requires the use of the Arkansas version of the uniform manifest form; the use of the generic uniform manifest is not allowed.

• Regulation No. 23 § 262.24 contains additional requirements for generators not found in the Federal program including (1) submitting documentation that a weight difference of more than 10% between the initial and final weights on a manifest has been resolved between the generator and the treatment, storage, and disposal facility (TSDF). Under the Federal requirements only the TSDF has to submit such documentation, and (2) submitting a discrepancy report as per the criteria defined by the State's counterpart to § 265.72. Under the Federal program, only the TSDF has to submit this report.

• Regulation No. 23 § 262.35 contains more stringent management requirements for conditionally-exempt small quantity generators.

• Regulation No. 23 § 262.41 requires that generators submit annual rather than biennial reports. This is a more stringent requirement.

• Under Regulation No. 23 § 262.41(e), Arkansas provision is more stringent in that a generator must report accumulated wastes in addition to stored wastes. Under the Federal program, only stored wastes must be reported.

• Arkansas does not have an analog to § 262.44 which subjects generators of between 100 and 1000 kg per month to reduced recordkeeping requirements. This difference makes the State program more stringent than the Federal program.

• Regulation No. 23 § 262.50(c) requires that a copy of all export notifications and manifests that are submitted to EPA be also submitted to the Department. This is a more stringent requirement.

• Reg. No. 23 § 260.10, definition of ''commingling'' prohibits transporters from commingling wastes in any manner that constitutes treatment.

• Reg. No. § 263.11(c) requires that each transfer facility obtain an EPA identification number. This difference makes the State's provisions more stringent than the Federal program.

• Arkansas has several specific authorities which relate to siting of hazardous waste management facilities. A.C.A. § 8–7–223 specifically prohibits a landfill disposal facility from being located within one-half mile of any occupied dwelling unless the applicant can demonstrate and the Department finds that a lesser distance will provide an adequate margin of safety under normal operating conditions. Likewise, A.C.A. § 8–6–1504 (in the Arkansas Environmental Equity Act (Act 1263 of 1993)) establishes a rebuttable presumption against siting any ''high impact solid waste management facility'' within 12 mile radius of any other such facility. The definition of a high impact solid waste management facility includes all commercial hazardous waste incinerators and commercial hazardous waste treatment, storage, or disposal facilities.

• Reg. No. 23 § 264.16(f) has no Federal counterpart and requires that at least one person certified by the State be on duty at all times before a commercial hazardous waste treatment, storage, or disposal facility will be permitted to operate. Certified persons must meet certain qualifications including physical capability; a B.S. degree or equivalent related experience in engineering, physical science, health sciences or related disciplines; familiarity with principles of industrial operation; and be a U.S. citizen. Facilities must also maintain records of employees, provide personnel training and review and require annual health physicals. These provisions make the Arkansas program more stringent than the Federal program.

• Reg. No. 23 § 264.18(d)–(i) have no Federal counterpart and state that treatment, storage, and disposal facilities will not be permitted in an active fault zone, regulatory floodway, 100-year floodplain, recharge zone or wetland area unless it can be proven that there is no risk to public health or the environment. Facilities located within an area containing geologic or pedologic factors will not be permitted nor will any facility located within one half mile of an occupied dwelling, school or hospital. These provisions are more stringent than the Federal location requirements at 40 CFR 264.18.

• Reg. No. 23 §§ 264.19(a), 264.115 and 264.120 restrict the engineers who can develop and implement a CQA to those registered in Arkansas. The Federal regulations allow registration in any State. This difference makes the State more stringent.

• Reg. No. 23 § 264.20 has no Federal counterpart and contains performance standards that are specific to Arkansas. These standards make the State more stringent.

• Reg. No. 23 § 264.75 requires that facilities submit annual rather than biennial reports. This difference makes the State program more stringent than the Federal program.

• Reg. No. 23 § 264.75(i) requires annual submission of groundwater monitoring data. Under the Federal requirements, these data must only be submitted by interim status facilities. This difference makes the Arkansas program more stringent than the Federal program.

• Reg. No. 23 § 264.175(b)(2) has no Federal counterpart and requires an impermeable coating on all surfaces of the secondary containment structure for container storage areas. This difference makes Arkansas' program more stringent than the Federal program.

• Reg. No. 23 §§ 264.191 through 264.193 restrict those engineers who can inspect or certify a tank system's integrity to those registered in Arkansas. The Federal requirements allow registration in any State. Arkansas is therefore more stringent.

• Reg. No. 23 § 264.571(b) requires that for immediate protection of the environment, all existing drip pads must have an impermeable coating or cover in place not later than September 30, 1995. This requirement is more stringent than its Federal counterpart.

• Reg. No. 23 §§ 264.571(a)–(c) and 264.573(m)(3) restrict engineers who can certify a drip pad's integrity or completed repairs to those registered in Arkansas. The Federal counterparts allow engineers to certify that are registered in any state. This difference makes the State's program more stringent.

• Reg. No. 23 §§ 264.573(a)(4)(i) states that penetrating sealants are not adequate to meet the coating or cover requirements for drip pads. The Federal

requirements do not have this restriction; therefore, the State requirement is more stringent.

• Reg. No. 23 § 264.601(d)&(e) have no Federal counterpart and prohibit open burning or detonation of hazardous wastes on unprotected ground. Open burning or open detonation may only be conducted in or on an elevated containment device which will prevent leaching or migration of waste. Prior to open burning or detonation, a RCRA permit must be obtained and it must be demonstrated that no other feasible alternative is available. These requirements are consistent with Federal requirements at 40 CFR part 264, subpart X. However, the required demonstration that there are no other feasible alternatives is a more stringent provision.

• Reg. No. 23 § 264.1101(c)(2) & (c)(3)(iii) restrict the engineers who can certify a containment design or completed repairs to those registered in Arkansas. Under the Federal requirements the engineer can be registered in any state.

• Because Arkansas law does not distinguish between corrective action on-site and off-site, demonstration of financial responsibility is required for corrective action wherever it is needed.

• Arkansas allows existing facilities to continue operation only if the facility was in existence on March 14, 1979, and submitted an initial State application form to the Department by September 14, 1979. A.C.A.§ 8–7–216 requires that an initial State application for interim status be submitted to the Department by September 14, 1979. Thus, Arkansas has a more stringent form of interim status.

• Reg. No. 23 § 265.75 requires that facilities submit annual rather than biennial reports. This difference makes the State program more stringent than the Federal program.

• Reg. No. 23 §§ 265.143(h), 265.143(h) and 265.147(e) require that the engineer who certified closure be registered in Arkansas. Under the Federal requirements, the engineer may be registered in any state.

• Reg. No. 23 §§ 265.191 through 265.193, 265.196(f) and 265.280(e) restrict those engineers who can inspect or certify a tank system's integrity to those registered in Arkansas. The Federal requirements allow registration in any State. Arkansas is therefore more stringent.

• Reg. No. 23 §§ 265.441(a) and (c), 265.443(g) and (m)(3) and 265.444(a) restrict engineers who can certify a drip pad's integrity or completed repairs to those registered in Arkansas. The Federal counterparts allow engineers to certify that are registered in any state. This difference makes the State's program more stringent.

• Reg. No. 23 § 265.441(b) requires that for immediate protection of the environment, all existing drip pads must have an impermeable coating or cover in place not later than September 30, 1995. This requirement is more stringent than its Federal counterpart.

• Reg. No. 23 § 265.443(a)(4)(i) states that penetrating sealants are not adequate to meet the coating or cover requirements for drip pads. The Federal requirements do not have this restriction; therefore, the State's provision is more stringent.

• Reg. No. 23 § 265.1101(c)(2) and (c)(3)(iii) restrict the engineers who can certify a containment design or completed repairs to those registered in Arkansas. Under the Federal requirements the engineer can be registered in any state.

• At Reg. No. § 270.2 ''*existing hazardous waste management facility*'', the date to qualify for interim status is prior to the corresponding Federal date. This difference makes the state more stringent because fewer facilities qualify for the interim status requirements.

• Reg. No. 23 § 270.7 has no direct analog in the Federal requirements and includes additional requirement relative to permit application. Some of the requirements are a restatement of the Federal requirements, but others are additional demonstrations which must be made or information which must be provided. Included are such things as evidence that the contingency plan has been developed in consultation with the fire department, the Mayor/City Manager/County Judge in the municipality/county in which the facility is to be located; provision of contracts, agreements, and such other documentation to demonstrate that the waste which will be disposed of is waste which resulted from the treatment of waste to the full extent of known technology and economics or is waste for which there is no technically and economically feasible means of treatment available; demonstration of full fee ownership of lands and all mineral rights; location and places where public notice must be made; proof of public notice of application submission prior to any permit decision; written notice to all landholders and tenants of property contiguous to the proposed or existing facility; evidence of good faith effort to contact all contiguous landholders; and permittee must submit as part of the annual permit review process a plat of any landfill disposal area in which waste has been disposed. These requirements make the state's provision more stringent.

• Reg. No. 23 § 270.10(e)(1) requires that any facility in existence on March 14, 1979, submit a permit application on or before September 4, 1979. The State requirement is more stringent because if the application was not submitted to the Department as required under the State Act, the facility is not eligible for interim status.

• Under Reg. No. 23 § 270.10(e)(8), Arkansas can take immediate enforcement action relative to an application deficiency; whereas the Federal requirements allow 30 days to fix the application. This difference makes the state's requirement more stringent.

• Reg. No. 23 § 270.13(o), which does not have a Federal analog, requires disclosure information to be submitted as part of the permit application. A.C.A. § 8–1–106(b) provides the State with the authority to require this information. This requirement makes Arkansas more stringent than the Federal program.

• Reg. No. 23 §§ 270.14(a), 270.16(a), 270.26(c)(15) and 270.30(l)(2)(i) are more stringent because they restrict those registered professional engineers who can certify certain technical data those who are registered in Arkansas. The Federal requirements allow the engineer to be registered in any state.

• In Reg. No. 23 § 270.19(d), Arkansas uses ''may'' rather than ''shall'' giving the Director the discretion for non-approval. The Administrator does not have this discretion making the State more stringent.

• Reg. No. 23 § 270.30(l)(9) requires an annual rather than a biennial report.

• Reg. No. 23 § 270.34, which does not have a Federal analog, requires that a survey be conducted by any appropriate health agency to establish baseline health data. In addition, the state requires that if emissions from any hazardous waste management facility are related to disease etiology, the Department shall conduct pertinent epidemiologic investigation. This requirement makes the state more stringent.

• At Reg. No. 23 § 270.70(b), the analog to 40 CFR 270.70(b), Arkansas does not allow the owner/operator 30 days to explain or correct a deficiency. This difference makes the state more stringent.

• Reg. 23 § 273.5(b)(3) specifically excludes broken and crushed lamps as well as the debris from broken or crushed lamps from being managed under the universal waste program.

• Arkansas requires that used oil handlers use the State's Notification of

Regulated Waste Activity form to obtain an EPA identification number; requests via an ordinary letter are not accepted.

• Used oil transporters, processors, re-refiners, burners, and marketers who have previously obtained an EPA identification number must renotify in order to register their used oil activities with the Department.

• At Regulation No. 23 § 279.82, used oil used as a dust suppressant may not exhibit any characteristic of a hazardous waste, and such use must prevent the oil or any component of the oil from entering any waters of the State.

Areas Where the State Program Is Broader in Scope

The following State requirements are broader in scope than the corresponding Federal regulation. The reader is referred to the appropriate Statement of the Independent Legal Counsel in the authorization application for the specific Cluster for detailed discussion of the significance of these differences.

• Reg 23 § 6(n), (o), (p), and (q) establishes an annual monitoring and inspection fee for fully-regulated and small quantity generators; § 25 establishes an annual fee on hazardous waste generation.

• Regulation No. 23 §§ 262.13(d) and 262.24(e) require that generators give their wastes only to permitted transporters, because Arkansas requires that transporters be permitted by the Arkansas Highway Police. This is a broader in scope provision.

• Reg. No. 23 §§ 263.10(d) and 263.13 require that any person transporting hazardous waste in, from or through Arkansas must have a permit from the Arkansas Highway Police. § 263.13 outlines the specific requirements for this permit. This difference makes the State's program broader in scope than the Federal program. A.C.A § 8–7–209(a)(6) provides the authority to require such permits.

• In addition to the notification requirements found at 40 CFR 263.30(c)(1)&(2), Arkansas requires immediate notice to the Arkansas State Police and the principal officer or designated contact for the transporter.

• Reg. No. 23 § 263.30(c)(4) requires that copies of reports required by the U.S. Department of Transportation and the National Response Center be sent simultaneously to ADEQ.

• Reg. No. 23 § 6(a)-(n), (t), (u), (w), (x), and (z) establish a fee system for hazardous waste permitting and related activities; § 25 establishes an annual fee for treatment, storage, or disposal of out-of-state waste.

• Reg. No. 23 § 264.71(e) has no Federal counterpart and requires notification to the State of unpermitted transporters arriving at a transport, storage and disposal(TSD) facility, because all persons who transport hazardous waste in, from or through Arkansas must have a permit. This provision makes the State's program broader in scope.

• State corrective action authority covers hazardous substances (including petroleum and petroleum-based products), rather than only hazardous wastes and hazardous constituents as prescribed by Federal law. Thus, State authorities are broader in scope in this regard than the Federal program's. (See A.C.A. § 8–7–502, § 8–7–503(12), § 8–7–508(a)(1).)

• Reg. No. 23 § 265.71(e) has no Federal counterpart and requires notification to the State of unpermitted transporters arriving at a TSD facility, because all persons who transport hazardous waste in, from or through Arkansas must have a permit. This provision makes the State's program broader in scope.

• Fees are required by A.C.A. § 8–7–226 and Reg. No 23, Section 6 for permitting. This requirement is broader in scope because there is no direct Federal analog addressing permit fees.

• Arkansas distinguishes between commercial and non-commercial waste activities in setting its permit fee schedule.

Areas Where the State Program Differs From the Federal Program

• Arkansas does not provide for a State delisting program. To delist a waste in Arkansas, an applicant must first complete the process to obtain a final delisting decision from the EPA Administrator. Once a final federal delisting decision has been published in the **Federal Register**, it is not effective in Arkansas until the Arkansas Pollution Control and Ecology Commission completes rulemaking to approve and incorporate the federal decision in Regulation No. 23.

• Reg. No. 23 § 264.13(a)(1) provides that the analysis must, at a minimum, include a detailed waste characterization by a commercial facility for at least 10% of the waste handled for each large quantity generator shipping to the facility. The Federal requirements at 40 CFR 264.13(a) do not contain this specification; however, this additional State requirement is consistent with the Federal requirements.

• Reg. No. 23 § 265.13(a)(1) provides that the analysis must at a minimum include a detailed waste characterization by a commercial facility for at least 10 % of the waste handled for each large quantity generator shipping to the facility. The Federal requirements at 40 CFR 265.13(a) do not contain this specification; however, this requirement is consistent with the Federal requirements.

• Arkansas does not include an analog to the HSWA provision at 40 CFR 270.10(e)(1)(iii) because the date has passed and the Federal date overrides.

• Reg. No. 23 § 270.12 contains state- and program-specific requirements for the submittal and handling of confidential business information in conjunction with permit applications and processing.

GENERAL COMPARISON BETWEEN ARKANSAS'S HAZARDOUS WASTE REGULATIONS AND THE FEDERAL REGULATIONS

EPA regulation: Code of Federal Regulations (40 CFR)	State regulation	Description
No analogous provisions	Reg. 23 § 1	Authorities.
No analogous provisions	Reg. 23 § 2	Violations.
No analogous provisions	Reg. 23 § 3	Amendments and Updates.
No analogous provisions	Reg. 23 § 4	Conflict of Interest.
No analogous provisions	Reg. 23 § 6	Permit and Administrative Fees.
PART 260	Reg. 23 § 260	Hazardous Waste Management System: General.
PART 261	Reg. 23 § 261	Identification and Listing of Hazardous Waste.
PART 262	Reg. 23 § 262	Standards Applicable to Generators of Hazardous Waste.
PART 263	Reg. 23 § 263	Standards Applicable to Transporters of Hazardous Waste.

GENERAL COMPARISON BETWEEN ARKANSAS'S HAZARDOUS WASTE REGULATIONS AND THE FEDERAL REGULATIONS—Continued

EPA regulation: Code of Federal Regulations (40 CFR)	State regulation	Description
PART 264	Reg. 23 § 264	Standards for Owners and Operators of Hazardous Waste Treatment, Storage, and Disposal Facilities.
PART 265	Reg. 23 § 265	Interim Status Standards for Owners and Operators of Hazardous Waste Treatment, Storage, and Disposal Facilities.
PART 266	Reg. 23 § 266	Standards for the Management of Specific Hazardous Wastes and Specific Types of Hazardous Waste Management Facilities.
PART 268	Reg. 23 § 268	Land Disposal Restrictions.
PART 270/124	Reg. 23 § 270	The Hazardous Waste Permit Program.
PART 273	Reg. 23 § 273	Standards for Universal Waste Management.
PART 279	Reg. 23 § 279	Standards for the Management of Used Oil.
No analogous provisions	Reg. 23 § 19	Effect of Federal Regulations.
No analogous provisions	Reg. 23 § 20	Authority to Enter into Memoranda of Agreement.
No analogous provisions	Reg. 23 § 21	Definitions: Memoranda of Agreement.
No analogous provisions	Reg. 23 § 22	State/EPA Memorandum of Agreement.
No analogous provisions	Reg. 23 § 23	Authority: Remedial Actions Trust Fund.
No analogous provisions	Reg. 23 § 24	Remedial Action Revolving Loans.
No analogous provisions	Reg. 23 § 25	Fees on the Generation of Hazardous Waste.
No analogous provisions	Reg. 23 § 26	Criteria for Listing Hazardous Substance Sites.
No analogous provisions	Reg. 23 § 27	Remedial Action Trust Fund Priority List.
No analogous provisions	Reg. 23 § 28	Penalty Policy and Administrative Procedures.
No analogous provisions	Reg. 23 § 29	Severability.
No analogous provisions	Reg. 23 § 30	Effective Date.

In the Consolidated Independent Counsel's Statement for RCRA Clusters III, through IX and Checklist 181 in RCRA Cluster X (Universal Waste Rule; Specific Provisions for Lamps), the EPA considered the following State requirement to be more stringent than the Federal: Under Checklist 118 Liquids in Landfills, at State citation 364.314(a), 264.314(d), 265.314(a), & 265.314(c) which is the counterpart to the Federal citation, the State is more stringent because it prohibits the disposal of any liquids in hazardous waste landfills in lieu of the provisions of 40 CFR 364.314(a), 264.314(d), 265.314(a), & 265.314(c). The State citations 264.571(b), 264.573(a)(4)(i)–(ii), 265.441(a)–(b), 265.443(a)(4)(i)–(ii), the State has retained several more stringent requirements for drip pad construction, specifically a requirement to provide all existing drip pads with a impermeable coating prior to September 30, 1995 and a prohibition against using penetrating sealants to meet any requirements for an impermeable coating. Checklist 137 (Universal Treatment Standards and Treatment Standards for Organic Toxicity Characteristic Wastes and Newly Listed Wastes), the State requirements are equivalent to those of the Federal regulations with the exception of the provisions of 40 CFR 268.7(a)(10), which provides an exemption for wastes managed under tolling arrangements as provided under 40 CFR 262.20(e). Arkansas does not allow the exemptions provided under this federal rule, and thus , does not exempt the wastes listed at 40 CFR 268.7(a)(10). Therefore the State's regulation at § 268.7(a)(10) is more stringent than the Federal rule.

Under RCRA Expanded Public Participation (checklist 148), the requirements set forth at 40 CFR 124.31(a) have been adopted and incorporated into the previous State requirements for public participation in the permit process at Regulation No. 23 § 270.7. State requirements are generally equivalent to the Federal regulations with the following exception: Pursuant to A.C.A. § 8–7–217 Arkansas requires that a public notice be published ''in the largest newspaper published in the county in which a facility or facilities are located or proposed to be located, as well as published in the largest newspaper published in the adjoining counties.'' This provision makes the State requirement more stringent, as the Federal regulation simply specifies a display newspaper advertisement. Arkansas requires additional information to be submitted along with the description and location of the facility. This provision makes the State requirement broader in scope. At § 270.7(e)(2)(i), Regulation 23 requires the facility owner/operate to publish the public notice and then provide proof of such notice (a copy of the notice(s) along with a statement from the newspaper(s) listing when the advertisements run, and a copy of the paid receipt for the advertisements to the Director as part of the permit application. This provision makes the State requirements more stringent. In the same manner as above, Regulation 23 § 270.62(b)(6) and § 270.66(d)(3) require the owner/operator to provide public notice of the trial burn and provide proof of notice to the Director, instead of this notice being published by the Department. A.C.A § 8–4–203(d), Regulation No. 8 §§ 2.14(c) and 2.1.5(c), and Regulation No. 23 § 6(z) require that the costs of public notices be paid by the permit applicant, example the facility owner/operator. The mechanism for this process is that the Department drafts or approves) the public notice, for which the facility owner/operator arranges for publication and subsequently provides the Department with a copy of the published notice and proof of payment for publication costs for inclusion in the administrative record. This provision makes the State requirements more stringent.

The EPA considered the following State regulations to be broader in scope than the Federal regulations from the Consolidated Independent Counsel's Statement submitted for RCRA Clusters III through IX including Checklist 181, a portion of RCRA Cluster X. Regarding Checklist 121 (Corrective Action Management Units (CAMU)) which is included in this authorization application, the State of Arkansas'

definition of ''Facility'' when it comes to CAMU is considered consistent and equivalent with the federal definition with the exception of the State's Remedial Action Trust Fund (RATFA) A.C.A. Sections 8–7–501 et.al. which is included in the State's definition of facility. Sections 8–7–212, and 8 –7–214 are not considered by EPA to be part of the federally authorized RCRA program because those provisions are discretional dealing with site-specific management standards.

EPA is approving as part of the State of Arkansas' authorized RCRA program provision A.C.A 8–7–508(a)(1) of the Remedial Action Trust Fund Act of 1985 (RATFA). This provision provides that:

> Upon finding that a hazardous substance exists or may exist, the [ADEQ] may, upon reasonable notice and after opportunity for hearing, issue an order to any person liable for the site under [A.C.A] 8–7–512, if that person caused or contributed to the release or threatened release of hazardous substances at the site. This order shall require that such remedial action be taken as necessary to investigate, control, prevent, abate, treat, or contain any releases of or threatened releases of hazardous substances from the site.

EPA is approving this provision of RATFA so that Arkansas can ''assert without challenge the specific HSWA requirements in RCRA Section 3004(u) which call for authority to assure that permits issued after 11/8/84 require corrective action for releases of hazardous waste or hazardous constituents from **any solid waste management unit at a facility, regardless of when the waste was placed in the unit**''.[1] (Emphasis is in the original of the Independent Counsel's Statement, see pages 12 through 13 of the Statement.) Arkansas also cites to the same provision in RATFA in order to have an equivalent provision to RCRA 3004(v). EPA is also approving any other provision of RATFA necessary to effectuate the implementation of A.C.A 8–7–508(a)(1) of RATFA. EPA notes that A.C.A 8–7–508(a)(1) provides for the issuance of orders and not permits, ADEQ has explained in its Independent Counsel Statement how State law allows this provision to be used as authority to write RCRA corrective action permit terms. EPA is relying on the accuracy of this legal analysis in finding that Arkansas has equivalent provisions to RCRA 3004(u) and (v). EPA is approving this provision of RATFA as an equivalent permitting authority only and not as an enforcement/order authority. See the discussion below.

The EPA, as a point of clarification on the approval of Arkansas Corrective Action permitting authority,[2] is only approving a permitting program for corrective action and not for an order authority similar to RCRA section 3008(h). The EPA has had a longstanding policy of not authorizing States for corrective action order authority, but retaining that federal enforcement authority[3] (see 55 FR 30798, 30855 July 27, 1990). It is especially important that EPA clarify these matters since Arkansas is in the 8th Circuit Court of Appeals and subject to that Court's ruling in *Harmon Industries, Inc.* v. *Carol Browner,* 191 F 3rd 897 (8th Cir. Sept 16, 1999). This decision significantly reduced EPA's ability to take enforcement actions in an authorized State. In addition, RATFA is not a permitting program. RATFA is more similar to EPA's Superfund program in that it seeks to remediate releases of hazardous substances to the environment by issuing remediation orders. All of EPA's former and the present actions in revising Arkansas authorized RCRA program to include corrective action authority were done in the context of revising Arkansas' permitting authority to be equivalent to EPA's permitting authority at 40 CFR part 270. Furthermore, Arkansas' RATFA authority is broader in scope than the EPA RCRA program. It covers hazardous substances (as defined in the State Act)—not only hazardous waste, it allows for cost recovery by the State, and provides for responsible parties to share liability.

The State adopted the Federal rules addressed at Checklist 140 (Carbamate Production Identification and Listing of Hazardous Waste), as they were initially promulgated in the **Federal Register**, verbatim at the appropriate citations and without modification from the Federal language. The State conducted an independent rulemaking, and the subsequent vacatur of the Federal rules in *Dithiocarbamate Task Force* v. *EPA* does not apply to the State regulations. The State provisions included the vacated waste streams, which made the rule broader in scope than Federal provisions. Arkansas has only one generator of these wastes (Zeneca Ag Products), who subsequently applied to the Commission for a one-year variance from the State listing of these wastes. The Commission granted variance, which expired February 28, 1998. The State has listed wastes for K156, K157 and K158 including 3-iodo-2-propynyl n-butycarbamate (IPBC) which also was vacated by the Federal regulations.

A.C.A. § 8–7–214 does not limit the authority of A.C.A. § 8–7–204(b) to seek immediate relief in any court to retain any violations or compel any specific remedial action. In this sense, A.C.A § 8–7–204(b) is broader in scope and effect because this statute does not specifically require that the activity be ''endangering or causing damage to public health or the environment, it merely requires that there exists a violation. A.C.A § 8–7–214 authorizes the issuance of an administrative order without notice or hearing as necessary to protect the public health and environment. This statute does require that there be a finding of an ''imminent hazard'', but is also broader in scope than the Federal provisions in that an order under A.C.A. § 8–7–214 can be issued without there being any ''unauthorized activity.'' A.C.A. § 8–7–204(b), § 8–7–209(a)(7) and (8), and, § 8–7–214 are mutually independent alternatives which do not restrict or limit each other, and which provide a broad range of responses to a particular issue or situation. Broader in scope requirements are not part of the authorized program and EPA can not enforce them.

The EPA is also clarifying that the State has adopted 40 CFR part 268 and the following sections are not delegable to the State because of the national concerns which must be examined when decisions are made relative to them: 40 CFR part 268.5 (case-by-case effective date extensions) and 268.42(b) (application for alternate treatment method). ''No migration'' petitions

[1] As a point of clarification, EPA interprets RCRA sections 3004(u) and (v) as encompassing the statutory definition of hazardous waste found at RCRA section 1004(5) not just the regulatory definition of listed or identified characteristic hazardous waste found in 40 CFR part 261. Therefore, EPA can enforce any permit term issued my Arkansas that includes a solid waste which meets the statutory definition of being a hazardous waste or a hazardous waste constituent.

[2] The clarification applies not only to this authorization for RCRA Clusters III through IX and Checklist 181 a portion of Cluster X, but also to all previous revisions of the Arkansas Hazardous Waste Management Program where RCRA corrective action authority was discussed particularly the program revision found at 56 FR 47153, September 18, 1991.

[3] EPA is not establishing as part of Arkansas' authorized RCRA corrective action program any type of remedial order authority such as A.C.A. Sections 8–7–214, and 8–7–1101. These other laws/authorities were discussed in the State's Independent Counsel's Statement and its application for this and previous corrective action revisions. While illustrative of the State's overall authority to perform corrective action and order remedial actions, it is unrelated to whether or not its RCRA permit authority is equivalent to the Federal permit authority. The EPA is supportive of the States having broad authority to protect human health and the environment, but those additional authorities are not being approved as part of Arkansas' federally authorized RCRA corrective action program and are considered State only programs.

under 268.6 will be handled by EPA, even though States may be authorized to grant such petition in the future. The State also is seeking authorization for Checklist 162 (Clarification Standards for Hazardous Waste LDR Treatment Variances, and has adopted 40 CFR part 268.44(a), however, EPA wants to clarify that the provisions at 40 CFR part 268.44(a)–(g) addresses general treatment standard variances; and the authority for such variances is not delegable to the State because these variances could result in nationally applicable standards for a new waste treatability group.

H. Who Handles Permits After This Authorization Takes Effect?

The EPA will administer any RCRA permits or portions of permits it has issued to facilities in the State until the State becomes authorized. At the time the State program is authorized for new rules, EPA will transfer all permits or portions of permits issued by EPA to the State. The EPA will not issue any more permits or portions of permits for the provisions listed in this document after the effective date of this authorization. The EPA will continue to implement and issue permits for HSWA requirements for which the State is not yet authorized.

I. Why Wasn't There a Proposed Rule Before Today's Notice?

The EPA is authorizing the State's changes through this immediate final action and is publishing this rule without a prior proposal to authorize the changes because EPA believes it is not controversial and does not expect comments that oppose this action. The EPA is providing an opportunity for public comment now. In the proposed rules section of today's **Federal Register** we are publishing a separate document that proposes to authorize the State changes. If EPA receives comments which oppose this authorization, that document will serve as a proposal to authorize the changes.

J. Where Do I Send My Comments and When Are They Due?

You should send written comments to Alima Patterson, Regional Authorization Coordinator, Grants and Authorization Section (6PD–G), Multimedia Planning and Permitting Division, EPA Region 6, 1445 Ross Avenue, Dallas, Texas 75202–2733, (214) 665–8533. Please refer to Docket Number AR–00–0.

We must receive your comments by May 24, 2002. You may not have an opportunity to comment again. If you want to comment on this action, you must do so at this time.

K. What Happens if EPA Receives Comments Opposing This Action?

If EPA receives comments which oppose this authorization, a second **Federal Register** notice will be published before the time the immediate final rule takes effect. The second notice may withdraw the immediate final rule or identify the issues raised, or respond to the comments and affirm that the immediate final rule will take effect as scheduled.

L. When Will This Approval Take Effect?

Unless EPA receives comments that oppose this action, this final authorization approval will become effective without further notice on June 24, 2002.

M. Where Can I Review the State's Application?

You can view and copy the State of Arkansas' application from 8:30 a.m. to 4:00 p.m. Monday through Friday at the following addresses: Arkansas Department of Environmental Quality, 8101 Interstate 30, Little Rock, Arkansas 72219, (501) 682–0876 and EPA, Region 6, 1445 Ross Avenue, Dallas, Texas 75202–2733, (214) 665–6444. For further information contact Alima Patterson, Regional Authorization Coordinator, Grants and Authorization Section (6PD–G), Multimedia Planning and Permitting Division, EPA Region 6, 1445 Ross Avenue, Dallas, Texas 75202–2733, (214) 665–8533.

N. How Does Today's Action Affect Indian Country in Arkansas?

Arkansas is not authorized to carry out its Hazardous Waste Program in Indian country within the State. This authority remains with EPA. Therefore, this action has no effect in Indian country.

O. What Is Codification?

Codification is the process of placing the State's statutes and regulations that comprise the State's authorized Hazardous Waste Program into the CFR. The EPA does this by referencing the authorized State rules in 40 CFR part 272. The EPA reserves the amendment of 40 CFR part 272, subpart E for this codification of Arkansas' program changes until a later date.

Administrative Requirements

The Office of Management and Budget has exempted this action from the requirements of Executive Order 12866 (58 FR 51735, October 4, 1993), and therefore this action is not subject to review by OMB. This action authorizes State requirements for the purpose of RCRA 3006 and imposes no additional requirements beyond those imposed by State law. Accordingly, I certify that this action will not have a significant economic impact on a substantial number of small entities under the Regulatory Flexibility Act (5 U.S.C. 601 *et seq.*). Because this action authorizes pre-existing requirements under State law and does not impose any additional enforceable duty beyond that required by State law, it does not contain any unfunded mandate or significantly or uniquely affect small governments, as described in the Unfunded Mandates Reform Act of 1995 (Pub. L. 104–4). For the same reason, this action also does not significantly or uniquely affect the communities of Tribal governments, as specified by Executive Order 13175 (65 FR 67249, November 9, 2000). This action will not have substantial direct effects on the States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government, as specified in Executive Order 13132 (64 FR 43255, August 10, 1999), because it merely authorizes State requirements as part of the State RCRA hazardous waste program without altering the relationship or the distribution of power and responsibilities established by RCRA. This action also is not subject to Executive Order 13045 (62 FR 19885, April 23, 1997), because it is not economically significant and it does not make decisions based on environmental health or safety risks. This rule is not subject to Executive Order 13211, ''Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution, or Use'' (66 FR 28355 (May 22, 2001)) because it is not a significant regulatory action under Executive Order 12866.

Under RCRA 3006(b), EPA grants a State's application for authorization as long as the State meets the criteria required by RCRA. It would thus be inconsistent with applicable law for EPA, when it reviews a State authorization application, to require the use of any particular voluntary consensus standard in place of another standard that otherwise satisfies the requirements of RCRA. Thus, the requirements of section 12(d) of the National Technology Transfer and Advancement Act of 1995 (15 U.S.C. 272 note) do not apply. As required by section 3 of Executive Order 12988 (61 FR 4729, February 7, 1996), in issuing this rule, EPA has taken the necessary steps to eliminate drafting errors and ambiguity, minimize potential litigation, and provide a clear legal standard for

affected conduct. EPA has complied with Executive Order 12630 (53 FR 8859, March 15, 1988) by examining the takings implications of the rule in accordance with the ''Attorney General's Supplemental Guidelines for the Evaluation of Risk and Avoidance of Unanticipated Takings'' issued under the executive order. This rule does not impose an information collection burden under the provisions of the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 *et seq.*).

The Congressional Review Act, 5 U.S.C. 801 *et seq.*, as added by the Small Business Regulatory Enforcement Fairness Act of 1996, generally provides that before a rule may take effect, the agency promulgating the rule must submit a rule report, which includes a copy of the rule, to each House of the Congress and to the Comptroller General of the United States. EPA will submit a report containing this document and other required information to the U.S. Senate, the U.S. House of Representatives, and the Comptroller General of the United States prior to publication in the **Federal Register**. A major rule cannot take effect until 60 days after it is published in the **Federal Register**. This action is not a ''major rule'' as defined by 5 U.S.C. 804(2). This action will be effective June 24, 2002.

List of Subjects in 40 CFR Part 271

Administrative practice and procedure, Confidential business information, Hazardous materials transportation, Hazardous waste, Indian lands, Intergovernmental relations, Penalties, Reporting and recordkeeping requirements, Water pollution control, Water supply.

Authority: This notice is issued under the authority of sections 2002(a), 3006, and 7004(b) of the Solid Waste Disposal Act as amended, 42 U.S.C. 6912(a), 6926, 6974(b).

Dated: April 5, 2002.

Gregg A. Cooke,

Regional Administrator, Region 6.

[FR Doc. 02–10038 Filed 4–23–02; 8:45 am]

BILLING CODE 6560–50–P

FEDERAL COMMUNICATIONS COMMISSION

47 CFR Parts 32, 51 and 54

[CC Docket No. 00–199; FCC 02–68]

2000 Biennial Regulatory Review — Comprehensive Review of the Accounting Requirements and Reporting Requirements for Incumbent Local Exchange Carriers

AGENCY: Federal Communications Commission.

ACTION: Final rule; withdrawal of amendment and partial delay of effective date.

SUMMARY: In this document the Commission reinstates Account 3400, Accumulated amortization—tangible, a Class B Account. Reinstating Account 3400 is less burdensome for the Class B carriers. We also clarify that mid-sized carriers are not required to file ARMIS 43–02 (USOA Report), 43–03 (Joint Cost Report), and 43–04 (Separations and Access Report). The Commission delays the effective date of the changes to the part 32 chart of accounts, and derivative changes to parts 51 and 54 of the Commission rules. This delay would allow the accounting changes to be implemented at the beginning of the year.

DATES: The amendment removing § 32.3400, published at 67 FR 5688, (February 6, 2002), which was to become effective August 6, 2002 (however, carriers were permitted to implement part 32 accounting changes as of January 1, 2002) is withdrawn as of April 24, 2002. All other amendments to part 32 and parts 51 and 54 published at 67 FR 5679–5702, which were to become effective August 6, 2002 (however, carriers were permitted to implement part 32 accounting changes as of January 1, 2002) are delayed until January 1, 2003.

FOR FURTHER INFORMATION CONTACT: Clifford Rand, Deputy Chief, PPD, Wireline Competition Bureau.

SUPPLEMENTARY INFORMATION: This is a summary of the Commission's Order on Reconsideration adopted March 7, 2002 and released March 8, 2002. The full text of the document is available for public inspection and copying during regulator business hours at the FCC Reference Information Center, Portals II, 445 12th Street, SW., Room CY–A257, Washington DC, 20554. This document may also be purchased from the Commission's duplicating contractor, Qualex International, Portal II 445 12th Street, SW., Room CY–B402, Washington, DC, 20554, telephone 202–863–2893, facsimile 202–863–2898, or via e-mail *qualexint@aol.com.*

Synopsis of Order

I. Background

The Commission undertook a comprehensive review of the accounting rules and Automated Reporting Management Information System (ARMIS) reporting requirements in the *Phase 2 Report and Order,* 67 FR 5669 (February 6, 2002). Among other things, the Commission eliminated many part 32 accounts and reduced ARMIS reporting requirements for mid-sized local exchange carriers (LECs). On the Commission's motion, pursuant to § 1.108 of the Commission's rules, the Commission issues this limited reconsideration of the rules adopted in the *Phase 2 Report and Order.* In this Order, the Commission reinstates Account 3400, Accumulated amortization—tangible, a Class B account, at the request of United States Telecom Association (USTA). At Sprint's request, the Commission clarifies that mid-sized carriers are not required to file ARMIS 43–02 (USOA Report), 43–03 (Joint Cost Report), and 43–04 (Separations and Access Report). Finally, at the request of the Bell Operating Companies (BOCs), the Commission extends the effective date of the changes to the Part 32 chart of accounts, and derivative changes to parts 51 and 54, adopted in the *Phase 2 Report and Order,* to January 1, 2003.

II. Discussion

Account 3400, Accumulated amortization—tangible. In the *Phase 2 Report and Order,* the Commission consolidated many of the Class A and Class B accounts. The Commission reduced the number of Class A accounts by 45 percent while retaining the accounts needed by the Commission or the states for regulatory purposes. The Commission also added several Class A subaccounts requested by commenters. The Commission concluded that the Class B account consolidation should correspond with the Class A account consolidation; otherwise, the result would be contrary to the intent to adopt a less burdensome accounting system for the Class B carriers. The Commission therefore reduced the number of Class B accounts by 27 percent. One of the Class B accounts eliminated was Account 3400, Accumulated amortization—tangible.

Account 3400, Accumulated amortization—tangible is used by Class B companies to record accumulated amortization of the type and character required of Class A companies in

Accounts 3410 and 3420. The Commission eliminated this account in the *Phase 2 Report and Order,* but required Class B carriers to use Account 3410, Accumulated amortization—capitalized leases for part of what was entered into Account 3400. The remaining portion of what was in Account 3400 was intended to go into Account 2682, Leasehold improvements.

USTA argues that it would be easier for the Class B companies to use Account 3400, rather than allocate what formerly was in this account between two other accounts. USTA therefore proposes that the Commission reinstate Account 3400. The streamlining measures adopted in the *Phase 2 Report and Order* were intended to benefit LECs, both large and small, by reducing the number of accounts they were required to maintain, while maintaining those needed for regulatory purposes. In light of USTA's assertion that it is less burdensome for the Class B carriers to keep Account 3400, the Commission concludes that it would be appropriate to retain this account. Therefore, on reconsideration, and at the request of USTA, the Commission retains Account 3400, Accumulated amortization—tangible.

ARMIS Reports. ARMIS is an automated reporting system developed by the Commission to collect financial, operating, service quality, and network infrastructure information that carriers are required to collect under Commission rules. ARMIS Reports 43–01, 43–02, 43–03, and 43–04 contain financial information of carriers with annual operating revenues that are equal to or above the indexed revenue threshold, currently $117 million. ARMIS 43–04 (Separations and Access Report) collects information on how costs are separated between the federal and state jurisdictions.

At the request of Sprint, the Commission clarifies that mid-sized carriers are not required to file the ARMIS 43–02, 43–03, and 43–04 reports on April 1, 2002. As Sprint observes, one of the goals in this proceeding is to reduce reporting requirements for the mid-sized carriers. The Commission hereby clarifies that its intention was to eliminate the obligation of mid-sized carriers to file ARMIS 43–02, 43–03, and 43–04 on April 1, 2002, and to require the mid-sized carriers to file the revised 43–01 and 43–8 reports on the same schedule as the larger companies.

Extending the effective date of revisions to the Part 32 chart of accounts to January 1, 2003. In the *Phase 2 Report and Order,* the Commission adopted changes to the accounting rules. BellSouth, on behalf of itself and SBC Communications, Verizon, and Qwest, requests that the Commission extend the effective date of the changes to the part 32 chart of accounts to January 1, 2003.

The Commission agrees with these carriers that extending the effective date of the new part 32 chart of accounts to January 1, 2003 would allow the accounting changes to be implemented at the beginning of the fiscal year and would avoid the dual data capturing that could occur if the part 32 chart of accounts changes were implemented in mid-year. The Commission also notes that this extension will give carriers additional time to revise their accounting systems to incorporate the many changes to the part 32 chart of accounts adopted in the Phase 2 Report and Order. Therefore, on reconsideration, and at the request of the Bell Operating Companies, the Commission is extending the effective date of the changes to the part 32 chart of accounts to January 1, 2003.

As a result of changes in the effective date for the accounting rules, carriers will not be able to report revised 2002 data on April 1, 2003. Consequently, the revisions to the ARMIS Reports 43–01, 43–02, and 43–03 shall be effective for filings due April 1, 2004.

Therefore, on the Commission's own motion, pursuant to § 1.108 of the Commission's rules, the Commission is extending the effective date of the new part 32 chart of accounts and derivative changes to parts 51 and 54 adopted in the *Phase 2 Report and Order* to January 1, 2003. The Commission is retaining Account 3400, Accumulated amortization—tangible, and the Commission is clarifying that mid-sized LECs are not required to file the ARMIS 43–02, 43–03, and 43–04 reports on April 1, 2002.

III. Procedural Matters

Final Regulatory Flexibility Certification. The Regulatory Flexibility Act of 1980, as amended, (RFA), requires that a regulatory flexibility analysis be prepared for notice and comment proceedings, unless the agency certifies that ''the rule will not, if promulgated, have a significant economic impact on a substantial number of small entities.'' The RFA generally defines ''small entity'' as having the same meaning as the term ''small business,'' ''small organization,'' and ''small governmental jurisdiction.'' In addition, the term ''small business'' has the same meaning as the term ''small business concern'' under the Small Business Act, unless the Commission has developed one or more definitions that are appropriate to its activities. Under the Small Business Act, a ''small business concern'' is one that: (1) Is independently owned and operated; (2) is not dominant in its field of operation; and (3) meets any additional criteria established by the Small Business Administration (SBA).

In the *Phase 2 Report and Order,* the Commission streamlined the Class A and Class B accounts and ARMIS reporting requirements for incumbent LECs, and further reduced the accounting and reporting requirements for mid-sized incumbent LECs. These rule changes generally reduced the accounting and reporting requirements for all incumbent LECs. In this Order on Reconsideration, the Commission is reinstating one Class B account, at the request of USTA. The Commission is also clarifying that mid-sized carriers are not required to file the ARMIS 43–02, 43–03, and 43–04 Reports, also at the request of USTA. Finally, the Commission is extending the effective date for the new chart of accounts adopted in the *Phase 2 Report and Order* to January 1, 2003, pursuant to the BOCs' request. This will allow carriers, including small entities, more time to make the necessary changes to their accounting systems. These rule changes and clarification will further reduce accounting and reporting burdens for incumbent LECs. Therefore, we certify, pursuant to section 605(b) of the RFA, that the rules adopted herein will not have a significant economic impact on a substantial number of small entities.

IV. Ordering Clauses

Pursuant to section 220(g) of the Communications Act of 1934, as amended, 47 U.S.C. 220(g), changes to the chart of accounts in part 32, System of Accounts, adopted in the Report and Order in CC Docket No. 00–199 shall be effective January 1, 2003. We will, however, permit carriers to implement the § 32.3400 rule change as of January 1, 2002.

Pursuant to the authority contained in sections 1, 4(i), 4(j), 201–205, and 218–220 of the Communications Act of 1934, as amended, 47 U.S.C. sections 151, 154(i), 154(j), 201–205, and 218–220, that mid-sized incumbent local exchange carriers are not required to file FCC Report 43–02, the USOA Report; FCC Report 43–03, the Joint Cost Report; and FCC Report 43–04, the Separations and Access Report for filings due April 1, 2002.

Pursuant to the authority contained in sections 1, 4(i), 4(j), 201–205, and 218–220 of the Communications Act of 1934, as amended, 47 U.S.C. sections 151,

154(i), 154(j), 201–205, and 218–220, that revisions to FCC Report 43–01, the Annual Summary Report; FCC Report 43–02, the USOA Report; and FCC Report 43–03, the Joint Cost Report as set forth previously shall be effective for filings due April 1, 2004.

Pursuant to the authority contained in § 0.291 of the Commission's rules, 47 CFR 0.291, that the Common Carrier Bureau is delegated authority to implement all changes to ARMIS reporting as above set forth.

List of Subject in 47 CFR Parts 32, 51 and 54.

Communications common carriers, Reporting and recordkeeping requirements, Telephone.

Communications Commission.

William F. Caton,

Acting Secretary.

[FR Doc. 02–9880 Filed 4–23–02; 8:45 am]

BILLING CODE 6712–01–P

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

50 CFR Parts 222 and 223

[Docket No. 020418089–2089–01; I.D. 041702B]

RIN 0648–AP96

Sea Turtle Conservation; Restrictions Applicable to Shrimp Trawl Activities; Leatherback Conservation Zone

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

ACTION: Temporary area gear restriction.

SUMMARY: NMFS is closing, for a short 2–week period, all inshore waters and offshore waters 10 nautical miles (nm) (18.5 km) seaward of the COLREGS demarcation line, bounded by 31° N. lat. (approximately St. Andrews Sound, Georgia) and 32° N. lat. (approximately Tybee Island, Georgia) within the Leatherback Conservation Zone, to fishing by shrimp trawlers required to have a turtle excluder device (TED) installed in each net that is rigged for fishing, unless the TED has an escape opening large enough to exclude leatherback turtles, as specified in the regulations. This action is necessary to reduce mortality of endangered leatherback sea turtles incidentally captured in shrimp trawls.

DATES: This action is effective from April 19, 2002 through 11:59 p.m. (local time) on May 3, 2002.

ADDRESSES: Comments on this action should be addressed to the Chief, Endangered Species Division, Office of Protected Resources, NMFS, 1315 East-West Highway, Silver Spring, MD 20910. Comments may also be sent via fax to 301–713–0376. Comments will not be accepted if submitted via e-mail or the Internet.

FOR FURTHER INFORMATION CONTACT: David Bernhart (ph. 727–570–5312, fax 727–570–5517, e-mail *David.Bernhart@noaa.gov*); or Barbara Schroeder (ph. 301–713–1401, fax 301–713–0376, e-mail *Barbara.Schroeder@noaa.gov*).

For assistance in modifying TED escape openings to exclude leatherback sea turtles, fishermen may contact gear specialists at the NMFS, Pascagoula, MS laboratory by phone 228–762–4591 or fax 228–769–8699.

SUPPLEMENTARY INFORMATION: SUPPLEMENTARY INFORMATION: Prohibitions on taking sea turtles are governed by regulations implementing the Endangered Species Act at 50 CFR parts 222 and 223. The incidental take of turtles during shrimp fishing in the Atlantic Ocean off the coast of the southeastern United States and in the Gulf of Mexico is excepted from the taking prohibition pursuant to sea turtle conservation regulations at 50 CFR 223.206, which include a requirement that shrimp trawlers have a NMFS-approved TED installed in each net rigged for fishing. The use of TEDs significantly reduces mortality of loggerhead, green, Kemp's ridley, and hawksbill sea turtles. Because leatherback turtles are larger than the escape openings of most NMFS-approved TEDs, use of these TEDs is not an effective means of protecting leatherback turtles.

Through a final rule (60 FR 47713 September 14, 1995), NMFS established regulations to provide protection for leatherback turtles when they occur in locally high densities during their annual, spring northward migration along the Atlantic seaboard. Within the Leatherback Conservation Zone, NMFS may close an area for 2 weeks when leatherback sightings exceed 10 animals per 50 nm (92.6 km) during repeated aerial surveys pursuant to § 223.206(d)(2)(iv)(A) through (C).

An initial aerial survey conducted on March 29, 2002, along the Georgia coast documented 17 leatherback turtles over a total survey trackline of approximately 80 nm (148 km). Concentrations were noted in waters off Wassaw, Ossabaw, St. Catherines, and Sapelo Islands. No shrimp trawlers were seen working. Due to mechanical difficulties, the survey did not continue south of Sapelo Island. A replicate survey was flown along the entire Georgia coast on April 15, 2002. Thirty-three leatherback turtles and 77 shrimp trawlers were spotted, over a total survey trackline of approximately 190 nautical miles (352 km). Leatherbacks were concentrated again off Ossabaw, St. Catherines, and Sapelo Islands and also off Jekyll and St. Simons Islands. Leatherbacks were also spotted off Tybee Island in the north and Cumberland Island in the south. The sighting frequencies in the original and replicate surveys all met or exceeded the regulatory standard of at least 10 animals within a 50 nautical mile (92.6 km) length of survey trackline.

The Assistant Administrator for Fisheries, NOAA (AA), is closing all inshore waters and offshore waters within 10 nm (18.5 km) seaward of the COLREGS demarcation line, bounded by 31° N. lat. and 32° N. lat., within the Leatherback Conservation Zone to fishing by shrimp trawlers required to have a TED installed in each net that is rigged for fishing, unless the TED installed has an escape opening large enough to exclude leatherback turtles, meeting the specifications at 50 CFR 223.207(a)(7)(ii)(B)(1) or (2) or 223.207(c)(1)(iv)(B). These regulations specify modifications that can be made to either single-grid hard TEDs or Parker soft TEDs to allow leatherbacks to escape.

The regulations at 50 CFR 223.206(d)(2)(iv) also state that fishermen operating in the closed area with TEDs modified to exclude leatherback turtles must notify the NMFS Southeast Regional Administrator of their intention to fish in the closed area. This aspect of the regulations does not have a current Office of Management and Budget control number, issued pursuant to the Paperwork Reduction Act. Consequently, fishermen are not required to notify the Regional Administrator prior to fishing in the closed area, but they must still meet the gear requirements.

Classification

This action has been determined to be not significant for purposes of Executive Order 12866.

The AA is taking this action in accordance with the requirements of 50 CFR 223.206(d)(2)(iv) to provide protection for endangered leatherback sea turtles from incidental capture and drowning in shrimp trawls. Leatherback sea turtles are occurring in high concentrations in coastal waters in shrimp fishery statistical zone 31. This

action allows shrimp fishing to continue in the affected area so long as fishermen make the required gear modifications.

Pursuant to 5 U.S.C. 553(b)(B), the AA finds that there is good cause to waive prior notice and opportunity to comment on this action. As a sizeable concentration of leatherback turtles was recently observed in close proximity to a large number of shrimp trawlers, it is extremely likely that interactions will occur. It would be impracticable to provide prior notice and opportunity for comment because providing notice and comment would prevent the agency from implementing the necessary action in a timely manner to protect the endangered leatherback.

Pursuant to 5 U.S.C. 553(d)(3), the AA finds that there is good cause not to delay the effective date of this rule for 30 days. Such delay would prevent the agency from implementing the necessary action in a timely manner to protect the endangered leatherback. Accordingly, the AA is making the rule effective April 19, 2002 through May 3, 2002. This closure has been announced on the NOAA weather channel, in newspapers, and other media. Shrimp trawlers may also call (727)570–5312 for updated area closure information. As prior notice and an opportunity for public comment are not required to be provided for this notification by 5 U.S.C. 553, or by any other law, the analytical requirements of 5 U.S.C. 601 *et seq.*, are inapplicable.

The AA prepared an Environmental Assessment (EA) for the final rule requiring TED use in shrimp trawls and the regulatory framework for the Leatherback Conservation Zone (60 FR 47713, September 14, 1995). Copies of the EA are available (see **ADDRESSES**).

Dated: April 19, 2002.

Rebecca Lent

Deputy Assistant Administrator for Regulatory Programs, National Marine Fisheries.

[FR Doc. 02–10060 Filed 4–19–02; 3:30 pm]

BILLING CODE 3510–22–S

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

50 CFR Part 230

[I.D. 041602A]

Whaling Provisions: Aboriginal Subsistence Whaling Quotas

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

ACTION: Notification of aboriginal subsistence whaling quota.

SUMMARY: NMFS announces the aboriginal subsistence whaling quota for bowhead whales, and other limitations deriving from regulations adopted at the 1997 Annual Meeting of the International Whaling Commission (IWC). For 2002, the quota is 75 bowhead whales struck. This quota and other limitations will govern the harvest of bowhead whales by members of the Alaska Eskimo Whaling Commission (AEWC).

DATES: Effective April 24, 2002.

ADDRESSES: Office of Protected Resources, National Marine Fisheries Service, 1315 East West Highway, Silver Spring, MD 20910.

FOR FURTHER INFORMATION CONTACT: Chris Yates, (301) 713–2322.

SUPPLEMENTARY INFORMATION: Aboriginal subsistence whaling in the United States is governed by the Whaling Convention Act (16 U.S.C. 916 *et seq.*), which requires the Secretary of Commerce (Secretary) to publish, at least annually, aboriginal subsistence whaling quotas and any other limitations on aboriginal subsistence whaling deriving from regulations of the IWC.

At the 1997 Annual Meeting of the IWC, the Commission set quotas for aboriginal subsistence use of bowhead whales from the Bering-Chukchi-Beaufort Seas stock. The bowhead quota was based on a joint request by the United States and the Russian Federation, accompanied by documentation concerning the needs of 2 Native groups: Alaska Eskimos and Chukotka Natives in the Russian Far East.

This action by the IWC thus authorized aboriginal subsistence whaling by the AEWC for bowhead whales. This aboriginal subsistence harvest is conducted in accordance with a cooperative agreement between NOAA and the AEWC.

The IWC set a 5–year block quota of 280 bowhead whales landed. For each of the years 1998 through 2002, the number of bowhead whales struck may not exceed 67, except that any unused portion of a strike quota from any year, including 15 unused strikes from the 1995-1997 quota, may be carried forward. No more than 15 strikes may be added to the strike quota for any 1 year. The 2001 strike quota was 75. At the end of the 2001 harvest, there were 15 unused strikes available for carry-forward, so the combined strike quota for 2001 is also 82 (67 + 15).

The United States and the Russian Federation have concluded an arrangement to ensure that the total quota of bowhead whales landed and struck in 2002 will not exceed the quotas set by the IWC. Under that arrangement, the Russian natives may use no more than 7 strikes, and the Alaska Eskimos may use no more than 75 strikes.

NOAA is assigning 75 strikes to the Alaska Eskimos. The AEWC will allocate these strikes among the 10 villages whose cultural and subsistence needs have been documented in past requests for bowhead quotas from the IWC, and will ensure that its hunters use no more than 75 strikes.

Other Limitations

The IWC regulations, as well as the NOAA rule at 50 CFR 230.4(c), forbid the taking of calves or any whale accompanied by a calf.

NOAA rules (at 50 CFR 230.4) contain a number of other prohibitions relating to aboriginal subsistence whaling, some of which are summarized here. Only licensed whaling captains or crew under the control of those captains may engage in whaling. They must follow the provisions of the relevant cooperative agreement between NOAA and a Native American whaling organization. The aboriginal hunters must have adequate crew, supplies, and equipment. They may not receive money for participating in the hunt. No person may sell or offer for sale whale products from whales taken in the hunt, except for authentic articles of Native handicrafts. Captains may not continue to whale after the relevant quota is taken, after the season has been closed, or if their licenses have been suspended. They may not engage in whaling in a wasteful manner.

Dated: April 18, 2002.

Rebecca Lent,

Deputy Assistant Administrator for Regulatory Programs, National Marine Fisheries Service.

[FR Doc. 02–10082 Filed 4–23–02; 8:45 am]

BILLING CODE 3510–22–S

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

50 CFR Part 648

[Docket No. 011005245–2012–02; I.D. 041802A]

Fisheries of the Northeastern United States; Atlantic Herring Fishery; Total Allowable Catch Harvested for Period 1 in Management Area 1A

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

ACTION: Closure of directed fishery for Management Area 1A.

SUMMARY: NMFS announces that 95 percent of the Atlantic herring total allowable catch (TAC) allocated to Management Area 1A (Area 1A) for the first seasonal period of the fishing year 2002 has been harvested. Therefore, federally permitted vessels may not fish for, catch, possess, transfer or land more than 2,000 lb (907.2 kg) of Atlantic herring harvested from Area 1A per trip or calendar day until June 1, 2002, when the second seasonal period TAC becomes available. Regulations governing the Atlantic herring fishery require publication of this notification when 95 percent of the Atlantic herring TAC allocated to first seasonal period in Area 1A has been harvested to advise vessel and dealer permit holders that no TAC is available for the directed fishery for Atlantic herring harvested from Area 1A.

DATES: Effective 0001 hrs local time, April 26, 2002, through 2400 hrs local time, May 31, 2002.

FOR FURTHER INFORMATION CONTACT: Myles Raizin, Fishery Policy Analyst, at (978) 281–9104.

SUPPLEMENTARY INFORMATION: Regulations governing the Atlantic herring fishery are found at 50 CFR part 648. The regulations require annual specification of optimum yield, domestic and foreign fishing, domestic and joint venture processing, and management area TACs. The Atlantic herring specifications for fishing year 2002 were published in the **Federal Register** on January 24, 2002 (67 FR 3442). Framework 1 to the Atlantic Herring FMP was published in the **Federal Register** on January 24, 2002 (67 FR 3445). This action modified the specification of herring quota for Management Area 1A by establishing two quota periods. This action modified the 2002 Area 1A TAC of 60,000 mt by allocating 6,000 mt (13,224,000 lb) to the January - May period, leaving 54,000 mt for the June-December period.

The regulations at 50 CFR 648.202 require the Administrator, Northeast Region, NMFS (Regional Administrator) to monitor the Atlantic herring fishery in each of the four management areas designated in the FMP and, based upon dealer reports, state data, and other available information, to determine when the harvest of Atlantic herring is projected to reach 95 percent of the Period 1 TAC (5,700 mt; 12,562,800 lb) allocated to Area 1A. When such a determination is made, NMFS is required to publish notification in the **Federal Register** notifying vessel and dealer permit holders that, effective upon a specific date, vessels may not fish for, catch, possess, transfer or land more than 2,000 lb (907.2 kg) of herring per trip or calendar day from Area 1 until June 1, 2002, when the second seasonal period TAC becomes available.

The Regional Administrator has determined, based upon dealer reports and other available information, that 95 percent of the Atlantic herring TAC allocated to Area 1A for Period 1 of fishing year 2002 has been harvested. Therefore, effective 0001 hrs local time, April 26, 2002, federally permitted vessels may not fish for, catch, possess, transfer or land more than 2,000 lb (907.2 kg) of Atlantic herring harvested from Area 1A per trip or calendar day until the second seasonal period TAC becomes available at 0001 hrs, June 1, 2002. Vessels may transit an area that is limited to the 2,000–lb (907.2–kg) limit with more than 2,000 lb (907.2 kg) of herring on board, providing all fishing gear is stowed and not available for immediate use, as required by § 648.23(b). A vessel may land herring in an area that is limited to the 2,000–lb (907.2–kg) limit specified in § 648.202(a) with more than 2,000 lb (907.2 kg) of herring on board, providing such herring were caught in an area or areas not subject to the 2,000–lb (907.2–kg) limit and providing all fishing gear is stowed and not available for immediate use as required by § 648.23(b). Effective April 26, 2002, federally permitted dealers are also advised that they may not purchase Atlantic herring from federally permitted Atlantic herring vessels that harvest more than 2,000 lb (907.2 kg) of Atlantic herring from Area 1A through June 1, 2002, 0001 hrs local time.

Classification

This action is required by 50 CFR part 648 and is exempt from review under E.O. 12866.

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

Dated: April 18, 2002.

Bruce C. Morehead,

Acting Director, Office of Sustainable Fisheries, National Marine Fisheries Service.

[FR Doc. 02–9953 Filed 4–18–02; 3:26 pm]

BILLING CODE 3510–22–S

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

50 CFR Part 660

[Docket No. 010502110–1110–01; I.D. 040902H]

Fisheries Off West Coast States and in the Western Pacific; West Coast Salmon Fisheries; Inseason Adjustment #1-Commercial and Recreational Inseason Adjustments From Cape Falcon to Humbug Mountain, OR

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

ACTION: Inseason adjustments; request for comments.

SUMMARY: NMFS announces that the commercial and recreational fisheries for all salmon except coho, in the areas from Cape Falcon to Humbug Mountain, OR, opened March 20, 2002, and April 1, 2002, respectively, and will continue through dates to be determined in the management measures for year 2002 ocean salmon fisheries in the U.S. exclusive economic zone (EEZ). These actions are necessary to conform to the 2001 announcement of management measures, and subsequent recommendations by the Pacific Fisheries Management Council, for year 2002 salmon seasons opening earlier than May 1, 2002, and are intended to provide access to the year 2002 chinook salmon optimum yield.

DATES: Effective 0001 hours local time (l.t.) March 20, 2002, for the commercial fishery, and 0001 hours l.t. April 1, 2002, for the recreational fishery, until the effective date of the year 2002 management measures, which will be published in the **Federal Register** for the west coast salmon fisheries. Comments will be accepted through May 9, 2002.

ADDRESSES: Comments on these actions must be mailed to D. Robert Lohn, Regional Administrator, Northwest Region, NMFS, NOAA, 7600 Sand Point Way N.E., Bldg. 1, Seattle, WA 98115–0070; or faxed to 206–526–6376; or Rod

McInnis, Acting Regional Administrator, Southwest Region, NMFS, NOAA, 501 W. Ocean Blvd., Suite 4200, Long Beach, CA 90802–4132; or faxed to 562–980–4018. Comments will not be accepted if submitted via e-mail or the Internet. Information relevant to this document is available for public review during business hours at the Office of the Regional Administrator, Northwest Region, NMFS.

FOR FURTHER INFORMATION CONTACT: Christopher Wright, 206–526–6140.

SUPPLEMENTARY INFORMATION: In the 2001 annual management measures for ocean salmon fisheries (66 FR 23185, May 8, 2001), NMFS announced that the Pacific Fishery Management Council (Council) would consider at its March 2002 meeting a recommendation to open commercial and recreational seasons for all salmon except coho prior to May 1, 2002, in areas off Oregon. The data to determine appropriate opening dates for the fisheries prior to May 1 are not available until just before the March Council meeting. However, the fish become available for harvest before the April meeting and the setting of the 2002 seasons at that meeting. These inseason actions opening the recreational and commercial fisheries were necessary to implement the opening of these seasons and allowing fisheries prior to May 1, 2002.

At the March 2002 meeting, the Council made its inseason recommendations to open the recreational and commercial fisheries, for all salmon except coho, from Cape Falcon to Humbug Mountain, OR, on March 20, 2002, and April 1, 2002, respectively. The closing dates for both fisheries will be recommended during the April 2002 meeting when the entire 2002 management measures for the 2002 ocean salmon fisheries are adopted by the Council.

The commercial fishery for all salmon except coho, from Cape Falcon to Humbug Mountain, OR, opened on March 20, 2002. Single-point, single-shank barbless hooks are required. No more than four spreads are allowed per line. The minimum size limit is 26 inches (66.0 cm) total length (19.5 in (49.5 cm) head-off). Chinook not less than 26 inches (66.0 cm) total length (19.5 inches (49.5 cm) head-off) taken during open seasons south of Cape Falcon may be landed north of Cape Falcon only while the season is closed north of Cape Falcon. Oregon State regulations describe a closure at the mouth of the Tillamook Bay.

The recreational fishery for all salmon except coho, from Cape Falcon to Humbug Mountain, OR, opened on April 1, 2002. The daily possession limit is two fish per day, with no more than six fish retained in 7 consecutive days. The minimum size limit is 20 inches (50.8 cm) total length. All gear must have no more than two single-point, single-shank, barbless hooks. Oregon State regulations describe a closure at the mouth of of the Tillamook Bay.

The Regional Administrator consulted with representatives of the Council, Washington Department of Fish and Wildlife, Oregon Department of Fish and Wildlife, and the California Department Fish and Game regarding these adjustments at the March 2002 Council meeting in Sacramento, CA. As provided by the inseason notification procedures at 50 CFR 660.411, actual notice to fishermen of these actions was given prior to 0001 hours l.t., March 20, 2002, and 0001 hours l.t., April 1, 2002, by telephone hotline number 206–526–6667 or 800–662–9825 and by U.S. Coast Guard Notice to Mariners broadcasts on Channel 16 VHF-FM and 2182 kHz.

These actions do not apply to other fisheries that may be operating in other areas.

Classification

The Assistant Administrator for Fisheries, NOAA (AA), finds that good cause exists for this notification to be issued without affording prior notice and opportunity for public comment under 5 U.S.C. 553(b)(B), or delaying the effectiveness of this rule for 30 days under 5 U.S.C. 553(d)(3), because such notification and delay would be impracticable and contrary to the public interest. As previously noted, actual notice of these actions was provided to fishermen through telephone hotline and radio notification. This action complies with the requirements of the annual management measures for ocean salmon fisheries (66 FR 23185, May 8, 2001) and the West Coast Salmon Plan. Prior notice and opportunity for public comment is impracticable because NMFS and the state agencies have insufficient time to provide for a proposed rule and public comment between the time the fishery catch and effort data are collected to determine the extent of the fisheries and the time the fish are available to the ocean fisheries. Moreover, such prior notice and the opportunity for public comment is contrary to the public interest because it does not allow commercial and recreational fishermen appropriately controlled access to the available fish at the time they are available. The 30–day delay in effectiveness required under U.S.C. 553(d)(1) is also hereby waived as the inseason actions described in this document open areas previously closed to fishing, and thus relieve restrictions.

These actions are authorized by 50 CFR 660.409 and 660.411 and are exempt from review under Executive Order 12866.

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

Dated: April 18, 2002.

Bruce C. Morehead,

Acting Director, Office of Sustainable Fisheries, National Marine Fisheries Service.

[FR Doc. 02–10083 Filed 4–23–02; 8:45 am]

BILLING CODE 3510–22–S

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

50 CFR Part 679

[Docket No. 011218304–1304–01; I.D. 041902A]

Fisheries of the Exclusive Economic Zone Off Alaska; Species in the Rock Sole/Flathead Sole/''Other Flatfish'' Fishery Category by Vessels Using Trawl Gear in Bering Sea and Aleutian Islands Management Area

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

ACTION: Closure.

SUMMARY: NMFS is closing directed fishing for species in the rock sole/flathead sole/''other flatfish'' fishery category by vessels using trawl gear in the Bering Sea and Aleutian Islands management area (BSAI). This action is necessary to prevent exceeding the second seasonal apportionment of the 2002 Pacific halibut bycatch allowance specified for the trawl rock sole/flathead sole ''other flatfish'' fishery category.

DATES: Effective 1200 hrs, Alaska local time (A.l.t.), April 20, 2002, until 1200 hrs, A.l.t., June 30, 2002.

FOR FURTHER INFORMATION CONTACT: Mary Furuness, 907-586–7228.

SUPPLEMENTARY INFORMATION: NMFS manages the groundfish fishery in the BSAI exclusive economic zone according to the Fishery Management Plan for the Groundfish Fishery of the Bering Sea and Aleutian Islands Area (FMP) prepared by the North Pacific Fishery Management Council under authority of the Magnuson-Stevens Fishery Conservation and Management Act. Regulations governing fishing by U.S. vessels in accordance with the FMP

appear at subpart H of 50 CFR part 600 and 50 CFR part 679.

The second seasonal apportionment of the 2002 halibut bycatch allowance specified for the BSAI trawl rock sole/flathead sole/''other flatfish'' fishery category, which is defined at § 679.21(e)(3)(iv)(B)(2), is 164 metric tons (67 FR 956, January 8, 2002).

In accordance with § 679.21(e)(7)(v), the Administrator, Alaska Region, NMFS (Regional Administrator), has determined that the second seasonal apportionment of the 2002 halibut bycatch allowance specified for the trawl rock sole/flathead sole/≥other flatfish≥ fishery in the BSAI has been caught. Consequently, the Regional Administrator is closing directed fishing for species in the rock sole/flathead sole/≥other flatfish≥ fishery category by vessels using trawl gear in the BSAI.

Maximum retainable bycatch amounts may be found in the regulations at § 679.20(e) and (f).

Classification

This action responds to the best available information recently obtained from the fishery. The Assistant Administrator for Fisheries, NOAA, finds that the need to immediately implement this action to avoid exceeding the second seasonal apportionment of the halibut bycatch allowance for rock sole/flathead sole/''other flatfish'' fishery category constitutes good cause to waive the requirement to provide prior notice and opportunity for public comment pursuant to the authority set forth at 5 U.S.C. 553(b)(3)(B) and 50 CFR 679.20(b)(3)(iii)(A), as such procedures would be unnecessary and contrary to the public interest. Similarly, the need to implement these measures in a timely fashion to avoid exceeding the second seasonal apportionment of the halibut bycatch allowance for rock sole/flathead sole/''other flatfish'' fishery category constitutes good cause to find that the effective date of this action cannot be delayed for 30 days. Accordingly, under 5 U.S.C. 553(d), a delay in the effective date is hereby waived.

This action is required by 50 CFR 679.21 and is exempt from review under Executive Order 12866.

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

Dated: April 19, 2002.

Richard W. Surdi,

Acting Director, Office of Sustainable Fisheries, National Marine Fisheries Service.

[FR Doc. 02–10061 Filed 4–19–02; 3:30 pm]

BILLING CODE 3510–22–S

Proposed Rules

Federal Register
Vol. 67, No. 79
Wednesday, April 24, 2002

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

NUCLEAR REGULATORY COMMISSION

10 CFR Part 16

RIN 3150–AG96

Salary Offset Procedures for Collecting Debts Owed by Federal Employees to the Federal Government

AGENCY: Nuclear Regulatory Commission.

ACTION: Proposed rule.

SUMMARY: The Nuclear Regulatory Commission (NRC) is proposing to amend its regulations concerning the procedures used to collect debts that are owed to NRC by Federal employees. The proposed amendment would conform NRC regulations to the legislative changes enacted in the Debt Collection Improvement Act of 1996 (DCIA) and the amended procedures presented in the Federal Claims Collection Standards (FCCS) issued by the Department of the Treasury (Treasury) and the Department of Justice (DOJ). The proposed action is intended to allow the NRC to improve its collection of debts due the United States from Federal employees.

DATES: The comment period expires July 8, 2002. Comments received after this date will be considered if it is practical to do so, but the Commission is able to ensure consideration only for comments received on or before this date.

ADDRESSES: Submit comments to the Secretary, U.S. Nuclear Regulatory Commission, Washington, DC 20555–0001, ATTN: Rulemakings and Adjudications Staff. Deliver comments to: 11555 Rockville Pike, Rockville, Maryland, between 7:30 a.m. and 4:15 p.m. Federal workdays (Telephone 301–415–1678).

Comments also may be submitted via the NRC's interactive rulemaking Website at (*http://ruleforum.llnl.gov*). This site provides the capability to upload comments as files (any format), if your Web browser supports that function. For information about the interactive rulemaking Website, contact Ms. Carol Gallagher, 301–415–5905 (e-mail *CAG@nrc.gov*). Comments received also may be viewed and downloaded electronically via this interactive rulemaking website.

With the exception of restricted information, documents created or received at the NRC, after November 1, 1999, are also available electronically at the NRC's Public Electronic Reading Room on the Internet at *http://www.nrc.gov/reading-rm/ADAMS/index.html.* From this site, the public can gain entry into the NRC's Agencywide Document Access and Management System (ADAMS), which provides text and image files of NRC's public documents. For more information, contact the NRC Public Document Room (PDR) Reference staff at 1–800–397–4209 or 301–415–4737 *pdr@nrc.gov.*

FOR FURTHER INFORMATION CONTACT: Leah Tremper, Office of the Chief Financial Officer, U.S. Nuclear Regulatory Commission, 11545 Rockville Pike, Rockville, MD 20852–2738, Telephone 301–415–7347.

SUPPLEMENTARY INFORMATION:

I. Background
II. Section by Section Analysis
III. Plain Language
IV. Voluntary Consensus Standards
V. Finding of No Significant Environmental Impact
VI. Paperwork Reduction Act
VII. Regulatory Analysis
VIII. Regulatory Flexibility Certification
IX. Backfit Analysis

I. Background

On October 16, 1991 (56 FR 51829), the Nuclear Regulatory Commission (NRC) published a final rule concerning procedures for the collection of debts from Federal employees. Since then, the DCIA of 1996 (Pub. L. 104–134), was enacted on April 26, 1996. A major purpose of the DCIA of 1996 is to increase the collection of delinquent nontax debts owed to the Federal Government. Among other things, the DCIA of 1996 established a centralized process for withholding or reducing eligible Federal payments, including Federal salary payments, to pay the payee's delinquent debt owed to the United States. This process is known as ''centralized administrative offset.'' The DCIA of 1996 requires Federal agencies to match their delinquent debtor records with records of Federal employees, at least annually, to identify Federal employees who owe delinquent debt to the Federal Government. The Treasury and other disbursing officials will match payments from the Federal Government, including Federal salary payments, for the purpose of offsetting the payments of those debtors who owe debt to the United States. When a match occurs and all the requirements for offset have been met, the payment will be offset to satisfy the debt in whole or part. To meet this responsibility, Treasury has established the Treasury Offset Program. Under the DCIA of 1996, Federal agencies are required to notify the Financial Management Service (FMS) of all past-due, legally enforceable nontax debts owed to the United States that are over 180 days delinquent. The debts are included in the delinquent debtor database and include debts owed by Federal employees that the NRC seeks to collect from the employee's pay account at another agency. Compliance with the administrative offset provisions of the DCIA of 1996 will accomplish salary offset. This rule establishes NRC's procedures for notifying Treasury of delinquent debtors for the purpose of matching NRC's debtors against the delinquent debtor database.

The FCCS (31 CFR Chapter IX and parts 900, 901, 902, 903, and 904) were revised on November 22, 2000 (65 FR 70390). The revised FCCS clarify and simplify Federal debt collection procedures and reflect changes under the DCIA of 1996 and the General Accounting Office Act of 1996. The revised FCCS reflect legislative changes to Federal debt collection procedures enacted under the DCIA of 1996, Public Law 104–134, 110 Stat. 1321–358, as part of the Omnibus Consolidated Rescissions and Appropriations Act of 1996. The revised FCCS provide agencies with greater latitude to adopt agency-specific regulations, tailored to the legal and policy requirements applicable to the various types of Federal debt, to maximize the effectiveness of Federal debt collection procedures. The Secretary of the Treasury has been added as a co-promulgator of the FCCS in accordance with section 31001(g)(1)(C) of the DCIA of 1996. The Comptroller General has been removed as a co-promulgator in accordance with section 115(g) of the General Accounting Office Act of 1996, Public Law 104–316, 110 Stat. 3826 (October 19, 1996), (65 FR 70390

(November 22, 2000)). The Department of the Treasury and DOJ have published the revised FCCS as a joint final rule under new Chapter IX, 31 Code of Federal Regulations. The revised FCCS supersede the current FCCS codified at 4 CFR parts 101–105.

The revised FCCS prescribe standards for Federal agency use in the administrative collection, offset, compromise, and the suspension or termination of collection activity for civil claims for money, funds, or property, as defined by 31 U.S.C. 3701(b), unless specific Federal agency statutes or regulations apply to such activities, or as provided for by Title 11 of the United States Code when the claims involve bankruptcy. The revised FCCS also prescribe standards for referring debts to the Department of Justice for litigation.

II. Section by Section Analysis

Section 16.1 Purpose and Scope

This section would be amended to state (1) the NRC is not limited to collection remedies contained in the revised FCCS, (2) delete the statement that these procedures do not apply to the Social Security Act, 42 U.S.C. 301 et. seq., and (3) delete the reference to 4 CFR parts 101–105 and substitute the reference to 31 CFR Chapter IX, Parts 900–904.

Section 16.3 Definitions

This section would be amended to revise the definitions of ''agency,'' ''creditor agency,'' ''debt and claim,'' ''disposable pay,'' ''employee,'' and ''FCCS'' to conform with the DCIA of 1996. Other definitions such as ''centralized salary offset computer matching,'' ''debt collection center,'' ''delinquent debt record,'' ''disbursing official,'' and ''Treasury'' have been added to conform to the definitions in the DCIA of 1996.

Section 16.7 Notice Requirements

This section would be amended to state the amount of the intended deduction may be stated as a fixed dollar or a percentage of pay and delete the reference to 4 CFR 102.2(e) and substitute the reference to 31 CFR Chapter IX, 901.2(d).

Section 16.8 Information Collection Requirements: OMB Approval

This section would be added to state that this part contains no information collection requirements and is not subject to the requirements of the Paperwork Reduction Act.

Section 16.9 Hearing

This section would be amended to delete the reference to 4 CFR 102.3(c) and substitute the reference to 31 CFR Chapter IX, 901.3(e).

Section 16.13 Coordinating Offset With Another Federal Agency

This section would be amended to change the section heading from ''Coordinating offset with another Federal agency'' to ''Procedures for centralized administrative offset'' and amended in its entirety to include NRC's procedures for offset.

Section 16.15 Procedures for Salary Offset

This section would be amended to change the section heading from ''Procedures for salary offset'' to ''Procedures for internal salary offset.''

Section 16.23 Interest, Penalties, and Administrative Charges

This section would be amended to delete the reference to 4 CFR102.13 and substitute the reference to 31 CFR Chapter IX, 901.9.

III. Plain language

The Presidential Memorandum dated June 1, 1998, entitled ''Plain Language in Government Writing'' directed that the Government's writing be in plain language. This memorandum was published on June 10, 1998 (63 FR 31885). The NRC requests comments on this proposed rule specifically with respect to the clarity and effectiveness of the language used. Comments should be sent to the address listed under the **ADDRESSES** caption of the preamble.

IV. Voluntary Consensus Standards

The National Technology Transfer and Advancement Act of 1995, Public Law 104–113, requires that Federal agencies use technical standards that are developed or adopted by voluntary consensus standards bodies unless using such a standard is inconsistent with applicable law or is otherwise impractical. In this proposed rule, the NRC is amending Part 16 to reflect the current requirements of the DCIA of 1996 and the revised FCCS. This action does not constitute the establishment of a standard that contains generally applicable requirements.

V. Finding of No Significant Environmental Impact

The Commission has determined, under the National Environmental Policy Act of 1969, as amended, and the Commission's regulations in Subpart A of 10 CFR part 51, that this rule, if adopted, would not be a major Federal action significantly affecting the quality of the human environment and, therefore, an environmental impact statement is not required. This proposed rule is necessary to conform the NRC regulations to the amended procedures presented in the FCCS. Amending the procedures that the NRC uses to collect debts which are owed to it will not have any radiological environmental impact offsite and no impact on occupational radiation exposure onsite. The rule does not affect nonradiological plant effluents and has no other environmental impact. The environmental assessment and finding of no significant impact, on which this determination is based, are available for inspection at the NRC Public Document Room, 11555 Rockville Pike, Rockville, Maryland, between 7:30 a.m. and 4:15 p.m. except on Federal holidays.

VI. Paperwork Reduction Act

This proposed rule contains no information collection requirements and, therefore, is not subject to the requirements of the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 *et seq.*).

VII. Regulatory Analysis

The proposed rule will conform NRC procedures for collecting debts owed it with the amended procedures presented in the FCCS, the DCIA of 1996, 5 CFR part 550 Pay Administration, and 31 CFR part 285 Salary Offset and, as such, will not have a significant impact on state and local Governments and geographical regions; health, safety, and the environment; nor will it represent substantial costs to licensees, the NRC, or other Federal agencies. This constitutes the regulatory analysis for this proposed rule.

VIII. Regulatory Flexibility Certification

In accordance with the Regulatory Flexibility Act (5 U.S.C. 605(b)), the Commission certifies that this rule will not, if promulgated, have a significant economic impact on a substantial number of small entities because this rule applies only to Federal agencies and employees.

IX. Backfit Analysis

The NRC has determined that the backfit rule does not apply to this proposed rule; therefore, a backfit analysis is not required for this proposed rule because these amendments are mandated by the DCIA of 1996 (Pub. L. 104–134, 110 Stat. 1321–358 (April 26, 1996)).

List of Subjects in 10 CFR Part 16

Administrative practice and procedures, Debt collection, Salary offset, Government employees, Wages.

For the reasons set out in the preamble and under the authority of the Atomic Energy Act of 1954, as amended; the Energy Reorganization Act of 1974, as amended; and 5 U.S.C. 553, the NRC is proposing to adopt the following amendments to 10 CFR part 16.

PART 16—SALARY OFFSET PROCEDURES FOR COLLECTING DEBTS OWED BY FEDERAL EMPLOYEES TO THE FEDERAL GOVERNMENT

1. The authority citation for Part 16 is revised to read as follows:

Authority: Secs. 161, 186, 68 Stat. 948, 955, as amended (42 U.S.C. 2201, 2236); sec. 201, 88 Stat. 1242, as amended (42 U.S.C. 5841); sec. 1, Pub. L. 97–258, 96 Stat. 972 (31 U.S.C. 3713); sec 5, Pub. L. 89–508, 80 Stat. 308, as amended (31 U.S.C. 3711, 3717, 3718); Pub. L. 97–365, 96 Stat. 1749; Federal Claims Collection Standards, 31 CFR Chapter IX, Parts 900–904; 31 U.S.C. Secs. 3701, 3716; 31 CFR Sec 285; 26 U.S.C. Sec 6402(d); 31 U.S.C. Sec. 3720A; 26 U.S.C. Sec. 6402(c); 42 U.S.C. Sec. 664; Pub. L. 104–134, as amended (31 U.S.C. 3713); 5 U.S.C. 5514; Executive Order 12988 (3 CFR, 1996 Comp., pp. 157–163); 5 CFR 550.

2. In § 16.1 paragraph (b)(2) is removed, paragraphs (b)(3) and (b)(4) are redesignated as (b)(2) and (b)(3) and paragraph (d) is revised and paragraph (f) is added to read as follows:

§ 16.1 Purpose and scope.

* * * * *

(d) These procedures do not preclude the compromise, suspension, or termination of collection action where appropriate under the standards implementing the revised FCCS, 31 U.S.C. 3711 *et seq.*, 31 CFR Chapter IX, Parts 900–904.

* * * * *

(f) The NRC is not limited to collection remedies contained in the revised FCCS. The FCCS is not intended to impair common law remedies.

3. In § 16.3, the definitions of *agency, creditor agency, debt and claim, disposable pay, employee,* and *FCCS* are revised, and the definitions of *centralized salary offset computer matching, debt collection center, delinquent debt record, disbursing official,* and *Treasury* are added in alphabetical order to read as follows:

§ 16.3 Definitions.

* * * * *

Agency means any agency of the executive, legislative, and judicial branches of the Federal Government, including Government corporations.

Centralized salary offset computer matching describes the computerized process used to match delinquent debt records with Federal salary payment records when the purpose of the match is to identify Federal employees who owe debt to the Federal Government.

Creditor agency means the agency to which the debt is owed, including a debt collection center when acting in behalf of a creditor agency in matters pertaining to the collection of a debt.

Debt and *claim* are used synonymously to refer to an amount of money, funds, or property that has been determined by an agency official to be owed to the United States from any person, organization, or entity, except another Federal agency. For the purposes of administrative offset under 31 U.S.C. 3716, the terms debt and claim include an amount of money, funds, or property owed by a person to a State (including past-due support being enforced by a State), the District of Columbia, American Samoa, Guam, the United States Virgin Islands, the Commonwealth of the Northern Mariana Islands, or the Commonwealth of Puerto Rico.

Debt collection center means the Department of the Treasury or other Government agency or division designated by the Secretary of the Treasury with authority to collect debts on behalf of creditor agencies.

Delinquent debt record refers to the information about a debt that an agency submits to Treasury when the agency refers the debt for collection by offset in accordance with the provision of 31 U.S.C. 3716.

Disbursing official means an official who has authority to disburse Federal salary payments pursuant to 31 U.S.C. 3321 or another law.

Disposable pay means that part of current basic pay, special pay, incentive pay, retired pay, retainer pay, or in the case of an employee not entitled to basic pay, other authorized pay remaining after the deduction of (a) any amount required by law to be withheld; (b) amounts properly withheld for Federal, state or local income tax purposes; (c) amounts deducted as health insurance premiums; (d) amounts deducted as normal retirement contributions, not including amounts deducted for supplementary coverage; and (e) amounts deducted as normal life insurance premiums not including amounts deducted for supplementary coverage.

Employee is any individual employed by any agency of the executive, legislative, and judicial branches of the Federal Government, including Government corporations.

FCCS means the Federal Claims Collection Standards jointly published by the Department of the Treasury and the Department of Justice at 31 CFR Chapter IX, Parts 900–904.

* * * * *

Treasury as used in 10 CFR Part 16 means the Department of the Treasury.

* * * * *

4. In § 16.7, paragraphs (b)(3) and (b)(6) are revised to read as follows:

§ 16.7 Notice requirements.

* * * * *

(b) * * *

* * * * *

(3) The amount and frequency of the intended deduction (stated as a fixed dollar amount or as a percentage of pay, not to exceed 15 percent of disposable pay) and the intention to continue the deduction until the debt is paid in full or otherwise resolved.

* * * * *

(6) If not previously provided, the opportunity (under terms agreeable to the NRC) to establish a schedule for the voluntary repayment of the debt or to enter into a written agreement to establish a schedule for repayment of the debt in lieu of offset (31 CFR Chapter IX, Part 901.2). The agreement must be in writing, signed by the employee and the NRC, and documented in the NRC's files.

* * * * *

5. Section 16.8 is added to read as follows:

§ 16.8 Information collection requirements: OMB approval.

This part contains no information collection requirements, and, therefore, is not subject to the requirements of the Paperwork Reduction Act (44 U.S.C. 3501 *et. seq.*).

6. In § 16.9, paragraph (b)(2) is revised to read as follows:

§ 16.9 Hearing.

* * * * *

(b) * * *

(2) The hearing must conform to procedures contained in the revised FCCS, 31 CFR Chapter IX, 901.3(e). The burden is on the employee to demonstrate either that the existence or the amount of the debt is in error or that the terms of the repayment schedule would result in undue financial hardship or would be against equity and good conscience.

7. Section 16.13 is revised to read as follows:

§ 16.13 Procedures for centralized administrative offset.

(a) The NRC must notify Treasury of all debts that are delinquent as defined in the FCCS (over 180 days old) so that recovery may be made by centralized administrative offset. This includes those debts the NRC seeks to recover from the pay account of an employee of another agency via salary offset. The Treasury and other Federal disbursing officials will match payments, including Federal salary payments, against such debts. When a match occurs, and all the requirements for offset have been met, the payments will be offset to collect the debt. Prior to offset of the pay account of an employee, the NRC must comply with the requirements of 5 U.S.C. 5514, 5 CFR Part 550, and 10 CFR Part 15. Procedures for notifying Treasury of a debt for purposes of collection by centralized administrative offset are contained in 31 CFR Part 285 and 10 CFR 15.33. Procedures for internal salary offset are contained in § 16.15 of this chapter.

(b) When the NRC determines that an employee of another Federal agency owes a delinquent debt to the NRC, the NRC will, as appropriate:

(1) Arrange for a hearing upon the proper petitioning by the employee;

(2) Provide the Federal employee with a notice and an opportunity to dispute the debt as contained in 5 U.S.C. 5514 and 10 CFR 15.26.

(3) Submit the debt to Treasury for centralized administrative offset and certify in writing that the debtor has been afforded the legally required due process notification.

(4) If collection must be made in installments, the NRC must advise the paying agency of the amount or percentage of disposable pay to be collected in each installment.

(c) *Offset amount.* (1) The amount offset from a salary payment under this section shall be the lesser of:

(i) The amount of the debt, including any interest, penalties, and administrative costs; or

(ii) An amount up to 15% of the debtor's disposable pay.

(2) Alternatively, the amount offset may be an amount agreed upon, in writing, by the debtor and the NRC.

(3) Offsets will continue until the debt, including any interest, penalties, and costs, is paid in full or otherwise resolved to the satisfaction of the NRC.

(d) *Priorities.* (1) A levy pursuant to the Internal Revenue Code of 1986 shall take precedence over other deductions under this section.

(2) When a salary payment may be reduced to collect more than one debt, amounts offset under this section will be applied to a debt only after amounts offset have been applied to satisfy past due child support debt assigned to a State pursuant 26 U.S.C. 6402(c) and 31 CFR 285.7(h)(2).

(e) *Notice.* (1) Before offsetting a salary payment, the disbursing official, or the paying agency on behalf of the disbursing official, shall notify the Federal employee in writing of the date that deductions from salary will commence and of the amount of such deductions.

(2)(i) When an offset occurs under this section, the disbursing official, or the paying agency on behalf of the disbursing official, shall notify the Federal employee in writing that an offset has occurred including:

(A) A description of the payment and the amount of the offset taken;

(B) Identification of NRC as the agency requesting the offset; and,

(C) A contact point within the NRC that will handle concerns regarding the offset.

(ii) The information described in paragraphs (e)(2)(i)(B) and (e)(2)(i)(C) of this section does not need to be provided to the Federal employee when the offset occurs if such information was included in a prior notice from the disbursing official or paying agency.

(3) The disbursing official will advise the NRC of the names, mailing addresses, and taxpayer identifying numbers of the debtors from whom amounts of past-due, legally enforceable debt were collected and of the amounts collected from each debtor. The disbursing official will not advise the NRC of the source of payment from which such amounts were collected.

(f) *Fees.* Agencies that perform centralized salary offset computer matching services may charge a fee sufficient to cover the full cost of such services. In addition, Treasury or a paying agency acting on behalf of Treasury, may charge a fee sufficient to cover the full cost of implementing the administrative offset program. Treasury may deduct the fees from amounts collected by offset or may bill the NRC. Fees charged for offset shall be based on actual administrative offsets completed.

(g) *Disposition of amounts collected.* The disbursing official conducting the offset will transmit amounts collected for debts, less fees charged under paragraph (f) of this section, to NRC. If an erroneous offset payment is made to the NRC, the disbursing official will notify the NRC that an erroneous offset payment has been made. The disbursing official may deduct the amount of the erroneous offset payment from future amounts payable to the NRC. Alternatively, upon the disbursing official's request, the NRC shall return promptly to the disbursing official or the affected payee an amount equal to the amount of the erroneous payment (without regard to whether any other amounts payable to the agency have been paid). The disbursing official and the NRC shall adjust the debtor records appropriately.

8. Section 16.15 is amended by revising the section heading to read as follows:

§ 16.15 Procedures for internal salary offset.

9. Section 16.23 is revised to read as follows:

§ 16.23 Interest, penalties, and administrative charges.

Charges may be assessed for interest, penalties, and administrative charges in accordance with the FCCS, 31 CFR Chapter IX, 901.9.

Dated at Rockville, Maryland, this 16th day of April 2002.

For the Nuclear Regulatory Commission.

Jesse L. Funches,

Chief Financial Officer.

[FR Doc. 02–9885 Filed 4–23–02; 8:45 am]

BILLING CODE 7590–01–P

CONSUMER PRODUCT SAFETY COMMISSION

16 CFR Part 1500

Metal-Cored Candle Wicks Containing Lead and Candles With Such Wicks; Notice of Proposed Rulemaking

AGENCY: Consumer Product Safety Commission.

ACTION: Proposed Rule.

SUMMARY: The Commission is proposing to declare that metal-cored candle wicks containing more than 0.06 percent lead by weight in the metal and candles with such wicks are hazardous substances and to ban such wicks and candles with such wicks.[1] The Commission is issuing these proposed rules under authority of the Federal Hazardous Substances Act.

DATES: Written comments in response to this notice must be received by the Commission no later than July 8, 2002.

Comments on elements of the proposed rules that, if issued, would constitute collection of information requirements under the Paperwork Reduction Act may be filed with the Office of Management and Budget (''OMB'') and with the Commission. Comments will be received by OMB until June 24, 2002.

[1] The Commissioners voted 2–0 to issue this notice of proposed rulemaking.

ADDRESSES: Comments should be mailed, preferably in five (5) copies, to the Office of the Secretary, Consumer Product Safety Commission, Washington, DC 20207, or delivered to the Office of the Secretary, Consumer Product Safety Commission, Room 502, 4330 East-West Highway, Bethesda, Maryland 20814; telephone (301) 504–6800. Comments also may be filed by facsimile to (301) 504–0127 or by e-mail to *cpsc-os@cpsc.gov.* Comments should be captioned ''NPR for Candle Wicks Containing Lead.''

Comments to OMB should be directed to the Desk Officer for the Consumer Product Safety Commission, Office of Information and Regulatory Affairs, OMB, Washington, DC 20503. The Commission asks commenters to provide copies of such comments to the Commission's Office of the Secretary, with a caption or cover letter identifying the materials as comments submitted to OMB on the proposed collection of information requirements for the proposed ban on certain candle wicks and candles made with such wicks.

FOR FURTHER INFORMATION CONTACT: Kristina Hatlelid, Ph.D., M.P.H., Project Manager, Directorate for Health Sciences, Consumer Product Safety Commission, Washington, DC 20207; telephone (301) 504–0994, ext. 1389.

SUPPLEMENTARY INFORMATION:

A. Background

On February 24, 2000, the U.S. Consumer Product Safety Commission (CPSC or Commission) received a petition from Public Citizen requesting that the Commission ban candles with lead-containing wicks and wicks sold for candle-making that contain lead. On February 29, 2000, CPSC received a similar petition from the National Apartment Association and the National Multi Housing Council. These petitions were docketed collectively under the Federal Hazardous Substances Act (FHSA) (Petition No. HP 00–3) on March 17, 2000.

After analysis of the available data on lead-cored candle wicks and the information provided by the petitioners, the CPSC staff transmitted a briefing package to the Commission recommending that the Commission proceed with rulemaking to ban lead-cored candle wicks. The staff recommended that a lead-cored wick be defined as a wick containing a metal core with greater than 0.06 percent lead by weight in the metal, since laboratory test data indicate that burning candles with metal-cored wicks with lead concentrations of 0.06 percent or less by weight does not result in detectable emissions of lead into the air. On February 20, 2001, the Commission issued an advance notice of proposed rulemaking (ANPR) that could lead to a ban on metal-cored wicks containing more than 0.06 percent lead by weight in the metal and candles with such wicks. 66 FR 10863.

B. The Product

Lead-cored wicks are candle wicks with a metal wire in the center made of lead or lead alloy. The metal core is used to provide structural rigidity to the wick, *i.e.*, to keep the wick straight during candle production, and to provide an upright wick during burning.

C. The Risk of Illness

As a lead-cored wick candle burns, some of the lead may vaporize and be released into the air. This airborne lead may be inhaled. Some of this lead may deposit onto floors, furniture, and other surfaces in the room where children may be exposed to it. One cannot tell by looking at the wick core if it is made of lead, and there is no simple way for a consumer to determine its lead content. The presence of lead in a wick can be determined only by laboratory analysis.

Similarly, one cannot tell if lead is being released from a burning candle by observing smoke or soot; nor can one tell that lead is not being released by the lack of visible emissions. Determination of lead in room air or on surfaces must be done by professionals.

The toxic effects of lead and the risk to consumers, especially children, from exposure to lead emitted from lead-cored wick candles, including neurological damage, delayed mental and physical development, attention and learning deficiencies, and hearing problems, were detailed in the Commission briefing package on Petition No. HP 00–3.[2] In that briefing package, CPSC staff concluded that, under reasonable assumptions, exposure of children to indoor air lead levels from candles emitting 430 micrograms of lead per hour or more could result in elevated blood levels (greater than 10 micrograms of lead per deciliter of blood). Laboratory investigations by CPSC staff and others indicate that lead-cored wick candles can emit more than 3,000 μg of lead per hour during candle burning.[3] Thus, the Commission believes that under certain expected use conditions, the lead emitted from burning candles with lead-cored wicks presents a risk to consumers of substantial illness from exposure through inhalation of airborne lead. Children may also be exposed to lead that deposits onto surfaces in the room.

Several countries have acted on this issue. Officials in Canada issued an advisory in January, 2001, warning consumers that some candles sold in Canada contained lead-cored wicks, and offering advice on making informed purchasing decisions.[4] Officials in Australia and New Zealand have instituted provisional bans on candles with wicks containing any amount of lead.[5] Australia is now considering making the ban permanent.

Denmark issued a more comprehensive order in December 2000 banning a number of products containing lead.[6] Chafing dish candles and other candles are specifically included in the ban. The order defines a lead-containing product as one in which lead represents more than 50 mg/kg (0.005 percent) of the homogeneous components.

D. Statutory Authority

This proceeding is conducted under provisions of the FHSA. 15 U.S.C. 1261–1278. It involves three actions. First, pursuant to section 3(a) of the FHSA, the Commission is proposing to declare that metal-cored candle wicks containing more than 0.06 percent lead by weight of the metal and candles with such wicks are hazardous substances. (Proposed 16 CFR 1500.12(a)(2)). Second, pursuant to section 2(q)(1)(B) of the FHSA, the Commission is proposing to ban such wicks and candles with such wicks. (Proposed 16 CFR 1500.17(a)(13)). Third, pursuant to section 10(a) of the FHSA, the Commission is proposing to require that manufacturers and importers of metal-cored wicks and candles test and/or maintain records of testing performed by the supplier of the metal-cored wicks or the metal used in the metal cores. *Id.* The testing records must demonstrate compliance for the lots of wicks and/or

[2] Briefing memorandum from Kristina M. Hatlelid, Ph.D., M.P.H., Toxicologist, Directorate for Health Sciences, to the Commission, ''Petition HP 00–3 to Ban Lead-cored Candle Wicks,'' December 12, 2000. This and other CPSC materials for this rulemaking referenced in this preamble are available in PDF format on the CPSC World Wide Web site at *www.cpsc.gov.* Select ''Library (FOIA),'' Electronic Reading Room—Freedom of Information Act Information,'' ''2001 FOIA Information, and ''Commission Briefing Packages.'' Then scroll down to the materials captioned ''Ban of Candle Wicks.''

[3] *Id.*

[4] Health Canada Advisory 2001–02, January 2001.

[5] Commonwealth of Australia Consumer Protection Notice No. 11 of 1999 under the Trade Practices Act of 1974, September 1999; New Zealand Ministry of Consumer Affairs Unsafe Goods Notice under the Fair Trading Act 1986, June 2000.

[6] Danish Environmental Protection Agency Ministry of Environment and Energy Council Directive 89/677/EEC and implementing orders.

candles and must maintain a line of continuity between the two.

The Commission is proposing to declare that metal-cored candle wicks containing more than 0.06 percent lead by weight of the metal and candles with such wicks are ''hazardous substances'' within the meaning of section 2(f)(1)(A) of the FHSA because they are toxic, and ''may cause substantial personal injury or substantial illness during or as a proximate result of any customary or reasonably foreseeable handling or use * * *.'' 15 U.S.C. 1261(f)(1)(A). A proceeding to classify a substance as a hazardous substance under section 3(a) of the FHSA is governed by, *inter alia,* sections 701(e), (f), and (g) of the Federal Food, Drug, and Cosmetic Act (FDCA), 21 U.S.C. 371(e)–(g). *See* 15 U.S.C. 1262(a)(2).

Under section 2(q)(1)(B) of the FHSA, the Commission may classify as a ''banned hazardous substance'' any hazardous substance intended for household use which, notwithstanding the precautionary labeling required by the FHSA, presents such a hazard that keeping the substance out of interstate commerce is the only adequate means to protect the public health and safety. 15 U.S.C. 1261(q)(1)(B). A proceeding to classify a substance as a banned hazardous substance under section 2(q)(1)(B) of the FHSA is governed by the requirements set forth in section 3(f) of the FHSA, and by sections 701(e), (f), and (g) of the Federal Food, Drug, and Cosmetic Act (''FDCA'') (21 U.S.C. 371(e)). *See* 15 U.S.C. 1261(q)(2) and 1262(f).

The February 20, 2001, ANPR was the first step necessary to declare the specified candle wicks and candles to be banned hazardous substances under section 2(q)(1). *See* 15 U.S.C. 1262(f). The proposed regulations issued today continue the regulatory process in accordance with the requirements of 15 U.S.C. 1262(a) and (h). Under the rules proposed today, metal-cored candle wicks containing more than 0.06 percent lead by weight of the metal and candles with such wicks would be declared to be hazardous substances and would be banned.

If the Commission proceeds to issue a final rule banning these wicks and candles, it must publish the text of the final rule and a final regulatory analysis that includes: (1) A description of the potential costs and benefits of the rule; (2) A description of alternatives considered by the Commission (including a description of their potential costs and benefits and an explanation of why they were not chosen); and (3) a summary of significant issues raised by comments on the preliminary regulatory analysis published with these proposed rules. 15 U.S.C. 1262(i)(1). The Commission also must make findings that: (1) any relevant voluntary standard is unlikely to adequately reduce the risk of injury or substantial compliance with the voluntary standard is unlikely; (2) the expected benefits of the regulation bear a reasonable relationship to expected costs; and (3) the regulation imposes the least burdensome requirement that would adequately reduce the risk of injury. 15 U.S.C. 1262(i)(2).

Procedures established by section 701(e) of the FDCA would govern Commission action to finalize the hazardous substance declaration and the banning rule. 15 U.S.C. 1262(a)(2) and 1261(q)(2). These procedures provide that once the Commission issues a final rule, persons who would be adversely affected by the rule have a period of thirty (30) days in which to file objections stating reasonable grounds therefor, and to request a public hearing on those objections. 21 U.S.C. 371(e). Should valid objections be filed, a hearing to receive evidence concerning the objections would be held and the presiding officer would issue an order after the hearing, based upon substantial evidence. 21 U.S.C. 371(e); 16 CFR part 1502.

E. Response to Comments on the ANPR

Eleven comments were received in response to the ANPR. Nine comments were in favor of the proposal to ban lead-cored wicks. One commenter opposed forcing companies to compensate for parents who are not preventing their children from being exposed to lead emissions from such wicks. One commenter opposed a mandatory rule and submitted a voluntary standard that would ban the use of domestically produced metal-cored wicks containing greater than 0.01 percent lead and imported wicks with metal cores, irrespective of lead content. The issues raised by commenters and the Commission responses to them are discussed below.

1. Federal Regulation

Comments: Nine of the eleven comments support the proposal to ban lead-cored wicks. One dissenting comment from a consumer stated that the candle industry should not be made to bear the burden for parents who do not adequately protect their children. One commenter, representing a standards organization, submitted a voluntary standard to take the place of a mandatory rule. About half of the commenters, including a representative of the National Candle Association (NCA), stated that a voluntary standard would not adequately remove lead-cored wicks from commerce.

Response: The CPSC does not believe it is reasonable to expect that parents alone can protect children from all consumer product hazards, especially if potential hazards are not readily apparent. The Commission believes that a mandatory standard is necessary, in part because of the failure of the industry to maintain conformance with a voluntary commitment to eliminate lead wicks made in 1974, and recognizes that the NCA and its member firms support the development of the mandatory rule.

A mandatory standard would: (1) Apply to all domestic and imported candle and wick products containing metal-cored wicks regardless of a company's membership in a trade organization or knowledge of applicable standards; (2) deter manufacturers from making non-conforming wicks or candles and enable the staff to seek civil penalties for violations; (3) increase compliance by retailers and distributors who often require that products meet applicable federal standards; and (4) through cooperative efforts with the U.S. Customs Service, prevent non-complying products from entering the U.S.

2. Voluntary Standards

Comment: Voices of Safety International (VOSI) proffered a voluntary standard for lead in candle wicks, specifying that domestically produced metal-cored wicks contain no more than 0.01 percent lead in the metal. The standard further specifies that imported candle wicks may not contain metal cores. The VOSI standard includes a methodology, based on tensile strength of metals, for determining whether metal-cored wicks comply with the specified maximum lead content. VOSI also asserted that the provision of section 12(d) of the National Technology Transfer and Advancement Act of 1995 (NTTAA), Public Law 104–113, concerning adoption of voluntary consensus standards by federal agencies applies to this proceeding.

Response: The CPSC staff analysis of the submitted standard uncovered a number of difficulties concerning the scope of the standard, the proposed tensile test methodology, and the acceptance of the standard by the intended industry. The Commission thus finds preliminarily that the VOSI standard is not likely to result in the elimination or adequate reduction of the risk at issue in this proceeding and that substantial compliance with it is

unlikely. See a more detailed discussion of the bases for these findings in Section F.2, *Voluntary Standards,* below.

VOSI's assertion that the NTTAA applies to this proceeding is incorrect. Office of Management and Budget (OMB) Circular A–119 expressly excludes from the NTTAA requirements ''independent regulatory commissions insofar as they are subject to separate statutory requirements regarding the use of voluntary consensus standards,'' as is the Commission under the FHSA. *Federal Participation in the Development and Use of Voluntary Consensus Standards and in Conformity Assessment Activities,* OMB Circular A–119, February 10, 1998, at section 5.

3. Health Effects

Comments: A number of commenters reiterated the harmful effects of lead exposure in children and the potential for lead exposure from candles.

Response: As discussed above, the toxic effects of lead and the risk to consumers, especially children, from exposure to lead emitted from lead-cored wick candles were presented in the initial CPSC staff briefing package on Petition No. HP 00–3.[7]

4. Substitute Materials

Comments: Three commenters discussed available substitutes and their use by manufacturers. Three commenters reiterated that other countries have issued bans on the import and sale of lead-containing wicks. The National Candle Association stated that use of lead-cored wicks has been broadly discontinued domestically, and that zinc-cored wicks currently in use would comply with a ban on metal-cored wicks exceeding 0.06 percent lead by weight in the metal. One commenter claimed that paper- or cotton-cored wicks would not be acceptable because they are less rigid than zinc and have a higher burning rate.

Response: The CPSC staff economic analysis supports the proposition that alternatives to the use of lead core are available. The staff believes that no wick manufacturer in the U.S. currently uses lead core in the production of its wicks. The Commission preliminarily concludes, based on that analysis, that the cost to manufacturers or consumers of a ban on lead-cored wicks would be small.

The CPSC staff has found no basis for the commenter's claim that paper-or cotton-cored wicks are unacceptable alternatives to lead-cored wicks.

As discussed above, Canada, Australia, New Zealand, and Denmark have acted on this issue, limiting the use of lead in candle wicks or providing guidance to consumers.

5. Metal-Cored Wicks

Comments: Two commenters expressed concern about the presence of even small amounts of lead in metal-cored wicks.

Response: Metals, such as zinc, may be used in candle wicks. The lead content of the zinc used in zinc-cored wicks has been determined by CPSC and others to range from about 0.0005 percent to 0.06 percent by weight in the metal.[8] CPSC laboratory and other tests have shown no detectable levels of airborne lead emissions from candles with metal wicks containing 0.06 percent lead or less by weight. Therefore, the Commission is proposing a ban on metal-cored wicks containing more than 0.06 percent lead by weight in the metal and candles with such wicks, but is not proposing to limit the use of metal cores that contain 0.06 percent lead or less.

6. Labeling

Comments: Three commenters believe that regulating lead-cored wick candles by requiring warning labels would not adequately protect public health, and one commenter suggested that candles that comply with the proposed 0.06 percent maximum lead limit should be labeled with that information.

Response: The CPSC agrees that lead-cored wicks and candles containing lead-cored wicks should be banned and that precautionary labeling is not an acceptable strategy for protecting vulnerable populations from lead poisoning that may be induced by burning candles with lead-cored wicks.[9] The Commission does not believe that requiring individual complying candles to be labeled would add to the safety of these products.

The proposed rule would require labeling of each shipping container of metal-cored wicks, and each shipping container of candles with metal-cored wicks, with the statement ''Conforms to 16 CFR 1500.17(a)(13)'' and a number or other designation that relates back to the test results demonstrating compliance for the wicks/candles in that shipping container. CPSC specifically invites interested parties to comment on this feature of the proposal.

F. Alternatives to Proposed Ban

1. No Action

If the Commission took no action, lead-cored candle wicks could continue to be sold in the U.S. In the mid-1970's the domestic candle industry stopped using lead in wicks, but lead-cored wicks reappeared on the domestic market some time thereafter. While the domestic industry states that it has now voluntarily eliminated lead in their wicks, imports may continue to be a source of lead in the absence of a mandatory standard. Under the no action scenario, CPSC enforcement staff would be limited to taking action against lead-containing wicks under the FHSA on a case-by-case basis.

2. Voluntary Standards

In 1974, the Candle Manufacturers Association industry group submitted a statement informing the Commission of an agreement among candle manufacturers to convert to substitutes for lead-cored wicks in candles by the end of the third quarter 1974. They also agreed not to import candles with lead-cored wicks. Further, the major domestic wick manufacturer at that time agreed to discontinue the production of lead-cored wicks.

Despite this agreement, some wick manufacturers resumed producing lead-cored wicks and some candle manufacturers resumed producing and importing candles with lead-cored wicks after 1974.

In May 2000, a task group for candle wicks was formed under the ASTM F15.45 Candle Products Subcommittee to develop a consensus standard to address the lead content of candle wicks. The task group stopped their standards development process in February 2001 in favor of supporting the CPSC mandatory rulemaking process.

During the public comment period on the ANPR, VOSI proffered a voluntary standard for lead in candle wicks. The VOSI standard specifies that metal-cored wicks may contain no more than 0.01 percent lead in the metal. The standard further specifies that imported candle wicks may not contain metal cores. The standard includes a methodology, based on tensile strength of metals, for determining whether metal-cored wicks comply with the specified maximum lead content.

CPSC technical staff reviewed the standard and noted a number of difficulties. Although the standard states that a maximum of 0.01 percent

[7] *See* fn. 2 above.

[8] See fn. 2 above.

[9] Memorandum from Carolyn Meiers, Engineering Psychologist, Human Factors, to Kristina Hatlelid, Ph.D., M.P.H., Directorate for Health Sciences, ''Labeling of Candles with Lead-cored Wicks (Petition HP 00–3),'' October 18, 2000. See fn. 2 above for information on the availability of this and other related documents on the Internet and at the CPSC reading room.

lead is required to protect consumer health, no technical or health basis for this level is provided. The CPSC staff maintains that the proposed limit of 0.06 percent lead by weight in the metal is appropriate and supported by the laboratory analyses performed by CPSC staff and others.

The CPSC staff further states that the analytical methodology in the submitted standard is not capable of reliably determining either the presence or concentration of lead in metal-cored candle wicks. The CPSC staff concludes that the tensile strength of a metal alloy would not definitively identify zinc cored wicks with less than the maximum allowable lead content in the metal, but could falsely detect alloys not containing lead, causing them to fail the test and be needlessly prohibited from wick use. The staff states that the metal's lead content, not its physical attributes, is the important characteristic in protecting consumers' health.

The VOSI standard specifies different standards for domestic and imported products. Specifically, the standard specifies that domestically produced metal-cored wicks may contain no more than 0.01 percent lead in the metal but that imported candle wicks may not contain metal cores. The FHSA gives CPSC the authority to regulate hazardous substances. In the absence of evidence that a specific type of metal wick meets the definition of a hazardous substance under the FHSA, the CPSC cannot ban it. Furthermore, a discriminatory approach to imports with no basis in fact would in all likelihood be a violation of the North American Free Trade Agreement (NAFTA), if not other U.S. treaty obligations.

The Commission believes that membership in standards organizations, such as ASTM, serves, in part, to transmit applicable standards to member firms. VOSI has offered no information that its members include candle or wick manufacturers. VOSI has not shown that the standard was developed within an industry consensus framework or is otherwise widely known to candle and wick manufacturers in the United States or elsewhere.[10] Nor has it provided any evidence that there would be substantial compliance with the voluntary standard.

Based on the foregoing analysis, the Commission finds that the VOSI standard is technically unsound, and thus would not result in the elimination or adequate reduction of the risk, and that substantial compliance with it is unlikely.

Even if a technically valid voluntary standard were developed, the Commission maintains that a mandatory standard is necessary to adequately protect public health.

3. Precautionary Labeling

A CPSC Human Factors staff analysis concludes that precautionary labeling of individual candles is not an acceptable strategy for protecting vulnerable populations from lead poisoning that may be caused by burning candles with lead-cored wicks.[11]

That analysis shows that since lead is emitted from a candle when the candle is used as intended, the only preventative measures consumers could take to protect themselves against the hazard would be to not burn candles with lead-cored wicks. No label or subsequent action by the consumer would prevent the release of lead into the air if the candle is used as intended. The staff analysis therefore concludes that it is not realistic to expect consumers to comply with a warning label advising not to burn the candles, but to use them only for decorative purposes.[12]

G. Comment Period

In accordance with section 4 of Executive Order 12889 implementing NAFTA, the Commission is providing a 75 day public comment period on the proposed rules. The Commission is particularly interested in acquiring additional data on the effect the proposed rules would have on prices to consumers and costs to wick and candle manufacturers.

H. Preliminary Regulatory Analysis

1. FHSA Requirement

The Commission has preliminarily determined to issue a rule declaring a ban on metal-cored wicks containing more than 0.06 percent lead by weight in the metal and candles with such wicks. Section 3(h) of the FHSA requires that the Commission prepare a preliminary regulatory analysis for this action. 15 U.S.C. 1261(h). The following discussion addresses this requirement.

2. Introduction

The Commission is considering amending the FHSA regulations to declare that metal-cored wicks containing more than 0.06 percent lead by weight in the metal and candles with such wicks are hazardous substances and to ban such wicks and candles. In February 2001, the Commission voted to issue an ANPR that could lead to such a declaration and ban. 66 FR 10863. On April 17, 2002, the Commission voted to issue proposed rules declaring that such wicks and candles with such wicks are hazardous substances and banning them.

3. Required Content of the Regulatory Analysis

To accomplish rulemaking under the FHSA, the Commission must publish preliminary and final regulatory analyses containing a discussion of various factors. These factors include a description of the potential benefits and potential costs of the rule, including any benefits and costs that cannot be quantified in monetary terms, and an identification of those most likely to receive the benefits and bear the costs. The FHSA also requires a description of any reasonable alternatives to the rule, together with a summary description of their costs and benefits, and a brief explanation of why such alternatives were not chosen. 15 U.S.C. 1262(h) and 1262(i). In addition, the Commission must address the requirements of the Regulatory Flexibility Act, which considers effects on small firms, and the requirement for review pursuant to the National Environmental Policy Act.

4. Analysis of Proposed Hazardous Substance Declaration/Ban[13]

(a) Potential Benefits

The benefits to consumers of eliminating lead-cored wicks as a source of lead exposure are not quantifiable. Nonetheless, the proposed ban may result in positive health benefits in individual cases, and will contribute to the gradual reduction in lead exposure to the U.S. population. Additionally, the Commission did not regulate

[10] As of January 16, 2002, The VOSI world wide web site states, with respect to the candle wick standard, that ''These standards have been approved by VOSI and are for reference only.'' That page of the website goes on to provide for ongoing public review of ''Approved VOSI Public Health Standards.''

Section 3(i)(2) of the FHSA requires that a voluntary standard be ''adopted and implemented'' before the Commission must defer to it rather than promulgating a mandatory standard. Thus, based on VOSI's public statements on the status of its candle wick standard, the Commission would also be justified in eliminating it from further consideration in this rulemaking without reaching its technical and procedural flaws. 15 U.S.C. 1262(i)(2).

[11] See fn. 9.

[12] Id.

[13] The following discussion of potential costs and potential benefits of the proposed rules is extracted from Memorandum from Mary F. Donaldson, CPSC Directorate for Economic Analysis to Kristina Hatlelid, CPSC Directorate for Health Sciences, ''Preliminary Regulatory Analysis of a Proposed Ban of Lead in Candlewicks,'' March 5, 2002. See fn. 2 above for information on the availability of this and other related documents on the Internet and at the CPSC reading room.

candlewicks in the mid-1970s because the industry voluntarily agreed to eliminate lead from candlewicks. A ban of the use of lead in candlewicks will therefore help ensure that lead will not be used in candlewicks in the future.

(b) Potential Costs

The costs of replacing lead-cored candlewicks with non-leaded wicks are expected to be small. The current use of lead in wicks is already small, since none of the NCA members use lead in their wicks beyond the acceptable trace levels found in zinc cores, and information obtained from an industry source indicates that the cost of substitutes for lead-cored wicks is not higher than the cost of wicks made with lead. In fact, when lead-cored candlewicks were available, they cost more per yard than candlewicks made with other materials.

However, there are some costs associated with testing, tracking, maintaining records of candles and candlewicks with metal cores, and labeling of shipping containers. The proposed rule requires firms that manufacturer, import, or otherwise distribute metal-cored candlewicks and candles perform testing or obtain records of testing to assure compliance. Records of testing would have to bear a lot designation that relates to the candles and candlewicks and be retained for as long as the product the testing pertains to is being distributed plus three years. In addition, firms would have to label shipping containers.

Based on discussions with representatives of the candle and candlewick industries, the metal-cored wick testing burden will likely be minimal for domestic manufacturers of candles and candlewicks, because most candlewicks used in the U.S. are produced by a small number of manufacturers, and the testing of the metal used in the wicks already takes place in the course of manufacturing of the metal used in the wire. The recordkeeping associated with the testing may demand, from candlewick manufacturers and distributors, as much as 40 hours per metal candlewick lot produced annually. From a discussion with a representative of the industry, there may be 5 to 15 lots of wire used in candlewick production per year. Recordkeeping by the domestic candlewick manufacturers and distributors may require as much as 200 to 600 hours per year.

Developing a tracking system for lots may involve some costs. Candle and candlewick manufacturers would have to keep track of when lot numbers for wicks with metal cores changed, and adjust any existing identification system to reflect this. According to the National Candle Association, lot identification might be somewhat problematic for the industry.

Importers would also have to obtain appropriate test results, and develop a system of identification in order to track test results with shipments. The differences in the costs of the testing and labeling requirements for importers, relative to domestic candle manufacturers, are not clear, but it seems likely that the coordination of testing and labeling would be somewhat more complex for importers and therefore more costly, since candles are imported from many countries. One large importer did not think the impact of the rule would be substantial, but was unable to describe how the testing requirements would affect costs.

Domestic producers, distributors, private labelers, and importers of candles, as well as importers of candlewicks, would not have to conduct tests as long as they maintain copies of prior test results for metal candlewicks. Recordkeeping may require as much as 40 hours per firm per year. The exact number of manufacturers and importers is not known and not every firm uses metal-cored wicks. If there are 460 domestic producers of candles in the U.S., and an equivalent number of importers of candles and candlewicks, and if we assume that half of all manufacturers and importers have metal in their candlewicks, then the estimated number of hours for complying with the recordkeeping requirements of the rule for these firms could be as high as 18,400 hours. The total estimated annual employee compensation cost for the paperwork burden may be as high as $400,000, industry wide.

For most candle producers, the costs of labeling are likely to be small. The majority of candles are not produced with metal-cored wicks and therefore will not need to be labeled. Additionally, the labeling requirements will add little to the cost of manufacturing candles when labels are needed if existing labeling machines can be used to add the information required by the rule's labeling requirements.

Although the labeling costs are likely to be low, we can estimate the number of boxes of candles that might be affected. If we assume that $270 to $540 million in candle shipments are affected (*i.e.,* 15–30 percent of all candles shipped with metal wicks), and that each shipping container holds 144 candles (*i.e.,* 12 boxes of a dozen candles), perhaps 2 to 4 million shipping containers would need to be labeled annually. If a label costs 5 to 10 cents (not including the initial purchase of the labeling machine), then $100,000 to $400,000 in annual costs would be absorbed by the candle industry for labeling.

Combined, labeling and recordkeeping may cost the candle industry about $500,000 to $800,000 per year. On a percentage basis, these costs would represent a small fraction (about 0.03 to 0.04 percent) of the overall value of candle shipments which, in 1999, was about $1.8 billion.

Finally, there might also be some costs associated with inventories of uncertified or non-complying candlewicks held by candle manufacturers. These candlewicks would have to be certified or scrapped under the standard. The proposed rule would apply to candles and candlewicks manufactured after the rule's effective date. Although non-complying candlewicks may have been manufactured prior to the effective date, they would not be usable in candles manufactured after the effective date. It is not anticipated, however, that a large amount of candlewick inventory will be affected.

One possible impact of the rule is the movement away from the use of metal core wicks due to the added burden of recordkeeping, labeling and testing. Based on discussions with several candle manufacturers, this has already started to occur. Manufacturers desiring to eliminate metal-cored wicks would have to perform product testing to find a suitable substitute wick for the candle design. The cost of the substitute wick material will not likely be a significant factor in the decision to change wicks because candle wicks are a very low cost item that do not vary much by type. Based on compliance cost and performance factors, each firm will decide whether they will continue to use metal-cored wicks in their candles.

It is anticipated that the costs of the rule, although small, will be absorbed by both consumers and suppliers (including manufacturers and importers). Costs associated with the initial implementation of the rule are likely to be borne by the suppliers. These start-up costs will not likely be passed on to consumers, because the costs may not be uniform across the industry. Some firms may have to develop tracking systems for lot identification, acquire additional labeling machinery, and certify or scrap old candlewicks. Costs associated with ongoing compliance with the rule are expected to be small and these costs will likely be passed along to the consumer in the form of higher prices.

The actual amount of these costs is not clear at this time.

In summary, while the benefits of a ban of lead in candlewicks are likely to be small, the costs of the ban are also small. The action will, however, contribute to the gradual reduction in lead exposure in the U.S. population.

5. Alternatives to the Rule

The Commission has considered several other alternatives, including: no action, product labeling and deferral to a voluntary standard. *See* discussion above at Section F., *Alternatives to Proposed Ban.*

I. Paperwork Reduction Act

The proposed ban regulation will require manufacturers and importers of metal-cored candle wicks and candles with such wicks to perform testing or obtain records of testing, maintain records, and label shipping containers for metal-cored candle wicks and candles with such wicks that they produce or import. For this reason, the rule proposed below contains ''collection of information requirements,'' as that term is used in the Paperwork Reduction Act, 44 U.S.C. 3501–3520. Therefore, the proposed rule is being submitted to the Office of Management and Budget (''OMB'') in accordance with 44 U.S.C. 3507(d) and implementing regulations codified at 5 CFR 1320.11.

Based on estimates made in the course of developing the metal-cored candle wick standard and on information obtained from industry sources, the Commission estimates that complying with the recordkeeping requirements of the proposed banning rule will require approximately 40 hours per metal-cored candle wick lot produced annually. The CPSC staff does not anticipate that domestic producers or distributors of metal-cored candle wicks will conduct testing, since the content of the metal wire used in the candle wicks is analyzed in the course of the manufacturing of the metal. These analyses are provided routinely by the manufacturers of the wire. Since 5 to 15 lots of metal-cored candle wicks are produced per year in the U.S., recordkeeping by domestic metal-cored wick manufacturers under the regulation as proposed would require no more than an estimated 200 to 600 hours per year.

The exact number of manufacturers and importers of candles and of importers of candle wicks is not known. Not every producer/importer uses metal-cored wicks in its candles. CPSC staff estimates that there may be as many as 460 domestic producers of candles. If there are an equivalent number of importers of candles/candle wicks and it is assumed that half of all these manufacturers and importers have metal in their candle wicks, then the estimated number of hours annually that would be expended by these entities for complying with the recordkeeping requirements of the rule may be as high as 18,400.

Combining these two estimates, the estimated total burden on metal-cored wick producers and producers/importers of candles with metal-cored wicks would be 18,600 to 19,000 hours per year.

OMB may comment to CPSC between 30 and 60 days after the publication of the proposed banning rule. Therefore, although OMB will accept comments until June 24, 2002, a comment will be assured of having its maximum effect if it is filed by May 24, 2002.

Comments to OMB should be directed to the Desk Officer for the Consumer Product Safety Commission, Office of Information and Regulatory Affairs, OMB, Washington, DC 20503; telephone (202) 395–7340. The Commission encourages commenters to provide copies of such comments to the Commission's Office of the Secretary, with a caption or cover letter identifying the materials as comments submitted to OMB on the proposed rule to ban certain metal-cored candle wicks and candles with such wicks.

J. Regulatory Flexibility Act Certification

When an agency undertakes a rulemaking proceeding, the Regulatory Flexibility Act (RFA), as amended by the Small Business Regulatory Enforcement Fairness Act of 1996, 5 U.S.C. 601 *et seq.*, generally requires the agency to prepare initial and final regulatory flexibility analyses describing the impact of the rule on small businesses and other small entities. Section 605 of the RFA provides that an agency is not required to prepare a regulatory flexibility analysis if the head of an agency certifies that the rule will not have a significant economic impact on a substantial number of small entities.

The Commission's Directorate for Economic Analysis prepared a preliminary assessment of the impact of a rule to declare that metal-cored wicks containing more than 0.06 percent lead by weight in the metal and candles with such wicks are hazardous substances and to ban such wicks and candles. A copy of the preliminary analysis is available for inspection in the docket for this rulemaking. The assessment reports that the costs to consumers and candle wick and candle manufacturers are likely to be small.

At present, the Commission does not have quantitative information on the number of small businesses that might be affected by the proposed rules, although we believe that almost all domestic candle and candle wick manufacturers are small. The staff assessment concludes that because the incremental cost of the proposals is likely to be small, it is unlikely that the proposals will have a substantial effect on a significant number of small businesses.

The Commission requests comment from companies that supply candle wicks and candles that would be affected by these proposed rules. The Commission is particularly interested in information on the likely effect on small businesses of the testing, recordkeeping, and shipping container labeling requirements of the proposed banning rule.

Based on the foregoing assessment, the Commission certifies that the rules to declare that metal-cored wicks containing more than 0.06 percent lead by weight in the metal and candles with such wicks are hazardous substances and to ban such wicks and candles, if promulgated in final form as proposed, would not have a significant adverse impact on a substantial number of small businesses or other small entities.

K. Environmental Considerations

Pursuant to the National Environmental Policy Act, and in accordance with Council on Environmental Quality regulations and CPSC procedures for environmental review, the Commission has preliminarily assessed the possible environmental effects associated with the proposed hazardous substance declaration and ban for metal-cored candle wicks containing more than 0.06 percent lead by weight of the metal and candles with such wicks.

The Commission's regulations at 16 CFR 1021.5(c)(1) state that rules or safety standards to provide design or performance requirements for products normally have little or no potential for affecting the human environment. Preliminary analysis of the impact of the rules proposed today indicates that they will have no significant effects on the environment. This would be especially true if the effective date of the banning rule were to enable firms affected by the rule to deplete any existing non-complying inventory. Thus, the Commission concludes that no environmental assessment or environmental impact statement is required in this proceeding.

L. Effective Date

The rule proposed today would provide a period of one-hundred eighty (180) days for depletion of any existing stocks of candle wick material and candles subject to the proposed ban. It would then apply to any metal-cored candle wick containing more than 0.06 percent lead by weight in the metal, and any candle with such a wick, that is manufactured or imported on or after that date.

M. Executive Order 12988

As provided for in Executive Order 12988 (February 5, 1996), the CPSC states the preemptive effect of these proposed regulations as follows.

The FHSA provides that, generally, if the Commission issues a banning rule under section 2(q) of the FHSA to protect against a risk of illness or injury associated with a hazardous substance, ''no State or political subdivision of a State may establish or continue in effect a requirement applicable to such substance and designed to protect against the same risk of illness or injury unless such requirement is identical to the requirement established under such regulations.'' 15 U.S.C. 1261n(b)(1)(B). Upon application to the Commission, a State or local standard may be excepted from this preemptive effect if the State or local standard (1) provides a higher degree of protection from the risk of injury or illness than the FHSA standard and (2) does not unduly burden interstate commerce. In addition, the Federal government, or a State or local government, may establish and continue in effect a non-identical requirement that provides a higher degree of protection than the FHSA requirement for the hazardous substance for the Federal, State or local government's own use. 15 U.S.C. 1261n(b)(2). Thus, with the exceptions noted above, the proposed rule banning metal-cored candle wicks containing more than 0.06 percent lead by weight of the metal and candles with such wicks would preempt non-identical state or local requirements applicable to such wicks and candles designed to protect against the same risk of injury.

N. Trade Secret or Proprietary Information

Any person responding to this notice who believes that any information submitted is trade secret or proprietary should specifically identify the exact portions of the document claimed to be confidential. The Commission's staff will receive and handle such information confidentially and in accordance with section 6(a) of the Consumer Product Safety Act (CPSA), 15 U.S.C. 2055(a). Such information will not be placed in the public docket for the rulemaking and will not be made available to the public simply upon request. If the Commission receives a request for disclosure of the information or concludes that its disclosure is necessary to discharge the Commission's responsibilities, the Commission will inform the person who submitted the information and provide that person an opportunity to present additional information and views concerning the confidential nature of the information. 16 CFR 1015.18(b) (1999).

The Commission's staff will then make a determination of whether the information is trade secret or proprietary information that cannot be released. That determination will be made in accordance with applicable provisions of the CPSA; the Freedom of Information Act (FOIA), 5 U.S.C. 552b; 18 U.S.C. 1905; the Commission's procedural regulations at 16 CFR part 1015 governing protection and disclosure of information under provisions of FOIA; and relevant judicial interpretations. If the Commission concludes that any part of the information that has been submitted with a claim that the information is a trade secret or proprietary is disclosable, it will notify the person submitting the material in writing and provide at least 10 calendar days from the receipt of the letter to allow for that person to seek judicial relief. 15 U.S.C. 2055(a)(5) and (6); 16 CFR 1015.19(b).

O. Conclusion

For the reasons stated in this preamble, the Commission preliminarily finds that metal-cored candle wicks containing more than 0.06 percent lead by weight in the metal and candles with such wicks are hazardous substances, that cautionary labeling required by the FHSA is not adequate for such wicks and candles, and that, due to the degree and nature of the hazard presented by these items, in order to protect the public health and safety it is necessary to keep them out of commerce.

List of Subjects in 16 CFR Part 1500

Consumer protection, Hazardous materials, Hazardous substances, Imports, Infants and children, Labeling, Law enforcement, and Reporting and recordkeeping.

For the reasons stated in the preamble, the Commission proposes to amend Title 16 of the Code of Federal Regulation to read as follows:

PART 1500—HAZARDOUS SUBSTANCES AND ARTICLES; ADMINISTRATION AND ENFORCEMENT REGULATIONS.

1. The authority for part 1500 continues to read as follows:

Authority: 15 U.S.C. 1261–1278.

2. In § 1500.12, add a new paragraph (a)(2) to read as follows:

§ 1500.12 Products declared to be hazardous substances under section 3(a) of the act.

(a) * * *

(2) metal-cored candle wicks that have a lead content of more than 0.06 percent of the total weight of the metal core, and candles made with such wicks.

3. In § 1500.17, add a new paragraph (a)(13) to read as follows:

§ 1500.17 Banned hazardous substances.

(a) * * *

(13)(i) Candles made with metal-cored wicks. Lots of candles manufactured or imported on or after _____, 2002 [insert date 180 days after promulgation of final rule] made with metal-cored candle wicks, unless:

(A) The metal core of each candle wick has a lead content (calculated as the metal) of not more than 0.06 percent of the total weight of the metal core;

(B) The manufacturer, importer, private labeler, or distributor of each lot of candles with metal-cored wicks conducts, or obtains a report of the results of, reasonable and representative tests on either the candles in that lot, the metal-cored candle wicks used in that lot of candles, or the metal used to produce the wicks that were used in that lot of candles, that establish that the lead content of the metal used in the wicks is not more than 0.06 percent (of the total weight of the metal core);

(C) The records of such testing are in English, identify each lot of candles to which the test results apply, identify all numbers or other designations used to represent each lot on the label of containers as required in paragraph (a)(13)(i)(D) of this section, are maintained in the United States for as long as the candles the testing pertains to are being distributed plus three (3) years, and are made available for inspection and copying within 48 hours of a request by any officer, employee, or agent acting on behalf of the Consumer Product Safety Commission; and

(D) Each outer container or wrapper in which candles from a lot subject to paragraphs (a)(13)(i)(B) and (a)(13)(i)(C) of this section are shipped, including each outer container or wrapper of such candles distributed to a retail outlet, is

labeled ''Conforms to 16 CFR 1500.17(a)(13)'' and bears a number or other designation that relates back to the test results for that lot. For purposes of this paragraph (a)(13)(i)(D), the term ''outer container or wrapper'' does not include the immediate container in which candle(s) is/are intended to be displayed at retail or during use in the home, unless that container or wrapper is also the only container or wrapper in which the candle(s) is/are shipped to a retailer. For purposes of this paragraph (a)(13)(i)(D), a lot of metal-cored wick candles shall consist of all of the candles covered by any report of testing required by paragraph (a)(13)(i)(B) of this section.

(ii) *Metal-cored candle wicks.* Lots of metal-cored candle wicks manufactured or imported on or after _____ , ____ 2002 [insert date 180 days after promulgation of final rule] unless:

(A) The metal core of each candle wick has a lead content (calculated as the metal) of not more than 0.06 percent of the total weight of the metal core;

(B) The manufacturer, importer, private labeler, or distributor of each lot of metal-cored candle wicks conducts, or obtains a report of the results of, reasonable and representative tests on either the candle wicks in that lot, or on the metal used to produce the wicks that were used in that lot, that establish that the lead content of the metal used in the wicks is not more than 0.06 percent (of the total weight of the metal core);

(C) The records of such testing are in English, identify each lot of candle wicks to which the test results apply, identify all numbers or other designations used to represent each lot on the label of containers as required in paragraph (a)(13)(ii)(D) of this section, are maintained in the United States for as long as the candle wicks the testing pertains to are being distributed plus three (3) years, and are made available for inspection and copying within 48 hours of a request by any officer, employee, or agent acting on behalf of the Consumer Product Safety Commission; and

(D) Each outer container or wrapper in which candle wicks from a lot subject to paragraphs (a)(13)(ii)(B) and (a)(13)(ii)(C) of this section are shipped, including each outer container or wrapper of such candle wicks distributed to a retail outlet, is labeled ''Conforms to 16 CFR 1500.17(a)(13)'' and bears a number or other designation that relates back to the test results for that lot. For purposes of this paragraph (a)(13)(ii)(D), the term ''outer container or wrapper'' does not include the immediate container in which candle wick(s) is/are intended to be displayed or sold at retail, unless that container or wrapper is also the only container or wrapper in which the candle wick(s) is/are shipped to a retailer. For purposes of this paragraph (a)(13)(ii)(D), a lot of metal-cored wicks shall consist of all of the candle wicks covered by any report of testing required by paragraph (a)(13)(ii)(B) of this section.

(iii) *Findings—(A) General.* In order to issue a rule under section 2(q)(1) of the FHSA, 15 U.S.C. 1261(q)(1), classifying a substance or article as a banned hazardous substance, the FHSA requires the Commission to make certain findings and to include these in the regulation. These findings are discussed in paragraphs (a)(13)(iii)(B) through (D) of this section.

(B) *Voluntary Standard.* (1) One alternative to the ban that the Commission considered is to take no mandatory action, and to depend on a voluntary standard. One organization has a standard for candle wicks intended to address the potential for substantial illness posed by such wicks and candles with such wicks. The Commission has found that the standard is technically unsound and that substantial compliance with it is unlikely. Furthermore, there is no evidence that the standard has been adopted and implemented by candle wick or candle manufacturers.

(C) *Relationship of Benefits to Costs.* The Commission estimates that the ban will reduce the potential for exposure to lead and resulting lead poisoning because there is no ''safe'' level of lead in the blood. The annual cost to the candle/wick industry of the ban is estimated by the Commission to be in the range of $500,000 to $800,000. On a percentage basis these costs represent only 0.03 to 0.04 percent of the overall value of candle shipments in 1999, which was approximately $1.8 billion. Accordingly, the Commission finds that the benefits from the regulation bear a reasonable relationship to its costs.

(D) *Least burdensome requirement.* The Commission considered the following alternatives: No action; labeling all metal-cored candles with wicks containing more than 0.06 percent lead by weight of the metal; and relying on the voluntary standard. Neither no action, nor labeling, nor reliance on the voluntary standard would adequately reduce the risk of illness. Therefore the Commission finds that a ban on candle wicks containing more than 0.06 percent lead by weight of the metal and candles with such wicks is the least burdensome requirement that would prevent or adequately reduce the risk of illness.

Dated: April 18, 2002.

Todd A. Stevenson,

Secretary, Consumer Product Safety Commission.

List of Relevant Documents

The following documents contain information relevant to this rulemaking, can be accessed on the World Wide Web at *www.cpsc.gov,* and are available for inspection at the Office of the Secretary, Consumer Product Safety Commission, Room 502, 4330 East-West Highway, Bethesda, Maryland 20814:

1. Briefing memorandum from Kristina M. Hatlelid, Ph.D., M.P.H., Toxicologist, Directorate for Health Sciences, to the Commission, ''Petition HP 00–3 to Ban Lead-cored Candle Wicks,'' December 12, 2000.
2. Memorandum from K.M. Hatlelid, Ph.D., M.P.H., Toxicologist, Directorate for Health Sciences, to Mary Ann Danello, Ph.D., Associate Executive Director, Directorate for Health Sciences, ''Review of Lead Emissions from Candles,'' November 15, 2000.
3. Memorandum from Carolyn Meiers, Engineering Psychologist, Human Factors, to Kristina Hatlelid, Ph.D., M.P.H., Directorate for Health Sciences, ''Labeling of Candles with Lead-cored Wicks (Petition HP 00–3),'' October 18, 2000.
4. Briefing memorandum from Kristina M. Hatlelid, Ph.D., M.P.H., Toxicologist, Directorate for Health Sciences, to the Commission, ''Proposal to Ban Lead-Cored Candle Wicks,'' March 18, 2002.
5. Memorandum from Mary F. Donaldson, CPSC Directorate for Economic Analysis to Kristina Hatlelid, CPSC Directorate for Health Sciences, ''Preliminary Regulatory Analysis of a Proposed Ban of Lead in Candlewicks,'' March 5, 2002.

[FR Doc. 02–9960 Filed 4–23–02; 8:45 am]

BILLING CODE 6355–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Parts 201, 312, 314, and 601

[Docket No. 02N–0152]

Obtaining Timely Pediatric Studies of and Adequate Pediatric Labelingfor Human Drugs and Biologics

AGENCY: Food and Drug Administration, HHS.

ACTION: Advanced notice of proposed rulemaking.

SUMMARY: Given the present authorities contained in the Best Pharmaceuticals for Children Act (BPCA), which was signed into law January 2002, the Food and Drug Administration (FDA) is issuing this advanced notice of proposed rulemaking (ANPRM) to solicit comments on the most appropriate ways to update the 1998

''pediatric rule'' so that it can most effectively address FDA's interest in timely pediatric studies of and adequate pediatric labeling for human drugs and biological products that are used or will be used in the treatment of children. FDA is interested in what mechanisms, if any, may be necessary to augment the programs described in the BPCA and what present authorities, if any, have not proven effective, are now redundant, or need to be updated because of the BPCA.

DATES: Submit written or electronic comments on the ANPRM by July 8, 2002.

ADDRESSES: Submit written comments to the Dockets Management Branch (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Submit electronic comments to http://www.fda.gov/dockets/ecomments.

FOR FURTHER INFORMATION CONTACT: Terrie Crescenzi, Office of Pediatric Drug Development and Program Initiatives (HFD–960), Center for Drug Evaluation and Research, Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–594–7337, e-mail: crescenzit@cder.fda.gov.

SUPPLEMENTARY INFORMATION:

I. Background

In the **Federal Register** of December 2, 1998, FDA issued the final pediatric rule that requires manufacturers to assess the safety and effectiveness of certain human drugs and biological products in pediatric patients. This rule became effective in April 1999.

Under this rule, any application for approval of a human drug or biologic with a new active ingredient, new indication, new dosage form, new dosing regimen, or new route of administration is expected to contain data to assess the safety and effectiveness of the drug or biologic in pediatric patients. The pediatric rule also contains provisions for industry-FDA meetings and early consultation during the investigational study of a drug or biologic to facilitate the design and timely conduct of adequate pediatric studies of the drug or biologic, when appropriate to conduct such studies. In addition, this rule also provided FDA with the ability to require the development of a pediatric formulation, if necessary, to study a particular pediatric group; and to require manufacturers of already marketed human drugs and biologics to conduct certain pediatric studies when they seek approval for certain other changes to their drug or biologic. Manufacturers may obtain from FDA a waiver (e.g., the disease does not occur in the pediatric population) or deferral (e.g., pediatric studies to be conducted later in the development cycle) of some or all of these requirements. Under these provisions, many drugs have been studied in children and many companies have built an infrastructure that fosters pediatric studies of their products. In addition, under these provisions, as new drugs are developed, it has become more routine for companies to evaluate and plan appropriately for studying the new product in children.

For certain human drugs and biologics already on the market, under certain circumstances, the pediatric rule further authorizes FDA to require manufacturers to submit an application containing data adequate to assess whether the product is safe and effective in pediatric populations, even when the company has not submitted an application for certain other changes to their drug or biologic. FDA has, to date, not invoked this latter aspect of the pediatric rule.

After FDA issued its proposed pediatric rule (62 FR 43900, August 15, 1997), but before it issued the final pediatric rule, Congress passed the Food and Drug Administration Modernization Act of 1997 (FDAMA). This act included a provision that authorized specific market exclusivity incentives to manufacturers who voluntarily conducted and submitted to FDA pediatric studies of their drugs as requested by FDA and who met certain statutory criteria. This provision has resulted in numerous pediatric studies of many of the drugs to which it applied. Nonetheless, when FDA issued the pediatric rule, the agency indicated that the FDAMA provisions left some significant gaps in obtaining pediatric studies to provide safety and effectiveness labeling information for certain products. Examples of these ''gap'' products include already marketed drugs no longer under patent or market exclusivity protection, certain antibiotics, biological products approved under section 351 of the Public Health Service Act (PHSA), and products for which the manufacturers simply choose not to perform pediatric studies requested by FDA, despite the exclusivity incentive to do so. The exclusivity incentive provision of FDAMA, as written, does not to apply to biological products approved under section 351 of the PHSA, certain antibiotics, and products that did not have specific existing patent or exclusivity protection that could be prolonged under this authority. In addition, the exclusivity provision could only effectively be employed once with respect to an active ingredient. Thus, if further studies in certain groups of children (for example, neonates) were needed at a later date, the exclusivity provision was restricted and thus did not provide an economic incentive for the additional needed studies. Also, the exclusivity incentive provisions of FDAMA expired on January 1, 2002.

On January 4, 2002, the President signed into law the BPCA. This legislation both reauthorizes the exclusivity incentive program enacted originally in FDAMA (essentially without any change relevant here) and establishes an additional mechanism for obtaining information on the safe and effective use of drugs in pediatric patients. The new BPCA mechanism consists primarily of authorizing several National Institutes of Health (NIH) funding mechanisms, including the NIH Foundation, as vehicles for funding, using both public and private funds, studies of certain drugs under certain circumstances if the manufacturers of those drugs decline to conduct the requested pediatric studies. BPCA also provides a mechanism for including information from such studies in the label of pediatric products. Because it involves paying others to do the studies rather than having to litigate with a company to force it to conduct needed studies, some have argued that this new BPCA mechanism is a more cost- and time-efficient way of achieving the goal of adequate pediatric safety and efficacy labeling of these ''gap'' products than are some of the provisions of the pediatric rule. Others point out that while these NIH funding mechanisms may be used to contract for pediatric studies of certain human drugs, the provision of BPCA for awarding study contracts does not extend to awarding contracts to study human biologics and certain antibiotics. In addition, the public funding of these mechanisms is dependent on yearly congressional appropriations and the private donations are purely voluntary. Whether funds appropriated for such studies will be adequate to ensure that studies are performed and data submitted for all needed drug products remains uncertain. By statute, the BPCA is to sunset in 2007. Because of these uncertainties in funding, limitations on the products covered, and the lack of required early planning regarding pediatrics in a drug's development process, some have argued that without the ''requirement'' provisions of the pediatric rule, FDA will not have the authority it needs to ensure that all medicines used in children of all ages

are indeed safe and effective for that use.

Given the present authorities contained in the BPCA and the pediatric rule, this ANPRM is intended to solicit comments on the most appropriate ways to balance FDA's interest in timely pediatric studies of and adequate pediatric labeling for human drugs and biological products that are used or will be used in the treatment of children and FDA's interest in not imposing unnecessary human drug and biologic study requirements. FDA is particularly interested in what mechanisms, if any, may be necessary to augment the programs described in the BPCA and what present authorities, if any, are perhaps now redundant because of the BPCA.

Therefore, FDA is soliciting comments on these issues. The agency is particularly interested in the relationship between the approach to acquiring pediatric labeling information promulgated in the pediatric rule, and the approaches authorized in the BPCA. While FDA is interested in hearing any comments the public would like to submit on this issue, questions of specific interest to FDA include:

1. What changes to the pediatric rule, if any, would be necessary to integrate the BPCA and the pediatric rule more effectively?

2. How would the criteria used by NIH and FDA under section 3 of the BPCA to request studies of already approved drugs relate to the standards promulgated in the pediatric rule and described in 21 CFR 201.23, 314.55, and 601.27 for requiring pediatric labeling for certain drugs and biological products? Which criteria are more appropriate for determining when studies are conducted?

3. What provisions, if any, of the BPCA could apply to biological products regulated under section 351 of the PHSA?

4. How does the provision in section 3 of the BPCA providing for a recommendation for a formulation change relate to the pediatric rule provision stating that in certain cases a sponsor may be required to develop a pediatric formulation? Should pediatric formulations be required in certain cases?

Resolution of these and other questions will be required before FDA can determine the optimum approach to ensuring that human drugs and biologics used in children have adequate information regarding the safe and effective use of these products in pediatric patients.

II. Requests for Comments

Interested persons may submit to the Dockets Management Branch (see **ADDRESSES**) written or electronic comments regarding this document by July 8, 2002. 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 Docket Management Branch between 9 a.m. and 4 p.m., Monday through Friday.

This document was reviewed by the Office of Management and Budget under Executive Order 12866.

Dated: April 18, 2002.

Margaret M. Dotzel,

Associate Commissioner for Policy.

[FR Doc. 02–9980 Filed 4–19–02; 12:00 pm]

BILLING CODE 4160–01–S

DEPARTMENT OF JUSTICE

Drug Enforcement Administration

21 CFR Part 1308

[DEA # 225]

Schedule of Controlled Substances: Proposed Rule: Rescheduling of Buprenorphine From Schedule V to Schedule III

AGENCY: Drug Enforcement Administration (DEA), Justice.

ACTION: Proposed rule; extension of comment period.

SUMMARY: The DEA is extending the comment period and time to request a hearing on the **Federal Register** Notice of proposed rulemaking entitled ''Schedule of Controlled Substances: Proposed Rule: Rescheduling of Buprenorphine From Schedule V to Schedule III'' published on March 21, 2002 (67 FR 13114).

DATES: The period for public comment that was to close on April 22, 2002, will be extended to May 22, 2002.

ADDRESSES: Comments should be submitted to the Administrator, Drug Enforcement Administration, Washington, DC 20537, Attn.: DEA Federal Register Representative (CCR).

FOR FURTHER INFORMATION CONTACT: Frank L. Sapienza, Chief, Drug and Chemical Evaluation Section, Drug Enforcement Administration, Washington, DC 20537, Telephone: (202) 307–7183.

SUPPLEMENTARY INFORMATION: The DEA published a notice of proposed rulemaking (67 FR 13114) to reschedule buprenorphine from Schedule V to Schedule III of the Controlled Substances Act (CSA). The proposed rescheduling action is based on a scientific and medical evaluation and recommendation by the Department of Health and Human Services and an evaluation of this and other information by DEA. On April 12, 2002, DEA received a request for a sixty day extension of the period in which to comment and request a hearing. The requestor indicated that the additional time is necessary to obtain and evaluate the nearly one hundred scientific articles cited by DEA in support of its scheduling proposal. Upon consideration of this request, a thirty day extension of the time to comment and request a hearing is granted. This allows sufficient time for interested persons to evaluate and consider all relevant information and respond accordingly. Therefore, the comment period and time to request a hearing is extended to May 22, 2002. Comments must be received by the DEA on or before this date.

Dated: April 18, 2002.

Asa Hutchinson,

Administrator.

[FR Doc. 02–10044 Filed 4–19–02; 3:03 pm]

BILLING CODE 4410–09–P

DEPARTMENT OF THE TREASURY

Internal Revenue Service

26 CFR Parts 1 and 301

[REG–107184–00]

RIN 1545–AY04

Guidance Necessary To Facilitate Electronic Tax Administration

AGENCY: Internal Revenue Service (IRS), Treasury.

ACTION: Notice of proposed rulemaking by cross-reference to temporary regulations.

SUMMARY: The IRS is proposing regulations designed to eliminate regulatory impediments to the electronic filing of the Form 1040, ''U.S. Individual Income Tax Return.'' The text of the temporary regulations published in the Rules and Regulations section of this issue of the **Federal Register** also serves as the text of these proposed regulations. These regulations generally affect taxpayers who file Form 1040 electronically and who are required to file any of the following forms: Form 56, ''Notice Concerning Fiduciary Relationship''; Form 2120,

''Multiple Support Declaration''; Form 2439, ''Notice to Shareholder of Undistributed Long-Term Capital Gains''; Form 3468, ''Investment Credit''; and Form T (Timber), ''Forest Activities Schedules.''

DATES: Written or electronically generated comments and requests for a public hearing must be received by July 23, 2002.

ADDRESSES: Send submissions to: CC:ITA:RU (REG–107184–00), room 5226, Internal Revenue Service, POB 7604, Ben Franklin Station, Washington, DC 20044. Submissions may be hand delivered between the hours of 8 a.m. and 5 p.m. to: CC:ITA:RU (REG–107184–00), Courier's Desk, Internal Revenue Service, 1111 Constitution Ave., NW., Washington, DC. Alternatively, taxpayers may submit comments electronically directly to the IRS internet site at *www.irs.gov/regs.*

FOR FURTHER INFORMATION CONTACT: Concerning the regulations, James C. Gibbons, (202) 622–4910; concerning submissions of comments and/or requests for a hearing, LaNita Van Dyke, (202) 622–7180 (not toll-free numbers).

SUPPLEMENTARY INFORMATION:

Paperwork Reduction Act

The collections of information contained in this notice of proposed rulemaking have been submitted to the Office of Management and Budget for review in accordance with the Paperwork Reduction Act of 1995 (44 U.S.C. 3507(d)). Comments on the collections of information should be sent to the Office of Management and Budget, Attn: Desk Officer for the Department of the Treasury, Office of Information and Regulatory Affairs, Washington, DC 20503, with copies to the Internal Revenue Service, Attn: IRS Reports Clearance Officer, W:CAR:MP:FP:S, Washington, DC 20224. Comments on the collections of information should be received by June 24, 2002. Comments are specifically requested concerning:

Whether the proposed collections of information are necessary for the proper performance of the functions of the Internal Revenue Service, including whether the information will have practical utility;

The accuracy of the estimated burden associated with the proposed collection of information (see below);

How the quality, utility, and clarity of the information to be collected may be enhanced;

How the burden of complying with the proposed collections of information may be minimized, including through the application of automated collection techniques or other forms of information technology; and

Estimates of capital or start-up costs and costs of operation, maintenance, and purchase of service to provide information.

The collections of information in this proposed regulation are in §§ 1.48–12T(d)(7), 1.152–3T(c), 1.611–3T(h), 1.852–9T(c), and 301.6903–1T(b). The proposed regulations require taxpayers to retain their tax records for as long as the contents may become material in the administration of any internal revenue law. This information is required for substantiation purposes. This information will be used to verify the information provided by the taxpayer. The likely respondents are individuals.

An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a valid control number assigned by the Office of Management and Budget.

Books or records relating to a collection of information must be retained as long as their contents may become material in the administration of any internal revenue law. Generally, tax returns and tax return information are confidential, as required by 26 U.S.C. 6103. The burden imposed in §§ 1.48–12T(d)(7), 1.152–3T(c), 1.611–3T(h), 1.852–9T(c), and 301.6903–1T(b) will be reflected in Form 3468, Form 2120, Form T (Timber), Form 2439 and Form 56 respectively.

Background

Temporary regulations in the Rules and Regulation section of this issue of the **Federal Register** contain amendments to the Income Tax Regulations (26 CFR part 1) and the Procedure and Administration Regulations (26 CFR part 301) designed to eliminate regulatory impediments to the electronic filing of the Form 1040. The text of those regulations also serves as the text of these proposed regulations. The preamble to the temporary regulations explains the temporary regulations and these proposed regulations. Generally, the regulations will be effective for taxable years beginning after December 31, 2001. Taxpayers may, however, rely on these proposed regulations to the extent that the impediments were removed in forms filed for taxable years beginning after December 31, 2000.

Special Analyses

It has been determined that this notice of proposed rulemaking is not a significant regulatory action as defined in Executive Order 12866. Therefore, a regulatory assessment is not required. It also has been determined that section 553(b) of the Administrative Procedure Act (5 U.S.C. chapter 5) does not apply to these regulations. It is hereby certified that the collection of information in these regulations will not have a significant economic impact on a substantial number of small entities. This certification is based upon the fact that the persons responsible for recordkeeping are principally individuals, and the burden is not significant as described earlier in the preamble. Therefore, a Regulatory Flexibility Analysis under the Regulatory Flexibility Act (5 U.S.C. chapter 6) is not required. Pursuant to section 7508(f) of the Internal Revenue Code, this notice will be submitted to the Chief Counsel for Advocacy of the Small Business Administration for comment on its impact on small business.

Comments and Requests for a Public Hearing

Before these proposed regulations are adopted as final regulations, consideration will be given to any electronic or written comments (a signed original and eight (8) copies of written comments) that are submitted timely (in the manner described in the **ADDRESSES** caption) to the IRS. The IRS and Treasury request comments on the clarity of the proposed rules and how they may be made easier to understand. All comments will be available for public inspection and copying. A public hearing may be scheduled if requested by any person who timely submits comments. If a public hearing is scheduled, notice of the date, time, and place for the hearing will be published in the **Federal Register**.

Drafting Information

The principal author of these regulations is Sara Paige Shepherd, Office of Associate Chief Counsel (Procedure and Administration), Administrative Provisions and Judicial Practice Division. However, other personnel from the IRS and the Treasury Department participated in the development of the regulations.

List of Subjects

26 CFR Part 1

Income taxes, Reporting and recordkeeping requirements.

26 CFR Part 301

Employment taxes, Estate taxes, Excise taxes, Gift taxes, Income taxes, Penalties, Reporting and recordkeeping requirements.

Adoption of Amendments to the Regulations

Accordingly, 26 CFR parts 1 and 301 are amended as follows:

PART 1—INCOME TAXES

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

Authority: 26 U.S.C. 7805 * * *

2. Section 1.48–12, paragraph (d)(7)(iii) is revised to read as follows:

§ 1.48–12 Qualified rehabilitated building; expenditures incurred after December 31, 1981.

* * * * *

(d) * * *

(7) * * *

(iii) [The text of proposed paragraph (d)(7)(iii) is the same as the text of § 1.48–12T(d)(7)(iii) published elsewhere in this issue of the **Federal Register**].

3. In § 1.152–3, paragraph (c) is revised to read as follows:

§ 1.152–3 Multiple support agreements.

* * * * *

(c) [The text of proposed paragraph (c) is the same as the text of § 1.152–3T(c) published elsewhere in this issue of the **Federal Register**].

* * * * *

4. Section 1.611–3, paragraph (h) is revised to read as follows:

§ 1.611–3 Rules applicable to timber.

* * * * *

(h) [The text of proposed paragraph (h) is the same as the text of § 1.611–3T(h) published elsewhere in this issue of the **Federal Register**].

5. In § 1.852–9, paragraph (c)(1) is revised to read as follows:

§ 1.852–9 Special procedural requirements applicable to designation under section 852(b)(3)(D).

* * * * *

(c)(1) [The text of proposed paragraph (c)(1) is the same as the text of § 1.852–9T(c)(1) published elsewhere in this issue of the **Federal Register**].

* * * * *

PART 301—PROCEDURE AND ADMINISTRATION

6. The authority citation for part 301 continues to read in part as follows:

Authority: 26 U.S.C. 7805 * * *

7. Section 301.6011–1 is revised to read as follows:

§ 301.6011–1 General Requirement of return, statement or list.

[The text of proposed section is the same as the text of § 301.6011–1T published elsewhere in this issue of the **Federal Register**].

8. Section 301.6903–1(b) is added to read as follows:

§ 301.6903–1 Notice of fiduciary.

* * * * *

(b) [The text of proposed paragraph (b) is the same as the text of § 301.6903–1T(b) published elsewhere in this issue of the **Federal Register**].

* * * * *

Robert E. Wenzel,

Deputy Commissioner of Internal Revenue.

[FR Doc. 02–9820 Filed 4–23–02; 8:45 am]

BILLING CODE 4830–01–P

POSTAL SERVICE

39 CFR Part 111

Firm Pieces in Carrier Route and Presorted Bound Printed Matter Mailings

AGENCY: Postal Service.

ACTION: Request for comment on application of agency rule.

SUMMARY: The Postal Service requests comments from the mailing industry (especially the presort software industry) as to how Bound Printed Matter (BPM) mailings with individually addressed ''firm pieces'' can be prepared under current eligibility and mail preparation standards. The term ''firm piece'' is generally used to describe a mailpiece that consists of more than one component (all destined for the same delivery address, which is often a company or business firm) composited into a single mailpiece. The existence of firm packages in Periodicals mailings is due to separate per-copy and per-addressed piece rates that do not exist within other classes of mail. The Postal Service is not proposing to change Domestic Mail Manual (DMM) standards in this notice.

DATES: Comments must be received on or before May 22, 2002.

ADDRESSES: Written comments should be delivered to the Manager, Mail Preparation and Standards, United States Postal Service, 1735 N. Lynn St., Room 3025, Arlington, VA 22209–6038. Comments may be transmitted via facsimile to 703–292–4058 or via e-mail to *tdevaugh@email.usps.gov.* Copies of all written comments will be available for inspection and photocopying at USPS Headquarters Library, 475 L'Enfant Plaza SW, 11th Floor N, Washington DC 20260–1450 between 9 a.m. and 4 p.m., Monday through Friday.

FOR FURTHER INFORMATION CONTACT: Tom DeVaughan, 703–292–3640; or Marc McCrery, 202–268–2704.

SUPPLEMENTARY INFORMATION: On January 7, 2001, the Postal Service adopted new standards for Bound Printed Matter (BPM) that formalized the packaging and sacking or palletizing of BPM mailings according to shape (processing category) and destination entry (if any). These standards were incorporated into the Domestic Mail Manual (DMM). At the same time, new destination entry discounts were implemented. These standards were published for comment in the **Federal Register** on August 29, 2000, as part of the proposed DMM changes to implement the R2000–1 Omnibus Rate Case after extensive meetings with an Implementation Readiness Team (IRT) comprised of mailers, printers, publishers, and mailer associations. No comments were received on the BPM mail preparation standards from the IRT participants or others in the industry, and the final rule was published in the **Federal Register** on December 15, 2000.

After implementation of the new standards on January 7, 2001, the Postal Service has been receiving BPM firm pieces in Presorted BPM mailings that do not comply with the January 2001 eligibility criteria and mail preparation standards for BPM rates. Those standards prescribe specific preparation for flats, irregular parcels weighing less than 10 pounds, irregular parcels weighing 10 pounds or more, and machinable parcels. Although the issue may arise with some traditional BPM mailers (especially those taking advantage of drop ship incentives), it also impacts major printers who print Standard Mail pieces and prepare a portion of their mailings as BPM mail. An exhibit is provided at the end of this notice to illustrate a firm piece.

Firm Package and Firm Piece Preparation

Within Periodicals mailings, a ''firm package'' is defined in the DMM as two or more copies (pieces) for the same address placed in a single package. For presort eligibility and postage calculation, such pieces are treated in one of two ways:

- If each copy within the firm package has a delivery address, each may be claimed as a separate addressed piece (i.e., the number of pieces within the firm package multiplied by the ''piece rate'' of postage); or
- The firm package itself may be claimed as only one addressed piece.

In either case, one unit of piece rate postage is paid for each addressed piece claimed. A firm package sorted and

claimed as one addressed piece must be accompanied by (but can be physically separate from) other addressed pieces packaged to the same presort destination to satisfy the minimum package requirement when applicable, regardless of the number of pieces within the firm package.

Within BPM standards, there is no mention of the terms ''firm package,'' ''firm piece,'' and ''firm bundle'' in the DMM. However, these terms are used industry-wide in a number of situations to describe mailpieces that consist of more than one component composited into a single mailpiece addressed to a single delivery point. Within this notice, the term ''firm piece'' is used, for discussion purposes only, to represent a single addressed piece with one unit of ''piece rate'' postage paid.

Firm piece preparation for BPM mailings existed in the DMM for carrier route mailings until June 30, 1996 (DMM Issue 49). It defined a ''firm package'' like the definition above for Periodicals mailings, with one exception. The BPM firm package (for reasons stated below) was not permitted to be physically separate from other addressed pieces to the same presort destination. DMM Issue 49, M403.3.4 stated:

> A ''firm package'' is two or more pieces for the same address placed in one package. If each piece has a delivery address, each may be claimed as a separate addressed piece for presort and on the mailing statement. The firm package may be claimed as one addressed piece for presort and on the mailing statement. If the pieces are unaddressed, the firm package is considered as one addressed piece. A firm package presorted and claimed as one addressed piece must be placed with other addressed pieces to form the minimum volume per package regardless of the number of pieces in the firm package.

Throughout the current DMM the term ''addressed piece'' is used to identify a single individually addressed mailpiece bearing evidence of postage payment and which, at a minimum, has a unit of ''piece rate'' postage paid. An addressed piece can include a firm (composite) piece consisting of:

- One addressed piece with one or more unaddressed pieces; or
- Two or more pieces each bearing the same delivery address.

In either case, one unit of piece rate postage is paid for each addressed piece. Presort destinations are comprised of a required minimum number of addressed pieces or pounds (of addressed pieces), whichever occurs first.

A firm piece is often secured together with shrinkwrap, plastic straps, or a combination of the two. The intent of the mailer is for the Postal Service to treat the firm piece as a single-addressed (composite) piece and deliver it to the delivery address on the top piece. The firm piece could be envisioned as the equivalent of multiple addressed (or unaddressed) catalogs placed in an addressed carton for delivery to the address appearing on the carton (along with evidence of postage payment). For the firm piece, the ''mailing container'' (carton) is made of shrinkwrap, plastic straps, or both, which makes this hybrid piece look like a presort destination package of flats (or irregular parcels) that should be opened for distribution at some point prior to delivery. The only difference may be the mailer's use of the ''firm'' optional endorsement line (OEL) identifying the top piece as ''firm'' (i.e., all pieces in this ''container'' for the same address). There currently are no DMM standards for preparing and identifying individually addressed firm pieces (packages) using OELs other than with Periodicals mailings (DMM M013.1).

Firm Piece Preparation in Bound Printed Matter Mailings

Some mailers currently use a facing slip affixed to the top of the package to indicate that the package is not to be opened and must be delivered intact to the address on the top piece. This extra step adds production costs for the mailer but helps assure the piece is delivered intact. However, the mailer who chooses to count the firm piece as one addressed piece saves postage since the firm piece is treated as one addressed piece, rather than as individual copies.

When a typical automated production line is presented with a BPM mailing that includes firm pieces, it is not capable of first producing and grouping components into firm pieces and then regrouping these firm pieces with other individual addressed pieces into appropriate required presort destination packages to qualify for the rates claimed. Compounding the problem is the fact that the number of component pieces comprising a firm piece is likely to vary (e.g., some firm pieces consist of nine catalogs, others consist of seven, and others consist of 11). Therefore, because each firm piece is reported as (and postage is paid as) one addressed piece, the mailings will consist of nonidentical-weight pieces that must be accepted under an approved postage payment system (manifest mailing system or alternate mailing system). In addition, depending on the size (thickness) of the individual component pieces, firm piece preparation can lead to some firm pieces that fit into two different processing categories (flats and irregular parcels). DMM standards do not permit two processing categories in the same bulk mailing for any class of mail. So, although there is potential for postage savings from the creation of firm pieces, production line complications result in improperly prepared mailings. Additionally, effective with R2001–1 implementation (June 30, 2002) and introduction of shape-based categories (i.e., flats and parcels) two separate rates will apply to all BPM.

For Periodicals mailings, the minimums for presort destinations and sacking are simple and straightforward: only six addressed pieces for package preparation and 24 addressed pieces per sack. By contrast, Carrier route and Presorted BPM, the minimums for package and sack preparation standards are more complicated. They are based on a minimum number of addressed pieces or a minimum weight to the presort destination, whichever occurs first (e.g., 10 addressed pieces or 20 pounds). These required minimums create additional challenges to production lines and presort software when BPM pieces and weight from ''presort destination to presort destination'' vary dramatically within the same mailing job. The preparation standards for any particular BPM mailing can be checked in the appropriate sections in DMM M700. Eligibility standards for destination entry discounts are published in DMM E752. The DMM is available online through Postal Explorer at *http://pe.usps.gov.*

Destination Entry Rate Mailings

For Carrier Route and Presorted BPM mailings to be eligible for destination bulk mail center (DBMC), destination sectional center facility (DSCF), and destination delivery unit (DDU) rates, they must first meet the required preparation standards based on the physical attributes of the (finished) pieces, and then the eligibility standards in DMM E752. Unlike Parcel Select mail, single-piece BPM is not eligible for destination entry rates. As a result, if individually addressed BPM firm pieces (comprised of flats or irregular parcels) are not packaged with other pieces to the required presort level prior to sacking or palletizing, these individually addressed pieces are not eligible for Carrier Route or Presorted rates (as appropriate) and, therefore, are not eligible for destination entry rates.

Single (individually prepared) firm pieces require the Postal Service to manually sort the pieces to the appropriate 5-digit destination. DSCF rates for Carrier Route and Presorted

BPM mailings assume pieces are sorted (packaged) in accordance with DMM standards, prior to placing into sacks or onto pallets. Therefore, firm pieces in the flat-size and irregular parcel (less than 10 pounds) category are not permitted as single pieces on pallets or in sacks, with the exception of those limited circumstances of the last physical package to a carrier route destination or, for presorted, a mixed ADC package. The only destination entry rate available for pieces in mixed ADC packages is DBMC.

Available Options

In the past seven months, the Postal Service conducted a series of meetings and teleconferences with mailing industry representatives to determine how to accommodate firm piece preparation in BPM mailings, especially destination entry BPM mailings. The consensus was that firm piece preparation within BPM mailings works best when the pieces are prepared as machinable parcels. Unless prepared on 5-digit and 5-digit scheme pallets or in sacks, machinable parcel preparation may not offer the lowest postage rates when compared with rates for destination entry mailings of flats and irregular parcels prepared in 5-digit and 3-digit presort destination packages first, then placed on 5-digit, 3-digit and SCF pallets or in sacks. However, mailers should consider the overall total production (nonpostage) costs as well as delivery and transportation costs associated with the separate mail preparation standards.

Machinable parcels sorted to BMC pallets and sacks must meet the standards in DMM C010.8.0 and M020.1.5b for machinability on BMC parcel sorting machines (PSMs). Such parcels bearing a barcode in accordance with DMM C850 are entitled to the additional $0.03 discount. Because parcels sorted on 5-digit and 5-digit scheme pallets or in sacks are not required to meet machinability standards, they would not be eligible for this additional $0.03 discount.

Whenever possible, firm pieces comprised of component pieces secured together with shrinkwrap and/or plastic straps should be placed at the bottom of each ''logical'' package (the total group of pieces in a required presort destination package). In addition to the package labeling standards in DMM M020.1.3 (pressure-sensitive labels or OELs), firm pieces should bear a facing slip containing instructions such as ''DO NOT OPEN, ALL FOR ADDRESS ON TOP PIECE'' to ensure that the firm piece arrives intact. Firm OELs are permitted only with Periodicals mailings. If a logical package consists of only firm pieces (two or more), an additional facing slip or label must identify the logical package destination (e.g., 5-digit, 3-digit, or ADC). Facing slips must contain the same three-line information as for a corresponding sack label:

Line 1: Destination city, SCF, or ADC, as appropriate.

Line 2: Content [PSVC FLTS or PSVC IRREG].

Line 3: City and two-letter state abbreviation of origin post office.

All pieces within a BPM mailing must consist of addressed pieces within the same processing category: all flats, all irregular parcels, or all machinable parcels.

For the reasons stated above, the Postal Service seeks comments and recommendations on the preparation issues arising from firm pieces in BPM mailings.

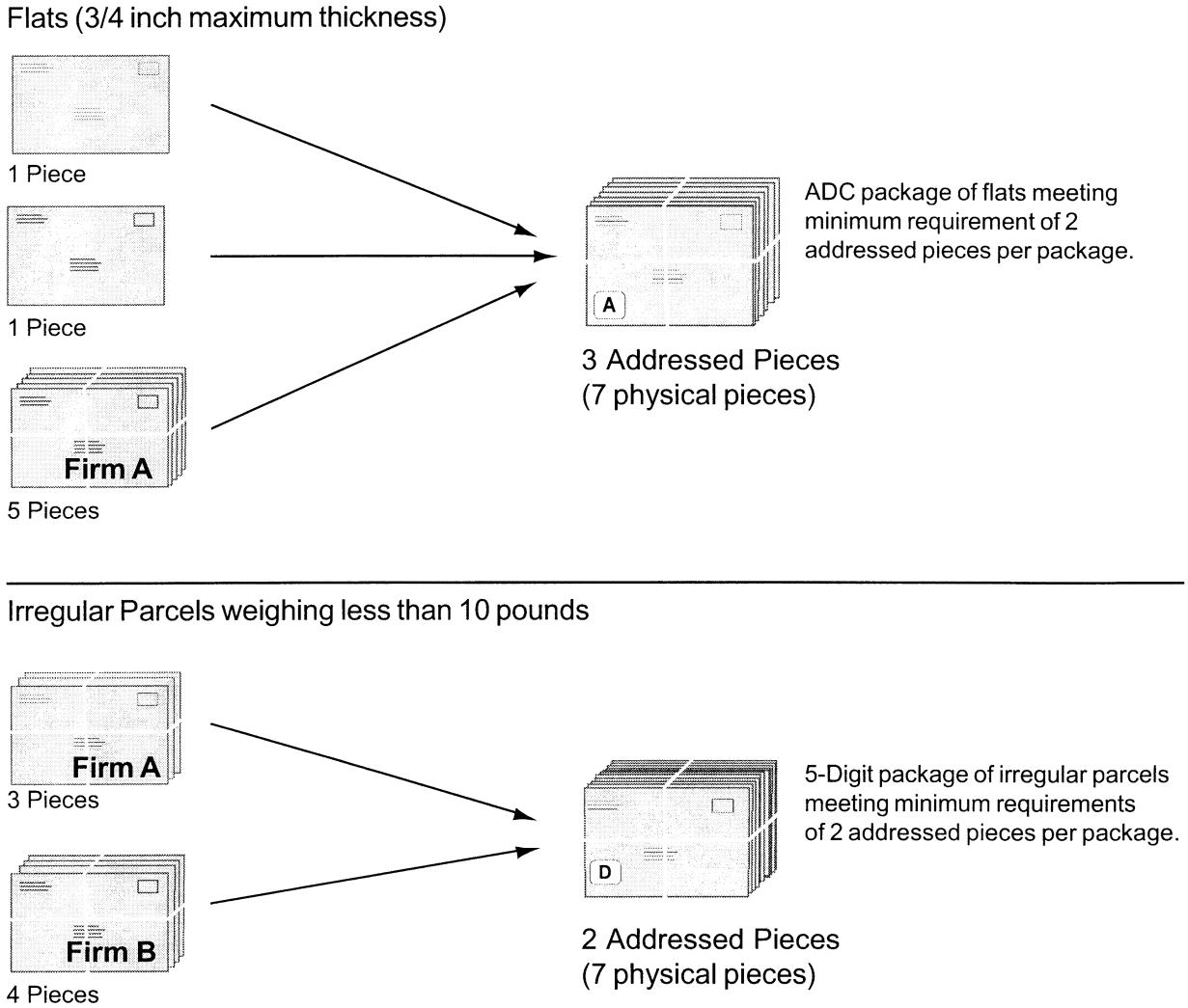
Authority: 5 U.S.C. 552(a); 39 U.S.C. 101, 401, 403, 404, 414, 3001–3011, 3201–3219, 3403–3406, 3621, 3626, 5001.

Neva R. Watson,

Attorney, Legislative.

BILLING CODE 7710–12–P

Bound Printed Matter Package Preparation



[FR Doc. 02–10037 Filed 4–23–02; 8:45 am]

BILLING CODE 7710–12–C

POSTAL SERVICE

39 CFR Part 501

Authorization To Manufacture and Distribute Postage Meters

AGENCY: Postal Service.

ACTION: Proposed rule.

SUMMARY: This proposed rule amends the regulations for postage meter inventory control and for the protection and control of internal and security components.

DATES: The Postal Service must receive your comments on or before May 24, 2002.

ADDRESSES: Mail or deliver written comments to the Manager, Postage Technology Management, 1735 N. Lynn Street, Room 5011, Arlington, VA 22209–6050. You can view and copy all written comments at the same address between 9 a.m. and 4 p.m., Monday through Friday.

FOR FURTHER INFORMATION CONTACT: Wayne Wilkerson by fax at 703–292–4050.

SUPPLEMENTARY INFORMATION: The United States Postal Service is seeking to improve the secure handling of postage meters and their security components by the approved postage meter manufacturers, and to extend the regulations to third-party agents and representatives of the manufacturers. We are proposing to amend the regulations to address these concerns and to align the regulations with changes to the *Domestic Mail Manual* (DMM) regarding postage meters published in the **Federal Register** (66 FR 56432–56447) on November 8, 2001. We will review any public comments and will issue a final rule amending these sections. We will amend the remaining sections of CFR part 501 in the near future so that they all reflect the changes in the postage meter population and the changes in the DMM.

List of Subjects in 39 CFR Part 501

Administrative practice and procedure, Postal Service.

Notice and Comment

Although exempt from the notice and comment requirements of the Administrative Procedure Act (5 U.S.C. 553(b), (c)) regarding proposed rulemaking by 39 U.S.C. 410(a), the

Postal Service invites public comments on the following proposed amendments to the Code of Federal Regulations.

For the reasons set out in this document, the Postal Service is proposing to amend 39 CFR part 501 as follows:

PART 501—AUTHORIZATION TO MANUFACTURE AND DISTRIBUTE POSTAGE METERS

1. The authority citation for part 501 continues to read as follows:

Authority: 5 U.S.C. 552(a); 39 U.S.C. 101, 401, 403, 404, 410, 2601, 2605; Inspector General Act of 1978, as amended (Public Law 95–452, as amended), 5 U.S.C. App. 3.

2. Sections 501.22 and 501.28 are revised to read as follows:

§ 501.22 Inventory control.

(a) An authorized manufacturer must maintain sufficient facilities for and records of the distribution, control, storage, maintenance, repair, replacement, and destruction or disposal of all meters and their components to enable accurate accounting thereof throughout the entire life cycle of the meter.

Recordkeeping is required for all meters including newly produced meters; active leased meters; inactive, unleased meters; and lost and stolen meters. All such facilities and records are subject to inspection by Postal Service representatives.

(b) If the manufacturer uses a third party to control, distribute, maintain, replace, repair, or dispose of meters, the Manager of Postage Technology Management, USPS Headquarters, must specifically authorize in writing all aspects of the arrangement between the parties relating to the custody and control of postage meters.

(1) The third-party relationship shall not compromise any security element of the meter. The functions of the third party with respect to meters are subject to the same scrutiny as the equivalent functions of the manufacturer.

(2) Any authorized third party must keep adequate facilities for and records of meters and their components in accordance with (a). All such facilities and records are subject to inspection by Postal Service representatives, in so far as they are used to distribute, control, store, maintain, repair, replace, destroy, or dispose of meters.

(3) The manufacturer must ensure that any party acting in its behalf in any of the functions described in subsection (a) maintains adequate facilities, records, and procedures for the security of the meters. The Postal Service can request termination of the third-party arrangement relating to the custody and control of postage meters if it finds deficiencies and the deficiencies are not corrected in a timely manner.

* * * * *

§ 501.28 Protection and control of internal and security components.

Any physical or electronic access to the internal components of a meter, as well as any access to software or security parameters, must be conducted within an approved factory or meter repair facility under the manufacturer's direct control and active supervision. The Postal Service must check meters out of service before any component, software, or security parameter is accessed or modified in any way or internal repairs are undertaken. This does not apply to Postal Service-approved user, field, or postal access to a specific internal component or software. To prevent unauthorized use, the manufacturer or any third party acting on its behalf must keep secure any equipment or other component that can be used to open or access the internal, electronic, or secure components of a meter.

* * * * *

An appropriate amendment to 30 CFR part 501 to reflect these changes will be published if the proposal is adopted.

Stanley F. Mires,

Chief Counsel, Legislative.

[FR Doc. 02–9921 Filed 4–23–02; 8:45 am]

BILLING CODE 7710–12–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 52

[CA 262–0338b; FRL–7174–3]

Revisions to the California State Implementation Plan, San Joaquin Valley Unified Air Pollution Control District

AGENCY: Environmental Protection Agency (EPA).

ACTION: Proposed rule.

SUMMARY: EPA is proposing to approve revisions to the San Joaquin Valley Unified Air Pollution Control District (SJVUAPCD) portion of the California State Implementation Plan (SIP). These revisions concern SJVUAPCD Rule 4354, which controls oxides of nitrogen (NO_X) emissions from glass melting furnaces. We are proposing to approve a local rule to regulate these emission sources under the Clean Air Act as amended in 1990 (CAA or the Act). We are taking comments on this proposal and plan to follow with a final action.

DATES: Any comments must arrive by May 24, 2002.

ADDRESSES: Mail comments to Andy Steckel, Rulemaking Office Chief (AIR–4), U.S. Environmental Protection Agency, Region IX, 75 Hawthorne Street, San Francisco, CA 94105–3901.

You can inspect copies of the submitted SIP revisions and EPA's technical support document (TSD) at our Region IX office during normal business hours. You may also see copies of the submitted SIP revisions at the following locations:

California Air Resources Board, Stationary Source Division, Rule Evaluation Section, 1001 ''I'' Street, Sacramento, CA 95814.

San Joaquin Valley Unified Air Pollution Control District, 1990 E. Gettysburg Ave., Fresno, CA 93726.

FOR FURTHER INFORMATION CONTACT: Charnjit Bhullar, Rulemaking Office (AIR–4), U.S. Environmental Protection Agency, Region IX, (415) 972–3960.

SUPPLEMENTARY INFORMATION: Throughout this document, ''we,'' ''us'' and ''our'' refer to EPA.

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I. The State's Submittal

A. What Rule Did the State Submit?

Table 1 lists the rule addressed by this proposal with the dates that it was adopted by the local air agency and submitted by the California Air Resources Board (CARB).

TABLE 1.—SUBMITTED RULES

Local agency	Rule #	Rule title	Adopted	Submitted
SJVUAPCD	4354	Glass Melting Furnaces	02/21/02	03/05/02

On March 27, 2002, this rule submittal was found to meet the completeness criteria in 40 CFR part 51, appendix V, which must be met before formal EPA review.

B. Are There Other Version of This Rule?

On September 1, 2000, EPA published a limited approval and limited disapproval of a version of rule 4354 that was submitted to EPA on September 29, 1998.

C. What Is the Purpose of the Submitted Rule?

The EPA published a limited approval and limited disapproval of a previous version of this rule because some rule provisions conflicted with section 110 and part D of the Clean Air Act. Those provisions included the following:

1. Section 3.17.3 and 4.2 allowed unlimited exemption periods as long as the furnace operated below 60% capacity.
2. The equation to calculate the Tier 1 emission limit in section 5.3 needed to be clarified.
3. Section 7.1 did not specify a final date for major NO_X sources to adopt CEMS or alternate continuous monitoring methods to prevent avoidance of continuous monitoring by running forever without an official ''rebuild''.
4. Section 7.2.3 did not specify a final date for facilities to achieve full Tier 2 compliance.
5. Section 9.0, 9.4, and 9.7 provided an Alternate Emission Control Plan (AECP) which was not consistent with the EPA Emissions Trading Policy Statement (ETPS), the Economic Incentive Program Rules (EIP), and EPA policies regarding equivalency provisions.

The TSD has more information about this rule.

II. EPA's Evaluation and Action

A. How Is EPA Evaluating This Rule?

Generally, SIP rules must be enforceable (*see* section 110(a) of the Act), must require Reasonably Available Control Technology (RACT) for major sources in nonattainment areas (*see* section 182(a)(2)(A) and 182(f)), and must not relax existing requirements (*see* sections 110(l) and 193). The SJVUAPCD regulates an ozone nonattainment area (*see* 40 CFR part 81), so Rule 4354 must fulfill RACT.

Guidance and policy documents that we used to help evaluate the criteria consistently include the following:

1. Issues Relating to VOC Regulation, Cut points, Deficiencies, and Deviations (the ''Blue Book''), U.S. EPA, May 25, 1988.
2. Guidance Document for Correcting VOC Rule Deficiencies: U.S. EPA Region IX and California Air Resources Board, April 1991.
3. State Implementation Plans; Nitrogen Oxides Supplement to the General Preamble for the Implementation of Title I of the Clean Air Act Amendment of 1990 (the ''NO_X Supplement to the General Preamble''), U.S. EPA, 57 FR 55620, November 25, 1992.
4. Requirements for Preparation, Adoption, and Submittal of Implementation Plans, U.S. EPA, 40 CFR part 51.
5. State Implementation Plans for National Primary and Secondary Ambient Air Quality Standards, Section 110 of the Clean Air Act, and Plan Requirements for Nonattainment Areas, Title I Part D of the Clean Air Act.
6. State of California, Air Resources Board, Suggested Control Measure for the Control of Oxides of Nitrogen from Glass Melting Furnaces, September 5, 1980.
7. Cost Effective Nitrogen Oxides (NO_X) Reasonably Available Control Technology (RACT), U.S. EPA Office of Air Quality Planning and Standards, March 16, 1994.
8. State Implementation Plans (SIPS): Policy Regarding Excess Emissions During Malfunctions, Startup, and Shutdown, dated September 20, 1999.

B. Does This Rule Meet the Evaluation Criteria?

We believe this rule is consistent with the relevant policy and guidance regarding enforceability, RACT, and SIP relaxations. The TSD has more information on our evaluation and how the previously identified deficiencies have been corrected.

C. EPA Recommendations To Further Improve This Rule

None.

D. Public Comment and Final Action

Because EPA believes the submitted rule fulfills all relevant requirements, we are proposing to fully approve it as described in section 110(k)(3) of the Act. We will accept comments from the public on this proposal for the next 30 days. Unless we receive convincing new information during the comment period, we intend to publish a final approval action that will incorporate this rule into the federally enforceable SIP.

III. Background Information

Why Was This Rule Submitted?

NO_X helps produce ground-level ozone, smog and particulate matter, which harm human health and the environment. Section 110(a) of the CAA requires states to submit regulations that control NO_X emissions. Table 2 lists some of the national milestones leading to the submittal of this local agency NO_X rule.

TABLE 2.—OZONE NONATTAINMENT MILESTONES

Date	Event
March 3, 1978	EPA promulgated a list of ozone nonattainment areas under the Clean Air Act as amended in 1977. 43 FR 8964; 40 CFR 81.305.
May 26, 1988	EPA notified Governors that parts of their SIPs were inadequate to attain and maintain the ozone standard and requested that they correct the deficiencies (EPA's SIP-Call). See section 110(a)(2)(H) of the pre-amended Act.
November 15, 1990	Clean Air Act Amendments of 1990 were enacted. Pub. L. 101–549, 104 Stat. 2399, codified at 42 U.S.C. 7401–7671q.
May 15, 1991	Section 182(a)(2)(A) requires that ozone nonattainment areas correct deficient RACT rules by this date.

IV. Administrative Requirements

Under Executive Order 12866 (58 FR 51735, October 4, 1993), this proposed action is not a ''significant regulatory action'' and therefore is not subject to review by the Office of Management and Budget. For this reason, this proposed action is also not subject to Executive Order 13211, ''Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution, or Use'' (66 FR 28355, May 22, 2001). This proposed action merely approves state law as meeting Federal requirements and imposes no additional requirements beyond those imposed by state law. Accordingly, the Administrator certifies that this proposed rule will not have a significant economic impact on a substantial number of small entities under the Regulatory Flexibility Act (5 U.S.C. 601 *et seq.*). Because this rule proposes to approve pre-existing requirements under state law and does not impose any additional enforceable duty beyond that required by state law, it does not contain any unfunded mandate or significantly or uniquely affect small governments, as described in the Unfunded Mandates Reform Act of 1995 (Pub. L. 104–4).

This rule also does not have tribal implications because it will not have a substantial direct effect on one or more Indian tribes, on the relationship between the Federal Government and Indian tribes, or on the distribution of power and responsibilities between the Federal Government and Indian tribes, as specified by Executive Order 13175 (65 FR 67249, November 9, 2000). This action also does not have Federalism implications because it does not have substantial direct effects on the States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government, as specified in Executive Order 13132 (64 FR 43255, August 10, 1999). This action merely proposes to approve a state rule implementing a Federal standard, and does not alter the relationship or the distribution of power and responsibilities established in the Clean Air Act. This proposed rule also is not subject to Executive Order 13045, ''Protection of Children from Environmental Health Risks and Safety Risks'' (62 FR 19885, April 23, 1997), because it is not economically significant.

In reviewing SIP submissions, EPA's role is to approve state choices, provided that they meet the criteria of the Clean Air Act. In this context, in the absence of a prior existing requirement for the State to use voluntary consensus standards (VCS), EPA has no authority to disapprove a SIP submission for failure to use VCS. It would thus be inconsistent with applicable law for EPA, when it reviews a SIP submission, to use VCS in place of a SIP submission that otherwise satisfies the provisions of the Clean Air Act. Thus, the requirements of section 12(d) of the National Technology Transfer and Advancement Act of 1995 (15 U.S.C. 272 note) do not apply. This proposed rule does not impose an information collection burden under the provisions of the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 *et seq.*).

List of Subjects in 40 CFR Part 52

Environmental protection, Air pollution control, Intergovernmental relations, Nitrogen dioxide, Ozone, Reporting and recordkeeping requirements.

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

Dated: April 10, 2002.

Nora L. McGee,

Acting Regional Administrator, Region IX.

[FR Doc. 02–9910 Filed 4–23–02; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 52

[MO 155–1155; FRL–7175–2]

Approval and Promulgation of Implementation Plans; State of Missouri

AGENCY: Environmental Protection Agency (EPA).

ACTION: Proposed rule.

SUMMARY: EPA proposes to approve the State Implementation Plan (SIP) revision submitted by the state of Missouri for the purpose of controlling volatile organic compound (VOC) emissions from stationary and area sources in Clay, Platte, and Jackson Counties in the Kansas City, Missouri, area. This action also proposes to provide full approval of the revised maintenance plan and rescinds the prior conditional approval of the revised maintenance plan. In the final rules section of the **Federal Register**, EPA is approving the State's SIP revision and providing full approval of the revised maintenance plan as a direct final rule without prior proposal because the Agency views this as a noncontroversial revision amendment and anticipates no relevant adverse comments to this action. A detailed rationale for the approval is set forth in the direct final rule. If no relevant adverse comments are received in response to this action, no further activity is contemplated in relation to this action. If EPA receives relevant adverse comments, the direct final rule will be withdrawn and all public comments received will be addressed in a subsequent final rule based on this proposed action. EPA will not institute a second comment period on this action. Any parties interested in commenting on this action should do so at this time. Please note that if EPA receives adverse comment on an amendment, paragraph, or section of this rule and if that provision is severed from the remainder of the rule, EPA may adopt as final those provisions of the rule that are not the subject of an adverse comment.

DATES: Comments on this proposed action must be received in writing by May 24, 2002.

ADDRESSES: Comments may be mailed to Leland Daniels, Environmental Protection Agency, Air Planning and Development Branch, 901 North 5th Street, Kansas City, Kansas 66101.

FOR FURTHER INFORMATION CONTACT: Leland Daniels at (913) 551–7651.

SUPPLEMENTARY INFORMATION: See the information provided in the direct final rule which is located in the rules section of the **Federal Register**.

Dated: April 11, 2002.

James B. Gulliford,

Regional Administrator, Region 7.

[FR Doc. 02–9912 Filed 4–23–02; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 271

[FRL–7173–8]

Hazardous Waste Management Program: Final Authorization of State Hazardous Waste Management Program Revisions for State of Arkansas

AGENCY: Environmental Protection Agency (EPA).

ACTION: Proposed rule and request for comment.

SUMMARY: The EPA (also, ''the Agency'' in this preamble) is proposing to grant final authorization to the hazardous waste program revisions submitted by the State of Arkansas Department of Environmental Quality for its hazardous waste program revisions, specifically, revisions needed to meet the Resource Conservation and Recovery Act Clusters

III through IX, which contain Federal rules promulgated between July 1, 1992 to June 30, 1999 and a portion of RCRA Cluster X promulgated July 6, 1999.

The State of Arkansas is using Arkansas Code Annotated 8–7–508(a)(1) of the Remedial Action Trust Fund Act of 1985 (RATFA) to establish equivalent authorities to RCRA sections 3004(v) and (u). EPA would like to receive specific comments from the public on this approach. This approach is discussed further in the **Federal Register** notice, ''Immediate Final Rule'' that EPA has determined to be Broader in Scope. Also see Arkansas' Independent Counsel Statement on pages 12 through 13 of the State of Arkansas Consolidated Attorney General Statement for RCRA Clusters III through IX and portion of RCRA Cluster X.

In the ''Rules and Regulations'' section of this **Federal Register** (FR), EPA is authorizing the State's program revisions as an immediate final rule without prior proposal because the EPA views this action as noncontroversial and anticipates no adverse comments. The Agency has explained the reasons for this authorization in the preamble to the immediate final rule. If EPA does not receive adverse written comments, the immediate final rule will become effective and the Agency will not take further action on this proposal. If EPA receives adverse written comments, a second **Federal Register** document will be published before the time the immediate final rule takes effect. The second document may withdraw the immediate final rule or identify the issues raised, respond to the comments and affirm that the immediate final rule will take effect as scheduled. Any parties interested in commenting on this action should do so at this time.

DATES: Written comments must be received on or before May 24, 2002.

ADDRESSES: Mail written comments to Alima Patterson, Region 6, Regional Authorization Coordinator, Grants and Authorization Section (6PD–G), Multimedia Planning and Permitting Division, at the address shown below. You can examine copies of the materials submitted by the State of Arkansas during normal business hours at the following locations: EPA Region 6, 1445 Ross Avenue, Dallas, Texas 75202–2733, (214) 665–6444; or Arkansas Department of Environmental Quality, 8101 Interstate 30, Little Rock, Arkansas 72219, (501) 682–0876.

FOR FURTHER INFORMATION CONTACT: Alima Patterson (214) 665–8533.

SUPPLEMENTARY INFORMATION: For additional information, please see the immediate final rule published in the ''Rules and Regulations'' section of this **Federal Register**.

Dated: April 4, 2002.

Gregg A. Cooke,

Regional Administrator, Region 6.

[FR Doc. 02–10039 Filed 4–23–02; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 432

[FRL–7175–5]

RIN 2040–AD56

Effluent Limitations Guidelines and New Source Performance Standards for the Meat and Poultry Products Point Source Category

AGENCY: Environmental Protection Agency (EPA).

ACTION: Extension of comment period on proposed rule and clarification on public meetings.

SUMMARY: On February 25, 2002 (67 FR 8582), EPA proposed effluent limitations guidelines for wastewater discharges associated with the operation of new and existing meat and poultry products facilities. The original comment period was 60 days, ending on April 26, 2002. The comment period will now end 60 days later on June 25, 2002. In the preamble to the proposal, EPA incorrectly stated that we would be holding two ''public hearings'' on March 14, 2002 and April 9, 2002, whereas EPA intended only to hold public meetings on those dates. EPA is providing this extension of the comment period in part to ensure that anyone who expected to provide their comments orally at a public hearing, has an ample opportunity to provide EPA with written comments. EPA regrets any inconvenience or confusion this mistake in terminology has caused the public.

DATES: Comments on the proposed rule will be accepted through June 25, 2002.

ADDRESSES: Submit written comments to Ms. Samantha Lewis, Office of Water, Engineering and Analysis Division (4303T), U.S. EPA, 1200 Pennsylvania Avenue, NW, Washington, DC 20460. For hand-deliveries or Federal Express, please send comments to Ms. Samantha Lewis, Office of Water, Engineering and Analysis Division, Room 6233L, 1301 Constitution Avenue, NW, 6th Floor, Connecting Wing, Washington, DC 20460. Comments may be sent by email to the following email address: ''meatproducts.rule@epa.gov''. EPA requests an original and three copies of your comments and enclosures (including references). Commenters who want EPA to acknowledge receipt of their comments should enclose a self-addressed, stamped envelope. No facsimiles (faxes) will be accepted.

FOR FURTHER INFORMATION CONTACT: Ms. Samantha Lewis at (202) 566–1058.

Dated: April 17, 2002.

Diane C. Regas,

Acting Assistant Administrator for Water.

[FR Doc. 02–10040 Filed 4–23–02; 8:45 am]

BILLING CODE 6560–50–P

Notices

Federal Register

Vol. 67, No. 79

Wednesday, April 24, 2002

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

Commodity Credit Corporation

Farm Service Agency

Notice of Intent To Prepare a Programmatic Environmental Impact Statement for the Conservation Reserve Program, Conservation Reserve Enhancement Program and the Emergency Conservation Program and Hold Public Scoping Meetings

AGENCY: Commodity Credit Corporation; Farm Service Agency, USDA.

ACTION: Notice of Intent to Prepare a Programmatic Environmental Impact Statement.

SUMMARY: The Commodity Credit Corporation (CCC) announces its intention to prepare a programmatic environmental impact statement (PEIS) for the Conservation Reserve Program (CRP) and Emergency Conservation Program (ECP). The Draft PEIS will assess the potential environmental impacts of alternatives for administration of the CRP and ECP. Under the CRP, the PEIS will address general sign-up, continuous sign-up, and the Conservation Reserve Enhancement Program (CREP).

The USDA Farm Service Agency (FSA) administers these programs on behalf of the CCC and is now conducting a comprehensive review of them. New regulations may be needed to implement new farm legislation. Also, the PEIS can help review current policies and achievements. FSA hopes to analyze a range of CRP/CREP and ECP program alternatives. The Draft PEIS also provides a means for the public to have opportunities to voice any concerns they may have about the programs, and any ideas for improving them. This Notice of Intent informs the public of the proposal, announces the dates, times, and places for public scoping meetings, solicits public comment, and describes in general the preliminary Draft PEIS proposed action and alternatives.

DATES: To ensure that the full range of issues and alternatives related to the CRP/CREP and ECP are addressed, FSA invites comments on the scope of this proposed Draft PEIS. Comments should be submitted by close of business on May 30, 2002, to ensure consideration. Comments submitted after this date will be considered to the extent possible. *See* the **SUPPLEMENTARY INFORMATION** section for the public scoping meeting dates and locations.

ADDRESSES: Written comments on the scope of the draft PEIS and requests for copies of draft PEIS information packages should be directed to CRP PEIS, Post Office Box 6830, Falls Church, Virginia 22046, *CRP@mangi.com* or telephone (toll free) 1–877–271–3842. *See* the **SUPPLEMENTARY INFORMATION** section for public scoping meetings dates and locations.

FOR FURTHER INFORMATION CONTACT: Don Steck, USDA/FSA/CEPD/Stop 0513, 1400 Independence Ave., SW., Washington, DC 20250–0513, (202) 690–0224, or e-mail at: *don_steck@wdc.usda.gov* or *CRP@mangi.com.* More detailed information on these programs may also be obtained from the FSA Worldwide Web site at: *http://www.fsa.usda.gov/pas/default.asp* (general); *http://www.fsa.usda.gov/dafp/cepd/default.htm* (CRP, CREP and ECP).

SUPPLEMENTARY INFORMATION: The PEIS being prepared on the CRP and ECP will seek to provide FSA decision makers and the public with an analysis that evaluates program effects in many appropriate contexts, describes the intensity of adverse as well as beneficial impacts, and addresses cumulative impacts of the programs being analyzed.

The Food Security Act of 1985, as amended (16 U.S.C. 3831–3836), authorizes the CRP. The program is also governed by the regulations published in 7 CFR part 1410. The CRP is administered by the CCC through the FSA. The purpose of the CRP is to cost-effectively assist farm owners and operators in conserving and improving soil, water, air and wildlife resources. This is accomplished by converting highly-erodible and other environmentally-sensitive acreage normally devoted to the production of agricultural commodities to a long-term resource-conserving cover. CRP participants enter into contracts for 10–15 years in exchange for annual rental payments, cost-share and technical assistance for implementing approved conservation practices.

The CREP is a joint, State/Tribal/Federal land retirement conservation program under the CRP that is targeted to address State, tribal, and nationally significant agriculture-related environmental effects. The primary objectives of CREP are to coordinate Federal and non-federal resources to address specific conservation objectives of a State or tribe and the nation in a cost-effective manner, and to improve water quality, air quality, erosion control, and wildlife habitat related to agricultural use in specific geographic areas.

Title IV of the Agricultural Credit Act of 1978, as amended (16 U.S.C. 2201–2205) authorized the ECP, which provides emergency funding for farmers and ranchers to rehabilitate farmland damaged by wind erosion, floods, hurricanes, or other natural disasters, and for carrying out emergency water conservation measures during periods of severe drought. Conservation problems existing prior to the disaster involved are not eligible for cost-sharing assistance. ECP is administered by the Farm Service Agency State and county committees.

The Draft PEIS will help to review potential environmental impacts resulting from these programs and the results will be used in implementing and approving projects for CRP/CREP and ECP funding. The Record of Decision resulting from the final PEIS will serve as guidance to FSA staff. The Draft PEIS will likely use scenarios to evaluate the environmental and socioeconomic impacts of CRP/CREP and ECP conservation practices in relation to their effectiveness in achieving environmental goals and minimizing any attendant potentially adverse effects. In parallel with preparation of the draft PEIS, FSA will revise the administrative rules for the CRP/CREP and ECP and incorporate any changes that may result from the new Farm Bill.

Public Participation

The public is urged to participate in helping to define the scope of the

proposed Programmatic Environmental Impact Statement. In addition to allowing the opportunity to comment via a toll-free telephone line, mail, and e-mail at the addresses listed previously, FSA plans to hold six public scoping meetings to provide information and opportunities for discussing the issues and alternatives to be covered in the Draft PEIS and to receive oral and written comments. Each scoping meeting will be conducted in the evening, from 7:00 p.m. to 9:00 p.m., to allow the greatest opportunity for public input.

The meetings will be held on the following dates in these locations:

- May 7, 2002 7–9 p.m.; Chesapeake College Auditorium; 1000 College Drive; Wye Mills, Maryland 21679
- May 9, 2002 7–9 p.m.; Mobile County Cooperative Extension Auditorium; 1070 Schiller Road North; Mobile, Alabama 36608
- May 14, 2002 7–9 p.m.; Ambassador Hotel; 3100 I–40 West; Amarillo, Texas 79102
- May 16, 2002 7–9 p.m.; Mt. Hood Community College; 2600 SE Stark St.; Portland, Oregon 90730
- May 21, 2002 7–9 p.m.; Holiday Inn; 200 McDonald Dr.; Lawrence, Kansas 66044
- May 23, 2002 7–9 p.m.; Northwest Technical College; 1900 28th Ave. S; Moorehead, Minnesota 56560

Description of Preliminary PEIS Alternatives

FSA has developed a set of preliminary alternatives to be studied in the draft PEIS to initiate the process. This is not a final list of alternatives. The alternatives will be amended, as appropriate, based on input by the public and agencies during the public scoping process.

CRP/CREP Alternatives

New Farm Bill changes

The proposed action is for FSA to implement changes in CRP/CREP administration based on the requirements of new farm legislation should the current Farm Bill under consideration produce new provisions dealing with these programs. Some of the changes being considered in Congress currently include increasing the enrollment cap for CRP/CREP acreage and changing the eligibility and cropping history requirements.

No Program (baseline)

This alternative would be used as an analytical device to establish a baseline upon which to evaluate the other alternatives.

No Action (Current program)

To continue FSA administration of the CRP/CREP as they are now carried out. Under this alternative, FSA will continue administration of the CRP/CREP with no substantive changes.

Program Realignment

Under this alternative FSA would alter the mix of program goals and change acreage allocations to CREP, continuous sign-up and general CRP.

ECP Alternatives

Program Modifications

The proposed action would provide for consolidation of possible program changes including changes to allow for a consistent cost-share rate, do away with the tiered level of cost sharing currently in use, and provide for a higher level of cost share for limited resource producers.

No Action

Under this alternative, ECP would continue as currently administered with no substantive changes.

No Program

This program would be used as an analytical device to establish a baseline upon which to evaluate the other alternative.

Signed in Washington, DC, on April 22, 2002.

James R. Little,

Administrator, Farm Service Agency, and Executive Vice President, Commodity Credit Corporation.

[FR Doc. 02–10165 Filed 4–22–02; 12:45 pm]

BILLING CODE 3410–05–P

DEPARTMENT OF AGRICULTURE

Economic Research Service

Notice of Intent of Seek Approval To Collect Information

AGENCY: Economic Research Service, USDA.

ACTION: Notice and request for comments.

SUMMARY: In accordance with the Paperwork Reduction Act of 1995 (Pub. L. 104–13) and Office of Management and Budget (OMB) regulations at 5 CFR part 1320 (60 FR 44978, August 29, 1995), this notice announces the Economic Research Service's (ERS) intention to request renewal of approval for annual information collection on supplemental food security questions in the Current Population Survey, commencing with the December 2002 survey. These data will be used: to monitor household level food security, food insecurity, and hunger in the United States; to assess food security and changes in food security for population subgroups; to assess the need for, and performance of, domestic food assistance programs; to improve the measurement of food security; and to provide information to aid in public policy decision making.

DATES: Comments on this notice must be received by June 28, 2002 to be assured of consideration.

ADDRESSES: Address all comments concerning this notice to Mark Nord, Team Leader for Food Stamp and Food Security Research, Food and Rural Economics Division, Economic Research Service, U.S. Department of Agriculture, 1800 M Street NW Room N–2078, Washington, DC 20036–5831. Tel. 202–694–5433. Submit electronic comments to *marknord@ers.usda.gov*.

SUPPLEMENTARY INFORMATION:

Title: Application for Annual Food Security Supplement to the Current Population Survey, beginning in December 2002.

Type of Request: Approval to collect information on household food insecurity.

OMB Number: New number not yet assigned. Number for previous collection, 0536–0043.

Expiration Data: N/A

Abstract: The U.S. Census Bureau will supplement the December Current Population Survey, beginning in 2002, with questions regarding household food shopping, food sufficiency, coping mechanisms and food scarcity, and concern about food sufficiency. A similar supplement has been appended to the CPS annually since 1995. The last collection was in December 2001. Copies of the information to be collected can be obtained from the address in the preamble.

ERS is responsible for conducting studies and evaluations of the Nation's food assistance programs that are administered by the Food and Nutrition Service (FNS), U. S. Department of Agriculture. The Department spends about $38 billion each year to ensure access to nutritious, healthful diets for all Americans. The Food and Nutrition Service administers the 15 food assistance programs of the USDA including Food Stamps, Child Nutrition, and WIC programs. These programs, which serve 1 in 6 Americans, represent our Nation's commitment to the principle that no one in our country should lack the food needed for an active healthy life. They provide a safety net to people in need. The programs' goals are to provide needy persons with

access to a more nutritious diet, to improve the eating habits of the Nation's children, and to help America's farmers by providing an outlet for the distribution of food purchased under farmer assistance authorities.

These data will be used to monitor the prevalence of food security, food insecurity, and hunger among the Nation's households. The prevalence of these conditions as well as year-to-year trends in their prevalence will be estimated at the national level and for population subgroups. The data will also be used to monitor the amounts that households spend for food and their use of community food pantries and emergency kitchens. These statistics along with research based on the data will be used to identify the causes and consequences of food insecurity, and to assess the need for, and performance of, domestic food assistance programs. The data will also be used to improve the measurement of food security and to develop measures of additional aspects and dimensions of food security. This consistent measurement of the extent and severity of food insecurity will aid in policy decision making. The supplemental survey instrument was developed in conjunction with food security experts nationwide as well as survey method experts within the Census Bureau. This supplemental information will be collected by both personal visit and telephone interviews in conjunction with the regular monthly CPS interviewing. All interviews, whether by personal visit or by telephone, are conducted using computers.

Estimate of Burden: Public reporting burden for this data collection is estimated to average 7.5 minutes for each household that responds to the laborforce portion of the CPS.

Respondents: Individuals or households.

Estimated Number of Respondents: 57,000.

Estimated Total Annual Burden on Respondents: 7,126 hours.

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 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; (d) ways to minimize the burden of the collection of information on those who are to respond, including through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology. Comments should be sent to the address in the preamble. 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: March 14, 2002.

Susan Offutt,

Administrator, Economic Research Service.

[FR Doc. 02–9967 Filed 4–23–02; 8:45 am]

BILLING CODE 3410–18–P

DEPARTMENT OF AGRICULTURE

Forest Service

Trinity County Resource Advisory Committee (RAC); Meeting

AGENCY: Forest Service, USDA.

ACTION: Notice of meeting.

SUMMARY: The Trinity County Resource Advisory Committee (RAC) will meet on April 29, 2002, Weaverville, Calif. The purpose of the meeting is voting on road restoration and vegetation reduction projects; forming subcommittees to address contracting, grants and agreements; and discussing the community model forest concept.

DATES: The meeting will be held on April 29, 2002 from 6:30 to 8:30 p.m.

ADDRESSES: The meeting will be held at the Trinity County Office of Education conference room, 201 Memorial Drive, Weaverville, Calif.

FOR FURTHER INFORMATION CONTACT: Joyce Andersen, Designated Federal Official, USDA, Shasta-Trinity National Forest, P.O. Box 1190, Weaverville, CA 96093. Phone: (530) 623–2121. Email: *jandersen@fs.fed.us.*

SUPPLEMENTARY INFORMATION: The meeting is open to the public. Public input opportunity will be provided and individuals will have the opportunity to address the committee at that time.

Dated: April 16, 2002.

James M. Peña,

Deputy Forest Supervisor.

[FR Doc. 02–9968 Filed 4–23–02; 8:45 am]

BILLING CODE 3410–11–M

DEPARTMENT OF AGRICULTURE

Forest Service

Madera County Resource Advisory Committee

AGENCY: Forest Service, USDA.

ACTION: Notice of Resource Advisory Committee Meeting.

SUMMARY: Pursuant to the authorities in the Federal Advisory Committee Act of 1972 (Pub. L. 92–463) and under the secure Rural Schools and Community Self-Determination Act of 2000 (Public Law 106–393) the Sierra National Forest's Resource Advisory Committee for Madera County will meet on Monday, May 20, 2002. The Madera Resource Advisory Committee will meet at the Yosemite Sierra Visitor Bureau, 40637 Highway 41, Oakhurst, CA 93644. The purpose of the meeting is to review current project proposal applications.

DATES: The Madera Resource Advisory Committee meeting will be held Monday, May 20, 2002. The meeting will be held from 7 p.m. to 9 p.m.

ADDRESSES: The Madera County RAC meeting will be held at the Yosemite Sierra Visitor Bureau, 40637 Highway 41, Oakhurst, CA 93644.

FOR FURTHER INFORMATION CONTACT: Dave Martin, U.S.D.A., Sierra National Forest, 57003 Road 225, North Fork, CA, 93643 (559) 877–2218 ext. 3100; e-mail: *dmartin05@fs.fed.us.*

SUPPLEMENTARY INFORMATION: Agenda items to be covered include: (1) Review current project proposal applications, (2) public comments. The meeting is open to the public. Public input opportunity will be provided and individuals will have the opportunity to address the Committee at that time.

Dated: April 17, 2002.

David W. Martin,

District Ranger.

[FR Doc. 02–9981 Filed 4–23–02; 8:45 am]

BILLING CODE 3410–11–M

DEPARTMENT OF COMMERCE

Submission for OMB Review: Comment Request

DOC has submitted to the Office of Management and Budget (OMB) for clearance of the following proposal for collection of information under the provisions of the Paperwork Reduction Act of 1995, Public Law 104–13.

International Trade Administration

Title: Application for an Export Trade Certificate of Review.

Agency Form Number: ITA–4093P.

OMB Number: 0625–0125.

Type of Request: Regular Submission.

Burden: 960 hours.

Number of Respondents: 30.

Avg. Hours per Response: 32 hours.

Needs and Uses: Title III of the Export Trading Company Act of 1982 (Pub.L.

97–290, 96 Stat. 1233–1247), requires the Department of Commerce to establish a program to evaluate applications for an Export Trade Certificate of Review (antitrust preclearance for joint export related activities), and with the concurrence of the Department of Justice, issue such certificates where the requirements of the Act are satisfied. The Act requires that Commerce and Justice conduct economic and legal antitrust analyses prior to the issuance of a certificate. The collection of information is necessary to conduct the required economic and legal antitrust analyses. Without the information, there could be no basis upon which a certificate could be issued.

In the Department of Commerce, the economic and legal analyses are performed by the Office of Export Trading Company Affairs and the Office of General Counsel, respectively. The Department of Justice analyses will be conducted by its Antitrust Division. The purpose of such analyses is to make a determination as to whether or not to issue an Export Trade Certificate of Review.

A certificate provides its holder and the members named in the certificate (a) immunity from government actions under state and Federal antitrust laws for the export conduct specified in the certificate; (b) some protection from frivolous private suits by limiting their liability in private actions from treble to actual damages when the challenged activities are covered by an Export Certificate of Review. Title III was enacted to reduce uncertainty regarding the application of U.S. antitrust laws to export activities—especially those involving actions by domestic competitors. Application for an export trade certificate of review is voluntary.

Affected Public: Business or other for-profit; not-for-profit institutions and State, local or Tribal Government.

Frequency: On occasion.

Respondent's Obligation: Required to obtain or retain a benefit, voluntary.

OMB Desk Officer: David Rostker, (202) 395–3897.

Copies of the above information collection can be obtained by calling or writing Madeleine Clayton, Departmental Paperwork Clearance Officer, (202) 482–3129, Department of Commerce, Room 6608, 14th & Constitution Avenue, NW, Washington, DC 20230 or via the Internet at *MClayton@doc.gov.*

Written comments and recommendations for the proposed information collection should be sent to David Rostker, OMB Desk Officer, Room 10202, New Executive Office Building, Washington, DC 20503 within 30 days of the publication of this notice in the **Federal Register**.

Dated: April 18, 2002.

Madeleine Clayton,

Department Paperwork Clearance Officer, Office of the Chief Information Officer.

[FR Doc. 02–9978 Filed 4–23–02; 8:45 am]

BILLING CODE 3510–DR–P

DEPARTMENT OF COMMERCE

Census Bureau

Monthly Wholesale Trade Survey

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 June 24, 20002.

ADDRESSES: Direct all written comments to Madeleine Clayton, Departmental Paperwork Clearance Officer, Department of Commerce, Room 6608, 14th and Constitution Avenue, NW, Washington, DC 20230 (or via the Internet at *mclayton@doc.gov*).

FOR FURTHER INFORMATION CONTACT: Requests for additional information or copies of the information collection instrument(s) and instructions should be directed to Scott Scheleur, U.S. Census Bureau, Room 2626–FOB 3, Washington, DC 20223–6500, at (301) 457–2713.

SUPPLEMENTARY INFORMATION:

I. Abstract

The Monthly Wholesale Trade Survey provides the only continuous measure of monthly sales, end-of-month inventories, method of inventory valuation, and inventories/sales ratios in the United States by selected kinds of business for merchant wholesalers. The Bureau of Economic Analysis (BEA) uses this information to improve the inventory valuation adjustments applied to estimates of the Gross Domestic Product (GDP). The Bureau of Labor Statistics (BLS) uses the data as input to their Producer Price Indexes and in developing productivity measurements.

Estimates produced from the Monthly Wholesale Trade Survey are based on a probability sample and are published on the North American Industry Classification System (NAICS) basis. The sample design consists of small, medium, and large cases requested to report sales and inventories each month. The sample, consisting of about 3,800 wholesale businesses, is drawn from the Business Register, which contains all Employer Identification Numbers (EINs) and listed establishment locations. The sample is updated quarterly to reflect employer business ''births'' and ''deaths''; adding new employer businesses identified in the Business and Professional Classification Survey and deleting firms and EINs when it is determined they are no longer active.

The Monthly Wholesale Trade Survey will continue to generate its monthly report form through a print-on demand system. This system allows us to tailor the survey instrument to a specific industry. For example, it will print an additional instruction for a particular NAICS code. This system also reduces the time and cost of preparing mailout packages that contain unique variable data, while improving the look and quality of the products being produced.

II. Method of Collection

We collect this information by mail, fax, and telephone follow-up.

III. Data

OMB Number: 0607–0190.

Form Number: SM–42 (00).

Type of Review: Regular submission.

Affected Public: Wholesale firms in the United States.

Estimated Number of Respondents: 3,800.

Estimated Time Per Response: 7 minutes.

Estimated Total Annual Burden Hours: 5,320.

Estimated Total Annual Cost: The cost to the respondents for fiscal year 2003 is estimated to be $111,241 based on the annual response burden of 5,320 hours and an hourly salary rate of $20.91 to complete the form.

Respondent's Obligation: The collection of information is voluntary.

Legal Authority: Title 13, United States Code, 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: April 18, 2002.

Madeleine Clayton,

Departmental Paperwork Clearance Officer, Office of the Chief Information Officer.

[FR Doc. 02–9977 Filed 4–23–02; 8:45 am]

BILLING CODE 3510–07–P

DEPARTMENT OF COMMERCE

Foreign-Trade Zones Board

[Docket 20–2002]

Foreign-Trade Zone 191—Palmdale, California Area; Application for Expansion

An application has been submitted to the Foreign-Trade Zones (FTZ) Board (the Board) by the City of Palmdale, California, grantee of Foreign-Trade Zone 191, requesting authority to expand FTZ 191, in the Palmdale, California, area, adjacent to the Los Angeles-Long Beach Customs port of entry. The application was submitted pursuant to the provisions of 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 April 16, 2002.

FTZ 191 was approved on January 15, 1993 (Board Order 628, 58 FR 6614, 2/1/93). The zone project currently consists of the following sites located within two miles of the Palmdale Regional Airport in Palmdale: *Site 1* (800 acres)—3 parcels within the 1,297 acre Lockheed Martin Aeronautics Industrial Park; *Site 2* (87 acres)—Antelope Valley Business Park; *Site 3* (30 acres)—Freeway Business Center; *Site 4* (70 acres)—Palmdale Trade & Commerce Center; *Site 5* (120 acres)—Fairway Business Park; *Site 6* (140 acres)—Sierra Gateway Center; *Site 7* (15 acres)—Pacific Business Park; *Site 8* (20 acres)—Winnell Industrial Park; and, *Site 9* (33 acres)—Park One Industrial Center.

The applicant is now requesting authority to expand the general-purpose zone to include an additional site (40 acres) in California City: *Proposed Site 10* (40 acres)—California City Airport Industrial Park, located on Lindbergh Boulevard between Gnatt Boulevard and Curtiss Place in California City, approximately 40 miles northeast of Palmdale. The site is owned by the California City Redevelopment Agency. No specific manufacturing authority is being requested at this time. Such requests would be made to the Board on a case-by-case basis.

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 3 copies) shall be addressed to the Board's Executive Secretary at one of the addresses below:

1. *Submissions via Express/Package Delivery Services:* Foreign-Trade Zones Board, U.S. Department of Commerce, Franklin Court Building—Suite 4100W, 1099—14th Street NW, Washington, DC 20005; or

2. *Submissions via the U.S. Postal Service:* Foreign-Trade Zones Board, U.S. Department of Commerce, FCB—Suite 4100W, 1401 Constitution Avenue NW, Washington, DC 20230.

The closing period for their receipt is June 24, 2002. Rebuttal comments in response to material submitted during the foregoing period may be submitted during the subsequent 15-day period (to July 8, 2002).

A copy of the application and accompanying exhibits will be available for public inspection at the Office of the Foreign-Trade Zones Board's Executive Secretary at the first address listed above, and at the City of Palmdale's Office of Economic Development, 38250 N. Sierra Highway, Palmdale, California 93550.

Dated: April 17, 2002.

Dennis Puccinelli,

Executive Secretary.

[FR Doc. 02–10072 Filed 4–23–02; 8:45 am]

BILLING CODE 3510–DS–P

DEPARTMENT OF COMMERCE

Foreign-Trade Zones Board

[Order No. 1221]

Grant of Authority for Subzone Status; Motiva Enterprises, LLC (Petroleum Storage), Broward County, FL

Pursuant to its authority under the Foreign-Trade Zones Act of June 18, 1934, as amended (19 U.S.C. 81a-81u), the Foreign-Trade Zones Board (the Board) adopts the following Order:

WHEREAS, the Foreign-Trade Zones Act provides for " * * * the establishment * * * of foreign-trade zones in ports of entry of the United States, to expedite and encourage foreign commerce, and for other purposes," and authorizes the Foreign-Trade Zones Board to grant to qualified corporations the privilege of establishing foreign-trade zones in or adjacent to U.S. Customs ports of entry;

WHEREAS, the Board's regulations (15 CFR part 400) provide for the establishment of special-purpose subzones when existing zone facilities cannot serve the specific use involved, and when the activity results in a significant public benefit and is in the public interest;

WHEREAS, Broward County, Florida, grantee of Foreign-Trade Zone 25, has made application to the Board for authority to establish special-purpose subzone status at the petroleum product storage facilities of Motiva Enterprises, LLC (Motiva), located in the Broward County, Florida, area (FTZ Docket 29–2001, filed June 29, 2001).

WHEREAS, notice inviting public comment has been given in the **Federal Register** (66 FR 36249, 7/11/01); and,

WHEREAS, the Board adopts the findings and recommendations of the examiner's report, and finds that the requirements of the FTZ Act and the Board's regulations are satisfied, and that approval of the application is in the public interest;

Now, therefore, the Board hereby grants authority for subzone status at the petroleum storage facilities of Motiva Enterprises, L.L.C., located in the Broward County, Florida, area, (Subzone 25D), at the locations described in the application, subject to the FTZ Act and the Board's regulations, including § 400.28.

Signed at Washington, DC, this 15th day of April 2002.

Faryar Shirzad,

Assistant Secretary of Commerce for Import Administration, Alternate Chairman, Foreign-Trade Zones Board.

[FR Doc. 02–10078 Filed 4–23–02; 8:45 am]

BILLING CODE 3510–DS–P

DEPARTMENT OF COMMERCE

Foreign-Trade Zones Board

[Order No. 1222]

Approval for Expansion of Subzone 72B; Eli Lilly and Company Plants (Pharmaceuticals), Indianapolis, IN Area

Pursuant to its authority under the Foreign-Trade Zones Act of June 18, 1934, as amended (19 U.S.C. 81a–81u), the Foreign-Trade Zones Board (the Board) adopts the following Order:

Whereas, the Indianapolis Airport Authority, grantee of Foreign-Trade Zone 72, has requested authority on behalf of Eli Lilly and Company (Lilly) to add FTZ manufacturing capacity and to expand the scope of manufacturing authority under zone procedures at Subzone 72B at the Lilly plants in the Indianapolis, Indiana, area (FTZ Docket 37–2001, filed 9/13/2001);,

Whereas, notice inviting public comment has been given in the **Federal Register** (66 FR 48424, 9/20/01);,

Whereas, the Board adopts the findings and recommendation of the examiner's report, and finds that the requirements of the FTZ Act and Board's regulations are satisfied, and that the proposal is in the public interest;,

Now, therefore, the Board hereby orders:

The application to add capacity and to expand the scope of authority under zone procedures within Subzone 72B on behalf of Eli Lilly and Company, is approved, subject to the FTZ Act and the Board's regulations, including Section 400.28.

Signed at Washington, DC, this 15th day of April 2002.

Faryar Shirzad,

Assistant Secretary of Commerce for Import Administration, Alternate Chairman, Foreign-Trade Zones Board.

[FR Doc. 02–10079 Filed 4–23–02; 8:45 am]

BILLING CODE 3510–DS–P

DEPARTMENT OF COMMERCE

Foreign-Trade Zones Board

[Order No. 1226]

Expansion of Foreign-Trade Zone 15, Kansas City, Missouri

Pursuant to its authority under the Foreign-Trade Zones Act of June 18, 1934, as amended (19 U.S.C. 81a–81u), the Foreign-Trade Zones Board (the Board) adopts the following Order:

Whereas, the Greater Kansas City Foreign Trade Zone, Inc., grantee of Foreign-Trade Zone 15, submitted an application to the Board for authority to expand FTZ status at a site (50 acres) located in St. Joseph, Missouri (Site 9), adjacent to the Kansas City, Missouri, Customs port of entry (FTZ Docket 32–2001; filed 7/6/01);

Whereas, notice inviting public comment was given in the **Federal Register** (66 FR 37638, 7/19/01) and the application has been processed pursuant to the FTZ Act and the Board's regulations; and,

Whereas, the Board adopts the findings and recommendations of the examiner's report, and finds that the requirements of the FTZ Act and Board's regulations are satisfied, and that the proposal is in the public interest;

Now, Therefore, the Board hereby orders:

The application to expand FTZ 15 is approved, subject to the Act and the Board's regulations, including Section 400.28.

Signed at Washington, DC, this 15th day of April, 2002.

Faryar Shirzad,

Assistant Secretary of Commerce for Import Administration, Alternate Chairman, Foreign-Trade Zones Board.

[FR Doc. 02–10075 Filed 4–23–02; 8:45 am]

BILLING CODE 3510–DS–P

DEPARTMENT OF COMMERCE

Foreign-Trade Zones Board

[Order No. 1224]

Expansion of Foreign-Trade Zone 40, Cleveland, Ohio Area

Pursuant to its authority under the Foreign-Trade Zones Act of June 18, 1934, as amended (19 U.S.C. 81a–81u), the Foreign-Trade Zones Board (the Board) adopts the following Order:

Whereas, the Cleveland-Cuyahoga County Port Authority, grantee of Foreign-Trade Zone 40, submitted an application to the Board for authority to expand FTZ 40 to include a temporary site (Site 9) on a permanent basis and to include a new site in Ashtabula County at the Frane Properties Industrial Park (Site 10), within the Cleveland Customs port of entry area (FTZ Docket 33–2001; filed 7/24/01);

Whereas, notice inviting public comment was given in the **Federal Register** (66 FR 39729, 8/1/01) and the application has been processed pursuant to the FTZ Act and the Board's regulations; and,

Whereas, the Board adopts the findings and recommendations of the examiner's report, and finds that the requirements of the FTZ Act and the Board's regulations are satisfied, and that the proposal is in the public interest;

Now, Therefore, the Board hereby orders:

The application to expand FTZ 40 is approved, subject to the Act and the Board's regulations, including Section 400.28, and further subject to the Board's standard 2,000-acre activation limit for the overall zone project.

Signed at Washington, DC, this 15th day of April, 2002.

Faryar Shirzad,

Assistant Secretary of Commerce for Import Administration, Alternate Chairman, Foreign-Trade Zones Board.

[FR Doc. 02–10073 Filed 4–23–02; 8:45 am]

BILLING CODE 3510–DS–P

DEPARTMENT OF COMMERCE

Foreign-Trade Zones Board

[Order No. 1225]

Expansion of Foreign-Trade Zone 171, Liberty County, TX

Pursuant to its authority under the Foreign-Trade Zones Act of June 18, 1934, as amended (19 U.S.C. 81a–81u), the Foreign-Trade Zones Board (the Board) adopts the following Order:

Whereas, the Liberty County Economic Development Corporation, grantee of Foreign-Trade Zone 171, submitted an application to the Board for authority to expand FTZ status at a site (200 acres) within the Cedar Crossing Industrial Park, designated as Site 6, and to restore FTZ status to the Port of Liberty County Industrial Park (45 acres), designated as Site 2, located in Liberty County, Texas, adjacent to the Houston Customs port of entry (FTZ Docket 31–2001; filed 7/3/01);

Whereas, notice inviting public comment was given in the **Federal Register** (66 FR 36251, 7/11/01) and the application has been processed pursuant to the FTZ Act and the Board's regulations; and,

Whereas, the Board adopts the findings and recommendations of the examiner's report, and finds that the requirements of the FTZ Act and Board's regulations are satisfied, and that the proposal is in the public interest;

Now, Therefore, the Board hereby orders:

The application to expand FTZ 171 is approved, subject to the Act and the Board's regulations, including Section 400.28.

Signed at Washington, DC, this 15th day of April, 2002.

Faryar Shirzad,

Assistant Secretary of Commerce for Import Administration, Alternate Chairman, Foreign-Trade Zones Board.

[FR Doc. 02–10074 Filed 4–23–02; 8:45 am]

BILLING CODE 3510–DS–P

DEPARTMENT OF COMMERCE

Foreign-Trade Zones Board

[Order No. 1227]

Approval for Expansion of Subzone 199C, Valero Refining Company, (Oil Refinery), Texas City, TX

Pursuant to its authority under the Foreign-Trade Zones Act of June 18, 1934, as amended (19 U.S.C. 81a-81u), the Foreign-Trade Zones Board (the Board) adopts the following Order:

Whereas, the Texas City Foreign-Trade Zone Corporation, grantee of FTZ 199, has requested authority on behalf of Valero Refining Company (Valero), to add capacity and to expand the scope of authority under zone procedures within Subzone 199C at the Valero refinery in Texas City, Texas (FTZ Docket 40–2001, filed 9/19/2001);

Whereas, notice inviting public comment has been given in the **Federal Register** (66 FR 49163, 9/26/01);

Whereas, pursuant to § 400.32(b)(1) of the FTZ Board regulations (15 CFR 400), the Secretary of Commerce's delegate on the FTZ Board has the authority to act for the Board in making decisions regarding manufacturing activity within existing zones when the proposed activity is the same, in terms of products involved, to activity recently approved by the Board and similar in circumstances (15 CFR 400.32(b)(1)(i)); and,

Whereas, the Board adopts the findings and recommendations of the examiner's report, and finds that the requirements of the FTZ Act and Board's regulations would be satisfied, and that approval of the application would be in the public interest if approval is subject to the conditions listed below;

Now, Therefore, the Board hereby orders:

The application to add capacity and to expand the scope of authority under zone procedures within Subzone 199C on behalf of Valero, is approved, subject to the FTZ Act and the Board's regulations, including § 400.28, and subject to the following conditions:

1. Foreign status (19 CFR 146.41, 146.42) products consumed as fuel for the petrochemical complex shall be subject to the applicable duty rate.

2. Privileged foreign status (19 CFR 146.41) shall be elected on all foreign merchandise admitted to the subzone, except that non-privileged foreign (NPF) status (19 CFR 146.42) may be elected on refinery inputs covered under HTSUS Subheadings #2709.00.10, #2709.00.20, #2710.11.25, #2710.11.45, #2710.19.05, #2710.19.10, #2710.19.45, #2710.91.00, #2710.99.05, #2710.99.10, #2710.99.21, #2710.99.45, and which are used in the production of:

—petrochemical feedstocks (examiner's report, Appendix ''C'');

—products for export;

—and, products eligible for entry under HTSUS #9808.00.30 and #9808.00.40 (U.S. Government purchases).

Signed at Washington, DC, this 15th day of April, 2002.

Faryar Shirzad,

Assistant Secretary for Import Administration, Alternate Chairman, Foreign-Trade Zones Board.

[FR Doc. 02–10076 Filed 4–23–02; 8:45 am]

BILLING CODE 3510–DS–P

DEPARTMENT OF COMMERCE

Foreign-Trade Zones Board

[Order No. 1223]

Approval for Expanded Manufacturing Authority and Subzone Expansion; (Motor Vehicle Air-Conditioning Components), Foreign-Trade Subzone 39C, Sanden International (USA), Inc., Wylie, TX

Pursuant to its authority under the Foreign-Trade Zones Act of June 18, 1934, as amended (19 U.S.C. 81a–81u), the Foreign-Trade Zones Board (the Board) adopts the following Order:

Whereas, the Dallas/Fort Worth International Airport Board, grantee of FTZ 39, has requested authority on behalf of Sanden International (USA), Inc. (Sanden), operator of FTZ 39C, at the Sanden motor vehicle air-conditioner components manufacturing facility in Wylie, Texas, to expand the scope of authority to include new manufacturing capacity under FTZ procedures and requesting authority to expand the boundaries of Subzone 39C to include a new site in Dallas, Texas (FTZ Doc. 10–2001, filed 2–14–2001);

Whereas, notice inviting public comment was given in the **Federal Register** (66 FR 12460, 2–27–2001);

Whereas, the Board adopts the findings and recommendations of the examiner's report, and finds that the requirements of the FTZ Act and the Board's regulations are satisfied, and that approval of the application is in the public interest;

Now therefore, the Board hereby approves the request, subject to the FTZ Act and the Board's regulations, including Section 400.28.

Signed at Washington, DC, this 15th day of April 2002.

Faryar Shirzad,

Assistant Secretary of Commerce for Import Administration, Alternate Chairman, Foreign-Trade Zones Board.

[FR Doc. 02–10080 Filed 4–23–02; 8:45 am]

BILLING CODE 3510–DS–P

DEPARTMENT OF COMMERCE

Foreign Trade-Zone Board

[Order No. 1216]

Grant of Authority for SubZone Status; BP Products North America, Inc. (Oil Refinery), Bellingham, WA Area

Pursuant to its authority under the Foreign-Trade Zones Act of June 18, 1934, as amended (19 U.S.C. 81a–81u), the Foreign-Trade Zones Board (the Board) adopts the following Order:

Whereas, by an Act of Congress approved June 18, 1934, an Act ''To provide for the establishment * * * of foreign-trade zones in ports of entry of the United States, to expedite and encourage foreign commerce, and for other purposes,'' as amended (19 U.S.C. 81a–81u) (the Act), the Foreign-Trade Zones Board (the Board) is authorized to grant to qualified corporations the privilege of establishing foreign-trade zones in or adjacent to U.S. Customs ports of entry;

Whereas, the Board's regulations (15 CFR part 400) provide for the establishment of special-purpose subzones when existing zone facilities cannot serve the specific use involved, and when the activity results in a significant public benefit and is in the public interest;

Whereas, an application from the Port of Bellingham, Washington, grantee of Foreign-Trade Zone 129, for authority to establish special-purpose subzone status at the oil refinery complex of BP Products North America, Inc. (formerly Atlantic Richfield Company (ARCO)), in the Bellingham, Washington, area, was filed by the Board on January 25, 2001, and notice inviting public comment was given in the **Federal Register** (FTZ Docket 7–2001, (66 FR 8930, 2/5/01); and,

Whereas, the Board adopts the findings and recommendations of the examiner's report, and finds that the requirements of the FTZ Act and Board's regulations would be satisfied, and that approval of the application would be in the public interest if approval is subject to the conditions listed below;

Now, therefore, the Board hereby authorizes the establishment of a subzone (Subzone 129A) at the oil refinery complex of BP Products North America, Inc., in the Bellingham, Washington, area, at the location described in the application, subject to the FTZ Act and the Board's regulations, including § 400.28, and subject to the following conditions:

1. Foreign status (19 CFR 146.41, 146.42) products consumed as fuel for the refinery shall be subject to the applicable duty rate.

2. Privileged foreign status (19 CFR 146.41) shall be elected on all foreign merchandise admitted to the subzone, except that non-privileged foreign (NPF) status (19 CFR 146.42) may be elected on refinery inputs covered under HTSUS Subheadings #2709.00.10, #2709.00.20, #2710.11.25, #2710.11.45, #2710.19.05, #2710.19.10, #2710.19.45, #2710.91.00, #2710.99.05, #2710.99.10, #2710.99.16, #2710.99.21, and #2710.99.45 which are used in the production of:

—petrochemical feedstocks and refinery by-products (examiners report, Appendix ''C'');

—products for export;

—and, products eligible for entry under HTSUS # 9808.00.30 and

—#9808.00.40 (U.S. Government purchases).

Signed at Washington, DC, this 15th day of April 2002.

Faryar Shirzad,

Assistant Secretary of Commerce for Import Administration, Alternate Chairman, Foreign-Trade Zones Board.

[FR Doc. 02–10077 Filed 4–23–02; 8:45 am]

BILLING CODE 3510–DS–P

DEPARTMENT OF COMMERCE

International Trade Administration

Initiation of Antidumping and Countervailing Duty Administrative Reviews

AGENCY: Import Administration, International Trade Administration, Department of Commerce.

ACTION: Notice of initiation of antidumping and countervailing duty administrative reviews.

SUMMARY: The Department of Commerce (the Department) has received requests to conduct administrative reviews of various antidumping and countervailing duty orders and findings with March anniversary dates. In accordance with the Department's regulations, we are initiating those administrative reviews.

EFFECTIVE DATE: April 24, 2002.

FOR FURTHER INFORMATION CONTACT: Holly A. Kuga, Office of AD/CVD Enforcement, Import Administration, International Trade Administration, U.S. Department of Commerce, 14th Street and Constitution Avenue, NW, Washington, DC 20230, telephone: (202) 482–4737.

SUPPLEMENTARY INFORMATION:

Background

The Department has received timely requests, in accordance with 19 CFR 351.213(b)(2001), for administrative reviews of various antidumping and countervailing duty orders and findings with March anniversary dates.

Initiation of Reviews

In accordance with section 19 CFR 351.221(c)(1)(i), we are initiating administrative reviews of the following antidumping and countervailing duty orders and findings. We intend to issue the final results of these reviews not later than March 31, 2003.

	Period to be Reviewed
Antidumping Duty Proceedings	
Canada:	
Iron Construction Castings A–122–503	3/1/01–2/28/02
Canada Pipe Company, Ltd.	
Countervailing Duty Proceedings	
Iran:	
In-Shell Raw Pistachios C–507–501	1/1/01–12/31/01
Rafsanjan Pistachio Producers Cooperative	
Turkey:	
Certain Welded Carbon Steel Pipe and Tube C–489–502	1/1/01–12/31/01
Borusan Boru Birlesik Fabrikalari Mannesmann Boru	
Suspension Agreements	
None.	

During any administrative review covering all or part of a period falling between the first and second or third and fourth anniversary of the publication of an antidumping duty order under § 351.211 or a determination under § 351.218(f)(4) to continue an order or suspended investigation (after sunset review), the Secretary, if requested by a domestic interested party within 30 days of the date of publication of the notice of initiation of the review, will determine whether antidumping duties have been absorbed by an exporter or producer subject to the review if the subject merchandise is sold in the United States through an importer that is affiliated with such exporter or producer. The request must include the name(s) of the exporter or producer for which the inquiry is requested.

Interested parties must submit applications for disclosure under administrative protective orders in accordance with 19 CFR 351.305.

These initiations and this notice are in accordance with section 751(a) of the Tariff Act of 1930, as amended (19 U.S.C. 1675(a)), and 19 CFR 351.221(c)(1)(i).

Dated: April 17, 2002.

Holly A. Kuga,

Senior Office Director, Group II, Office 4, Import Administration.

[FR Doc. 02–10070 Filed 4–23–02; 8:45 am]

BILLING CODE 3510–DS–P

DEPARTMENT OF COMMERCE

International Trade Administration

[A–570–873, A–791–815]

Ferrovanadium from the People's Republic of China and the Republic of South Africa: Notice of Postponement of Preliminary Antidumping Duty Determinations

AGENCY: Import Administration, International Trade Administration, Department of Commerce.

ACTION: Notice of Postponement of Preliminary Antidumping Duty Determinations.

EFFECTIVE DATE: April 24, 2002.

FOR FURTHER INFORMATION CONTACT: Mark Manning or Chris Brady, AD/CVD Enforcement, Office 4, Group II, Import Administration, International Trade Administration, U.S. Department of Commerce, 14th Street and Constitution Avenue NW, Washington, DC 20230; telephone (202) 482–5253 or (202) 482–4406, respectively.

SUMMARY: The Department of Commerce (the Department) is postponing the preliminary determinations in the antidumping duty investigations of ferrovanadium from the People's Republic of China and the Republic of South Africa from May 6, 2002, until June 25, 2002. This postponement is made pursuant to section 733(c)(1)(B) of the Tariff Act of 1930, as amended by the Uruguay Round Agreements Act.

SUPPLEMENTARY INFORMATION:

The Applicable Statute and Regulations

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 19 CFR Part 351 (2001).

Background

On December 17, 2001, the Department initiated the above-referenced investigations. See Notice of Initiation of Antidumping Duty

Investigations: Ferrovanadium from the People's Republic of China and the Republic of South Africa, 66 FR 66398 (December 26, 2001).

Postponement of Preliminary Determination

Currently, the preliminary determinations are due no later than May 6, 2002. However, pursuant to section 733(c)(1)(B) of the Act, we have determined that these investigations are ''extraordinarily complicated'' and are postponing the preliminary determinations by 50 days to June 25, 2002. Under section 733(c)(1)(B) of the Act, the Department can extend the period for reaching a preliminary determination until not later than the 190th day after the date on which the administering authority initiates an investigation if:

(B) The administering authority concludes that the parties concerned are cooperating and determines that

(i) the case is extraordinarily complicated by reason of

(I) the number and complexity of the transactions to be investigated or adjustments to be considered;

(II) the novelty of the issues presented; or

(III) the number of firms whose activities must be investigated; and

(ii) additional time is necessary to make the preliminary determination.

The parties concerned are cooperating in these investigations. Additional time is necessary, however, to complete the preliminary determinations due to the complexity of the transactions to be investigated and adjustments to be considered, and the novelty of issues presented.

With respect to the PRC, the Department needs to consider a number of complex issues that will impact our selection of the surrogate country. Ferrovanadium is produced by only a few countries that are all more economically advanced than the PRC, thus complicating our evaluation and determination of the appropriate surrogate country. We must also determine whether there exists a product that is comparable to ferrovanadium and, if so, whether such a product is produced in a country that is economically comparable to the PRC.

In regard to South Africa, on February 21, 2002, the petitioners alleged that during the POI Xstrata made sales below the cost of production (COP) in Germany, the country from which we will calculate normal value. On March 12 and 15, 2002, the petitioners submitted addenda to their cost allegation to include price and cost information placed on the record by Xstrata in its section A questionnaire response. We reviewed this allegation and initiated an investigation of sales below COP on March 26, 2002. In addition, Xstrata has a complex chain of distribution, involving multiple affiliated companies in South Africa, the United States, and Europe, for sales to the U.S. and German markets. We issued extensive supplemental questionnaires in order to understand the function of these companies in Xstrata's sales process. For these reasons, pursuant to section 733(c)(1)(B) of the Act, we are postponing the preliminary determinations in these investigations until June 25, 2002.

This notice is issued and published pursuant to section 733(c)(2) of the Act and 19 CFR 351.205(f).

Dated: April 17, 2002

Bernard T. Carreau,

Acting Assistant Secretary for Import Administration.

[FR Doc. 02–10067 Filed 4–23–02; 8:45 am]

BILLING CODE 3510–DS–S

DEPARTMENT OF COMMERCE

International Trade Administration

[A–570–868]

Notice of Final Determination of Sales at Less Than Fair Value: Folding Metal Tables and Chairs from the People's Republic of China

AGENCY: Import Administration, International Trade Administration, Department of Commerce.

DATES: April 24, 2002.

FOR FURTHER INFORMATION CONTACT: Helen Kramer or John Drury at (202) 482–0405 and (202) 482–0195, respectively, Import Administration, International Trade Administration, U.S. Department of Commerce, 14th Street and Constitution Avenue, NW, Washington, D.C. 20230.

SUPPLEMENTARY INFORMATION:

The Applicable Statute and Regulations

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 (''URAA''). In addition, unless otherwise indicated, all citations to the Department of Commerce (''the Department'') regulations are to the regulations at 19 CFR Part 351 (2001).

Final Determination

We determine that folding metal tables and chairs (''FMTC'') from the People's Republic of China are being, or are likely to be, sold in the United States at less than fair value (''LTFV''), as provided in section 735 of the Act. The estimated margin of sales at LTFV is shown in the ''Continuation of Suspension of Liquidation'' section of this notice.

Scope of Investigation

The merchandise subject to this investigation consists of assembled and unassembled folding tables and folding chairs made primarily or exclusively from steel or other metal, as described below:

1) Assembled and unassembled folding tables made primarily or exclusively from steel or other metal (''folding metal tables''). Folding metal tables include square, round, rectangular, and any other shapes with legs affixed with rivets, welds, or any other type of fastener, and which are made most commonly, but not exclusively, with a hardboard top covered with vinyl or fabric. Folding metal tables have legs that mechanically fold independently of one another, and not as a set. The subject merchandise is commonly, but not exclusively, packed singly, in multiple packs of the same item, or in five piece sets consisting of four chairs and one table. Specifically excluded from the scope of folding metal tables are the following:

- Lawn furniture;
- Trays commonly referred to as ''TV trays '';
- Side tables;
- Child-sized tables;
- Portable counter sets consisting of rectangular tables 36'' high and matching stools; and
- Banquet tables. A banquet table is a rectangular table with a plastic or laminated wood table top approximately 28'' to 36'' wide by 48'' to 96'' long and with a set of folding legs at each end of the table. One set of legs is composed of two individual legs that are affixed together by one or more cross-braces using welds or fastening hardware. In contrast, folding metal tables have legs that mechanically fold independently of one another, and not as a set.

2) Assembled and unassembled folding chairs made primarily or exclusively from steel or other metal (''folding metal chairs''). Folding metal chairs include chairs with one or more cross-braces, regardless of shape or size, affixed to the front and/or rear legs with rivets, welds or any other type of fastener. Folding metal chairs include: those that are made solely of steel or other metal; those that have a back pad, a seat pad, or both a back pad and a seat pad; and those that have seats or backs

made of plastic or other materials. The subject merchandise is commonly, but not exclusively, packed singly, in multiple packs of the same item, or in five piece sets consisting of four chairs and one table. Specifically excluded from the scope of folding metal chairs are the following:

- Folding metal chairs with a wooden back or seat, or both;
- Lawn furniture;
- Stools;
- Chairs with arms; and
- Child-sized chairs.

The subject merchandise is currently classifiable under subheadings 9401710010, 9401710030, 9401790045, 9401790050, 9403200010 and 9403200030 of the HTSUS. Although the HTSUS subheadings are provided for convenience and U.S. Customs Service purposes, the Department's written description of the merchandise is dispositive.

Case History

The preliminary determination in this investigation was published on December 3, 2001. *See Notice of Preliminary Determination of Sales at Less Than Fair Value:Folding Metal Tables and Chairs from the People's Republic of China*, 66 FR 60185 (''Preliminary Determination''). The investigation covers two manufacturers/exporters, Feili Furniture Development Co., Ltd. and Feili (Fujian) Co., Ltd. (''Feili Group'') and Shin Crest Pte. Ltd. (''Shin Crest''). The petitioner is Meco Corporation.

The Department verified Feili Group's and Shin Crest's responses to the antidumping questionnaire from January 14 - 18, 2002 (Feili Group) and from January 21 - 25, 2002 (Shin Crest). We invited parties to comment on our *Preliminary Determination*. We received comments and rebuttal briefs from the petitioner, Feili Group, and Shin Crest. At the requests of the petitioner and Feili Group, a hearing was held on March 22, 2002. On March 22, 2002, the petitioner filed an allegation of critical circumstances in this investigation.

Based on our analysis of verification findings and the comments received, we have made changes in the margin calculation. Therefore, the final determination differs from the preliminary determination.

Period of Investigation

The Period of Investigation (''POI'') is October 1, 2000 through March 31, 2001.

Non-Market Economy

The Department has treated the PRC as a non-market economy (NME) country in all its past antidumping investigations. *See, e.g., Notice of Final Determination of Sales at Less Than Fair Value: Honey from the People's Republic of China*, 66 FR 50608 (October 4, 2001) and *Notice of Final Determination of Sales at Less Than Fair Value: Certain Folding Gift Boxes from the People's Republic of China*, 66 FR 58115 (November 20, 2001). A designation as an NME country remains in effect until it is revoked by the Department. See section 771(18)(C) of the Act. The respondents in this investigation have not requested a revocation of the PRC's NME status. Therefore, we have continued to treat the PRC as an NME in this investigation. For further details, see the department's *Preliminary Determination*.

Separate Rates

In our *Preliminary Determination*, we found that the mandatory respondents, Feili Group and Shin Crest, had met the criteria for the application of separate antidumping duty rates and that the cooperative PRC companies, Dongguan Shichang Metals Factory Co. Ltd. (''Dongguan'') and New-Tec Integration Co., Ltd. (''New-Tec''), had met the criteria for a rate equal to the weighted-average of the mandatory respondents' rates (excluding zero or *de minimis* rates and rates based entirely on adverse facts available). We have not received any other information since the *Preliminary Determination* which would warrant reconsideration of our separates rates determination with respect to these companies. Therefore, we continue to find that the respondents should be assigned individual dumping margins and that Dongguan and New-Tec should be assigned a weighted-average rate. For a complete discussion of the Department's determination that the respondents are entitled to separate rates, see the *Preliminary Determination*.

The PRC-Wide Rate

For the reasons set forth in the *Preliminary Determination*, we continue to believe that use of adverse facts available for the PRC-wide rate is appropriate. *See Preliminary Determination*, 66 FR at 60189–90.

Surrogate Country

For purposes of the final determination, we find that India remains the appropriate surrogate country for the PRC. For further discussion and analysis regarding the surrogate country selection for the PRC, see the Department's *Preliminary Determination* and the Memorandum to Richard O. Weible from John Drury and Helen M. Kramer on Surrogate Country Selection (November 23, 2001) on file in the Department's Central Records Unit, Room B–099 of the Main Department of Commerce Building.

Critical Circumstances

On March 22, 2002, the petitioner filed an allegation of critical circumstances in this investigation based on data for one importer. Because the calculated margins for both Shin Crest and Feili Group in the final determination are below 25 percent, the Department's threshold for imputing knowledge of dumping for EP sales is not met. We therefore do not find critical circumstances with respect to these companies. As to Dongguan and New-Tec, the PRC exporters that were not selected as respondents but did not fail to respond to our requests for information, the final margins also are below 25 percent. Therefore, we do not find critical circumstances with respect to these exporters. *See Notice of Final Determination of Sales at Less Than Fair Value: Certain Non-Frozen Apple Juice Concentrate from the People's Republic of China,* 65 FR 19873 (April 13, 2000).

With respect to exporters subject to the PRC-wide rate, the final margin is above 25 percent. Furthermore, the ITC preliminarily determined that there is material injury by reason of imports of the subject merchandise. Therefore, the first prong of the test is met. With regard to massive imports, because the PRC-wide entity failed to respond to our request for information, the Department has based its massive imports determination on facts available and used an adverse inference in accordance with section 776(b) of the Act. We cannot use U.S. Customs import data to analyze imports from the PRC-wide entity, in part because the relevant product categories include both subject and non-subject merchandise. Because we have no independent means by which to determine import levels for the PRC-wide entity, we have determined, as adverse facts available, that there were massive imports. Accordingly, we determine that there are critical circumstances with respect to the PRC-wide entity.

For a discussion of interested party comments on this issue, see Issues and Decision Memorandum for the Less Than Fair Value Investigation of Folding Metal Tables and Chairs from the People's Republic of China from Joseph A. Spetrini, Deputy Assistant Secretary, Import Administration, to Faryar Shirzad, Assistant Secretary for Import Administration, dated April 17, 2002 (''Issues and Decision Memorandum'').

Analysis of Comments Received

All issues raised in the case briefs by parties to this investigation are addressed in the Issues and Decision Memorandum. A list of the issues which parties raised, and to which we have responded, all of which are in the Issues and Decision Memorandum, is attached to this notice as an Appendix. Parties can find a complete discussion of all issues raised in this investigation and the corresponding recommendations in this public memorandum, which is on file in the Central Records Unit. In addition, a complete version of the Issues and Decision Memorandum can be accessed directly on the Internet at http://ia.ita.doc.gov/. The paper copy and electronic version of the Issues and Decision Memorandum are identical in content.

Changes Since the Preliminary Determination

Based on our findings at verification, and analysis of comments received, we have made corrections to the respondents' reported factor usage and surrogate value changes. We have also corrected certain clerical errors in our preliminary determination. These changes are discussed in the relevant sections of the Issues and Decision Memorandum. *See* also the Factors of Production Valuation Memorandum for the Final Determination, dated April 17, 2002, and the respective Analysis Memorandum for the Final Determination for Feili Group and Shin Crest on the same date.

Verification

As provided in section 782(i) of the Act, we verified the information submitted by the mandatory respondents for use in our final determination. We used standard verification procedures including examination of relevant accounting and production records, and originalsource documents provided by the respondents. For changes from the Preliminary Determination as a result of verification, see the Analysis Memorandums.

Continuation of Suspension of Liquidation

In accordance with section 735(c)(1)(B)(ii) of the Act, we are directing the Customs Service to continue to suspend liquidation of entries of subject merchandise from the PRC exported by Feili Group, Shin Crest, Dongguan and New-Tec that are entered, or withdrawn from warehouse, for consumption on or after December 3, 2001. With respect to the PRC-wide entity, we are directing the Customs Service to suspend liquidation of entries of subject merchandise entered on or afer September 4, 2001, the date 90 days prior to the date of publication of the preliminary determination in the **Federal Register**, in accordance with our critical circumstances finding. We will instruct the Customs Service to require a cash deposit or the posting of a bond equal to the weighted-average amount by which the normal value exceeds the U.S. price, as indicated in the chart below. These suspension-of-liquidation instructions will remain in effect until further notice.

The margins in the final determination are as follows:

Exporter/Manufacturer	Weighted-Average Percent Margin
Shin Crest Pte. Ltd.	00.00
Feili Furniture Development Co., Ltd. and Feili (Fujian) Co., Ltd.	23.48
Dongguan Shichang Metals Factory Co. Ltd.	23.48
New-Tec Integration Co., Ltd.	23.48
PRC-Wide	70.71

ITC Notification

In accordance with section 735(d) of the Act, we have notified the International Trade Commission (''ITC'') of our determination. As our final determination is affirmative, the ITC will, within 45 days, determine whether these imports are materially injuring, or threaten material injury to, the U.S. industry. If the ITC determines that material injury, or threat of material injury does not exist, the proceeding will be terminated and all securities posted will berefunded or canceled. If the ITC determines that such injury does exist, the Department will issue an antidumping duty order directing Customs officials to assess antidumping duties on all imports of the subject merchandise entered for consumption on or after the effective date of the suspension of liquidation.

This determination is issued and published in accordance with sections 735(d) and 777(i)(1) of the Act.

DATED: April 17, 2002

Bernard T. Carreau,

Acting Assistant Secretaryfor Import Administration.

Appendix

List of Comments and Responses

1. Whether import prices paid by Feili Group for cold-rolled steel coils from Korea may be distorted by reason of subsidies
2. Whether import prices paid by Feili Group and Shin Crest for inputs from Taiwan may be distorted by reason of subsidies
3. Whether Shin Crest is affiliated with its steel supplier in Taiwan by reason of control and its import prices should be disregarded
4. Whether the Department's practice regarding allegedly dumped inputs is too restrictive, and the Department should disregard Shin Crest's import prices for steel as putatively dumped
5. Whether it is appropriate to use Indian surrogate values for steel if the Department disregards market economy prices for steel from Korea and/or Taiwan
6. Whether the Department should disregard Indian steel imports from Belgium, Brazil, France, Korea, Russia, South Africa, Thailand and Ukraine in calculating surrogate value
7.Whether Feili Group's ''multi-chair'' falls within the scope of the investigation
8. Whether National Public Seating Corp.'s double-hinged commercial chair is within the scope
9. Whether the Department should use P.T. Lion Metal Works' financial statements to value overhead, SG&A and profit
10. Whether the Department should use adverse facts available (''FA'') to calculate the PRC-wide margin
11. Whether the Department should use updated Indian import statistics for surrogate values and ''correct'' the exchange rate
12. Whether the dates of sale for Feili Group and Shin Crest should be the purchase order date
13. Whether the Department should apply adverse FA to Feili Group's steel consumption
14. Whether the Department should apply a value to steel Feili Group purchased before the POI and used during the POI
15. Whether Feili Group should be required to report usage rates for inputs purchased from third parties
16. Whether the Department should deny a steel scrap adjustment to Feili Group
17. Whether the Department should apply the Indian surrogate value for supported vinyl to all of Feili Group's vinyl consumption
18. Whether Feili Group impermissibly included physically different models in the same control number
19. Whether the Department should require Feili Group to report the usage rate for plastic pellets used to make cup corners for folding metal tables
20. Whether the Department should assume Feili Group's production workers worked 12–hour shifts

21. Whether the Department used the wrong weight for sets in the margin calculation program for Feili Group

22. Whether the Department used the wrong inflation rate to value electricity for Feili Group

23. Whether the Department incorrectly used Feili Group's market economy purchases of plastic pellets to value nylon caps instead of the Indian surrogate value for plastic caps

24. Whether the Department incorrectly calculated the surrogate value of poly bags for Feili Group

25. Whether the Department erred in adding, instead of subtracting, the steel scrap offset for Feili Group

26. Whether the Department should correct the surrogate value for wooden pallets by dividing the average value by the average pallet weight for Feili Group

27. Whether the Department incorrectly included Indian import values for cardboard other than boxes in its calculation of surrogate value for cardboard cartons for Feili Group

28. Whether the Department made clerical errors in calculations of surrogate values for screws. other metal fittings and rubber washers for Feili Group

29. Whether the Department should correct the weights of foam, vinyl and fabric inputs incorrectly reported by Feili Group

30. Whether the Department should correct the number of tables packed in a carton for Feili Group

31. Whether Shin Crest should include inland freight for one U.S. sale in the sales listing

32. Whether the Department should apply adverse FA for Shin Crest's consumption of hardboard because it was not verified

33. Whether the Department should apply Feili Group's usage of wooden pallets for packing to Shin Crest as FA

34. Whether the Department's calculations of the surrogate value of water were incorrect

35. Whether the Department should make a finding of critical circumstances for all Chinese producers of folding metal tables and chairs

[FR Doc. 02–10071 Filed 4–23–02; 8:45 am]

BILLING CODE 3510–DS–S

DEPARTMENT OF COMMERCE

International Trade Administration

[C–507–501; C–507–601]

Certain In–Shell Pistachios from Iran and Certain In–Shell Roasted Pistachios from Iran: Extension of Time Limit for Preliminary Results of Countervailing Duty New Shipper Reviews

AGENCY: Import Administration, International Trade Administration, Department of Commerce.

ACTION: Notice of Extension of Time Limit for Preliminary Results of Countervailing Duty New Shipper Reviews.

EFFECTIVE DATE: April 24, 2002.

FOR FURTHER INFORMATION CONTACT: Eric B. Greynolds or Darla Brown, AD/CVD Enforcement, Office VI, Group II, Import Administration, International Trade Administration, U.S. Department of Commerce, 14th Street and Constitution Avenue, NW, Washington, DC 20230; telephone: (202) 482–2786.

SUPPLEMENTARY INFORMATION:

Time Limits:

Statutory Time Limits

Section 751(a)(2)(B)(iv) of the Tariff Act of 1930, as amended (the Act), requires the Department of Commerce (the Department) to make a preliminary determination within 180 days after the date on which the review is initiated and a final determination within 90 days after the date the preliminary determination is issued. However, if the Department concludes that the case is extraordinarily complicated such that it cannot complete the review within these time periods, section 751(a)(2)(B)(iv) of the Act allows the Department to extend the time limit for the preliminary determination to a maximum of 300 days and 150 days for the final determination from the date of publication of the preliminary determination.

Background

On November 7, 2001, and November 27, 2001, the Department published notices of initiation of new shipper reviews of the countervailing duty orders on certain in-shell pistachios from Iran and certain in-shell roasted pistachios from Iran covering the period October 1, 2000 through September 30, 2001 (66 FR 59277 and 66 FR 59235, respectively). The preliminary results are currently due no later than April 29, 2002 for certain in-shell pistachios and May 18, 2002 for certain in-shell roasted pistachios.

Extension of Time Limit for Preliminary Results of Review

We determine that these cases are extraordinarily complicated because there are a large number of complex issues which require thorough consideration and analysis by the Department, including allegations of new subsidy programs that were not examined during the original investigations and a complex system of exchange rates in Iran. Consequently, we are not able to complete the preliminary results of these reviews within the time limit. Therefore, the Department is extending the time limit for completion of the preliminary results for both of these new shipper reviews until no later than August 27, 2002. This date is the full 120 days extension for the new shipper review of in-shell pistachios. We intend to issue the final results no later than 90 days after the publication of the preliminary results notice.This extension is in accordance with section 751(a)(2)(B)(iv) of the Act.

Dated: April 18, 2002

Bernard T. Carreau,

Deputy Assistant Secretary for Import Administration.

[FR Doc. 02–10069 Filed 4–23–02; 8:45 am]

BILLING CODE 3510–DS–S

DEPARTMENT OF COMMERCE

International Trade Administration

[C–580–835]

Stainless Steel Sheet and Strip in Coils from the Republic of Korea: Extension of Preliminary Results of Countervailing Duty Administrative Review

AGENCY: Import Administration, International Trade Administration, Department of Commerce.

ACTION: Notice of Extension of Time Limit for Preliminary Results of Countervailing Duty Administrative Review.

EFFECTIVE DATE: April 24, 2002.

FOR FURTHER INFORMATION CONTACT: Tipten Troidl or Carrie Farley, Office of AD/CVD Enforcement VI, Import Administration, International Trade Administration, U.S. Department of Commerce, 14th Street and Constitution Ave, N.W., Washington, D.C. 20230; telephone: 202–482–1767 or 202–482–0395, respectively.

SUPPLEMENTARY INFORMATION:

Statutory Time Limits

Section 751(a)(3)(A) of the Tariff Act of 1930, as amended (the Act), requires the Department to make a preliminary determination within 245 days after the last day of the anniversary month of an order/finding for which a review is requested and a final determination within 120 days after the date on which the preliminary determination is published. However, if it is not practicable to complete the review within the time period, section 751(a)(3)(A) of the Act allows the Department to extend these deadlines to a maximum of 365 days and 180 days, respectively.

Background

On September 24, 2001, the Department published a notice of initiation of administrative review of the countervailing duty order on stainless steel sheet and strip from the Republic of Korea, covering the period January 1, 2000 through December 31, 2000 (see 65 FR 49924). The preliminary results are currently due no later than May 3, 2002.

Extension of Preliminary Results of Review

In this administrative review, we are analyzing whether a program-wide change occurred with respect to one of the programs we found countervailable in the original investigation. This program–wide change involves an issue of change of ownership. Additional information, and possible verification of this information, is required. Due to these considerations, we determine that it is not practicable to complete the preliminary results of this review within the original time limit. Therefore, the Department is extending the time limits for completion of the preliminary results until no later than September 3, 2002. We intend to issue the final results no later than 120 days after the publication of the preliminary results.This extension is in accordance with section 751(a)(3)(A) of the Act.

Dated: April 18, 2002

Bernard T. Carreau,

Deputy Assistant Secretary for Import Administration.

[FR Doc. 02–10068 Filed 4–23–02; 8:45 am]

BILLING CODE 3510–DS–S

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

[I.D. 041802B]

Endangered Species; Permits

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

ACTION: Receipt of an application for a research and enhancement permit (1380).

SUMMARY: Notice is hereby given of the following actions regarding permits for takes of endangered and threatened species for the purposes of scientific research and/or enhancement under the Endangered Species Act (ESA): NMFS has received an application for a research/enhancement permit from Mr. Christopher Slay, of Coastwise Consulting (1380).

DATES: Comments or requests for a public hearing on the new application must be received at the appropriate address or fax number no later than 5 p.m. eastern standard time on May 24, 2002.

ADDRESSES: Written comments on the new application should be sent to the appropriate office as indicated below. Comments may also be sent via fax to the number indicated for the application. Comments will not be accepted if submitted via e-mail or the Internet. The application and related documents are available for review in the indicated office, by appointment:

Permits, Conservation and Education Division, F/PR1, 1315 East West Highway, Silver Spring, MD 20910 (phone:301–713–2289, fax: 301-713-0376).

FOR FURTHER INFORMATION CONTACT: Lillian Becker, Silver Spring, MD (phone: 301–713–2319, fax: 301–713–0376, e-mail: Lillian.Becker@noaa.gov).

SUPPLEMENTARY INFORMATION:

Authority

Issuance of permits and permit modifications, as required by the Endangered Species Act of 1973 (16 U.S.C. 1531–1543) (ESA), is based on a finding that such permits/modifications: (1) are applied for in good faith; (2) would not operate to the disadvantage of the listed species which are the subject of the permits; and (3) are consistent with the purposes and policies set forth in section 2 of the ESA. Scientific research and/or enhancement permits are issued under section 10(a)(1)(A) of the ESA. Authority to take listed species is subject to conditions set forth in the permits. Permits and modifications are issued in accordance with and are subject to the ESA and NMFS regulations governing listed fish and wildlife permits (50 CFR parts 222–226).

Those individuals requesting a hearing on an application listed in this notice should set out the specific reasons why a hearing on that application would be appropriate (see **ADDRESSES**). The holding of such hearing is at the discretion of the Assistant Administrator for Fisheries, NOAA. All statements and opinions contained in the permit action summaries are those of the applicant and do not nece ssarily reflect the views of NMFS.

Species Covered in This Notice

The following species are covered in this notice:

Sea turtles

Threatened and endangered Green turtle (*Chelonia mydas*)

Endangered Hawksbill turtle (*Eretmochelys imbricata*)

Endangered Kemp's ridley turtle (*Lepidochelys kempii*)

Endangered Leatherback turtle (*Dermochelys coriacea*)

Threatened Loggerhead turtle (*Caretta caretta*)

Application 1380

The applicant proposes to capture live sea turtles using shrimp trawlers in association with hopper dredge activities along the southeastern U.S. coast and the Gulf of Mexico. Trawling may be conducted prior to dredging to assess the abundance of sea turtles in an area and/or during dredging operations to relocate turtles away from the channel being dredged. Captured turtles will be identified, measured, photographed, and tagged with both flipper and PIT tags before being released. The annual number of takes requested are: 750 loggerhead, 225 Kemp's ridley, 150 green, 50 hawksbill, and 22 leatherback turtles. Precautions will be taken to insure the health and safety of the turtles while onboard the trawler.

Dated: April 18, 2002.

Ann Terbush,

Chief, permits, Conservation, and Education Division, Office of Protected Resources, National Marine Fisheries Service.

[FR Doc. 02–10084 Filed 4–23–02; 8:45 am]

BILLING CODE 3510–22–S

DEPARTMENT OF DEFENSE

Department of the Air Force

Privacy Act of 1974; System of Records

AGENCY: Department of the Air Force, DoD.

ACTION: Notice to alter systems of records.

SUMMARY: The Department of the Air Force is proposing to alter a system of records notice in its existing inventory of record systems subject to the Privacy Act of 1974, (5 U.S.C. 552a), as amended. The alteration adds routine uses to the existing system of records so that information may be released for the purpose of collecting debts owed to the U.S. Government.

DATES: This proposed action will be effective without further notice on May 24, 2002, unless comments are received which result in a contrary determination.

ADDRESSES: Send comments to the Air Force Privacy Act Manager, AF CIO/P, 1155 Air Force Pentagon, Washington, DC 20330–1155.

FOR FURTHER INFORMATION CONTACT: Mrs. Anne Rollins at (703) 601–4043 or DSN 329–4043.

SUPPLEMENTARY INFORMATION: The Department of the Air Force systems of records notices subject to the Privacy Act of 1974, (5 U.S.C. 552a), as amended, have been published in the **Federal Register** and are available from the address above.

The proposed system reports, as required by 5 U.S.C. 552a(r) of the Privacy Act of 1974, as amended, was submitted on April 11, 2002, to the House Committee on Government Reform, the Senate Committee on Governmental Affairs, and the Office of Management and Budget (OMB) pursuant to paragraph 4c of Appendix I to OMB Circular No. A–130, ''Federal Agency Responsibilities for Maintaining Records About Individuals,'' dated February 8, 1996 (February 20, 1996, 61 FR 6427).

Dated: April 17, 2002.

Patricia L. Toppings,

Alternate OSD Federal Register Liaison Officer, Department of Defense.

F065 AF SVA A

SYSTEM NAME:

Non-appropriated Fund Instrumentalities (NAFIs) Financial System (June 11, 1997, 62 FR 31793).

CHANGES:

* * * * *

CATEGORIES OF INDIVIDUALS COVERED BY THE SYSTEM:

Delete entry and replace with ''All personnel who are members of Air Force membership associations or authorized patrons of any activity operated by one of the above NAFIs, and with whom financial transactions are conducted, *e.g.,* the extension of credit in accordance with Air Force regulations, or the acceptance and cashing of personal checks. In accordance with appropriate Air Force regulations concerning NAFI participation, the above personnel may include, but are not limited to: Active duty and retired military members; members of United States Reserve components and Federally recognized National Guard units; military members of foreign governments on duty with the Department of Defense (DoD); DoD employees; other Federal Government employees working on military installations, retired DoD employees; contractor employees; technical representatives; and others who are authorized logistic support and work at the installation and where membership or usage would be in the best interest of the installation; paid members of the American Red Cross; children of deceased active duty or retired members of the United States Armed Forces; certain other categories of individuals identified as authorized personnel who directly support Air Force mission requirements; and authorized dependents or guests. Also covered are all personnel employed by or assigned to a NAFI who are involved in financial transactions involving the NAFI, whether internal or external, including, but not limited to, the receipt or control of cash or other properties.''

CATEGORIES OF RECORDS IN THE SYSTEM:

Delete entry and replace with ''Records resulting from financial transactions with authorized members, patrons, vendors, contractors, or those otherwise entitled to utilize or deal with a NAFI. Such records include, but are not limited to: Subsidiary account ledgers maintained on individual members/authorized patrons who are charged dues and/or extended credit including the use of billeting type facilities prior to payment; form(s) on which delinquent accounts or dishonored checks and their disposition are maintained; and records of other sales or services. Records necessitated for internal/external financial record keeping or asset control, including but not limited to any account receivable, the receipt and control of cash; custody of tangible property, and any actions taken as a result of any irregularity. Case files relating to debts owed by individuals or entities also include those for salary/travel advances, pecuniary liability claims, overpayments, and credit cards. These files contain correspondence pertaining to the debts, *e.g.,* notices from banks or other financial institutions concerning indebtedness, originals or copies of returned checks, memos reflecting attempts to contact the debtor, repayment requests, payment options, charges on accounts, account statements, and other related documents and correspondence.''

* * * * *

ROUTINE USES OF RECORDS MAINTAINED IN THE SYSTEM, INCLUDING CATEGORIES OF USERS AND THE PURPOSES OF SUCH USES:

Add five new paragraphs to the entry ''To the U.S. Department of Justice/U.S. Attorneys for legal action and/or final disposition of the debt claim.

To the Internal Revenue Service (IRS) to obtain locator status for delinquent accounts receivables (controls exist to preclude redisclosure of solicited IRS address data; and/or to report write-off amounts as taxable income as pertains to amounts compromised and accounts barred from litigation due to age).

To private collection agencies for collection action when the internal collection efforts have been exhausted.

To the Department of the Treasury, Financial Management Service, for the purpose of collecting delinquent debts owed to the U.S. Government via administrative offset.

To any employer (person or entity) that employs the services of others where the employee owes a delinquent nontax debt to the United States. The term employer includes, but is not limited to, state and local government, but does not include any agency of the Federal Government.''

Add a new entry ''Disclosure to consumer reporting agencies: Disclosure pursuant to 5 U.S.C. 552a(b)(12) may be made from this system to consumer reporting agencies as defined in the Fair Credit Reporting Act (14 U.S.C. 1681a(f)) or the Federal Claims Collection Act of 1966 (31 U.S.C. 3701(a)(3)). The purpose of this disclosure is to aid in the collection of outstanding debts owed to the Federal Government, typically to provide an incentive for debtors to repay delinquent Federal Government debts by making these debts part of their credit records.

The disclosure is limited to information necessary to establish the identity of the individual, including name, address, and taxpayer identification number (Social Security

Number); the amount, status, and history of the claim; and the agency or program under which the claim arose for the sole purpose of allowing the consumer reporting agency to prepare a commercial credit report.''

* * * * *

F065 AF SVA A

SYSTEM NAME:

Non-appropriated Fund Instrumentalities (NAFIs) Financial System.

SYSTEM LOCATION:

Headquarters Air Force Services Agency, 10100 Reunion Place, Suite 400, San Antonio, TX 78216–4138, major commands, field operating agencies, and individual Air Force bases. System exists within approximately 500 NAFIs which include resale and revenue-sharing NAFIs; base Morale, Welfare, and Recreation Fund (MWRF) NAFIs; and supplemental mission services NAFIs. Official mailing addresses are published as an appendix to the Air Force's compilation of record systems notices.

CATEGORIES OF INDIVIDUALS COVERED BY THE SYSTEM:

All personnel who are members of Air Force membership associations or authorized patrons of any activity operated by one of the above NAFIs, and with whom financial transactions are conducted, *e.g.,* the extension of credit in accordance with Air Force regulations, or the acceptance and cashing of personal checks. In accordance with appropriate Air Force regulations concerning NAFI participation, the above personnel may include, but are not limited to: Active duty and retired military members; members of United States Reserve components and Federally recognized National Guard units; military members of foreign governments on duty with the Department of Defense (DoD); DoD employees; other Federal Government employees working on military installations, retired DoD employees; contractor employees; technical representatives; and others who are authorized logistic support and work at the installation and where membership or usage would be in the best interest of the installation; paid members of the American Red Cross; children of deceased active duty or retired members of the United States Armed Forces; certain other categories of individuals identified as authorized personnel who directly support Air Force mission requirements; and authorized dependents or guests. Also covered are all personnel employed by or assigned to a NAFI who are involved in financial transactions involving the NAFI, whether internal or external, including, but not limited to, the receipt or control of cash or other properties.

CATEGORIES OF RECORDS IN THE SYSTEM:

Records resulting from financial transactions with authorized members, patrons, vendors, contractors, or those otherwise entitled to utilize or deal with a NAFI. Such records include, but are not limited to: Subsidiary account ledgers maintained on individual members/authorized patrons who are charged dues and/or extended credit including the use of billeting type facilities prior to payment; form(s) on which delinquent accounts or dishonored checks and their disposition are maintained; and records of other sales or services. Records necessitated for internal/external financial record keeping or asset control, including but not limited to any account receivable, the receipt and control of cash; custody of tangible property, and any actions taken as a result of any irregularity. Case files relating to debts owed by individuals or entities also include those for salary/travel advances, pecuniary liability claims, overpayments, and credit cards. These files contain correspondence pertaining to the debts, *e.g.,* notices from banks or other financial institutions concerning indebtedness, originals or copies of returned checks, memos reflecting attempts to contact the debtor, repayment requests, payment options, charges on accounts, account statements, and other related documents and correspondence.

AUTHORITY FOR MAINTENANCE OF THE SYSTEM:

10 U.S.C. 8013, Secretary of the Air Force; Federal Claims Collection Act of 1966 (Pub. L. 89–508, as amended); Debt Collection Act of 1982 (Pub. L. 97–365), as amended by the Debt Collection Improvement Act of 1996 (Pub. L. 104–134, Section 31001); 31 CFR 285.11, Administrative Wage Garnishment; Air Force Instruction 34–209, Non-appropriated Funds Financial Management and Accounting; Air Force Instruction 34–202, Protecting Non-appropriated Fund Assets; and Air Force Manual 34–214, Procedures for Non-appropriated Funds Financial Management and Accounting; and E.O. 9397 (SSN).

PURPOSE(S):

To record charges and credits of members and others authorized credit. To prepare billing statements or furnish data to an outside party to prepare billing statements. To maintain a record of returned checks. To assist in collecting all amounts due in accordance with established Air Force procedures. To compile a statistical quarterly report on returned checks and statistical data on delinquent accounts receivable for use with the financial reports. To verify eligibility to engage in financial transactions with a NAFI and other sales and extensions of credit. To form a database within the financial system of the NAFI used by personnel responsible for conducting Air Force NAF financial transactions.

Routine uses of records maintained in the system, including categories of users and the purposes of such uses: In addition to those disclosures generally permitted under 5 U.S.C. 552a(b) of the Privacy Act, these records or information contained therein may specifically be disclosed outside the DoD as a routine use pursuant to 5 U.S.C. 552a(b)(3) as follows:

To the U.S. Department of Justice/U.S. Attorneys for legal action and/or final disposition of the debt claim.

To the Internal Revenue Service (IRS) to obtain locator status for delinquent accounts receivables (controls exist to preclude redisclosure of solicited IRS address data; and/or to report write-off amounts as taxable income as pertains to amounts compromised and accounts barred from litigation due to age).

To private collection agencies for collection action when the internal collection efforts have been exhausted.

To the Department of the Treasury, Financial Management Service, for the purpose of collecting delinquent debts owed to the U.S. Government via administrative offset.

To any employer (person or entity) that employs the services of others where the employee owes a delinquent nontax debt to the United States. The term employer includes, but is not limited to, state and local government, but does not include any agency of the Federal Government.

Records from this system may be disclosed to other government agencies, commercial or nonprofit concerns conducting activities in support of, similar to, or in furtherance of, the Air Force programs involved.

The DoD ''Blanket Routine Uses'' published at the beginning of the Air Force's compilation of record system notices apply to this system.

DISCLOSURE TO CONSUMER REPORTING AGENCIES:

Disclosure pursuant to 5 U.S.C. 552a(b)(12) may be made from this system to consumer reporting agencies as defined in the Fair Credit Reporting Act (14 U.S.C. 1681a(f)) or the Federal

Claims Collection Act of 1966 (31 U.S.C. 3701(a)(3)). The purpose of this disclosure is to aid in the collection of outstanding debts owed to the Federal Government, typically to provide an incentive for debtors to repay delinquent Federal Government debts by making these debts part of their credit records.

The disclosure is limited to information necessary to establish the identity of the individual, including name, address, and taxpayer identification number (Social Security Number); the amount, status, and history of the claim; and the agency or program under which the claim arose for the sole purpose of allowing the consumer reporting agency to prepare a commercial credit report.

POLICIES AND PRACTICES FOR STORING, RETRIEVING, ACCESSING, RETAINING, AND DISPOSING OF RECORDS IN THE SYSTEM:

STORAGE:

Maintained in visible file binders/cabinets, in computers and on computer output products.

RETRIEVABILITY:

Retrieved by name, membership organization account number, and/or Social Security Number.

SAFEGUARDS:

Records are accessed by person(s) responsible for servicing the record system in performance of their official duties and by authorized personnel who are properly screened and cleared for need-to-know. Records stored in locked rooms, cabinets, and in computer storage devices protected by computer system software.

RETENTION AND DISPOSAL:

Subsidiary accounts receivable are retained throughout the life cycle of credit sales and for as long as an individual remains in an active member/authorized patron status. Those forms used in connection with delinquent accounts or returned checks are retained until no longer needed. Records are destroyed by tearing into pieces, shredding, pulping, macerating or burning. Computer records are destroyed by erasing, deleting or overwriting.

SYSTEM MANAGER(S) AND ADDRESS:

Director, Financial Management and Comptroller, Headquarters Air Force Services Agency (HQ AFSVA/SVF), 10100 Reunion Place, Suite 400, San Antonio, TX 78216–4138.

NOTIFICATION PROCEDURE:

Individuals seeking to determine whether this system of records contains information on them should address inquiries to or visit the Directorate of Financial Management and Comptroller, Headquarters Air Force Services Agency (HQ AFSVA/SVF), 10100 Reunion Place, Suite 400, San Antonio, TX 78216–4138.

Individuals may also contact the appropriate base NAF Accounting Office or the appropriate operating manager. Official mailing addresses are published as an appendix to the Air Force's compilation of record systems notices.

RECORD ACCESS PROCEDURES:

Individuals seeking to access records about themselves contained in this system should address requests to the Directorate of Financial Management and Comptroller, Headquarters Air Force Services Agency (HQAFSVA/SVF), 10100 Reunion Place Suite 400, San Antonio, TX 78216–4138.

Individuals may also contact the appropriate base NAF Accounting Office or the appropriate operating manager. Official mailing addresses are published as an appendix to the Air Force's compilation of record systems notices.

CONTESTING RECORD PROCEDURES:

The Air Force rules for accessing records, and for contesting contents and appealing initial agency determinations are published in Air Force Instruction 37–132; 32 CFR part 806b; or may be obtained from the system manager.

RECORD SOURCE CATEGORIES:

Individual members/patrons/users of a service themselves, charge slips, payment receipts, checks, and other authorized financial forms and records.

EXEMPTIONS CLAIMED FOR THE SYSTEM:

None.

[FR Doc. 02–9962 Filed 4–23–02; 8:45 am]

BILLING CODE 5001–08–P

DEPARTMENT OF DEFENSE

Department of the Navy

Record of Decision for Disposal and Reuse of the Naval Air Station, South Weymouth, MA

AGENCY: Department of the Navy, DOD.

ACTION: Notice of record of decision.

SUMMARY: The Department of the Navy announces its decision to dispose of the Naval Air Station (NAS), in South Weymouth, MA, in a manner consistent with the Final Reuse Plan adopted by the South Shore Tri-Town Development Corporation (SSTTDC).

SUPPLEMENTARY INFORMATION: Under the authority of the Defense Authorization Amendments and Base Closure and Realignment Act, Public Law 100–526, 10 U.S.C. section 2687 note (1994), pursuant to section 102(2)(C) of the National Environmental Policy Act (NEPA) of 1969, and the Council on Environmental Quality Regulations for implementing NEPA procedures (40 CFR parts 1500–1508), the Department of the Navy (Navy) announces its decision to dispose of NAS South Weymouth in a manner consistent with the Final Reuse Plan adopted by the South Shore Tri-Town Development Corporation.

The disposal and subsequent reuse of this property will be in accordance with the preferred alternative as described in the Final Environmental Impact Statement (FEIS).

Background: NAS South Weymouth is situated on 1,450 acres in the towns of Weymouth (Norfolk County), Abington and Rockland (Plymouth County) approximately 15 miles south of the capital city of Boston. The site contains two runways and 85 buildings providing nearly 600,000 square feet of space. Approximately 45 acres of property with 165 units of housing have been transferred to the U.S. Coast Guard (USCG). Another 4.8 acre parcel has been transferred to the USCG for continued operation of their buoy maintenance and storage program. A half-acre parcel with Doppler radar equipment has been transferred to the Federal Aviation Administration.

In addition to the main station, two non-contiguous sites were also controlled by NAS South Weymouth: the Squantum Gardens and Naval Terrace housing areas consisting of 27 acres located in Quincy, MA, and Nomans Land Island, 628 acres about three miles south of Martha's Vineyard. A separate Environmental Assessment was prepared for the disposal and reuse of Squantum Gardens and Naval Terrace housing areas and these properties have been transferred to the City of Quincy. Nomans Land Island, a former Naval bombing range, has been transferred to the U.S. Department of the Interior. These land holdings are not part of this Record of Decision.

Alternatives Considered: The proposed action is the disposal of the NAS South Weymouth property and the subsequent reuse in a manner consistent with the Final Reuse Plan as adopted by the SSTTDC. The FEIS analyzed the effects of the Preferred Reuse Plan, as well as the effects of two other reuse plan alternatives.

The Preferred Reuse Plan proposes a mix of business (office, research and

development (R&D), manufacturing, and industrial), retail, residential, institutional, recreational, open space, and infrastructure uses. A total of about 3.6 million square feet of new and existing buildings would provide employment opportunities for about 9,540 workers. Approximately 500–700 units of senior housing would provide housing for 1,140 senior citizens. A new access road, referred to as the Route 3 access roadway, would be necessary to accommodate the increased traffic. This access roadway would connect Route 3 to Route 18 transiting through the NAS South Weymouth. Full build-out of the NAS South Weymouth property under the Preferred Reuse Plan would occur over a 20-year period.

The Environmental Impact Statement (EIS) evaluated the development of NAS South Weymouth under a more intensive reuse plan identified as the New South Shore Community Alternative. Under this plan, there would be about 3 million square feet of business/R&D space; 150,000 square feet of retail space; 1400 housing units; 60 acres set-aside for government or institutional use; and recreational and open space. The Route 3 access roadway would also be constructed under this alternative. This development would provide employment opportunities for about 12,400 workers.

The EIS evaluated a third reuse plan that would be the least intensive of the three alternatives. The Minimal Investment Alternative would provide 610,000 square feet for business/R&D use; 150,000 square feet of retail space; 930 family housing units; 60 acres for government or instutitional use; and recreational and open space. The Route 3 access roadway also be constructed under this alternative. This alternative would provide housing for about 3,000 persons and job opportunities for approximately 3,800 employees.

Under the No Action Alternative, the NAS South Weymouth property would remain in U.S. Government ownership. The property would be placed in Federal caretaker status with the Navy maintaining the physical condition of the property, providing a security force, and making repairs essential to safety.

Environmental Impacts of the Preferred Alternative: The FEIS analyzed the direct, indirect and cumulative environmental impacts of the Preferred Reuse Plan. Redevelopment of the property will generate an estimated 9,540 new jobs, resulting in beneficial socioeconomic impacts. Annual estimated earnings of these jobs would be about $305 million. Other employment occurring in the region as a result of the new development on the NAS South Weymouth property is estimated at 8,000 new jobs providing an additional $257 million in earnings. As the property is transitioned to private ownership, and thereby subject to local real estate taxes, the estimated tax generated would be about $10 million.

The Preferred Reuse Plan would construct up to 700 units of senior housing providing homes for about 1,140 senior citizens. Since the new housing population would be limited to seniors and the new workers at the NAS South Weymouth site are expected to commute from elsewhere in the region, the local school systems will not be significantly impacted. Even if there is worker migration into the area, local school systems have sufficient capacity to accommodate any corresponding increase in student enrollment. There will be additional demands on community support services such as police, fire, and emergency care. It is expected that this need would increase gradually over several years. The Preferred Reuse Plan provides for additional property tax revenue to support increased service costs.

The Preferred Reuse Plan would generate 32,600 average daily weekday (one way) trips. This new traffic is expected to cause significant degraded levels of service at several intersections in the vicinity of the NAS South Weymouth site. State and local governments will need to make intersection and roadway improvements to mitigate the impacts of the increased traffic. In order to minimize traffic impacts, the Board of Directors of the SSTTDC has endorsed the Preferred Reuse Plan on the following guidelines: redevelopment would be staged over a period of ten or more years; development would occur as infrastructure impacts are addressed and mitigation measures are put in place; and the scope and mix of development would be as defined in the Preferred Reuse Plan.

The Clean Air Act General Conformity rule is not applicable to the disposal of the NAS South Weymouth property as stated in 40 CFR Part 153(c), exemptions (XIV) and (XIX). While there will be an increase in carbon monoxide emissions due to the increase in traffic, the increase in carbon monoxide will not be significant since the levels will remain below the National Ambient Air Quality Standards.

Noise level increases off-base due to additional traffic would be less than three decibels, a generally accepted level of perceptible change. A noise level increase greater than three decibels would occur on the redeveloped Shea Memorial Drive due to the additional traffic. However these higher noise levels will not exceed the Federal Highway Administration (FHWA) standards for residential property located in the surrounding area. With respect to the Route 3 access roadway, lands within 180 feet of the road centerline would experience noise levels significantly above the FHWA standards for land uses such as schools, churches, and residences.

Projected infrastructure impacts, such as water supply, wastewater, stormwater system, electric, gas, steam, and telecommunications, were examined in the FEIS for the Preferred Reuse Plan. SSTTDC is investigating the following water supply sources: Groundwater from aquifers underlying the site; surplus water from local communities; the Bluestone Desalination Project; and, water from the Massachusetts Water Resource Authority (MWRA). The demand for utility services will grow as the site is developed over a 20-year period. This will provide time for coordination between SSTTDC, local towns and authorities to develop infrastructure capacity in sequence with the project.

There are no buildings, structures or districts that are eligible for listing on the National Register of Historic Properties at NAS South Weymouth. The majority of NAS South Weymouth's ground surface has been highly disturbed through previous development. The Massachusetts Historical Commission determined that closure/realignment of NAS South Weymouth would be unlikely to affect significant archaeological resources.

Implementation of the Preferred Reuse Plan would result in a loss of vegetation and habitat. Wetlands are located on the site and may be impacted by new development. However, any new construction that may impact wetlands must comply with appropriate Federal and state regulations governing development in or near wetlands. The groundwater beneath NAS South Weymouth property is not currently used for water supply purposes. This on-site aquifer may be utilized in the future to meet the potable water supply demands of the Preferred Reuse Plan.

No Federally listed threatened or endangered species are known to inhabit the NAS South Weymouth property, thus no significant impacts on those species are anticipated.

There will be no significant impacts associated with existing hazardous waste sites. Transfer of Navy property must include a determination of the environmental suitability of the land for transfer to a non-Federal agency or to

the public. Early transfer of Navy property before the property is environmentally suitable may also occur as authorized under the Comprehensive Environmental Response, Compensation, and Liability Act of 1980 (CERCLA).

The Navy analyzed the direct and indirect effects of the proposed conveyance and reuse on low income and minority populations. The conveyance and reuse will not cause adverse and disproportionately high environmental or economic impacts to minority or low-income populations residing in the region.

Mitigation: Implementation of the decision to transfer Navy property does not require the Navy to perform any mitigation measures. No mitigation is required for direct impacts associated with conveyance of the property. Reuse will result in indirect impacts that can be mitigated through measures taken directly by state and local governments or imposed on the SSTTDC through state and local permitting processes.

Reuse will cause significant traffic impact at various intersections in the study area surrounding NAS South Weymouth. Potential mitigation measures may include changing of traffic signal timing and/or geometric improvements. These measures could be implemented by the state, Norfolk and/or Plymouth Counties or the SSTTDC proposing redevelopment at NAS South Weymouth.

With respect to the Route 3 Access Roadway, noise levels are predicted to exceed the FHWA Noise Abatement Criterion. Potential mitigation measures include the installation of noise barriers along the Route 3 Access Roadway and placing a Category B land use restriction within the area of potential impact.

Implementation of the Preferred Reuse Plan without the expansion of the existing water supply/distribution and wastewater infrastructure would result in a significant adverse impact. The SSTTDC has identified the following potential alternative sources of water: groundwater from aquifers underlying the site; surplus water from local communities; the Bluestone Desalination Project; and water from the MWRA. The SSTTDC has identified the following potential alternatives for treatment of wastewater flows generated by redevelopment of NAS South Weymouth: local municipal facilities; on-site treatment and land disposal; and MWRA. The viability of any potential water supply or wastewater system enhancement would be dependent upon coordination among local towns, authorities, and the SSTTDC.

The Preferred Reuse Plan would affect on-site wetlands and their buffers. Any disturbance to wetlands would require compliance with the Massachusetts Wetlands Protection Act by the acquiring entity.

Comments Received on the FEIS: The Navy received eight comment letters on the FEIS, including the U.S. Environmental Protection Agency (EPA); the Commonwealth of Massachusetts Department of Food and Agriculture; the Massachusetts Highway Department (MHD); the Town of Weymouth, MA; and four private citizens. U.S. EPA reiterated their concerns on the impacts to water supplies and quality, wetlands, local roadway network and air quality, as previously provided in their comments on the draft DEIS. Additionally, EPA emphasized that the redevelopment benefit and not the burden of surrounding communities be based on the principles of smart growth, and be supported by local infrastructure. In response to these concerns, the Navy notes that the responsibility to develop the reuse plan is the local reuse authority.

The Massachusetts Department of Food and Agriculture requested that the prime agricultural land and soils on the NAS South Weymouth remain available for the production of agricultural crops. While the Navy will not place land use restrictions on the transfer of the property, the SSTTDC has committed to resolve or mitigate adverse impacts to agricultural resources through the Massachusetts Environmental Policy Act process.

The MHD provided comments with regard to a traffic study prepared for the MHD by Wilbur Smith Associates and referenced in the FEIS. This study, entitled the South Weymouth Access Study, was prepared for the Final Reuse Plan and while its conclusions were similar to the findings of the FEIS, the MHD noted that there were some differences in the Access Study and the FEIS. Among their comments, the MHD noted that while the FEIS reported that the MHD would be responsible for the planning, funding, design, and construction of the Route 3 access road, no such determination of this responsibility has been made. The Navy acknowledges that there are differences in the traffic studies prepared for the FEIS and by the MHD; however, the overall findings of traffic impacts expressed in the FEIS are considered valid.

The Town of Weymouth stated its concerns over the ongoing Installation Restoration Program and requested that the Navy remain committed to the thorough cleanup of all identified contaminants on the NAS South Weymouth site. The Navy acknowledges its responsibility for the timely completion of the ongoing site remediation process that will be defined in South Weymouth CERCLA RODs.

Comments received from private citizens expressed concern with regard to traffic, air, noise, infrastructure, land use, and terrestrial and aquatic environmental impacts due to the development and reuse of NAS South Weymouth. Additionally, comments expressed concern over the ongoing site remediation program. These issues were addressed in the FEIS and do not require further clarification.

Conclusion: The Preferred Reuse Plan adopted by the SSTTDC was identified by popular vote of the residents of the local communities as the plan that best responds to local and regional economic conditions and promotes economic recovery from the closure of NAS South Weymouth. The Preferred Reuse Plan complies with the conditions imposed by Congress on the conveyance of the NAS South Weymouth property. Potentially significant environmental impacts associated with implementation of the Preferred Reuse Plan can be mitigated either directly by the state and local governments or indirectly through the regulatory authorities exercised by the state and local governments over private landowners and developers. Although the ''no action'' alternative has less potential for adverse environmental impacts and is the environmentally preferred alternative, it would not promote local economic redevelopment and create jobs. Keeping the property in caretaker status would not be the highest and best use of the property because it would not take advantage of the property's physical characteristics and infrastructure.

Based on the analysis contained in the FEIS and the associated administrative record, I have decided to convey the Naval Air Station in South Weymouth, MA, in a manner that is consistent with the reuse plan adopted by the South Shore Tri-Town Development Corporation, as provided for in the Defense Authorization Act for fiscal year 1994.

Dated: April 11, 2002.

Duncan Holaday,

Deputy Assistant Secretary, (Installations and Facilities).

[FR Doc. 02–10030 Filed 4–23–02; 8:45 am]

BILLING CODE 3810–FF–M

DEPARTMENT OF DEFENSE

Department of the Navy

Privacy Act of 1974; System of Records

AGENCY: Department of the Navy, DoD.

ACTION: Notice to Add and Delete a System of Records.

SUMMARY: The Department of the Navy proposes to add a system of records notice to its inventory of record systems subject to the Privacy Act of 1974 (5 U.S.C. 552a), as amended, and at the same time, delete one.

DATES: This action will be effective on May 24, 2002, unless comments are received that would result in a contrary determination.

ADDRESSES: Send comments to the Department of the Navy, PA/FOIA Policy Branch, Chief of Naval Operations (N09B10), 2000 Navy Pentagon, Washington, DC 20350–2000.

FOR FURTHER INFORMATION CONTACT: Mrs. Doris Lama at (202) 685–6545 or DSN 325–6545.

SUPPLEMENTARY INFORMATION: The Department of the Navy's record system notices for records systems subject to the Privacy Act of 1974 (5 U.S.C. 552a), as amended, have been published in the **Federal Register** and are available from the address above.

The proposed system report, as required by 5 U.S.C. 552a(r) of the Privacy Act, was submitted on April 11, 2002, to the House Committee on Government Reform, the Senate Committee on Governmental Affairs, and the Office of Management and Budget (OMB) pursuant to paragraph 4c of Appendix I to OMB Circular No. A–130, ''Federal Agency Responsibilities for Maintaining Records About Individuals,'' dated February 8, 1996, (61 FR 6427, February 20, 1996).

Dated: April 17, 2002.

Patricia L. Toppings,

Alternate OSD Federal Register Liaison Officer, Department of Defense.

Deletion
N05527–4

SYSTEM NAME:

Naval Security Group Personnel Security/Access Files (February 22, 1993, 58 FR 10767).

REASON:

The system of records is no longer needed. Files have been merged into N05520–5, Personnel Security Program Management Records.

Addition
N01560–1

SYSTEM NAME:

Navy College Management Information System.

SYSTEM LOCATION:

Naval Education and Training Professional Development and Technology Center, 6490 Saufley Field Road, Pensacola, FL 32509–5241.

CATEGORIES OF INDIVIDUALS COVERED BY THE SYSTEM:

Navy and Marine Corps military personnel and Coast Guard Civil Service members who receive tuition assistance (TA); dependents of Marine Corp service members OCONUS who receive tuition assistance (TA); Navy and Marine Corp service members who participate in the Navy College Program for Afloat College Education (NCPACE); and Navy, Marine Corps, Adult Family Members (AFM) of service members and Civil Service employees who participate in the Academic Skills Program.

CATEGORIES OF RECORDS IN THE SYSTEM:

Individual's application for tuition assistance; personnel data; counseling notes and education plans; degree, course completion and grade reports from academic institutions and contract training providers; authorization for disbursement; agency approval/disapproval.

AUTHORITY FOR THE MAINTENANCE OF THE SYSTEM:

5 U.S.C. 301, Departmental Regulations; DoD 1322.8, Voluntary Education Programs for Military Personnel; SECNAVINST 1560.4, Department of the Navy Voluntary Education Program; and OPNAVINST 1560.9A, Voluntary Education Programs for Navy Personnel; and E.O. 9397 (SSN).

PURPOSE(S):

To maintain information on participants in the tuition assistance program, Navy College Program for Afloat College Education (NCPACE) and Academic Skills programs.

To provide information to education counselors for the purpose of determining TA eligibility; education and degree plans; and course selection and eligibility.

To provide information to fiscal and accounting personnel for the purpose of financial management and funds disbursement.

To provide supervisory and management personnel access to the individual's degree and course completion records via the Electronic Training Jacket produced by the Navy Training Management and Planning System (NTMPS) for the purpose of personnel evaluation, determining special program eligibility, and duty assignments.

To provide degree and course completion information to NTMPS in the form of an electronic extract.

ROUTINE USES OF RECORDS MAINTAINED IN THE SYSTEM, INCLUDING CATEGORIES OF USERS AND THE PURPOSES OF SUCH USES:

In addition to those disclosures generally permitted under 5 U.S.C. 552a(b) of the Privacy Act, these records or information contained therein may specifically be disclosed outside the DoD as a routine use pursuant to 5 U.S.C. 552a(b)(3) as follows:

To United States Coast Guard Voluntary Education Program Office for the purpose of education counseling, financial management and funds disbursement.

The DoD ''Blanket Routine Uses'' set forth at the beginning of the Navy's compilation of systems of records notices also apply to this system.

POLICIES AND PRACTICES FOR STORING, RETRIEVING, ACCESSING, RETAINING, AND DISPOSING OF RECORDS IN THE SYSTEM:

STORAGE:

Paper and electronic media.

RETRIEVABILITY:

By individual's name, Social Security Number and branch of service.

SAFEGUARDS:

Paper copies of tuition applications are maintained in file cabinets under the control of authorized personnel during working hours; the office space in which the file cabinets are located is locked outside official working hours. Automated records are password protected.

RETENTION AND DISPOSAL:

Paper and/or electronic copies of the individual's signed Tuition Assistance applications are retained at the originating NCO for three years and then shredded or burned. Copies of tuition assistance authorizations for officers are maintained in their official personnel record for two years following the completion of courses paid by tuition assistance. All other records are maintained in electronic format within NCMIS indefinitely.

SYSTEM MANAGER(S) AND ADDRESS:

Commanding Officer, Naval Education and Training Professional Development and Technology Center, 6490 Saufley Field Road, Pensacola, FL 32509–5241.

NOTIFICATION PROCEDURE:

Individuals seeking to determine whether information about them is contained in this system should address written inquiries to the Commanding Officer, Naval Education and Training Professional Development and Technology Center, 6490 Saufley Field Road, Pensacola, FL 32509–5241.

Individuals should provide their full name, Social Security Number, branch of service, and signature.

RECORD ACCESS PROCEDURES:

Individuals seeking access to information about them contained in this system should address written inquiries to the Commanding Officer, Naval Education and Training Professional Development and Technology Center, 6490 Saufley Field Road, Pensacola, FL 32509–5241.

Individuals should provide their full name, Social Security Number, branch of service, and signature.

CONTESTING RECORD PROCEDURES:

The Navy's rules for accessing records, and for contesting contents and appealing initial agency determinations are published in Secretary of the Navy Instruction 5211.5; 32 CFR part 701; or may be obtained from the system manager.

RECORD SOURCE CATEGORIES:

Subject individual; Standard Training Activity Support System; Navy Personnel Command; Application for Tuition Assistance Form (NAVMC 10883); education counselors; educational institutions; Tuition Assistance Authorization form (NAVEDTRA 1560/5); and Academic Skills contractor.

EXEMPTIONS CLAIMED FOR THE SYSTEM:

None.

[FR Doc. 02–9961 Filed 4–23–02; 8:45 am]

BILLING CODE 5001–08–P

DEPARTMENT OF EDUCATION

Notice of Proposed Information Collection Requests

AGENCY: Department of Education.

SUMMARY: The Acting Leader, Regulatory Information Management Group, Office of the Chief Information Officer, invites comments on the proposed information collection requests as required by the Paperwork Reduction Act of 1995.

DATES: Interested persons are invited to submit comments on or before June 24, 2002.

SUPPLEMENTARY INFORMATION: Section 3506 of the Paperwork Reduction Act of 1995 (44 U.S.C. Chapter 35) requires that the Office of Management and Budget (OMB) provide interested Federal agencies and the public an early opportunity to comment on information collection requests. OMB may amend or waive the requirement for public consultation to the extent that public participation in the approval process would defeat the purpose of the information collection, violate State or Federal law, or substantially interfere with any agency's ability to perform its statutory obligations. The Acting Leader, Regulatory Information Management Group, Office of the Chief Information Officer, publishes that notice containing proposed information collection requests prior to submission of these requests to OMB. Each proposed information collection, grouped by office, contains the following: (1) Type of review requested, e.g. new, revision, extension, existing or reinstatement; (2) Title; (3) Summary of the collection; (4) Description of the need for, and proposed use of, the information; (5) Respondents and frequency of collection; and (6) Reporting and/or Recordkeeping burden. OMB invites public comment.

The Department of Education is especially interested in public comment addressing the following issues: (1) Is this collection necessary to the proper functions of the Department; (2) will this information be processed and used in a timely manner; (3) is the estimate of burden accurate; (4) how might the Department enhance the quality, utility, and clarity of the information to be collected; and (5) how might the Department minimize the burden of this collection on the respondents, including through the use of information technology.

Dated: April 18, 2002.

William Burrow,

Acting Leader, Regulatory Information Management, Office of the Chief Information Officer.

Federal Student Aid

Type of Review: Revision.

Title: Federal Family Education Loan (FFEL) Deferment Requests.

Frequency: Annually.

Affected Public: Individuals or household.

Reporting and Recordkeeping Hour Burden

Responses: 1,148,819, *Burden Hours:* 183,811.

Abstract: These forms will serve as the means of collecting information necessary to determine whether a FFEL borrower qualifies for a specific type of loan deferment.

Requests for copies of the proposed information collection request may be accessed from *http://edicsweb.ed.gov,* or should be addressed to Vivian Reese, Department of Education, 400 Maryland Avenue, SW, Room 4050, Regional Office Building 3, Washington, DC 20202–4651. Requests may also be electronically mailed to the internet address *OCIO_IMG_Issues@ed.gov* or faxed to 202–708–9346. Please specify the complete title of the information collection when making your request. Comments regarding burden and/or the collection activity requirements should be directed to Joseph Schubart at (202) 708–9266 or via his internet address *Joe.Schubart@ed.gov.* Individuals who use a telecommunications device for the deaf (TDD) may call the Federal Information Relay Service (FIRS) at 1–800–877–8339.

[FR Doc. 02–9969 Filed 4–23–02; 8:45 am]

BILLING CODE 4000–01–P

DEPARTMENT OF EDUCATION

[CFDA No. 84.259A]

Native Hawaiian Vocational Education Program

AGENCY: Office of Vocational and Adult Education, Department of Education.

ACTION: Notice of availability of assistance for ALU LIKE, Inc. under the Native Hawaiian Vocational Education Program (NHVEP).

SUMMARY: The NHVEP provides financial assistance to projects that provide vocational training and related activities for the benefit of Native Hawaiians. Eligible program applicants are organizations primarily serving and representing Native Hawaiians that are recognized by the Governor of the State of Hawaii (the Governor).

In December 2001, the Governor recommended that the Department of Education consider ALU LIKE, Inc. of Honolulu for funding under the NHVEP. We have, therefore, requested an application from ALU LIKE, Inc. We will review the ALU LIKE, Inc. application for compliance with section 116(h) of the Carl D. Perkins Vocational and Technical Education Act of 1998 (the Perkins Act). If the application is approved, we will award a grant of up to five years to ALU LIKE, Inc. on or about July 31, 2002.

Funds currently available for the NHVEP are $2,750,000 from the FY 2001 appropriation and $2,950,000 from the FY 2002 appropriation. Funding for

subsequent project years is subject to the availability of appropriations and to the grantee making substantial progress in meeting its goals and objectives, in accordance with 34 CFR 75.253.

FOR FURTHER INFORMATION CONTACT: Paul Geib, U.S. Department of Education, 400 Maryland Avenue, SW., room 4525, Mary E. Switzer Building, Washington, DC 20202–7242. Telephone: (202) 205–9962 or via Internet: *paul.geib@ed.gov.*

If you use a telecommunications device for the deaf (TDD), you may call the Federal Information Relay Service (FIRS) at 1–800–877–8339 between 8 a.m. and 8 p.m. Eastern Time.

Individuals with disabilities may obtain this document in an alternative format (*e.g.*, Braille, large print, audiotape, or computer diskette) on request to the program contact person listed at the beginning of this section.

Electronic Access to This Document

You may view this document, as well as all other Department of Education documents published in the **Federal Register**, in text or Adobe Portable Document Format (PDF) on the Internet at the following site: *www.ed.gov/legislation/FedRegister*.

To use PDF you must have Adobe Acrobat Reader, which is available free at this site. If you have questions about using PDF, call the U.S. Government Printing Office (GPO), toll free, at 1–888–293–6498; or in the Washington, DC area at (202) 512–1530.

Note: The official version of this document is the document published in the **Federal Register**. Free Internet access to the official edition of the **Federal Register** and the Code of Federal Regulations is available on GPO Access at: *http://www.access.gpo.gov/nara/index.html*.

Program Authority: 20 U.S.C. 2326.

Dated: April 19, 2002.

Carol D'Amico,

Assistant Secretary, Office of Vocational and Adult Education.

[FR Doc. 02–10022 Filed 4–23–02; 8:45 am]

BILLING CODE 4000–01–P

DEPARTMENT OF ENERGY

National Nuclear Security Administration Office of Los Alamos Site Operations; Floodplain Statement of Finding for the Connector Road Between Technical Areas 22 and 8 at Los Alamos National Laboratory, Los Alamos, New Mexico

AGENCY: National Nuclear Security Administration, Office of Los Alamos Site Operations, Department of Energy.

ACTION: Floodplain Statement of Finding.

SUMMARY: This Floodplain Statement of Findings is for the construction of a connector road about one mile in length between Technical Areas (TAs) 22 and 8 at Los Alamos National Laboratory (LANL). A short segment, less than 200 feet in length, of the road will cross a floodplain area within Pajarito Canyon, located within the western portion of LANL. In accordance with 10 CFR part 1022, the Department of Energy (DOE), National Nuclear Security Administration (NNSA) Office of Los Alamos Site Operations has prepared a floodplain/wetland assessment and will perform this proposed action in a manner so as to avoid or minimize potential harm to or within the affected floodplain.

FOR FURTHER INFORMATION CONTACT: Elizabeth Withers, U.S. Department of Energy, National Nuclear Security Administration, Office of Los Alamos Site Operations, 528 35th Street, Los Alamos, NM 87544. Telephone (505) 667–8690, of facsimile (505) 667–9998; or electronic address: *ewithers@doeal.gov*. For Further Information on General DOE Floodplain Environmental Review Requirements, contact: Carol M. Borgstrom, Director, Office of NEPA Policy and Compliance, EH–42, Department of Energy, 100 Independence Avenue, SW., Washington DC 20585–0119. Telephone (202) 586–4600 or (800) 472–2756, facsimile (202) 586–7031.

SUPPLEMENTARY INFORMATION: In accordance with DOE regulations for compliance with floodplain and wetlands environmental review requirements (10 CFR part 1022), NNSA prepared a floodplain/wetland assessment for this action. The NNSA published a Notice of Floodplain Involve (Volume 67, Number 63). This Notice announced that the floodplain/wetland assessment document was available for a 15-day review period and that copies of the document could be obtained by contacting Ms. Withers at the above address or were available for review at two public DOE reading rooms in Los Alamos and Albuquerque, New Mexico. No comments were received from the **Federal Register** notice on the proposed floodplain action.

Project Description: In March 2002, NNSA considered a proposal for constructing about a mile-long, two lane paved road that would link TA–22 with an existing road, Anchor Ranch Road, within TA–8. This new road will provide a second means for access to facilities located at TA–22; the existing TA–22 access road will be restricted to emergency use. The new road will correct traffic safety hazards associated with use of the existing TA–22 access road. The area surrounding TA–22 and TA–8 is forested and having a secondary access road to the TA–22 facilities is an important fire safety measure. Construction of the road will commence in fiscal year 2003 and be completed in less than 12 months.

Alternatives: Alternative routes for the road were considered but eliminated from future consideration. A combination of site factors were considered that lead to the identification of the proposed route as being the least disruptive to existing environmental resources in the area. The location of the road will also serve as a appropriately placed fuel break for enhancing the protection of TA–22 facilities in the event of a wildfire.

Floodplain Impacts: The proposed action would have the potential for minimal impacts the floodplain. Should a rain event occur during this activity, there may be some sediment movement down canyon because of the loosened condition of the soil from the clearing and construction activities.

Floodplain Mitigation: Placement of Best Management Practices (such as silt fences, straw bales or wattles, or wooden or rock structures to slow down water runoff and run-on at cleared sites) at the construction area and post-construction reseeding and revegetation along the sides of the roadway will minimize soil disturbance and reduce or prevent the potential for soil erosion. The road design will include an appropriately culvert so that downstream flow and function of the floodplain will not be impeded. No debris will be left at the work site. No vehicle maintenance or fueling within 100 feet of the floodplain would occur. Any sediment movement from the site would be short term and temporary.

Issued in Los Alamos, New Mexico on April 16, 2002.

Joseph Vozella,

Acting Director, Department of Energy, National Nuclear Security Administration, Office of Los Alamos Site Operations.

[FR Doc. 02–10020 Filed 4–23–02; 8:45 am]

BILLING CODE 6450–01–P

DEPARTMENT OF ENERGY

Solicitation Number DE–PS36–02GO92003; Hydrogen Generation From Electrolysis

AGENCY: Golden Field Office, Department of Energy.

ACTION: Issuance of solicitation for financial assistance applications.

SUMMARY: The U.S. Department of Energy (DOE) is announcing its intention to seek Financial Assistance Applications for the development and demonstration of an integrated renewable hydrogen generation system that will electrolyze water and produce hydrogen at 5000 psi pressure at a projected cost of less than $600/kW for a 10,000 scfpd unit and $300/kW for a 100,000 scfpd unit (by the year 2005, when produced in assumed quantities of 10,000 units).

DATES: Issuance of the Solicitation was April 10, 2002.

ADDRESSES: To obtain a copy of the solicitation, interested parties should access the DOE Golden Field Office Home Page at *http://www.golden.doe.gov/businessopportunities.html,* click on ''Solicitations'', and then access the solicitation number identified above. The Golden Home Page will provide a link to the Solicitation in the Industry Interactive Procurement System (IIPS) web site and provide instructions on using IIPS. The Solicitation can also be obtained directly through IIPS at *http://e-center.doe.gov* by browsing opportunities by Program Office for those solicitations issued by the Golden Field Office. DOE will not issue paper copies of the solicitation.

FOR FURTHER INFORMATION CONTACT: Andrea K. Lucero, Contract Specialist, via facsimile to (303) 275–4788, or electronically at *Andrea_Lucero@nrel.gov.* Responses to questions will be made by amendment to the Solicitation and posted on the IIPS Web site.

SUPPLEMENTARY INFORMATION: The Office of Power Technologies of the DOE Office of Energy Efficiency and Renewable Energy is soliciting Financial Assistance Applications for the development and demonstration of an integrated renewable hydrogen generation system that will electrolyze water to produce hydrogen. Through the award of Cooperative Agreements, DOE intends to provide financial support to assist in the development of such systems under provisions of the Hydrogen Future Act of 1996, Public Law 104–271.

The DOE Hydrogen Program works with U.S. industry to develop hydrogen technologies that will improve our nation's energy security, reduce greenhouse gas emissions, and create business opportunities for U.S. industry. The Hydrogen Future Act requires the Department to ensure that research and development activities bring hydrogen systems into the marketplace. Using renewable energy sources, the DOE Hydrogen Program has an interim goal to generate hydrogen with electrolyzers at a cost of less than $600 per kW where each unit would be capable of producing 10,000 standard cubic feet per day (scfpd) and $300 per kW for 100,000 scfpd units (by 2005, when produced in assumed quantities of 10,000 units). The system should be capable of delivering hydrogen at 5,000 psi to a vehicle. The work needed to reduce the costs of existing technology includes cost reductions in electrochemical technologies and other efficiency improvements.

Awards under this solicitation will be Cooperative Agreements with a term of up to three years. The required term will be specified by the Applicant, depending on the needs of the proposed project. Awards will be for the complete project period specified by the Applicant, with incremental funding provided by DOE during each year, as available. Subject to availability, the total DOE funding anticipated under this Solicitation will be approximately $3,000,000. DOE anticipates selecting two Applications for negotiation toward an award. Thus, the anticipated available funding is approximately $500,000 per award per year, for up to three years.

Eligibility for an award is not restricted to any particular category of Applicant. However, a minimum Cost Share of 50% of Total Project Costs is required in order to be considered for an award under this Solicitation.

Although this Solicitation is being issued in Fiscal Year (FY) 2002, potential awards will not be considered until early in FY 2003 (FY 2003 begins October 1, 2002). The possibility for awards to be made will depend on the availability of funds in the FY 2003 congressional appropriations. DOE reserves the right to make no awards under this Solicitation or to reduce the requested DOE funding commitment on any potential award through negotiated reductions in work scope.

Issued in Golden, Colorado, on April 10, 2002.

Jerry L. Zimmer,

Director, Office of Acquisition and Financial Assistance.

[FR Doc. 02–10019 Filed 4–23–02; 8:45 am]

BILLING CODE 6450–01–P

DEPARTMENT OF ENERGY

[Certification Notice—206]

Office of Fossil Energy; Notice of Filings of Coal Capability, Powerplant and Industrial Fuel Use Act

AGENCY: Office of Fossil Energy, Department of Energy.

ACTION: Notice of Filings.

SUMMARY: The owners/operators of 13 baseload electric powerplants have submitted coal capability self-certifications pursuant to section 201 of the Powerplant and Industrial Fuel Use Act of 1978, as amended, in accordance with 10 CFR 501.60, 61.

ADDRESSES: Copies of self-certification filings are available for public inspection, upon request, in the Office of Coal & Power Import/Export, Fossil Energy, Room 4G–039, FE–27, Forrestal Building, 1000 Independence Avenue, SW., Washington, DC 20585.

FOR FURTHER INFORMATION CONTACT: Ellen Russell at (202) 586–9624.

SUPPLEMENTARY INFORMATION: Title II of the Powerplant and Industrial Fuel Use Act of 1978 (FUA), as amended (42 U.S.C. 8301 *et seq.*), provides that no new baseload electric powerplant may be constructed or operated without the capability to use coal or another alternate fuel as a primary energy source. In order to meet the requirement of coal capability, the owner or operator of such facilities proposing to use natural gas or petroleum as its primary energy source shall certify, pursuant to FUA section 201(d), to the Secretary of Energy prior to construction, or prior to operation as a base load electric powerplant, that such powerplant has the capability to use coal or another alternate fuel. Such certification establishes compliance with section 201(a) as of the date filed with the Department of Energy (DOE). The Secretary is required to publish a notice in the **Federal Register** that a certification has been filed. The following owners/operators of proposed new baseload electric powerplants have filed self-certifications pursuant to section 201(d) and in accordance with DOE regulations in 10 CFR § 501.60, 61.

Owner/operator	Capacity MW	Plant location	In-service date
Duke Energy Arlington Valley, LLC	580	Arlington, AZ	June 1, 2002.
Otay Mesa Generating Co. LLC	510	San Diego, CA	3rd Quarter of 2003.
Moapa Energy Center, LLC	1100	Clark County, NV	April 2004.
Frederickson Power L.P	249.5	Tacoma, WA	July 2002.
Hot Spring Power Company, LLC	815	Hot Spring Cty, AK	July 1, 2004.
CPV Warren, LLC	520	Warren County, VA	2nd or 3rd Qrt 2005.
CPV Cunningham Creek, LLC	550	Fluvanna County, VA	2nd Qrt of 2005.
CPV Smyth, LLC	780	Smyth County, VA	3rd or 4th Qrt 2005.
CalPeak Power-Enterprise, LLC	49.5	Buttonwillow, CA	September 25, 2001.
Duke Energy Fayette, LLC	620	Masontown, PA	June 1, 2003.
Yuba City Energy Ctr., LLC	48.7	Yuba City, CA	Mid 2002.
King City Energy Ctr., LLC	48.7	King City, CA	Mid Feb. 2002.
Gilroy Energy Center, LLC	146.1	Gilroy, CA	Mid Feb. 2002.

Issued in Washington, DC, on April 18, 2002.

Anthony J. Como,

Deputy Director, Electric Power Regulation, Office of Coal & Power Import/Export, Office of Coal & Power Systems, Office of Fossil Energy.

[FR Doc. 02–10021 Filed 4–23–02; 8:45 am]

BILLING CODE 6450–01–P

DEPARTMENT OF ENERGY

Office of Energy Efficiency and Renewable Energy

Energy Conservation Program for Consumer Products Representative Average Unit Costs of Energy

AGENCY: Office of Energy Efficiency and Renewable Energy, Department of Energy.

ACTION: Notice.

SUMMARY: In this notice, the Department of Energy (DOE or Department) is forecasting the representative average unit costs of five residential energy sources for the year 2002. The five sources are electricity, natural gas, No. 2 heating oil, propane, and kerosene. The representative unit costs of these energy sources are used in the Energy Conservation Program for Consumer Products, established by Part B of Title III of the Energy Policy and Conservation Act.

EFFECTIVE DATE: The representative average unit costs of energy contained in this notice will become effective May 24, 2002 and will remain in effect until further notice.

FOR FURTHER INFORMATION CONTACT: Brian Card, U.S. Department of Energy, Office of Energy Efficiency and Renewable Energy, Forrestal Building, Mail Station EE–41, 1000 Independence Avenue, SW., Washington, DC 20585–0121, (202) 586–9228.

Francine Pinto, Esq., U.S. Department of Energy, Office of General Counsel, Forrestal Building, Mail Station GC–72, 1000 Independence Avenue, SW., Washington, DC 20585–0103, (202) 586–9507.

SUPPLEMENTARY INFORMATION: Section 323 of the EPCA (Act) [1] requires that DOE prescribe test procedures for the determination of the estimated annual operating costs or other measures of energy consumption for certain consumer products specified in the Act. These test procedures are found in 10 CFR part 430, subpart B.

Section 323(b) of the Act requires that the estimated annual operating costs of a covered product be calculated from measurements of energy use in a representative average use cycle or period of use and from representative average unit costs of the energy needed to operate such product during such cycle. The section further requires that DOE provide information to manufacturers regarding the representative average unit costs of energy. This cost information should be used by manufacturers to meet the obligations under section 323(c) of the Act. Most notably, these costs are used to comply with Federal Trade Commission (FTC) requirements for labeling. Manufacturers are required to use the revised DOE representative average unit costs when the FTC publishes new ranges of comparability for specific covered products, 16 CFR Part 305. Interested parties can also find information covering the FTC labeling requirements at www.ftc.gov/appliances.

The Department last published representative average unit costs of residential energy for use in the Energy Conservation Program for Consumer Products Other Than Automobiles on March 8, 2001 (66 FR 13917). Effective May 24, 2002, the cost figures published on March 8, 2001, will be superseded by the cost figures set forth in this notice.

The Department's Energy Information Administration (EIA) has developed the 2002 representative average unit after-tax costs of electricity, natural gas, No. 2 heating oil, propane, and kerosene prices found in this notice. The cost projections for heating oil, electricity, and natural gas are found in the December, 2001, EIA *Short-Term Energy Outlook,* DOE/EIA–0226 (01/12), and reflect the mid-price scenario. Projections for residential propane and kerosene prices are derived from their relative prices to that of heating oil, based on 1996–2000 averages for these three fuels. The source for these price data is the September 2001, *Monthly Energy Review* DOE/EIA–0035(01/09). The *Short-Term Energy Outlook* and the *Monthly Energy Review* are available at the National Energy Information Center, Forrestal Building, Room 1F–048, 1000 Independence Avenue, SW., Washington, DC 20585, (202) 586–8800.

We provide the 2002 representative average unit costs in Table 1 pursuant to section 323(b)(4) of the Act, and they will become effective May 24, 2002. They will remain in effect until further notice.

Issued in Washington, DC, on April 12, 2002.

David K. Garman,

Assistant Secretary for Energy Efficiency and Renewable Energy.

[1] References to the ''Act'' refer to the Energy Policy and Conservation Act, as amended. 42 U.S.C. 6291–6309.

TABLE 1.—REPRESENTATIVE AVERAGE UNIT COSTS OF ENERGY FOR FIVE RESIDENTIAL ENERGY SOURCES (2002)

Type of energy	Per million Btu [1]	In commonly used terms	As required by test procedure
Electricity	$24.27	8.28¢/kWh \2 3\	$ .0828/kWh
Natural gas	6.56	65.6¢/therm [4] or $6.74/MCF \5 6\	.00000656/Btu
No. 2 Heating Oil	7.79	$1.08/gallon [7]	.00000779/Btu
Propane	9.53	$0.87/gallon [8]	.00000953/Btu
Kerosene	9.11	$1.23/gallon [9]	.00000911/Btu

[1] Btu stands for British thermal units.
[2] kWh stands for kilowatt hour.
[3] 1 kWh = 3,412 Btu.
[4] 1 therm = 100,000 Btu. Natural gas prices include taxes.
[5] MCF stands for 1,000 cubic feet.
[6] For the purposes of this table, one cubic foot of natural gas has an energy equivalence of 1,027 Btu.
[7] For the purposes of this table, one gallon of No. 2 heating oil has an energy equivalence of 138,690 Btu.
[8] For the purposes of this table, one gallon of liquid propane has an energy equivalence of 91,333 Btu.
[9] For the purposes of this table, one gallon of kerosene has an energy equivalence of 135,000 Btu.

[FR Doc. 02–10147 Filed 4–23–02; 8:45 am]
BILLING CODE 6450–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Docket No. ER02–1545–000]

Alabama Power Company; Notice of Filing

April 17, 2002.

Take notice that on April 15, 2002, Alabama Power Company (APC) filed a Service Agreement for Supply of Electric Service to Electric Membership and Electric Cooperative Corporations under Rate Schedule REA–1 of its Second Revised FERC Electric Tariff Original Volume No. 1 (Tariff). Pursuant to that Service Agreement, APC will provide electric service to Black Warrior Electric Membership Corporation at the new Porter Delivery Point located in Perry County, Alabama.

Any person desiring to intervene or to protest this filing should file with the Federal Energy Regulatory Commission, 888 First Street, NE., Washington, DC 20426, Any person desiring to intervene or to protest this filing should file 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). Protests will be considered by the Commission in determining the appropriate action to be taken, but will not serve to make protestants parties to the proceeding. Any person wishing to become a party must file a motion to intervene. All such motions or protests should be filed on or before the comment date, and, to the extent applicable, must be served on the applicant and on any other person designated on the official service list. This filing is available for review at the Commission or may be viewed on the Commission's web site at *http://www.ferc.gov* using the ''RIMS'' link, select ''Docket #'' and follow the instructions (call 202–208–2222 for assistance). Protests and interventions may be filed electronically via the Internet in lieu of paper; see 18 CFR 385.2001(a)(1)(iii) and the instructions on the Commission's web site under the ''e-Filing'' link.

Comment Date: May 6, 2002.

Linwood A. Watson,

Deputy Secretary.

[FR Doc. 02–9965 Filed 4–23–02; 8:45 am]
BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Docket No. ER02–1546–000]

Ameren Services Company; Notice of Filing

April 17, 2002.

Take notice that on April 15, 2002, Ameren Services Company (Ameren Services) tendered for filing Service Agreements for Network Integration Transmission Service and a Network Operating Agreement between Ameren Services and MidAmerican Energy Company and Wayne-White Counties Electric Cooperative. Ameren Services asserts that the purpose of the Agreements is to permit Ameren Services to provide transmission service to MidAmerican Energy Company and Wayne-White Counties Electric Cooperative pursuant to Ameren's Open Access Tariff.

Any person desiring to intervene or to protest this filing should file with the Federal Energy Regulatory Commission, 888 First Street, NE., Washington, DC 20426, Any person desiring to intervene or to protest this filing should file 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). Protests will be considered by the Commission in determining the appropriate action to be taken, but will not serve to make protestants parties to the proceeding. Any person wishing to become a party must file a motion to intervene. All such motions or protests should be filed on or before the comment date, and, to the extent applicable, must be served on the applicant and on any other person designated on the official service list. This filing is available for review at the Commission or may be viewed on the Commission's web site at *http://www.ferc.gov* using the ''RIMS'' link, select ''Docket #'' and follow the instructions (call 202–208–2222 for assistance). Protests and interventions may be filed electronically via the Internet in lieu of paper; see 18 CFR 385.2001(a)(1)(iii) and the instructions on the Commission's web site under the ''e-Filing'' link.

Comment Date: May 6, 2002.

Linwood A. Watson,

Deputy Secretary.

[FR Doc. 02–9966 Filed 4–23–02; 8:45 am]
BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Docket No. RP01–612–002]

ANR Pipeline Company; Notice of Compliance Filing

April 18, 2002.

Take notice that on April 15, 2002, ANR Pipeline Company (ANR), tendered for filing an explanatory statement and Substitute Original Sheet No. 75G.02, Substitute Original Sheet No. 75G.03 and Substitute Seventh Revised Sheet No. 89.

ANR requests that the revised tariff sheets be made effective March 31, 2002. ANR states that the tariff sheets and explanatory statement are being filed in compliance with the Commission's March 15, 2002 order accepting the tariff sheets subject to ANR providing an explanation and further revisions to the tariff sheets to clarify the issues regarding ANR's proposed Associated Liquefiables pro forma Agreement.

Any person desiring to protest said filing should file a protest with the Federal Energy Regulatory Commission, 888 First Street, NE., Washington, DC 20426, in accordance with Section 385.211 of the Commission's Rules and Regulations. All such protests must be filed in accordance with Section 154.210 of the Commission's Regulations. Protests will be considered by the Commission in determining the appropriate action to be taken, but will not serve to make protestants parties to the proceedings. Copies of this filing are on file with the Commission and are available for public inspection. This filing may also be viewed on the web at *http://www.ferc.gov* using the ''RIMS'' link, select ''Docket#'' and follow the instructions (call 202–208–2222 for assistance). Comments, protests and interventions may be filed electronically via the Internet in lieu of paper. *See*, 18 CFR 385.2001(a)(1)(iii) and the instructions on the Commission's web site under the ''e-Filing'' link.

Linwood A. Watson,

Deputy Secretary.

[FR Doc. 02–10015 Filed 4–23–02; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Docket No. RP02–147–000]

ANR Pipeline Company; Notice To Convene Meeting

April 18, 2002.

On January 18, 2002, ANR Pipeline Company filed revised tariff sheets that limits the liability of ANR and its shippers to actual damages in certain circumstances. On February 28, 2002, the Commission accepted and suspended the tariff sheet to be effective on or earlier of August 1, 2002, or a date specified in a further order of the Commission, subject to refund and conditions. The Commission's Dispute Resolution Service convened a meeting of the parties on March 13, 2002 regarding the proposed tariff sheet.

The Commission's Dispute Resolution Service will conduct a second session on April 23, 2002, commencing at 1:00 p.m., in Room 3M–1 at the Federal Energy Regulatory Commission, 888 First Street, NE., Washington, DC At this session, the parties will attempt to achieve resolution on appropriate tariff language in the above-captioned docket through assisted negotiation. If a party has any questions, please call Deborah Osborne at (202) 208–0831.

Linwood A. Watson, Jr.,

Deputy Secretary.

[FR Doc. 02–10016 Filed 4–23–02; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Docket Nos. RP00–335–001, and RP01–414–001]

Black Marlin Pipeline Company; Notice of Compliance Filing

April 18, 2002.

Take notice that on April 15, 2002, Black Marlin Pipeline Company (Black Marlin) tendered for filing as part of its FERC Gas Tariff, First Revised Volume No. 1, revised pro forma tariff Sheet Nos. 109, 110, 111, 133, 134, 135, 200, 213, 213.01, 213.02, 222, 223, 224, 225, and 226–299.

Black Marlin states that the filing is being made to comply with the Commission's order issued March 14, 2002 in the referenced dockets.

Any person desiring to protest said filing should file a protest with the Federal Energy Regulatory Commission, 888 First Street, NE, Washington, DC 20426, in accordance with Section 385.211 of the Commission's Rules and Regulations. All such protests must be filed in accordance with Section 154.210 of the Commission's Regulations. Protests will be considered by the Commission in determining the appropriate action to be taken, but will not serve to make protestants parties to the proceedings. Copies of this filing are on file with the Commission and are available for public inspection. This filing may also be viewed on the web at *http://www.ferc.gov* using the ''RIMS'' link, select ''Docket#'' and follow the instructions (call 202–208–2222 for assistance). Comments, protests and interventions may be filed electronically via the Internet in lieu of paper. See, 18 CFR 385.2001(a)(1)(iii) and the instructions on the Commission's web site under the ''e-Filing'' link.

Linwood A. Watson,

Deputy Secretary.

[FR Doc. 02–10008 Filed 4–23–02; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Docket No. GT00–34–008]

Dauphin Island Gathering Partners; Notice of Proposed Changes in FERC Gas Tariff

April 18, 2002.

Take notice that on April 15, 2002, Dauphin Island Gathering Partners (DIGP) tendered for filing as part of its FERC Gas Tariff, First Revised Volume No. 1, the tariff sheets listed below to become effective April 1, 2002. DIGP states that these tariff sheets reflect changes to delivery points and Maximum Daily Quantities (MDQ's).

Ninth Revised Sheet No. 9
Seventh Revised Sheet No. 10

DIGP states that copies of its filing is being served on its customers and other interested parties.

Any person desiring to protest said filing should file a protest with the Federal Energy Regulatory Commission, 888 First Street, NE., Washington, DC 20426, in accordance with Section 385.211 of the Commission's Rules and Regulations. All such protests must be filed in accordance with Section 154.210 of the Commission's Regulations. Protests will be considered by the Commission in determining the appropriate action to be taken, but will not serve to make protestants parties to the proceedings. Copies of this filing are

on file with the Commission and are available for public inspection. This filing may also be viewed on the web at *http://www.ferc.gov* using the ''RIMS'' link, select ''Docket#'' and follow the instructions (call 202–208–2222 for assistance). Comments, protests and interventions may be filed electronically via the Internet in lieu of paper. See, 18 CFR 385.2001(a)(1)(iii) and the instructions on the Commission's web site under the ''e-Filing'' link.

Linwood A. Watson,

Deputy Secretary.

[FR Doc. 02–10002 Filed 4–23–02; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Docket Nos. RP00–401–001 and RP01–4–004]

Enbridge Pipelines (AlaTenn) Inc. (Formerly Midcoast Interstate Transmission, Inc.; Notice of Compliance Filing

April 18, 2002.

Take notice that on April 12, 2002, Enbridge Pipelines (AlaTenn) Inc., formerly Midcoast Interstate Transmission, Inc., (AlaTenn) tendered for filing as part of its FERC Gas Tariff, Third Revised Volume No. 1, the revised tariff sheets listed in Appendix A to the filing.

AlaTenn states that the filing is being made in compliance with the Commission's March 14, 2002, order in these proceedings.

AlaTenn states that complete copies of its filing are being mailed to all of the parties on the Commission's Official Service list for these proceedings, all of its jurisdictional customers, and applicable State Commissions.

Any person desiring to protest said filing should file a protest with the Federal Energy Regulatory Commission, 888 First Street, NE., Washington, DC 20426, in accordance with Section 385.211 of the Commission's Rules and Regulations. All such protests must be filed in accordance with Section 154.210 of the Commission's Regulations. Protests will be considered by the Commission in determining the appropriate action to be taken, but will not serve to make protestants parties to the proceedings. Copies of this filing are on file with the Commission and are available for public inspection. This filing may also be viewed on the web at *http://www.ferc.gov* using the ''RIMS'' link, select ''Docket#'' and follow the instructions (call 202–208–2222 for assistance). Comments, protests and interventions may be filed electronically via the Internet in lieu of paper. *See*, 18 CFR 385.2001(a)(1)(iii) and the instructions on the Commission's web site under the ''e-Filing'' link.

Linwood A. Watson, Jr.,

Deputy Secretary.

[FR Doc. 02–10010 Filed 4–23–02; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Docket No. EG00–12–000]

FortisUS Energy Corporation; Notice of Application for Commission Determination of Exempt Wholesale Generator Status

April 16, 2002.

On April 12, 2002, FortisUS Energy Corporation tendered for filing information with respect to a change in facts relative to its status as an exempt wholesale generator and a demonstration that such change does not affect such status pursuant to Section 32(a) of the Public Utility Holding Company Act of 1935, as amended and Section 365.8 of the Commission's regulations.

Any person desiring to intervene or to protest this filing should file with the Federal Energy Regulatory Commission, 888 First Street, NE., Washington, DC 20426, Any person desiring to intervene or to protest this filing should file 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). Protests will be considered by the Commission in determining the appropriate action to be taken, but will not serve to make protestants parties to the proceeding. Any person wishing to become a party must file a motion to intervene. All such motions or protests should be filed on or before the comment date, and, to the extent applicable, must be served on the applicant and on any other person designated on the official service list. This filing is available for review at the Commission or may be viewed on the Commission's web site at *http://www.ferc.gov* using the ''RIMS'' link, select ''Docket #'' and follow the instructions (call 202–208–2222 for assistance). Protests and interventions may be filed electronically via the Internet in lieu of paper; see 18 CFR 385.2001(a)(1)(iii) and the instructions on the Commission's web site under the ''e-Filing'' link.

Comment date: May 7, 2002.

Linwood A. Watson, Jr.,

Deputy Secretary.

[FR Doc. 02–9996 Filed 4–23–02; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Docket No. RP00–340–005]

Gulf South Pipeline Company, LP; Notice of Compliance Filing

April 18, 2002.

Take notice that on April 15, 2002, Gulf South Pipeline Company, LP (Gulf South) tendered for filing as part of its FERC Gas Tariff, Sixth Revised Volume No. 1, the tariff sheets listed on Attachment A to the filing, to be effective 30 days after a final order on rehearing and the tariff sheets listed on Attachment B to the filing, to be effective four months after a final order on rehearing.

This is Gulf South's compliance filing submitted consistent with the requirements of the Commission's Order on Compliance with Order Nos. 637, 587–G and 587–L.

Any person desiring to protest said filing should file a protest with the Federal Energy Regulatory Commission, 888 First Street, NE., Washington, DC 20426, in accordance with section 385.211 of the Commission's rules and regulations. All such protests must be filed in accordance with section 154.210 of the Commission's regulations. Protests will be considered by the Commission in determining the appropriate action to be taken, but will not serve to make protestants parties to the proceedings. Copies of this filing are on file with the Commission and are available for public inspection. This filing may also be viewed on the web at *http://www.ferc.gov* using the ''RIMS'' link, select ''Docket#'' and follow the instructions (call 202–208–2222 for assistance). Comments, protests and interventions may be filed electronically via the Internet in lieu of paper. See, 18 CFR 385.2001(a)(1)(iii) and the instructions on the Commission's web site under the ''e-Filing'' link.

Linwood A. Watson, Jr.,

Deputy Secretary.

[FR Doc. 02–10009 Filed 4–23–02; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Docket No. EL02–76–000]

Holy Cross Energy, Inc., and Yampa Valley Electric Association, Complainants, v. Public Service Company of Colorado, Respondent; Notice of Complaint

April 18, 2002.

Take notice that on April 17, 2002, Holy Cross Energy, Inc. and Yampa Valley Electric Association (collectively, HCE/Yampa), tendered for filing with the Federal Energy Regulatory Commission (Commission), a complaint, a request for investigation, and a refund of Fuel Clause Adjustment (FCA) charges against Public Service Company of Colorado (PSCo). The Complaint alleges overcharges of FCA Charges under existing FERC Rate Schedules and in violation of Section 35.14 of the Commission's Regulations

Copies of the complaint filing were served on PSCo and the Colorado Public Utilities Commission.

Any person desiring to be heard or to protest this filing should file a motion to intervene or protest with the Federal Energy Regulatory Commission, 888 First Street, NE., Washington, DC 20426, in accordance with Rules 211 and 214 of the Commission's Rules of Practice and Procedure (18 CFR 385.211 and 385.214). All such motions or protests must be filed on or before May 7, 2002. Protests will be considered by the Commission in determining the appropriate action to be taken, but will not serve to make protestants parties to the proceeding. Any person wishing to become a party must file a motion to intervene. Answers to the complaint shall also be due on or before May 7, 2002. Copies of this filing are on file with the Commission and are available for public inspection. This filing may also be viewed on the web at *http://www.ferc.gov* using the ''RIMS'' link, select ''Docket#'' and follow the instructions (call 202–208–2222 for assistance). Comments, protests, interventions and answers may be filed electronically via the Internet in lieu of paper. See, 18 CFR 385.2001(a)(1)(iii) and the instructions on the Commission's web site under the ''e-Filing'' link.

Linwood A. Watson, Jr.,

Deputy Secretary.

[FR Doc. 02–9997 Filed 4–23–02; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[RP00–305–008]

Mississippi River Transmission Corporation; Notice of Negotiated Rates

April 18, 2002.

Take notice that on April 15, 2002, Mississippi River Transmission Corporation (MRT) tendered for filing as part of its FERC Gas Tariff, Third Revised Volume No. 1, the following tariff sheet to be effective April 15, 2002:

First Revised Sheet No. 10D

MRT states that the purpose of this filing is to reflect the implementation of a new negotiated rate transaction.

Any person desiring to be heard or to protest said 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 or 385.211 of the Commission's Rules and Regulations. All such motions or protests must be filed in accordance with Section 154.210 of the Commission's Regulations. Protests will be considered by the Commission in determining the appropriate action to be taken, but will not serve to make 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. This filing may also be viewed on the web at *http://www.ferc.gov* using the ''RIMS'' link, select ''Docket#'' and follow the instructions (call 202–208–2222 for assistance). Comments, protests and interventions may be filed electronically via the Internet in lieu of paper. See, 18 CFR 385.2001(a)(1)(iii) and the instructions on the Commission's web site under the ''e-Filing'' link.

Linwood A. Watson, Jr.,

Deputy Secretary.

[FR Doc. 02–10007 Filed 4–23–02; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Docket Nos. ER01–3009–006, ER01–3153–006, and EL00–90–006]

New York Independent System Operator, Inc., Morgan Stanley Capital Group, Inc. v. New York Independent System Operator, Inc.; Notice of Filing

April 18, 2002.

Take notice that on April 3, 2002, the New York Independent System Operator, Inc. (NYISO) tendered for filing with the Federal Energy Regulatory Commission (Commission) a Motion to Defer the Effective Date of Proposed Tariff Revisions.

Any person desiring to intervene or to protest this filing should file 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). Protests will be considered by the Commission in determining the appropriate action to be taken, but will not serve to make protestants parties to the proceeding. Any person wishing to become a party must file a motion to intervene. All such motions or protests should be filed on or before the comment date, and, to the extent applicable, must be served on the applicant and on any other person designated on the official service list. This filing is available for review at the Commission or may be viewed on the Commission's web site at *http://www.ferc.gov* using the ''RIMS'' link, select ''Docket #'' and follow the instructions (call 202–208–2222 for assistance). Protests and interventions may be filed electronically via the Internet in lieu of paper; see 18 CFR 385.2001(a)(1)(iii) and the instructions on the Commission's web site under the ''e-Filing'' link.

Comment Date: April 24, 2002.

Linwood A. Watson, Jr.,

Deputy Secretary.

[FR Doc. 02–9999 Filed 4–23–02; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Docket No. ER02–638–002]

New York Independent System Operator, Inc.; Notice of Filing

April 18, 2002.

Take notice that on March 29, 2002, the New York Independent System Operator, Inc. (NYISO), tendered for filing with the Federal Energy Regulatory Commission (Commission), a Motion to Defer the Effective Date of Proposed Tariff Provisions.

Any person desiring to intervene or to protest this filing should file 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). Protests will be considered by the Commission in determining the appropriate action to be taken, but will not serve to make protestants parties to the proceeding. Any person wishing to become a party must file a motion to intervene. All such motions or protests should be filed on or before the comment date, and, to the extent applicable, must be served on the applicant and on any other person designated on the official service list. This filing is available for review at the Commission or may be viewed on the Commission's web site at *http://www.ferc.gov* using the ''RIMS'' link, select ''Docket #'' and follow the instructions (call 202–208–2222 for assistance). Protests and interventions may be filed electronically via the Internet in lieu of paper; see 18 CFR 385.2001(a)(1)(iii) and the instructions on the Commission's web site under the ''e-Filing'' link.

Comment Date: April 24, 2002.

Linwood A. Watson, Jr.,

Deputy Secretary.

[FR Doc. 02–10000 Filed 4–23–02; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Docket No. GT02–11–001]

Northwest Pipeline Corporation; Notice of Compliance Filing

April 18, 2002.

Take notice that on April 12, 2002, Northwest Pipeline Corporation (Northwest) tendered for filing as part of its FERC Gas Tariff, Third Revised Volume No.1, the following tariff sheet, with an effective date of April 1, 2002:

Substitute Fifth Revised Sheet No. 366

Northwest states that, consistent with the Commission's order in this proceeding, Northwest has eliminated a non-conforming provision from a transportation service agreement with Sempra Energy Trading Corporation (Sempra) and is submitting a tariff sheet to reflect removal of Northwest's agreement with Sempra from the list of non-conforming agreements in Northwest's tariff.

Any person desiring to protest said filing should file a protest with the Federal Energy Regulatory Commission, 888 First Street, NE., Washington, DC 20426, in accordance with Section 385.211 of the Commission's Rules and Regulations. All such protests must be filed in accordance with Section 154.210 of the Commission's Regulations. Protests will be considered by the Commission in determining the appropriate action to be taken, but will not serve to make protestants parties to the proceedings. Copies of this filing are on file with the Commission and are available for public inspection. This filing may also be viewed on the web at *http://www.ferc.gov* using the ''RIMS'' link, select ''Docket#'' and follow the instructions (call 202–208–2222 for assistance). Comments, protests and interventions may be filed electronically via the Internet in lieu of paper. See, 18 CFR 385.2001(a)(1)(iii) and the instructions on the Commission's web site under the ''e-Filing'' link.

Linwood A. Watson, Jr.,

Deputy Secretary.

[FR Doc. 02–10003 Filed 4–23–02; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Docket No. RP01–183–001]

OkTex Pipeline Company; Notice of Compliance Filing

April 18, 2002.

Take notice that on April 15, 2002 OkTex Pipeline Company (OkTex), tendered for filing to become part of its FERC Gas Tariff, Original Volume No. 1, the following pro forma tariff sheets:

Substitute 2nd Revised Sheet No. 1
Substitute 2nd Revised Sheet No. 4
Second Revised Sheet No. 5A
Substitute 2nd Revised Sheet No. 15
8th Revised Sheet No. 30
Second Revised Sheet No. 30A 3rd Revised Sheet No. 34
3rd Revised Sheet No. 35
3rd Revised Sheet No. 36
Fourth Revised Sheet No. 38
Substitute Original Sheet No. 40G
Substitute Original Sheet No. 40H
Substitute Original Sheet No. 40I
Substitute Original Sheet No. 40J
Original Sheet No. 40K
Substitute 1st Revised Sheet No. 47
Substitute 1st Revised Sheet No. 54
Substitute Second Revised Sheet No. 60C
Second Revised Sheet No. 61

OkTex states that on February 27, 2002 the Commission issued its Order on Compliance with Order No. 637 regarding OkTex's December 11, 2000 filing regarding the regulation of short-term interstate natural gas transportation services in Docket Nos. RM98–10–002 and RM98–12–002 (''Order No. 637, and 637–A''). In the instant filing OkTex is filing in to implement the Commission's rulings in the Order issued in Docket No RP01–183–000.

OkTex states that copies of the filing have been mailed to all affected customers and state regulatory commissions.

Any person desiring to protest said filing should file a protest with the Federal Energy Regulatory Commission, 888 First Street, NE., Washington, DC 20426, in accordance with Section 385.211 of the Commission's Rules and Regulations. All such protests must be filed in accordance with Section 154.210 of the Commission's Regulations. Protests will be considered by the Commission in determining the appropriate action to be taken, but will not serve to make protestants parties to the proceedings. Copies of this filing are on file with the Commission and are available for public inspection. This filing may also be viewed on the web at *http://www.ferc.gov* using the ''RIMS'' link, select ''Docket#'' and follow the instructions (call 202–208–2222 for assistance). Comments, protests and interventions may be filed electronically via the Internet in lieu of paper. *See*, 18 CFR 385.2001(a)(1)(iii) and the instructions on the Commission's web site under the ''e-Filing'' link.

Linwood A. Watson, Jr.,

Deputy Secretary.

[FR Doc. 02–10013 Filed 4–23–02; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Docket Nos. ER01–2998–000, ER02–358–000, and Docket No. EL02–64–000 (Not Consolidated)]

Pacific Gas & Electric Company, Pacific Gas & Electric Company, Northern California Power Agency v. Pacific Gas & Electric Company and the California Independent System Operator Corporation; Notice of Technical Conferences

April 18, 2002.

In the Commission's order issued on March 14, 2002,[1] the Commission directed a technical conference be held to address issues raised by the filing.

Take notice that a technical/settlement conference will be held on Wednesday through Friday, May 1–3, 2002 at 10 a.m. in a room to be designated at the offices of the Federal Energy Regulatory Commission, 888 First Street, NE., Washington, DC 20426.

A second technical/settlement conference will be held on Tuesday through Thursday, May 21–23, 2002 at 10:00 a.m. in a room to be designated at the offices of the Federal Energy Regulatory Commission, 888 First Street, NE., Washington, DC 20426.

The parties will file a list of common issues in the above-referenced dockets with the Commission by April 25, 2002. Parties may file comments following the technical/settlement conferences by June 4, 2002, and reply comments by June 14, 2002.

All interested parties and staff are permitted to attend the conferences.

Linwood A. Watson, Jr.,

Deputy Secretary.

[FR Doc. 02–9998 Filed 4–23–02; 8:45 am]

BILLING CODE 6717–01–P

[1] Pacific Gas & Electric Company, *et al.*, 98 FERC ¶ 61,281 (2002).

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Docket No. ER02–1351–000]

Pacific Gas and Electric Company; Notice of Filing

April 18, 2002.

Take notice that on March 22, 2002, Pacific Gas and Electric Company (PG&E) tendered for filing with the Federal Energy Regulatory Commission (Commission), a Motion to Withdraw Application seeking to withdraw its application regarding Generator Interconnection Agreements between PG&E and various parties filed with the Commission on March 20, 2002.

Any person desiring to intervene or to protest this filing should file 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). Protests will be considered by the Commission in determining the appropriate action to be taken, but will not serve to make protestants parties to the proceeding. Any person wishing to become a party must file a motion to intervene. All such motions or protests should be filed on or before the comment date, and, to the extent applicable, must be served on the applicant and on any other person designated on the official service list. This filing is available for review at the Commission or may be viewed on the Commission's web site at *http://www.ferc.gov* using the ''RIMS'' link, select ''Docket #'' and follow the instructions (call 202–208–2222 for assistance). Protests and interventions may be filed electronically via the Internet in lieu of paper; see 18 CFR 385.2001(a)(1)(iii) and the instructions on the Commission's web site under the ''e-Filing'' link.

Comment Date: April 29, 2002.

Linwood A. Watson, Jr.,

Deputy Secretary.

[FR Doc. 02–10001 Filed 4–23–02; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Docket No. RP02–216–001]

Reliant Energy Gas Transmission; Notice of Correction to Filing

April 18, 2002.

Take notice that on April 5, 2002, Reliant Energy Gas Transmission (REGT) submitted a corrected Page 1 to its Annual Revenue Crediting filing made on March 28, 2002 in this docket. Subsequent to the filing REGT discovered an error in a calculation on Page 1 of Appendix A.

REGT states that copies of the filing has been mailed to each of REGT's customers and interested state commissions.

Any person desiring to protest said filing should file a protest with the Federal Energy Regulatory Commission, 888 First Street, NE., Washington, DC 20426, in accordance with Section 385.211 of the Commission's Rules and Regulations. All such protests must be filed on or before April 25, 2002. 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. This filing may also be viewed on the web at *http://www.ferc.gov* using the ''RIMS'' link, select ''Docket#'' and follow the instructions (call 202–208–2222 for assistance). Comments, protests and interventions may be filed electronically via the Internet in lieu of paper. *See*, 18 CFR 385.2001(a)(1)(iii) and the instructions on the Commission's web site under the ''e-Filing'' link.

Linwood A. Watson, Jr.,

Deputy Secretary.

[FR Doc. 02–10018 Filed 4–23–02; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Docket No. GT02–16–000]

Sabine Pipe Line LLC; Notice of Proposed Changes in FERC Gas Tariff

April 18, 2002.

Take notice that on April 12, 2002, Sabine Pipe Line LLC (Sabine) tendered for filing as part of its FERC Gas Tariff, Original Volume No. 1, the following revised tariff sheets to be effective May 12, 2002:

First Revised Sheet No. 000
First Revised Sheet No. 222
First Revised Sheet No. 289
First Revised Sheet No. 405
First Revised Sheet No. 406
First Revised Sheet No. 445
First Revised Sheet No. 446
First Revised Sheet No. 472
First Revised Sheet No. 473

Sabine states that the revised tariff sheets were filed to amend the business address of Sabine as well as contact names and information.

Any person desiring to be heard or to protest said 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 or 385.211 of the Commission's Rules and Regulations. All such motions or protests must be filed in accordance with Section 154.210 of the Commission's Regulations. Protests will be considered by the Commission in

determining the appropriate action to be taken, but will not serve to make 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. This filing may also be viewed on the web at *http://www.ferc.gov* using the ''RIMS'' link, select ''Docket#'' and follow the instructions (call 202–208–2222 for assistance). Comments, protests and interventions may be filed electronically via the Internet in lieu of paper. See, 18 CFR 385.2001(a)(1)(iii) and the instructions on the Commission's web site under the ''e-Filing'' link.

Linwood A. Watson, Jr.,

Deputy Secretary.

[FR Doc. 02–10004 Filed 4–23–02; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Docket No. RP01–236–000]

Transcontinental Gas Pipe Line Corporation; Notice of Conference

April 18, 2002.

Take notice that Transcontinental Gas Pipe Line Corporation will make an informational presentation on its plan to implement the 1Line internet service delivery computer system on Thursday, April 25, 2002, at 1:30 p.m., in a room to be designated at the offices of the Federal Energy Regulatory Commission, 888 First Street, NE., Washington, DC 20426.

All interested persons and Staff are permitted to attend.

Linwood A. Watson, Jr.,

Deputy Secretary.

[FR Doc. 02–10014 Filed 4–23–02; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Docket Nos. RP00–536–001 and RP01–104–001]

Venice Gathering System, L.L.C.; Notice of Compliance Tariff Filing

April 18, 2002.

Take notice that on April 15, 2002, Venice Gathering System, L.L.C. (Venice) tendered for filing as part of its FERC Gas Tariff, Original Volume No. 1, the following tariff sheets, with an effective date of June 1, 2002:

First Revised Sheet No. 46
Fourth Revised Sheet No. 48
First Revised Sheet No. 94
Second Revised Sheet No. 95
First Revised Sheet No. 100
First Revised Sheet No. 107
First Revised Sheet No. 119
Second Revised Sheet No. 122
Second Revised Sheet No. 123
First Revised Sheet No. 138
First Revised Sheet No. 140
First Revised Sheet No. 141
Second Revised Sheet No. 141
First Revised Sheet No. 214
First Revised Sheet No. 215

Venice states that the revised tariff sheets are being filed in compliance with the Commission's March 1, 2002 order in the referenced dockets. Venice states that the revised sheets are intended to bring Venice in full compliance with FERC Order Nos. 637, 587–G and 587–L.

Venice states that on September 1, 2000 in Docket No. RP00–536–000, Venice filed *pro forma* tariff sheets to comply with Order No. 637. The filing included proposed revisions to Venice's scheduling procedures, capacity segmentation and penalty provisions, and other changes required by Order No. 637.

Venice further states that in a filing dated November 7, 2000, in Docket No. RP01–104–000, Venice defended its existing tariff provisions covering the netting and trading of imbalances (Article 11) as consistent with Order Nos. 587–G and 587–L. By order dated January 19, 2001, the Commission accepted Venice's explanation of its netting and trading provisions, found them compliant with the requirements of Order Nos. 587–G and 587–L, subject to the outcome of Venice's ongoing Order No. 637 proceeding.

On March 1, 2002, the Commission determined that Venice had generally complied with the Commission's requirements but required further modifications to certain of Venice's *pro forma* tariff sheets. On April 15, 2002, Venice filed revised tariff sheets in response to the Commission's March 1, 2002 order.

Venice states that copies of its April 15th filing have been mailed to each of the parties who have intervened in this proceeding.

Any person desiring to protest said filing should file a protest with the Federal Energy Regulatory Commission, 888 First Street, NE., Washington, DC 20426, in accordance with Section 385.211 of the Commission's Rules and Regulations. All such protests must be filed in accordance with Section 154.210 of the Commission's Regulations. Protests will be considered by the Commission in determining the appropriate action to be taken, but will not serve to make protestants parties to the proceedings. Copies of this filing are on file with the Commission and are available for public inspection. This filing may also be viewed on the web at *http://www.ferc.gov* using the ''RIMS'' link, select ''Docket#'' and follow the instructions (call 202–208–2222 for assistance). Comments, protests and interventions may be filed electronically via the Internet in lieu of paper. *See*, 18 CFR 385.2001(a)(1)(iii) and the instructions on the Commission's web site under the ''e-Filing'' link.

Linwood A. Watson, Jr.,

Deputy Secretary.

[FR Doc. 02–10012 Filed 4–23–02; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Docket No. ER02–1543–000]

Virginia Electric & Power Company; Notice of Filing

April 17, 2002.

Take notice that on April 15, 2002, Virginia Electric and Power Company (Virginia Power) tendered for filing an long-term Service Agreement for the Sale of Capacity, Energy and/or Ancillary Services and the Resale of Transmission Rights (Long-Term Agreement) between Virginia Power and the Borough of Tarentum, Pennsylvania (Tarentum) under Virginia Power's Wholesale Market-Based Rate Tariff, FERC Electric Tariff, Original Volume No. 6.

Virginia Power respectfully requests that the Commission waive its notice of filing requirements and allow the Long-Term Agreement to become effective on March 16, 2002, the date upon which service commenced.

Copies of the filing were served upon the Virginia State Corporation Commission, the North Carolina Utilities Commission, the Pennsylvania Public Utility Commission, and Tarentum.

Any person desiring to intervene or to protest this filing should file with the Federal Energy Regulatory Commission, 888 First Street, NE., Washington, DC 20426, Any person desiring to intervene or to protest this filing should file 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). Protests will be considered by the Commission in determining the appropriate action to be taken, but will not serve to make protestants parties to the proceeding. Any person wishing to become a party must file a motion to intervene. All such motions or protests should be filed on or before the comment date, and, to the extent applicable, must be served on the applicant and on any other person designated on the official service list. This filing is available for review at the Commission or may be viewed on the Commission's web site at *http://www.ferc.gov* using the ''RIMS'' link, select ''Docket #'' and follow the instructions (call 202–208–2222 for assistance). Protests and interventions may be filed electronically via the Internet in lieu of paper; see 18 CFR 385.2001(a)(1)(iii) and the instructions on the Commission's web site under the ''e-Filing'' link.

Comment Date: May 6, 2002.

Linwood A. Watson,

Deputy Secretary.

[FR Doc. 02–9964 Filed 4–23–02; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Docket No. ER02–1046–000]

Walton County Power, LLC, (Formerly LG&E Power Monroe LLC); Notice of Filing

April 18, 2002.

Take notice that on April 8, 2002, Walton County Power, LLC hereby gives notice that effective April 29, 2002, the proposed Service Agreement No. 2 filed with the Federal Energy Regulatory Commission by Progress Ventures, Inc. on behalf of LG&E Power Monroe LLC under LG&E Power Monroe LLC's Market-Based Rate Tariff in this docket on February 20, 2002, is withdrawn.

Notice of the proposed withdrawal was served upon LG&E Energy Marketing, Inc. and the interested state utility commissions.

Any person desiring to intervene or to protest this filing should file 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). Protests will be considered by the Commission in determining the appropriate action to be taken, but will not serve to make protestants parties to the proceeding. Any person wishing to become a party must file a motion to intervene. All such motions or protests should be filed on or before the comment date, and, to the extent applicable, must be served on the applicant and on any other person designated on the official service list. This filing is available for review at the Commission or may be viewed on the Commission's web site at http://www.ferc.gov using the ''RIMS'' link, select ''Docket #'' and follow the instructions (call 202–208–2222 for assistance). Protests and interventions may be filed electronically via the Internet in lieu of paper; see 18 CFR 385.2001(a)(1)(iii) and the instructions on the Commission's web site under the ''e-Filing'' link.

Comment Date: April 26, 2002.

Linwood A. Watson, Jr.,

Deputy Secretary.

[FR Doc. 02–9963 Filed 4–23–02; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Docket No. RP02–179–000]

Williams Gas Pipelines Central, Inc.; Notice of Technical Conference

April 18, 2002.

In the Commission's order issued on March 28, 2002,[1] the Commission directed a technical conference be held to address issues raised by the filing.

Take notice that a technical conference will be held on Tuesday, May 7, 2002 at 10 a.m. in a room to be designated at the offices of the Federal Energy Regulatory Commission, 888 First Street, NE., Washington, DC 20426.

All interested parties and staff are permitted to attend.

Linwood A. Watson, Jr.,

Deputy Secretary.

[FR Doc. 02–10017 Filed 4–23–02; 8:45 am]

BILLING CODE 6717–01–P

[1] Williams Gas Pipelines Central, Inc., 98 FERC ¶ 61,344 (2002).

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Docket No. RP00–484–003]

Wyoming Interstate Company, Ltd.; Notice of Compliance Filing

April 18, 2002.

Take notice that on April 15, 2002, Wyoming Interstate Company, Ltd. (WIC) tendered for filing as part of its FERC Gas Tariff, Second Revised Volume No. 2, the tariff sheets identified on the Appendix to the filing, to become effective July 1, 2002.

WIC states that the tariff sheets, which were included in WIC's Order No. 637 compliance filing, are being filed to comply with the Commission's order issued March 1, 2002 in this proceeding.

Any person desiring to protest said filing should file a protest with the Federal Energy Regulatory Commission, 888 First Street, NE., Washington, DC 20426, in accordance with Section 385.211 of the Commission's Rules and Regulations. All such protests must be filed in accordance with Section 154.210 of the Commission's Regulations. Protests will be considered by the Commission in determining the appropriate action to be taken, but will not serve to make protestants parties to the proceedings. Copies of this filing are on file with the Commission and are available for public inspection. This filing may also be viewed on the web at *http://www.ferc.gov* using the ''RIMS'' link, select ''Docket#'' and follow the instructions (call 202–208–2222 for assistance). Comments, protests and interventions may be filed electronically via the Internet in lieu of paper. *See*, 18 CFR 385.2001(a)(1)(iii) and the instructions on the Commission's web site under the ''e-Filing'' link.

Linwood A. Watson, Jr.,

Deputy Secretary.

[FR Doc. 02–10011 Filed 4–23–02; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

Notice of Application Tendered for Filing With the Commission, Soliciting Additional Study Requests, Establishing Procedures for Relicensing and a Deadline for Submission of Final Amendments

April 18, 2002.

Take notice that the following hydroelectric application has been filed

with the Commission and is available for public inspection.

a. *Type of Application:* New Major License.

b. *Project No.:* P–287–009.

c. *Date Filed:* April 8, 2002.

d. *Applicant:* Midwest Hydro Inc.

e. *Name of Project:* Dayton Hydroelectric Project.

f. *Location:* On the Fox River, near Dayton, in La Salle County, Illinois. The project does not affect federal lands.

g. *Filed Pursuant to:* Federal Power Act 16 U.S.C. §§ 791 (a)–825(r).

h. *Applicant Contact:* Loyal Gake, Midwest Hydro Inc., 116 State St., P.O. Box 167, Neshkoro, WI 54960, (920) 293–4628.

i. *FERC Contact:* Mark Pawlowski, (202) 219–2795, or *mark.pawlowski@ferc.gov.*

j. *Cooperating agencies:* We are asking Federal, state, local, and tribal agencies with jurisdiction and/or special expertise with respect to environmental issues to cooperate with us in the preparation of the environmental document. Agencies who would like to request cooperating status should follow the instructions for filing comments described in item k below.

k. *Deadline for filing additional study requests and requests for cooperating agency status:* June 7, 2002.

All documents (original and eight copies) should be filed with: Magalie R. Salas, Secretary, Federal Energy Regulatory Commission, 888 First Street, NE., Washington, DC 20426.

The Commission's Rules of Practice require all intervenors filing documents with the Commission to serve a copy of that document on each person on the official service list for the project. Further, if an intervenor files comments or documents with the Commission relating to the merits of an issue that may affect the responsibilities of a particular resource agency, they must also serve a copy of the document on that resource agency.

Additional study requests and requests for cooperating agency status may be filed electronically via the Internet in lieu of paper. See 18 CFR 385.2001(a)(1)(iii) and the instructions on the Commission's web site (*http://www.ferc.gov*) under the ''e-Filing'' link.

l. This application is not ready for environmental analysis at this time.

m. *The existing Dayton Hydroelectric Project consists of:* (1) 594-foot-long arch-buttress uncontrolled fixed crest overflow concrete dam; (2) a 200-foot-long left earthen embankment; (3) a concrete head gate structure with four 15.5-foot-wide and 9.5 foot-high wooden gates located at the right abutment; (4) a 900-foot-long power canal; (5) a 200 acre impoundment; (6) a powerhouse containing three turbines with an installed capacity of 3,680 kW; and (7) appurtenant facilities. The applicant estimates that the total average annual generation would be 14,200 megawatthours. All generated is sold to the Illinois Power Company.

n. A copy of the application is on file with the Commission and is available for public inspection. This filing may also be viewed on the web at *http://www.ferc.gov* using the ''RIMS'' link—select ''Docket #'' and follow the instructions (call 202–208–2222 for assistance). A copy is also available for inspection and reproduction at the address in item h above.

o. With this notice, we are initiating consultation with the ILLINOIS STATE HISTORIC PRESERVATION OFFICER (SHPO), as required by § 106, National Historic Preservation Act, and the regulations of the Advisory Council on Historic Preservation, 36 CFR 800.4.

p. *Procedural schedule and final amendments:* The application will be processed according to the following milestones, some of which may be combined to expedite processing:

Notice of application has been accepted for filing

Notice of application is ready for environmental analysis

Notice of the availability of the draft NEPA document

Notice of the availability of the final NEPA document

Order issuing the Commission's decision on the application

Final amendments to the application must be filed with the Commission no later than 30 days from the issuance date of the notice of ready for environmental analysis.

Linwood A. Watson, Jr.,

Deputy Secretary.

[FR Doc. 02–10005 Filed 4–23–02; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

Notice of Transfer of License and Soliciting Comments, Motions To Intervene, and Protests

April 18, 2002.

Take notice that the following application has been filed with the Commission and is available for public inspection:

a. *Application Type:* Transfer of License.

b. *Project No:* 2363–039.

c. *Date Filed:* April 10, 2002.

d. *Applicants:* Potlatch Corporation (Transferor) and Northern Holdings, LLC (Transferee).

e. *Name and Location of Project:* The Cloquet Hydroelectric Project is located on the St. Louis River in Carlton County, Minnesota.

f. *Filed Pursuant to:* Federal Power Act, 16 U.S.C. 791(a)—825(r).

g. *Applicants' Contacts:*

Transferor: Robert F. Shapiro, Chadbourne & Parke LLP, 1200 New Hampshire Ave., N.W.; Suite 300 Washington, DC 20036, (202) 974–5670; Fax: (202) 974–5602, E-mail address: *rshapiro@chadbourne.com*

Transferee: Nancy J. Skancke, GKRSE 1500 K St., NW., Suite 330, Washington, DC 20005, (202) 408–5400; Fax: (202) 408–5406, E-mail address: *njskancke@gkrse-law.com*

h. *FERC Contact:* Any questions on this notice should be addressed to Mr. Lynn R. Miles at (202) 219–2671.

i. *Deadline for filing comments and or motions:* May 3, 2002.

All documents (original and eight copies) should be filed with: Magalie R. Salas, Secretary, Federal Energy Regulatory Commission, 888 First Street, NE, Washington DC 20426. Comments, protests and interventions may be filed electronically via the Internet in lieu of paper; see 18 CFR 385.2001(a)(1)(iii) and the instructions on the Commission's web site under the ''e-Filing'' link.

Please include the project number (P–2363–039) on any comments or motions filed.

j. *Description of Transfer:* Licensee, Potlatch Corporation, proposes to transfer the license for the Cloquet Hydroelectric Project, No. 2363, to Northern Holdings LLC. In the near future, the name of Northern Holdings LLC will be changed, but its corporate structure will not be modified and it will remain the same legal entity. Northern Holdings LLC will supplement this application to reflect that name change.

k. *Locations of the application:* A copy of the application is available for inspection and reproduction at the Commission's Public Reference Room, located at 888 First Street, NE, Room 2A, Washington, DC 20426, or by calling (202) 208–1371. This filing may also be viewed on the Commission's web site at *http://www.ferc.gov* using the ''RIMS'' link, select ''Docket #'' and follow the instructions (call 202–208–2222 for assistance).

l. Individuals desiring to be included on the Commission's mailing list should so indicate by writing to the Secretary of the Commission.

Comments, Protests, or Motions to Intervene—Anyone may submit comments, a protest, or a motion to intervene in accordance with the requirements of Rules of Practice and Procedure, 18 CFR 385.210, .211, .214. In determining the appropriate action to take, the Commission will consider all protests or other comments filed, but only those who file a motion to intervene in accordance with the Commission's Rules may become a party to the proceeding. Any comments, protests, or motions to intervene must be received on or before the specified comment date for the particular application.

Filing and Service of Responsive Documents—Any filings must bear in all capital letters the title ''COMMENTS'', ''PROTEST'', OR ''MOTION TO INTERVENE'', as applicable, and the Project Number of the particular application to which the filing refers. An additional copy must be sent to the Director, Division of Hydropower Administration and Compliance, Federal Energy Regulatory Commission, at the above-mentioned address. A copy of any motion to intervene must also be served upon each representative of the Applicant specified in the particular application.

Agency Comments—Federal, state, and local agencies are invited to file comments on the described application. A copy of the application may be obtained by agencies directly from the Applicant. If an agency does not file comments within the time specified for filing comments, it will be presumed to have no comments. One copy of an agency's comments must also be sent to the Applicant's representatives.

Linwood A. Watson, Jr.,

Deputy Secretary.

[FR Doc. 02–10006 Filed 4–23–02; 8:45 am]

BILLING CODE 6717–01–P

ENVIRONMENTAL PROTECTION AGENCY

[OPP–2002–0027; FRL–6834–6]

ABT Associates, Inc. and Syracuse Research Corp. (SRC); Transfer of Data

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice.

SUMMARY: This notice announces that pesticide-related information submitted to EPA's Office of Pesticide Programs (OPP) pursuant to the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) and the Federal Food, Drug, and Cosmetic Act (FFDCA), including information that may have been claimed as Confidential Business Information (CBI) by the submitter, will be transferred to ABT Associates, Inc. and its subcontractor, Syracuse Research Corp., in accordance with 40 CFR 2.307(h)(3) and 2.308(i)(2). ABT Associates, Inc. and its subcontractor, Syracuse Research Corp., have been awarded a contract to perform work for OPP, and access to this information will enable ABT Associates, Inc. and its subcontractor, Syracuse Research Corp., to fulfill the obligations of the contract.

DATES: ABT Associates, Inc. and its subcontractor, Syracuse Research Corp., will be given access to this information on or before April 29, 2002.

FOR FURTHER INFORMATION CONTACT: By mail: Erik Johnson, FIFRA Security Officer, Information Resources and Services Division (7502C), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460; telephone number: (703) 305–7248; e-mail address: johnson.erik@epa.gov.

SUPPLEMENTARY INFORMATION:

I. General Information

A. Does this Action Apply to Me?

This action applies to the public in general. As such, the Agency has not attempted to describe all the specific entities that may be affected by this action. If you have any questions regarding the applicability of this action to a particular entity, consult the person listed under **FOR FURTHER INFORMATION CONTACT**.

B. How Can I Get Additional Information, Including Copies of this Document and Other Related Documents?

You may obtain electronic copies of this document, and certain other related documents that might be available electronically, from the EPA Internet Home Page at http://www.epa.gov. To access this document, on the home page select ''Laws and Regulations,'' ''Regulations and Proposed Rules,'' and then look up the entry for this document under the ''**Federal Register**—Environmental Documents.'' You can also go directly to the **Federal Register** listings at http://www.epa.gov/fedrgstr/.

II. Contractor Requirements

Under Contract No. 68–W0–1039, ABT Associates, Inc. and its subcontractor, Syracuse Research Corp., will perform the following: In response to the Food Quality Protection Act (FQPA), the Office of Science Coordination and Policy (OSCP) and the Office of Pesticide Programs (OPP) are conducting a pilot project to evaluate existing toxicity data and data bases in the Agency and the scientific literature for a sample group of approximately 30 pesticide active ingredients. Toxicity and endocrine-related mechanistic data shall be examined in detail to determine their adequacy to assess each chemical's potential to affect the endocrine system.

For this work assignment, the contractor shall examine Agency toxicity data files, (primarily located in OPP's Environmental Fate and Effects Division data bases), summary documents, electronic files, and the scientific literature for indications of endocrine system interaction, perturbation, or modulation in wildlife and aquatic organisms for up to 30 pesticide active ingredients.

OPP has determined that access by ABT Associates, Inc. and its subcontractor, Syracuse Research Corp., to information on all pesticide chemicals is necessary, for the performance of this contract.

Some of this information may be entitled to confidential treatment. The information has been submitted to EPA under sections 3, 4, 6, and 7 of FIFRA and under sections 408 and 409 of FFDCA.

In accordance with the requirements of 40 CFR 2.307(h)(2), the contract with ABT Associates, Inc. and its subcontractor, Syracuse Research Corp., prohibits the use of information for any purpose not specified in the contract; prohibits disclosure of the information to a third party without prior written approval from the agency; and requires that each official and employee of the contractor sign an agreement to protect the information from unauthorized release and to handle it in accordance with the FIFRA Information Security Manual. In addition, ABT Associates, Inc. and its subcontractor, Syracuse Research Corp., are required to submit for EPA approval a security plan under which any CBI will be secured and protected against unauthorized release or compromise. No information will be provided to ABT Associates, Inc. and its subcontractor, Syracuse Research Corp., until the requirements in this document have been fully satisfied. Records of information provided to ABT Associates, Inc. and its subcontractor, Syracuse Research Corp., will be maintained by EPA Project Officers for this contract. All information supplied to ABT Associates, Inc. and its subcontractor, Syracuse Research Corp., by EPA for use in connection with this contract will be returned to EPA when ABT Associates, Inc. and its

subcontractor, Syracuse Research Corp., have completed their work.

List of Subjects

Environmental protection, Business and industry, Government contracts, Government property, Security measures.

Dated: April 10, 2002.

Linda Vlier Moos,

Acting Director, Information Resources and Services Division, Office of Pesticide Programs.

[FR Doc. 02–9792 Filed 4–23–02; 8:45 am]

BILLING CODE 6560–50–S

ENVIRONMENTAL PROTECTION AGENCY

[FRL–7175–7]

Community Based In-Home Asthma Environmental Education and Management

AGENCY: Environmental Protection Agency (EPA).

ACTION: Request for grant proposals.

SUMMARY: Request for Proposals for Community Based In-Home Asthma Environmental Education and Management. This action announces the availability of FY 2002 and 2003 grant funds from the Environmental Protection Agency's (EPA) Indoor Environments Division/Office of Radiation and Indoor Air. Under Statutory Authority 42 U.S.C. 7401–7626; Public Law 159, 69 Stat. 322, EPA plans to award two to four one-time grants of up to $150,000.00 each. The number of awards and award amounts may vary depending on proposal quality and resource availability.

These funds will support performance-based pilot studies of asthma education and management, including indoor asthma trigger identification and mitigation, in existing community-based in-home environmental management or education programs. The purpose of this grant program is to assess the effectiveness of in-home asthma education and management approaches to educating children with asthma, their parents and/or primary care givers, and other people with asthma on how to identify and mitigate the indoor triggers to which the asthmatic(s) in the household may be sensitive.

DATES: 1. Submit letter of intent to apply for the grant on or before May 29, 2002.

2. Pre-application Assistance Conference Call date is: June 5, 2002, 1 until 3 p.m. Eastern Daylight Time.

3. The EPA must receive Applications on or before June 28, 2002.

4. Selected projects will be announced on or around October 15, 2002.

ADDRESSES: E-mail Letters of Intent to *in-home.grants@epa.gov.* Send Applications by private shipping company only (e.g., Federal Express, UPS, DHL, or courier) to the attention of Brenda Doroski, U.S. Environmental Protection Agency, Indoor Environments Division (6th Floor), 501 3rd Street, NW, Washington, DC 20001.

FOR FURTHER INFORMATION CONTACT: Brenda Doroski at (202) 564–9764 or at *in-home.grants@epa.gov.*

SUPPLEMENTARY INFORMATION: We encourage first time recipients of Federal funds to familiarize themselves with the regulations applicable to assistance agreements found in the Code of Federal Regulations (CFR) Title 40, part 30 for non-profit organizations and institutions of higher education group, and part 31 for State and local government entities. These rules can be found at *www.epa.gov/epacfr40/chapt-l.info/chi.toc.htm.* At that location, look under SUBCHAPTER B—GRANTS AND OTHER FEDERAL ASSISTANCE (parts 30–49).'' You may also obtain a copy of the CFR Title 40, part 30 and part 31 at your local U.S. Government Bookstore, the U.S. Government Printing Office or on the internet at *www.epa.gov/ogd/grants/how_to_apply.htm.* Once at this site, select ''Administrative Regulations and Policies/Subchapter B—Grants and Other Federal Assistance'.

I. Overview

Section 103(a)(1) of the Clean Air Act authorizes the Administrator to conduct and promote the coordination and acceleration of research, investigations, experiments, demonstrations, surveys and studies relating to the causes, effects (including health and welfare effects), extent, prevention, and control of air pollution by [(b)(3)] making grants to air pollution control agencies, to other public or nonprofit private agencies, institutions, and organizations, and to individuals, for purposes stated in 103(a)(1).

The goal is to develop nationally-applicable, performance-based pilot studies that will: (a) Reduce the impact of environmental asthma triggers on children with asthma; (b) strengthen the capacity of families to control environmental asthma triggers in their homes; and (c) assess the effectiveness and sustainability of strategies for in-home environmental asthma trigger management and education within communities.

The target population of focus is low-income, urban and/or disproportionately impacted (with respect to asthma severity or incidence) children with asthma and their parents and/or care-givers. Adults with asthma may be included in the in-home asthma education program; however, children with asthma should be given preference. Community-based asthma environmental education and management program(s) may occur inside or outside the home through clinical visits or community forums.

II. What Criteria Must I Meet To Be Eligible for This Grant?

To be eligible for funding, you must submit a Letter of Intent by May 29, 2002. In addition, you must:

(1) Meet the standards for eligibility as identified in Section 103 (b)(3) of the Clean Air Act (page 1, paragraph 1); e.g., be a non-profit organization or institute of higher education, or a State or local government entity;

(2) Request no more than $150,000.00 to accomplish pilot project goals and objectives;

(3) Properly complete and submit Standard Form 424 Application for Federal Assistance (SF–424) and a proposal by the established receipt date; and

(4) Commit to complete the proposed pilot project activities within 18—24 months of grant award.

III. How Do I Submit an Application?

The application process consists of a letter of intent to apply for the grant, a voluntary pre-application assistance conference call, and a completed application package. The application package consists of the SF–424 and a proposal. EPA must receive an original, plus two copies of your application package on or before June 28, 2002.

A. Letter of Intent

If you intend to complete the application process, you must e-mail a letter of intent to *in-home.grants@epa.gov* on or before May 29, 2002. Your letter of intent must include:

(1) Name of your organization
(2) Contact person's name
(3) Mailing address
(4) E-mail address
(5) Phone number and fax number
(6) If you would like to participate in the pre-application assistance conference call on June 5, 2002.

B. Pre-Application Assistance Conference Call

A pre-application assistance conference call has been scheduled for

June 5, 2002 from 1 until 3 p.m. Eastern Daylight Time to answer any questions prospective applicants may have. If you indicate a desire to participate in the pre-award assistance conference call in your letter of intent, you will be e-mailed instructions for participating in the conference call.

C. Standard Form 424, Application for Federal Assistance (SF–424)

The SF–424 is available at *www.epa.gov/iaq/asthma.* The SF–424 will only be used to process the grant if your organization is selected as one of the grantees. The review panel will not receive a copy of your SF–424. For more information on completing SF–424A Budget Forms and understanding cost principles for a Federal grant, visit *www.epa.gov/ogd/grants/how_to_apply/htm.*

D. Proposal

In addition to the SF–424, you must submit a proposal (no greater than nine pages in length) which includes a detailed work plan, itemized budget, and any supplementary biographical information you wish to provide. Text may be single or double spaced, no smaller than 12 point font. Margins are not specified. Proposals must be legible. No additional materials (e.g, brochures, videos, etc.), beyond the nine page limit, will be given to the review panel for consideration.

Your proposal should address the ranking criteria outlined below in section IV. To address the ranking criteria, your proposal should include:

(1) Project Title.

(2) Work Experience—describe your organization, experience in community-based environmental or public health education (especially with children with asthma), results of existing in-home education efforts and/or existing indoor air quality/asthma activities, and your organization's capacity to conduct in-home asthma assessments and/or education programs.

(3) Project Goals—include a summary of specific objectives, expected outcomes, and deliverables.

(4) Target Population—describe the target population, community, and any special asthma-related demographics of areas targeted for this work.

(5) Overview of Project—describe the basic structure of the proposed in-home asthma education and assessment pilot project, how many families will be reached, curricula and assessment tools to be used, and resource lists including references. Describe why the curricula and protocols were selected or created; what other materials you may have considered (including reasons for not selecting them); and, if possible, a discussion of how the asthma education approaches you wish to demonstrate compare or contrast to other known approaches.

(6) Meeting Community Needs—describe any types of additional materials or assistance that you may give to the households such as community resource lists, household repair and maintenance training, lessons on how to obtain services in the community, etc.

(7) Participant Follow-Up—describe mechanisms for following-up with asthmatics and their families and/or primary care givers following in-home visit(s) to answer questions and provide assistance. Reasons for selecting or creating these mechanisms and, if possible, a discussion of how the selected mechanisms compare to other available mechanisms.

(8) Monitoring and Evaluation—define outputs and outcomes and how project success will be measured. Describe mechanisms for tracking program outputs (e.g., how many households were educated, how many homes were assessed, in how many homes actions were taken), and evaluating program outcomes (e.g., the effectiveness of the education and mitigation methods, the level of increased awareness).

(9) Staff—describe staffing needed to implement the proposed work plan, including number of staff and qualifications. In particular, attention should be paid to the qualifications and experience of key personnel.

(10) Budget—itemize funds for salaries, materials, equipment, contracted activities, travel, overhead, and other pertinent information. Discuss how the budget relates to the objectives, outcomes, and deliverables in the work plan.

(11) Project Management Experience—describe your experience implementing evaluation and tracking procedures and managing grants (e.g., submitting reports, budgets, etc.).

(12) Timeline—indicate project length, tasks, quarterly report submission and final report submission dates.

(13) Sustainability—explain how you will sustain the project beyond the life of the EPA grant.

(14) Replicability—identify other localities, regions, or states that might benefit from the lessons you expect to learn as a result of your pilot project, and how you might promote replication of this project.

IV. How Will EPA Rank Applications?

Applications will be ranked on the basis of the criteria listed below. Ranking for each criterion is based on a scale of 0 (does not meet the requirement) to 5 (exceeds the requirement).

(1) Applicant is currently performing community-based environmental health or public health education programs which are achieving public health outcomes. (0–5 points)

(2) Applicant demonstrates the ability to implement an asthma education program [face-to-face instruction which can occur inside or outside the home, e.g., in a clinic or other community setting] which integrates indoor environmental trigger identification and mitigation approaches in the home into a comprehensive asthma management education program (i.e., medical management and the socio-economics of the target population are also addressed). (0–5 points)

(3) Applicant proposal has goals and objectives which are clearly stated and are likely to reduce the incidence and severity of asthma episodes in the target population, and create behavioral changes in the home as a result of its educational outreach activities. The grant budget is appropriate to accomplish the scope of the work (i.e., number of children with asthma, their parents and/or care-givers that will be reached). (0–5 points)

(4) Applicant proposed work targets low-income, urban and/or disproportionately impacted (with respect to asthma severity or incidence) children. (0–5 points)

(5) Applicant demonstrates it will use education strategies that are effective for varied populations and geographic locations in the United States, and will contribute to an improved understanding of how to conduct asthma education programs that address asthma triggers in homes. Education materials and assessment tools selected for the pilot project reflect current standards for conducting environmental health or public health education and outreach activities, particularly with respect to motivating behavioral changes in low-literacy, low-income, and disproportionately impacted populations. (0–5 points)

(6) Applicant outlines educational materials and mitigation methods for secondhand tobacco smoke, house dust mites, cockroaches, molds, and animal dander which are compatible with the guidance contained in EPA's asthma brochure, ''Clear Your Home Of Asthma Triggers: Your Children Will Breathe Easier'' (*www.epa.gov/iaq/pubs/*

asthma.html) and the findings and recommendations contained in the January, 2000 National Academy of Sciences report on asthma, ''Clearing the Air: Asthma and Indoor Air Exposures'' (*http://books.nap.edu/catalog/9610.html*). (0–5 points)

(7) Applicant staff have the knowledge and experience to successfully perform the proposed work. (0–5 points)

(8) Applicant describes methods that will be used to ensure sustained participant involvement throughout the duration of the grant. Applicant adequately describes mechanisms for obtaining feedback about program effectiveness from participants after the in-home education assessment visits. (0–5 points)

(9) Applicant clearly describes a monitoring and evaluation component (e.g., home visits and/or patient/family reporting) which is practical, reasonable and sound. The applicant must, at a minimum, report the number of homes visited, the number of children and adults with asthma educated, the number of homes in which indoor environmental triggers have been identified, and the number of households in which mitigation actions have been taken. In addition, the applicant describes any health outcomes data that will be obtained through this project, such as, the number of emergency room visits, inpatient hospital admissions, sick visits to primary care physicians for asthma, school days missed, symptom days, rescue medication used, and quality of life indicators. Applicant agrees to provide quarterly performance reports to EPA which shall include, at a minimum, information about the above. (0–5 points)

(10) Applicant addresses how they will sustain their project beyond the life of the EPA grant, and the steps they will take to promote replication of this project in other areas and with other populations. (0–5 points)

Answers to Questions You May Have

Question 1: What is an indirect cost, and what if we don't have an indirect cost rate established?

Answer: Indirect costs are explained in the grant application forms, SF–424, found at *www.epa.gov/iaq/asthma.* If your organization has an indirect cost (IDC) rate established, include it where appropriate in your budget. If your organization intends to claim indirect costs, and you do not already have a negotiated Federal IDC rate, you may submit your proposal with an estimated IDC rate. If your organization is selected to receive a grant, you will be required to establish an IDC rate within 30 days of notification of the award. Organizations may also opt to charge less than their established IDC rate.

Question 2: Is there a limit on indirect costs; and are they to be included within the $150,000?

Answer: There is no limit on indirect costs. All indirect costs should be included within the $150,000 and included on the Budget Information Form (SF–424A).

Question 3: Is there a cost-share (match) requirement? Will proposals that include cost-sharing be reviewed more favorably?

Answer: No, cost-sharing is not required, and will not be considered in the ranking process. However, you can include matching funds in the proposal, not on form SF–424.

Question 4: On SF–424, block 10, there is a space for ''Catalog of Federal Domestic Assistance Number.'' What number should we use?

Answer: The CFA number is 66–606.

Question 5: On SF–424, in block 16, it asks ''Is application subject to review by State Executive Order 12372 process?'

Answer: To determine whether your state requires review prior to receiving a Federal grant award, and a point of contact if it does, check the Office of Management and Budget website, *www.whitehouse.gov/OMB/grants/spoc.html.*

Question 6: What start date should we use on the SF–424 form?

Answer: Use November 30, 2002, as the start date, although the actual award date may vary. No pre-award costs will be approved for this pilot project, so please do not incur any costs unless and until you receive an assistance agreement from EPA.

Question 7: Are we required to include a quality assurance narrative statement?

Answer: If you are making environmental measurements or collecting data, your proposal should include a statement about the quality assurance practices you will put in place to ensure the accuracy of your data. If there is a need for additional information, our Grants Administration Division will contact you prior to award.

Question 8: Is the due date of June 28, 2002 flexible?

Answer: No. Applications must be received on or before June 28, 2002 no later than close of business (5pm EDT) as directed in the Request for Proposals. Due to mail delivery problems with the U.S. Postal Service, applications must be sent via private shipping company (e.g., Federal Express, UPS, DHL) or be hand-delivered by messenger to our street address listed in the RFP.

Question 9: Can grant funds be used to mitigate homes?

Answer: The Clean Air Act authority under which this project is being conducted provides for studies and demonstrations. Mitigation is acceptable under this grant only to the extent that it is done as a way to teach occupants how to clean-up and/or prevent indoor environmental triggers of asthma in their home. It is up to the applicant to propose mitigation methods, and their rationale, that they believe will be most effective given the scope of their proposal. Applicants should refer to EPA brochure ''Clear Your Home of Asthma Triggers'' and the National Academy of Sciences report on asthma, ''Clearing the Air: Asthma and Indoor Air Exposures'' for more information on recommended mitigation methods for indoor environmental asthma triggers. Budget may limit the degree of interventions. At a minimum, the education must be direct one-on-one, and should be clearly outlined in the proposal. Mitigations might include, but are not limited to, things like mold clean up or mattress covers. Interventions should be directly linked to your proposed project objectives and outcomes.

Question 10: Will our grant proposals be considered confidential?

Answer: While grant proposals are generally handled in a confidential manner, they may be disclosed under the Freedom of Information Act. If there is any information you wish to ensure remains confidential, please be sure to stamp ''confidential'' or ''restricted'' on each page on which such information occurs. If we receive a third-party request for information labeled confidential, we will follow procedures outlined in 40 CFR part 2, subpart B.

Question 11: Are we permitted to enter into contracts as part of the project we are proposing?

Answer: Yes, as long as the costs are allowable as defined under the Code of Federal Regulations 40 Part 30 and Part 31, which can be found at *www.epa.gov/ogd/grants.htm.*

Question 12: May we include collaborators, or submit our proposal with another organization?

Answer: Application packages must be submitted by the organization who submitted the letter of intent, but applications may include collaborators, and may be submitted as joint proposals. The funding will go to the lead organization.

Question 13: Does the proposal require that we demonstrate the efficacy of a specific approach using scientific

method such as a randomized, controlled study or experimental research, or a demonstration trial?

Answer: No, the proposal does not require that you use scientific method to demonstrate the efficacy of a specific approach. You should provide rationale for using a specific approach, including any past results you may have from using the approach. You should include the health outcomes you expect in the target community as a result of the proposed approach.

Question 14: If we have additional support for this program through other sources, can they be used? (Related to Ranking Criteria 9 and 10)

Answer: Yes, it is fine if you include additional resources you may have for the project.

Authority: 42 U.S.C. 7401–7626; Pub. L. 159, 69 Stat. 322.

Dated: April 17, 2002.

Elizabeth Craig,

Deputy Assistant Administrator, Office of Air and Radiation.

[FR Doc. 02–10041 Filed 4–23–02; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

[OPP–2002–0044; FRL–6835–8]

EPA Pesticide Program Dialogue Committee (PPDC); Notice of Public Meeting

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice.

SUMMARY: EPA's Office of Pesticide Programs will hold a public meeting of the Pesticide Program Dialogue Committee (PPDC) on May 9 and 10, 2002. An agenda will be available by May first and posted on EPA's website at www.epa.gov/pesticides/ppdc.

DATES: The meeting will be held on Thursday, May 9, 2002, from 9 a.m. to 5 p.m., and on Friday, May 10, 2002, from 9 a.m. to 1 p.m.

ADDRESSES: The meeting will be held at the Georgetown University Conference Center, Salons C and H, 3800 Reservoir Road, NW, Washington, DC 20057 (202) 687–3200.

FOR FURTHER INFORMATION CONTACT: Margie Fehrenbach, (7501C) Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460; telephone number: (703) 308–4775; fax number: (703) 308–4776; e-mail address: fehrenbach.margie@epa.gov.

SUPPLEMENTARY INFORMATION:

Background

The PPDC is composed of 42 members appointed by EPA's Deputy Administrator. Committee members were selected from a balanced group of participants from the following sectors: Pesticide users, grower, and commodity groups; industry and trade associations; environmental/public interest; and farmworker groups; Federal, State and tribal governments; public health organizations; animal welfare; and academia. PPDC was established to provide a public forum to discuss a wide variety of pesticide regulatory development and reform initiatives, evolving public policy and program implementation issues, and science policy issues associated with evaluating and reducing risks from use of pesticides.

I. Does this Action Apply to Me?

This action is directed to the public in general. This action may, however, be of interest to persons who are concerned about implementation of the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA); the Federal Food, Drug, and Cosmetic Act; and the amendments to both of these major pesticide laws by the Food Quality Protection Act (Public Law 104–170) of 1996. Since other entities may also be interested, the Agency has not attempted to describe all the specific entities that may be affected by this action. If you have any questions regarding the applicability of this action to a particular entity, consult the person listed under **FOR FURTHER INFORMATION CONTACT**.

II. How Can I Get Additional Information, Including Copies of this Document and Other Related Documents?

1. *Electronically.* You may obtain electronic copies of this document, and certain other related documents that might be available electronically, from the EPA Internet Home Page at http://www.epa.gov/. To access this document, on the Home Page select ''Laws and Regulations,'' ''Regulations and Proposed Rules,'' and then look up the entry for this document under the ''**Federal Register**—Environmental Documents.'' You can also go directly to the **Federal Register** listings at http://www.epa.gov/fedrgstr/. To access information about PPDC, go directly to the Home Page for EPA's Office of Pesticide Programs at http://www.epa.gov/pesticides/ppdc.

2. *In person.* The Agency has established an administrativerecord for this meeting under docket control number OPP–00439. The administrative record consists of the documents specifically referenced in this notice, any public comments received during an applicable comment period, and other information related to the PPDC. This administrative record includes the documents that are physically located in the docket, as well as the documents that are referenced in those documents. The public version of the administrative record, which includes printed, paper versions of any electronic comments that may be submitted during an applicable comment period, is available for inspection in the Public Information and Records Integrity Branch (PIRIB), Rm. 119, Crystal Mall #2, 1921 Jefferson Davis Hwy., Arlington, VA, from 8:30 a.m. to 4 p.m., Monday through Friday, excluding legal holidays. The PIRIB telephone number is (703) 305–5805.

III. How Can I Participate in this Meeting?

PPDC meetings and workshops are open to the public under section 10(a)(2) of the Federal Advisory Committee Act 9 (FACA), Public Law 92–463. Outside statements by observers are welcome. Oral statements will be limited to 3–5 minutes, and it is preferred that only one person per organization present the statement. Any person who wishes to file a written statement may do so before or after the meeting. These statements will become part of the permanent record and will be available for public inspection at the address in Section 2 above.

List of Subjects

Environmental protection, Agriculture, Chemicals, Foods, Pesticides, Biopesticides, Tolerances, Emergency exemptions, Pests.

Dated: April 17, 2002.

James Jones,

Acting Director, Office of Pesticide Programs.

[FR Doc. 02–10043 Filed 4–23–02; 8:45 a.m.]

BILLING CODE 6560–50–S

ENVIRONMENTAL PROTECTION AGENCY

[OPP–2002–0025; FRL–6773–1]

Chlorpyrifos-methyl; Receipt of Request for Registration Cancellation

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice.

SUMMARY: In accordance with section 6(f)(1) of the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), as amended, EPA is issuing a notice of receipt of request by Dow

AgroSciences LLC, and Gustafson LLC to voluntarily cancel certain pesticide registrations of products containing the active ingredient chlorpyrifos-methyl. The voluntary cancellations were received from Dow AgroSciences LLC on January 31, 2001 and Gustafson LLC on February 13, 2001. EPA will decide whether to approve the request after consideration of public comments.

DATES: Comments on the requested cancellation of product and use registrations must be submitted to the address provided below by May 24, 2002.

ADDRESSES: Comments may be submitted by mail, electronically, or in person. Please follow the detailed instructions for each method as provided in Unit I. of the **SUPPLEMENTARY INFORMATION.** To ensure proper receipt by EPA, it is imperative that you identify docket control number OPP–2002–0025 in the subject line on the first page of your response.

FOR FURTHER INFORMATION CONTACT: By mail: Jacqueline Mosby, Special Review and Reregistration Division (7508C), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460; telephone number: (703) 305–6792; e-mail address: mosby.jackie@epa.gov.

SUPPLEMENTARY INFORMATION:

I. General Information

A. Does this Action Apply to Me?

This action is directed to the public in general. Although this action may be of particular interest to persons who produce or use pesticides, the Agency has not attempted to describe all the specific entities that may be affected by this action. If you have any questions regarding the information in this notice, consult the person listed under **FOR FURTHER INFORMATION CONTACT**.

B. How Can I Get Additional Information, Including Copies of this Document and Other Related Documents?

1. *Electronically.* You may obtain electronic copies of this document, and certain other related documents that might be available electronically, from the EPA Internet Home Page at http://www.epa.gov/. To access this document, on the Home Page select ''Laws and Regulations'' and then look up the entry for this document under the ''**Federal Register**—Environmental Documents.'' You can also go directly to the **Federal Register** listings at http://www.epa.gov/fedrgstr/.

2. *In person.* The Agency has established an official record for this action under docket control number OPP–66284. The official record consists of the documents specifically referenced in this action, any public comments received during an applicable comment period, and other information related to this action, including any information claimed as Confidential Business Information (CBI). This official record includes the documents that are physically located in the docket, as well as the documents that are referenced in those documents. The public version of the official record does not include any information claimed as CBI. The public version of the official record, which includes printed, paper versions of any electronic comments submitted during an applicable comment period, is available for inspection in the Public Information and Records Integrity Branch (PIRIB), Rm. 119, Crystal Mall #2, 1921 Jefferson Davis Hwy., Arlington, VA, from 8:30 a.m. to 4 p.m., Monday through Friday, excluding legal holidays. The PIRIB telephone number is (703) 305–5805.

C. How and to Whom Do I Submit Comments?

You may submit comments through the mail, in person, or electronically. To ensure proper receipt by EPA, it is imperative that you identify docket control number OPP–66284 in the subject line on the first page of your response.

1. *Electronically.* You may submit your comments electronically by e-mail to: opp-docket@epa.gov, or you can submit a computer disk as described above. Do not submit any information electronically that you consider to be CBI. Avoid the use of special characters and any form of encryption. Electronic submissions will be accepted in WordPerfect 6.1/8.0 or ASCII file format. All comments in electronic form must be identified by docket control number OPP–66284. Electronic comments may also be filed online at many Federal Depository Libraries.

2. *By mail.* Submit your comments to: Public Information and Records Integrity Branch (PIRIB), Information Resources and Services Division (7502C), Office of Pesticide Programs (OPP), Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460.

3. *In person or by courier.* Deliver your comments to: Public Information and Records Integrity Branch (PIRIB), Information Resources and Services Division (7502C), Office of Pesticide Programs (OPP), Environmental Protection Agency, Rm. 119, Crystal Mall #2, 1921 Jefferson Davis Hwy., Arlington, VA. The PIRIB is open from 8:30 a.m. to 4 p.m., Monday through Friday, excluding legal holidays. The PIRIB telephone number is (703) 305–5805.

D. How Should I Handle CBI that I Want to Submit to the Agency?

Do not submit any information electronically that you consider to be CBI. You may claim information that you submit to EPA in response to this document as CBI by marking any part or all of that information as CBI. Information so marked will not be disclosed except in accordance with procedures set forth in 40 CFR part 2. In addition to one complete version of the comment that includes any information claimed as CBI, a copy of the comment that does not contain the information claimed as CBI must be submitted for inclusion in the public version of the official record. Information not marked confidential will be included in the public version of the official record without prior notice. If you have any questions about CBI or the procedures for claiming CBI, please consult the person listed under **FOR FURTHER INFORMATION CONTACT**.

E. What Should I Consider as I Prepare My Comments for EPA?

You may find the following suggestions helpful for preparing your comments:

1. Explain your views as clearly as possible.
2. Describe any assumptions that you used.
3. Provide copies of any technical information and/or data you used that support your views.
4. If you estimate potential burden or costs, explain how you arrived at the estimate that you provide.
5. Provide specific examples to illustrate your concerns.
6. Offer alternative ways to improve the notice or collection activity.
7. Make sure to submit your comments by the deadline in this notice.
8. To ensure proper receipt by EPA, be sure to identify the docket control number assigned to this action in the subject line on the first page of your response. You may also provide the name, date, and **Federal Register** citation.

II. What Action is the Agency Taking?

A. Background

EPA is publishing this notice in response to registrants' requests to cancel three pesticide products containing chlorpyrifos-methyl. (See the

table below for specific information regarding the cancellation requests).

Reregistration Eligibility Decision (RED) documents summarize the findings of EPA's reregistration process for individual chemical cases, and reflect the Agency's decision on risk assessment and risk management for uses of individual pesticides. Chlorpyrifos-methyl belongs to a group of pesticides known as organophosphates (OPs). EPA has issued a Report on FQPA Tolerance Reassessment Progress and Risk Management Decision (TRED) assessing the risks of exposure from chlorpyrifos-methyl. EPA will also consider the cumulative risks from all organophosphates, as they all share a common mechanism of toxicity affecting the nervous system by inhibiting cholinesterase.

In letters received by EPA on January 31, 2001 and February 13, 2001, the registrants of products containing chlorpyrifos-methyl agreed to several voluntary measures to cancel all products with this active ingredient. The registrants are requesting cancellation of these products after determining that they would not be generating or submitting data required by EPA under section 3(c)(2)(B) of FIFRA to support continued registration of chlorpyrifos methyl products.

As part of the Agreement, the signatory, and non-signatory registrants, among other things, agreed to cancel their manufacturing use product (EPA Reg. No. 62719–42) and the liquid formulations (EPA Reg. No. 7501–41 and 62719–43) and will not sell nor distribute the products after December 31, 2003. All sales, distribution, and use of existing stocks of the manufacturing use product and liquid formulations will be allowed until December 31, 2004.

EPA will consider any comments received within 180 days of publication of this notice in the **Federal Register** prior to cancelling affected uses.

B. Request for Voluntary Cancellation of Manufacturing Use, and Liquid Formulation Products

Under section 6(f)(1)(A) of FIFRA, registrants may request, at any time, that their pesticide registrations be canceled or amended to terminate one or more pesticide uses. Section 6(f)(1)(B) of FIFRA requires that before acting on a request for voluntary cancellation, EPA must provide a 30–day public comment period on the request for voluntary cancellation. In addition, section 6(f)(1)(C) of FIFRA requires that EPA provide a 180–day comment period on a request for voluntary termination of any minor agricultural use before granting the request, unless: (1) The registrants request a waiver of the comment period, or (2) the Administrator determines that continued use of the pesticide would pose an unreasonable adverse effect on the environment. EPA anticipates granting the cancellation request shortly after considering the comments received during the 30–day comment period for this notice.

Pursuant to section 6(f)(1)(A) of FIFRA, the following companies have submitted a request to cancel three pesticide products uses registered under section 3 or 24(c) of FIFRA containing chlorpyrifos-methyl. These registrations for which cancellations were requested are in Table 1.

TABLE 1.—REGISTRATIONS WITH PENDING REQUEST FOR CANCELLATION

Registration No.	Product Name	Intended Effective Date for Cancellation
7501–41	Gustafson Reldan 4E (43.%) Insecticide	December 31, 2004
62719–42	Reldan F Insecticidal (97.%)	December 31, 2004
62719–43	Reldan 4E (43.2%)	December 31, 2004

III. What is the Agency's Authority for Taking This Action?

Section 6(f)(1) of FIFRA provides that a registrant of a pesticide product may at any time request that any of its pesticide registrations be canceled. FIFRA further provides that, before acting on the request, EPA must publish a notice of receipt of any such request in the **Federal Register**, make reasonable efforts to inform persons who rely on the pesticide, and provide a 30–day period in which the public may comment. Thereafter, the Administrator may approve such a request.

IV. Procedures for Withdrawal of Request

Registrants who choose to withdraw a request for cancellation must submit such withdrawal in writing to the person listed under **FOR FURTHER INFORMATION CONTACT**, postmarked before May 24, 2002. This written withdrawal of the request for cancellation will apply only to the applicable FIFRA section 6(f)(1) request listed in this notice. If the product(s) have been subject to a previous cancellation action, the effective date of cancellation and all other provisions of any earlier cancellation action are controlling. The withdrawal request must also include a commitment to pay any reregistration fees due, and to fulfill any applicable unsatisfied data requirements.

V. Provisions for Disposition of Existing Stocks

The effective date of cancellation will be the date of the cancellation order. The orders effecting these requested cancellations will permit persons other than the registrant to sell, distribute, or use existing stocks for 1 year after December 31, 2003. This policy is in accordance with the Agency's statement of policy as prescribed in the **Federal Register** of June 26, 1991 (56 FR 29362) (FRL–3846–4). Exceptions to this general rule will be made if a product poses a risk concern, or is in noncompliance with reregistration requirements, or is subject to a Data Call-In. In all cases, product-specific disposition dates will be given in the cancellation orders.

Existing stocks are those stocks of registered pesticide products which are currently in the United States and which have been packaged, labeled, and released for shipment prior to the effective date of the cancellation action. Registrants would not sell or distribute products bearing old labeling after the stamped approval date of new labels, i.e., labels that conform to the provisions of this document. The following are the existing stocks provisions for the three products being canceled.

Liquid Formulations and Manufacturing Use Product (7501–41, 62719–43, and 62719–42)

Liquid formulation and manufacturing use products bearing the EPA approved amended labels shall not be sold or distributed by registrants after December 31, 2003. Persons other than registrants may not sell, distribute, or use existing stocks after December 31, 2004. In lieu of putting end use dates on the label, registrants have agreed to

notify their distributors of the last use date and the rationale for it.

Exception to these general rules will be made in specific cases when more stringent restrictions on sale, distribution, or use of the products or their ingredients have already been imposed, as in a Special Review action, or where the Agency has identified significant potential risk concerns associated with a particular chemical.

List of Subjects

Environmental protection, Chlorpyrifos-methyl, Pesticides and pests, Stored grain.

Dated: April 2, 2002.

Lois A. Rossi,

Director, Information Resources Services Division, Office of Pesticide Programs.

[FR Doc. 02–9654 Filed 4–23–02; 8:45 am]

BILLING CODE 6560–50–S

ENVIRONMENTAL PROTECTION AGENCY

[OPP–2002–0007; FRL–6832–1]

Notice of Filing a Pesticide Petition to Establish a Tolerance for a Certain Pesticide Chemical in or on Food

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice.

SUMMARY: This notice announces the initial filing of a pesticide petition proposing the establishment of regulations for residues of a certain pesticide chemical in or on various food commodities.

DATES: Comments, identified by docket control number OPP–2002–0007, must be received on or before May 24, 2002.

ADDRESSES: Comments may be submitted by mail, electronically, or in person. Please follow the detailed instructions for each method as provided in Unit I.C. of the **SUPPLEMENTARY INFORMATION**. To ensure proper receipt by EPA, it is imperative that you identify docket control number OPP–2002–0007 in the subject line on the first page of your response.

FOR FURTHER INFORMATION CONTACT: By mail: Marilyn Mautz, Registration Support Branch, Registration Division (7505C), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460; telephone number: (703) 305–6785; e-mail address: mautz.marilyn@epa.gov.

SUPPLEMENTARY INFORMATION:

I. General Information

A. Does this Action Apply to Me?

You may be affected by this action if you are an agricultural producer, food manufacturer, or pesticide manufacturer. Potentially affected categories and entities may include, but are not limited to:

Categories	NAICS codes	Examples of potentially affected entities
Industry	111 112 311 32532	Crop production Animal production Food manufacturing Pesticide manufacturing

This listing is not intended to be exhaustive, but rather provides a guide for readers regarding entities likely to be affected by this action. Other types of entities not listed in the table could also be affected. The North American Industrial Classification System (NAICS) codes have been provided to assist you and others in determining whether or not this action might apply to certain entities. If you have questions regarding the applicability of this action to a particular entity, consult the person listed under **FOR FURTHER INFORMATION CONTACT**.

B. How Can I Get Additional Information, Including Copies of this Document and Other Related Documents?

1. *Electronically*. You may obtain electronic copies of this document, and certain other related documents that might be available electronically, from the EPA Internet Home Page at http://www.epa.gov/. To access this document, on the Home Page select ''Laws and Regulations'' and then look up the entry for this document under the ''**Federal Register**—Environmental Documents.'' You can also go directly to the **Federal Register** listings at http://www.epa.gov/fedrgstr/.

2. *In person*. The Agency has established an official record for this action under docket control number OPP–2002–0007. The official record consists of the documents specifically referenced in this action, any public comments received during an applicable comment period, and other information related to this action, including any information claimed as Confidential Business Information (CBI). This official record includes the documents that are physically located in the docket, as well as the documents that are referenced in those documents. The public version of the official record does not include any information claimed as CBI. The public version of the official record, which includes printed, paper versions of any electronic comments submitted during an applicable comment period, is available for inspection in the Public Information and Records Integrity Branch (PIRIB), Rm. 119, Crystal Mall #2, 1921 Jefferson Davis Highway, Arlington, VA, from 8:30 a.m. to 4 p.m., Monday through Friday, excluding legal holidays. The PIRIB telephone number is (703) 305–5805.

C. How and to Whom Do I Submit Comments?

You may submit comments through the mail, in person, or electronically. To ensure proper receipt by EPA, it is imperative that you identify docket control number OPP–2002–0007 in the subject line on the first page of your response.

1. *By mail*. Submit your comments to: Public Information and Records Integrity Branch (PIRIB), Information Resources and Services Division (7502C), Office of Pesticide Programs (OPP), Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460.

2. *In person or by courier*. Deliver your comments to: Public Information and Records Integrity Branch (PIRIB), Information Resources and Services Division (7502C), Office of Pesticide Programs (OPP), Environmental Protection Agency, Rm. 119, Crystal Mall #2, 1921 Jefferson Davis Highway, Arlington, VA. The PIRIB is open from 8:30 a.m. to 4 p.m., Monday through Friday, excluding legal holidays. The PIRIB telephone number is (703) 305–5805.

3. *Electronically*. You may submit your comments electronically by e-mail to: opp-docket@epa.gov, or you can submit a computer disk as described above. Do not submit any information electronically that you consider to be CBI. Avoid the use of special characters and any form of encryption. Electronic submissions will be accepted in Wordperfect 6.1/8.0 or ASCII file format. All comments in electronic form must be identified by docket control number OPP–2002–0007. Electronic comments may also be filed online at many Federal Depository Libraries.

D. How Should I Handle CBI That I Want to Submit to the Agency?

Do not submit any information electronically that you consider to be CBI. You may claim information that you submit to EPA in response to this document as CBI by marking any part or

all of that information as CBI. Information so marked will not be disclosed except in accordance with procedures set forth in 40 CFR part 2. In addition to one complete version of the comment that includes any information claimed as CBI, a copy of the comment that does not contain the information claimed as CBI must be submitted for inclusion in the public version of the official record. Information not marked confidential will be included in the public version of the official record without prior notice. If you have any questions about CBI or the procedures for claiming CBI, please consult the person identified under **FOR FURTHER INFORMATION CONTACT**.

E. What Should I Consider as I Prepare My Comments for EPA?

You may find the following suggestions helpful for preparing your comments:

1. Explain your views as clearly as possible.
2. Describe any assumptions that you used.
3. Provide copies of any technical information and/or data you used that support your views.
4. If you estimate potential burden or costs, explain how you arrived at the estimate that you provide.
5. Provide specific examples to illustrate your concerns.
6. Make sure to submit your comments by the deadline in this notice.
7. To ensure proper receipt by EPA, be sure to identify the docket control number assigned to this action in the subject line on the first page of your response. You may also provide the name, date, and **Federal Register** citation.

II. What Action is the Agency Taking?

EPA has received a pesticide petition as follows proposing the establishment and/or amendment of regulations for residues of a certain pesticide chemical in or on various food commodities under section 408 of the Federal Food, Drug, and Cosmetic Act (FFDCA), 21 U.S.C. 346a. EPA has determined that this petition contains data or information regarding the elements set forth in section 408(d)(2); however, EPA has not fully evaluated the sufficiency of the submitted data at this time or whether the data support granting of the petition. Additional data may be needed before EPA rules on the petition.

List of Subjects

Environmental protection, Agricultural commodities, Feed additives, Food additives, Pesticides and pests, Reporting and recordkeeping requirements.

Dated: April 9, 2002.

Debra Edwards,

Acting Director, Registration Division, Office of Pesticide Programs.

Summary of Petition

The petitioner summary of the pesticide petition is printed below as required by section 408(d)(3) of the FFDCA. The summary of the petition was prepared by the Gowan Company, and represents the view of the Gowan Company. EPA is publishing the petition summary verbatim without editing it in any way. The petition summary announces the availability of a description of the analytical methods available to EPA for the detection and measurement of the pesticide chemical residues or an explanation of why no such method is needed.

Gowan Company

EPA has received a pesticide petition from Gowan Company, P.O. Box 5569, Yuma, AZ, 85366–5569 proposing, pursuant to section 408(d) of FFDCA, 21 U.S.C. 346a(d), to amend 40 CFR part 180 by: (1) Modifying the tolerance expression in 40 CFR 180.145 (a) General. from ''Tolerances are established for combined residues of the insecticidal fluorine compounds cryolite and synthetic cryolite (sodium aluminofluoride) in or on the following commodities:'' to ''Tolerances are established for residues of fluoride arising from the use of the insecticidal fluorine compounds cryolite and synthetic cryolite (sodium aluminofluoride), in or on the following commodities:''; (2) renewing and removing the time limitations for potato and potato waste tolerances, as an amendment to petitions (December 5, 1997 62 FR 64294) (FRL–5756–5); (3) modifying the existing tolerances, for cucumber and kiwifruit to reflect the tolerance expression stated as residues of fluoride; (4) modifying existing tolerances for apricots, nectarines, kale, cranberry and plums (included in the tolerance modifications for plums is the relocation in 40 CFR 180.145 from (a)(1) to (a)(c)), as a followup to the Cryolite Reregistration Eligibility Decision, and as recommended by the Agency; and (5) establishing new tolerances for prunes and the berry group (Crop Group 13) as a follow-up to the Cryolite Reregistration Eligibility Decision, and as recommended by the Agency. The following specific actions are proposed:

Modify existing tolerances:

Apricots from 7 ppm to 10 parts per million (ppm)
Cucumber from 7 ppm to 4 ppm
Cranberry from 7 ppm to 2 ppm
Kale from 7 ppm to 35 ppm
Kiwi from 15 ppm to 8 ppm
Nectarines from 7 ppm to 10 ppm
Plums from 7 ppm to 2 ppm (tolerance with regional registration)

Renew tolerances and remove time-limitation:

Potatoes - 2 ppm
Potatoes, waste from processing 22 ppm

Establish new tolerances:

Berries (crop group 13) - 0.5 ppm (replaces separate existing tolerances for blackberries, blueberries, boysenberries, dewberries, loganberries, raspberries and youngberries
Prunes - 7 ppm (tolerance with regional registration)

EPA has determined, that the petition contains data or information regarding the elements set forth in section 408(d)(2) of the FFDCA; however, EPA has not fully evaluated the sufficiency of the submitted data at this time, or whether the data support granting of the petition. Additional data may be needed before EPA rules on the petition.

A. Residue Chemistry

1. *Plant metabolism.* The metabolism of cryolite in plants and animals was reviewed in the Cryolite Reregistration Eligibility Decision (RED) of 1996 and in the December 5, 1997 **Federal Register**. The nature of the residues in plants is understood. Plant residues are inorganic surface residues of cryolite, that are measured as total fluoride. Uptake and translocation of cryolite residues from soil is unlikely, due to the low water solubility of cryolite.

2. *Analytical method.* Analytical methodology was reviewed in the Cryolite Reregistration Eligibility Decision of 1996 and in the December 5, 1997 **Federal Register.** An adequate analytical method (fluoride specific electrode) is available for enforcement purposes for plant and animal residues. The limit of quantitation is 0.05 ppm. EPA has previously concluded that, because cryolite is an inorganic ionic compound, the requirement for data using the multi-residue protocols in the Pesticide Analytical Manual (PAM) Vol. I is not applicable.

3. *Magnitude of residues.* Magnitude of the residue studies have been reviewed in the 1996 cryolite RED, and in the December 5, 1997 **Federal Register**. Magnitude of the residue studies have been conducted at the maximum label rates for the commodities. Results from the studies demonstrate that the highest fluoride

residues will not exceed the proposed tolerances, when the insecticide is applied following the label use directions.

B. Toxicological Profile

The cryolite RED concluded that the toxicological data base was adequate for a reregistration eligibility decision. No additional toxicology requirements were specified in the RED. The cryolite residue of toxicological concern is fluoride; and health effects identified for fluoride in humans and animals are skeletal and dental fluorosis. Dental fluorosis (mottling of tooth enamel) is not considered to be an adverse effect. Further, the Agency has determined that although, fluoride accumulation is demonstrated in a number of studies, the accumulation itself is not considered an adverse effect.

1. *Acute toxicity.* A rat acute oral toxicity study (MRID 00138096) showed an LD_{50} greater than 5,000 milligrams/kilogram (mg/kg). A rabbit acute dermal toxicity study (MRID 00128107) demonstrated an LD_{50} of 2,100 mg/kg. An $LC_{50} > 2.06$ milligrams per liter(mg/L) and < 5.03 mg/L was seen in an acute inhalation study with rats (MRID 00128107).Technical cryolite is a moderate eye irritant in rabbits (MRID 00128106). Cryolite is not a skin irritant to rabbits (MRID 00128106) and is not a dermal sensitizer to guinea pigs (MRID 00138097).

2. *Genotoxicty.* Cryolite was negative in an Ames reverse mutation test (MRID 41838401) using *Salmonella typhimurium* with and without activation at dose levels of 167, 500, 1,670, 5,000, 7,500, and 10,000 microgram/plate (µg/plate). Cryolite was tested in an *in vitro* chromosome aberration assay (MRID 41838402) using human lymphocytes at 100, 500, and 1,000 microgram milliliter (µg/ml), with and without activation. The results were negative. Cryolite was also negative in an unscheduled DNA synthesis study (MRID 41838403) with rat hepatocytes at dose levels up to and including 50 µg/mL.

3. *Reproductive and developmental toxicity—i. Reproductive toxicity.* A two-generation rat reproduction study (MRID 43387501) was conducted with cryolite at dietary dose levels of 0, 200, 600, and 1,800 ppm (representing 0, 14, 42, and 128 milligrams/kilogram/day (mg/kg/day) for males and 0, 16, 49, and 149 mg/kg/day for females, respectively, during premating). The systemic toxicity no observed adverse effect level (NOAEL) was not determined. The lowest observed adverse effect level (LOAEL), for systemic toxicity was 200 ppm (15 mg/kg/day) based on dental fluorosis. The NOAEL and LOAEL for reproductive toxicity were 600 and 1,800 ppm, respectively (46 and 138 mg/kg/day) based on decreased pup body weights.

ii. *Developmental toxicity.* A developmental toxicity study was performed with cryolite in rats (MRID 00128112) at dose levels of 0, 750, 1,500, and 3,000 mg/kg/day (gavage). The NOAEL for both developmental and maternal toxicity was 3,000 mg/kg/day. At this dose level, the only observation was whitening of the teeth of dams.

A developmental toxicity study was conducted in female mice (MRID 42297902) with cryolite at dose levels of 0, 30, 100, and 300 mg/kg/day (gavage). The NOAEL for maternal toxicity was 30 mg/kg/day and the LOAEL was 100 mg/kg/day, based on a single mortality in this group. Fetuses at 300 mg/kg/day exhibited bent ribs and bent limb bones. The NOAEL for developmental toxicity was 100 mg/kg/day. The LOAEL was 300 mg/kg/day based on an increase in bent ribs and bent limbs.

A range-finding developmental toxicity study in female rabbits (MRID 42297901), tested cryolite at dose levels of 0, 10, 30, 100, 300, and 1,000 mg/kg/day (gavage). The NOAEL for maternal toxicity was determined to be 10 mg/kg/day and the LOAEL was 30 mg/kg/day based on an increased incidence of soft stool and dark colored feces and decreased defecation and urination. The NOAEL for developmental toxicity was 30 mg/kg/day. The developmental LOAEL could not be assessed due to excessive maternal toxicity at dose levels of >30 mg/kg/day.

4. *Subchronic toxicity.* Cryolite was tested in a 28–day range-finding feeding study in rats (MRID 00128109), at dose levels of 0, 250, 500, 1,000, 2,000, 4,000, 10,000, 25,000, and 50,000 ppm in the diet (representing approximately 0, 25, 50, 100, 200, 400, 1,000, 2,500, and 5,000 mg/kg/day). The only compound-related effect seen in this study was a change in coloration and physical property of the teeth. A NOAEL was not determined in this study. The LOAEL is 250 ppm (25 mg/kg/day) based on dental fluorosis.

In a 90–day rat feeding study (MRID 00158000), cryolite was tested at dose levels of 0, 50, 5,000, and 50,000 ppm (corresponding to 0, 3.8, 399.2 and 4,172.3 mg/kg/day in males and 0, 4.5, 455.9, and 4,758.1 mg/kg/day in females). The NOAEL was 50 ppm (3.8 mg/kg/day) for effects other than fluoride accumulation. The LOAEL was 5,000 ppm (399.2 mg/kg/day) based on lesions observed in the stomach.

Cryolite was tested in a 90–day dog feeding study (MRID 00157999) at dose levels of 0, 500, 10,000, and 50,000 ppm (corresponding to 0, 17, 368, and 1,692 mg/kg/day). The NOAEL was 10,000 ppm (368 mg/kg/day). The LOAEL was 50,000 ppm (1,692 mg/kg/day) for effects other than fluoride accumulation.

5. *Chronic toxicity.* The Agency concluded in the cryolite RED that the available information does not support the regulation of cryolite insecticides as carcinogens. The Agency has classified cryolite as a Group ''D'' chemical not classifiable as to human carcinogenicity. Further, EPA has noted that fluoride has been the subject of a comprehensive review by the National Research Council (National Academy of Sciences Subcommittee of Health Effects of Ingested Fluoride) who concluded that, '' . . .the available laboratory data are insufficient to demonstrate a carcinogenic effect of fluoride in animals.'' and that '' . . . the weight of evidence from more than 50 epidemiological studies does not support the hypothesis of an association between fluoride exposure and increased cancer risk in humans.'' As stated in the cryolite RED, the Agency is in agreement with the conclusions reached by the National Academy of Science (NAS).

The following specific chronic/oncogenicity studies are included in the cryolite toxicology data base:

A 2–year bioassay in B6C3F1 mice (HED DOC No. 009682) was conducted by the National Toxicology Program (NTP) using sodium fluoride as the test material at dose levels of 0, 25, 100, and 175 ppm, in water, representing 0, 2.4, 9.6, and 16.7 mg/kg/day in males and 0, 2.8, 11.3, and 18.8 mg/kg/day in females. The NOAEL was less than 25 ppm (2.4 mg/kg/day). The LOAEL was 25 ppm (2.4 mg/kg/day) based on attrition of the teeth in males, discoloration and mottling of the teeth in males and females and increased bone fluoride in both sexes. NTP considered that, there was ''no evidence'' of carcinogenic activity in male and female mice.

A 2–year bioassay in F344/N rats (HED DOC No. 009682) also was conducted by the National Toxicology Program (NTP) using sodium fluoride as the test material at dose levels of 0, 25, 100, and 175 ppm, in water, representing 0, 1.3, 5.2, and 8.6 mg/kg/day in males and 0, 1.3, 5.5, and 9.5 mg/kg/day in females. Osteosarcoma of the bone was observed only in 1 male of 50 (1/50) in the 100 ppm group and in 3 of 80 (3/80) males in the 175 ppm group. The NOAEL was less than 25 ppm (1.3 mg/kg/day). The LOAEL was 25 ppm (1.3 mg/kg/day) based on

mottling of teeth, dentine incisor dysplasia, increased serum, urine and bone fluoride levels in males and females and incisor odontoblast and incisor ameloblast degeneration in males.

EPA concluded in the cryolite RED, that the NTP studies utilizing sodium fluoride in lieu of cryolite satisfy the guideline study requirements for both the rodent chronic feeding study and the rat carcinogenicity study. Fluoride has been identified as the residue of toxicological concern in cryolite and synthetic cryolite, and these compounds act as free fluoride.

A 1–year chronic dog feeding study (MRID 42575101) was conducted with cryolite at dose levels of 0, 3,000, 10,000, and 30,000 ppm, representing 0, 95, 366, and 1,137 mg/kg/day in males and 0, 105, 387, and 1,139 mg/kg/day in females (in terms of fluoride the doses are 0, 51, 198, and 614 mg F/kg/day for males and 0, 57, 209 and 615 mg F/kg/day for females). The NOAEL was less than 3,000 ppm (95 mg/kg/day in males and 105 mg/kg/day in females). The LOAEL was 3,000 ppm based on increases in emesis, nucleated cells in males, renal lesions and a decrease in urine specific gravity in females.

6. *Animal metabolism.* As noted in the RED, cryolite behaves toxicologically as free fluoride. That is, dissociation produces free fluoride ions which are assimilated into bone. There are numerous references in the open literature concerning the metabolism of cryolite and other fluoride salts. The National Research Council concluded in their 1993 comprehensive report titled *Health Effects of Ingested Fluoride*, that fluoride is readily absorbed by the gut and rapidly becomes associated with teeth and bones. The remaining fluoride is eliminated almost exclusively by the kidneys with the rate of renal clearance related directly to urinary pH.

7. *Metabolite toxicology.* The active moiety of cryolite is free fluoride, which does not further metabolize.

8. *Endocrine disruption.* No effects similar to those produced by naturally occurring estrogens, or other endocrine effects have been noted.

C. Aggregate Exposure

1. *Dietary exposure.* A tier 3, partially refined, chronic DEEM™ analysis has been conducted for cryolite. In this assessment, the most highly exposed population subgroup was determined to be children 1–6 years old, at 0.0067 mg/kg/day, or 5.9% of the toxicological endpoint used for risk assessment. The estimated dietary exposure in this assessment for cryolite is below EPA's level of concern for chronic exposure for all population subgroups. Grapes and grape products are the largest contributors to dietary exposure estimates for all population subgroups. Lettuce was also a significant source of exposure for adult populations.

i. *Food.* No acute endpoints have been identified for cryolite. For the chronic dietary exposure assessment, EPA has determined that the dose to be used for risk assessment for exposure to fluoride is 0.114 mg F/kg/day, per the 1996 Cryolite RED. This value is used for all population subgroups, and is derived from a maximum acceptable amount of fluoride in drinking water recommended to the EPA by the Surgeon General as providing an adequate margin of safety for avoiding skeletal fluorosis (1996 Cryolite RED). Tolerance level residues were assumed in this assessment for all crops. The tolerance expression currently used in the Code of Federal Regulations (40 CFR 180.145) for all cryolite tolerances is described as ''the combined residues of the insecticidal fluorine compounds cryolite and synthetic cryolite (sodium aluminum fluoride) in or on the following agricultural commodities.'' For this assessment, the cryolite tolerances have all been converted into ppm as fluoride and the toxic endpoint is also expressed as ppm fluoride.

Estimates of percent crop-treated data were incorporated into the assessment where they were available, or could be reasonably translated from related crops, but 100% crop-treated (%CT) was assumed for cranberries, mint, and berries. The estimates of percent crop-treated were taken from BEAD estimates in the 1996 RED. Experimental processing factors were used for mint, oil, grape raisins, grape juice, juice concentrate; and for citrus juices, juice concentrates, and citrus peel. For all other commodities DEEM™ default process factors were used.

ii. *Drinking water.* The cryolite RED concludes that use of cryolite should have negligible impacts on fluoride levels in ground and surface water. However, fluoride is intentionally supplemented to drinking water for prevention of dental caries, and may also be present at natural background levels. Levels of fluoride in/on food from the agricultural use of cryolite plus fluoride levels in U.S. drinking water supplies, results in a daily intake of fluoride of approximately 0.064 mg/kg/day for the most highly exposed population subgroup, children 1–6 years old. This is 56% of the dose used for chronic risk assessment (0.114 mg/kg/day), which represents a level, which provides no known or anticipated adverse health effect as determined by the Surgeon General. For the U.S. population, the exposure estimate is 0.060 mg/kg/day (53% of the dose used for risk assessment).

2. *Non-dietary exposure.* Non-dietary exposure to cryolite is anticipated to be negligible.

D. Cumulative Effects

EPA has not determined, that any pesticidal substance has a common mechanism of toxicity with cryolite.

E. Safety Determination

1. *U.S. population.* For the U.S. population, the combined exposure estimate to fluoride from the agricultural use of cryolite plus drinking water is 0.060 mg/kg/day.

2. *Infants and children.* Levels of fluoride in/on food from the agricultural use of cryolite plus fluoride levels in U.S. drinking water supplies results in a daily intake of fluoride of approximately 0.064 mg/kg/day for the most highly exposed population subgroup, children 1–6 years old.

F. International Tolerances

No Canadian, Codex or other international tolerances currently exist for cryolite.

[FR Doc. 02–9655 Filed 4–23–02; 8:45 am]

BILLING CODE 6560–50–S

FEDERAL COMMUNICATIONS COMMISSION

[Report No. AUC–02–31–B (Auction No. 31); DA 02–659]

Auction No. 31, Auction of Licenses in the 747–762 and 777–792 Mhz Bands Scheduled for June 19, 2002; Further Modification of Package Bidding Procedures and Other Procedures

AGENCY: Federal Communications Commission.

ACTION: Notice.

SUMMARY: This document modifies package bidding procedures and other procedural issues in the 747–762 and 777–792 MHz Bands to commence on June 19, 2002.

DATES: Auction No. 31 is scheduled for June 19, 2002.

FOR FURTHER INFORMATION CONTACT: Legal questions: Howard Davenport (202) 418–0660 or e-mail hdavenpo@fcc.gov For general auction questions: Craig Bomberger (202) 418–0660 or e-mail cbomberg@fcc.gov or Kathy Garland (717) 338–2888 or e-mail *kgarland@fcc.gov.*

SUPPLEMENTARY INFORMATION: This is a summary of the *Auction No. 31 Further*

Procedures Public Notice released March 19, 2002 as modified by an erratum dated April 16, 2002. The complete modified text of the *Auction No. 31 Further Procedures Public Notice,* including attachments, is available for public inspection and copying during regular business hours at the FCC Reference Information Center, Portals II, 445 12th Street, SW, Room CY–A257, Washington, DC, 20554. *The Auction No. 31 Further Procedures Public Notice* may also be purchased from the Commission's duplicating contractor, Qualex International, Portals II, 445 12th Street, SW, Room CY–B402, Washington, DC, 20554, telephone 202–863–2893, facsimile 202–863–2898, or via e-mail *qualexint@aol.com.*

I. General Information

A. Introduction

1. By the *Auction No. 31 Further Procedures Public Notice,* the Wireless Telecommunications Bureau (''Bureau'') announces the procedures, minimum opening bids, and aggregate reserve price for the upcoming auction of licenses in the 747–762 and 777–792 MHz (''Upper 700 MHz'') bands scheduled for June 19, 2002 (''Auction No. 31''). In a series of prior public notices, the Bureau sought comment on and announced various Auction No. 31 procedures. In the present public notice, the Bureau sets forth a single set of procedures, minimum opening bids, and an aggregate reserve price consolidating prior Auction No. 31 procedures public notices.

i. Background of Proceeding

2. Historically, the 746–806 MHz band has been used exclusively by television stations (Channels 60–69). In the Balanced Budget Act of 1997, Congress directed the Commission to reallocate this spectrum for public safety and commercial use by December 31, 1997, and to commence competitive bidding for commercial licenses on the reallocated spectrum after January 1, 2001. Incumbent analog television broadcasters, however, may continue operations until December 31, 2006, and, under certain circumstances, may be able to extend their operations beyond that date.

3. In the *Upper 700 MHz First Report and Order,* 65 FR 3139 (January 20, 2000), the Commission adopted service rules for the commercial use of the Upper 700 MHz bands that enable the broadest possible use of this spectrum, consistent with sound spectrum management. In its service rules, the Commission divided the Upper 700 MHz bands into one 20-megahertz block (consisting of paired 10 megahertz blocks) and one 10-megahertz block (consisting of paired 5 megahertz blocks). The Commission will license the blocks in the Upper 700 MHz bands over six 700 MHz band Economic Area Groupings (''EAGs''). All operations in the Upper 700 MHz bands will be generally regulated under the framework of part 27's technical, licensing, and operating rules.

4. In subsequent proceedings, the Commission provided guidance on its review of applications for approval of voluntary agreements accelerating the transition of incumbent analog television licensees and opening these bands for new 700 MHz licensee use, and several potential mechanisms to advance the spectrum clearing process. In connection with three-way spectrum clearing agreements (which would provide for TV incumbents on television Channels 59–69 to agree with new 700 MHz wireless licensees to relocate to lower band TV channels that, in turn, would be voluntarily cleared by the lower band TV incumbents), the Commission also provided guidance on interference issues that may arise from a proposal to relocate a broadcast operation to a channel below Channel 59, and adopted various procedural changes in order to streamline the process of reviewing regulatory requests needed to effectuate private band-clearing agreements.

ii. Licenses To Be Auctioned

5. Twelve licenses in the Upper 700 MHz bands will be available in Auction No. 31. These licenses consist of one 20 megahertz license (consisting of paired 10 megahertz blocks) and one 10 megahertz license (consisting of paired 5 megahertz blocks) in each of six 700 MHz band EAGs. These licenses are listed in Attachment A of the *Auction No. 31 Further Procedures Public Notice* and are shown in the table here.

UPPER 700 MHZ BAND LICENSES

	Pacific	Central/mountain	Great lakes	Southeast	Mid-atlantic	Northeast
10 MHz	WX–EAG706–C	WX–EAG705–C	WX–EAG704–C	WX–EAG703–C	WX–EAG702–C	WX–EAG701–C
20 MHz	WX–EAG706–D	WX–EAG705–D	WX–EAG704–D	WX–EAG703–D	WX–EAG702–D	WX–EAG701–D

6. Bidders may bid on individual licenses. In addition, bidders will be permitted to create and bid on up to twelve different packages of their own choosing during the course of the auction. Bidders will not be required to identify or create their packages before the start of the auction, but may create their packages as the auction progresses.

7. In the *Auction No. 31 Further Modifications Comment Public Notice,* 67 FR 6925 (February 14, 2002), the Bureau sought comment regarding the potential inclusion in Auction No. 31 of 24 additional licenses from the 698–746 MHz band (the ''Lower 700 MHz'' band). The licenses available for auction in the Lower 700 MHz band consist of 24 licenses to use spectrum in the 700 MHz band EAGs (four in each of the six EAGs) and 734 licenses to use spectrum in Metropolitan Statistical Areas/Rural Statistical Areas (''MSA/RSAs''). The Bureau sought comment on any potential advantages or disadvantages of enabling bidders in Auction No. 31 to create and bid on packages containing 700 MHz band EAG licenses from both the Upper and Lower 700 MHz bands. The Bureau also sought comment on this issue in a public notice regarding the auction of licenses from the Lower 700 MHz band (''Auction No. 44'').

8. Commenters were divided on whether to include the 24 Lower 700 MHz band EAG licenses in Auction No. 31. Commenters favoring the inclusion of the Lower 700 MHz band EAG licenses in Auction No. 31 tended to focus on separating the Lower 700 MHz band EAG licenses from the 734 Lower 700 MHz band MSA/RSA licenses rather than on combining the 24 Lower 700 MHz band EAG licenses with the 12 Upper 700 MHz band EAG licenses. Commenters opposing inclusion tended to focus on the possibility that

continuing rule making proceedings in the Lower 700 MHz band might delay auction of those licenses and any other licenses grouped with them, including the Upper 700 MHz band licenses.

9. After careful review of the comments, the Bureau concludes that it will not include the 24 Lower 700 MHz EAG licenses in Auction No. 31 with the Upper 700 MHz EAG licenses. The Bureau is not persuaded that grouping the MSA/RSA licenses in an auction with the Lower 700 MHz EAG licenses will create a disadvantage to small businesses and rural telephone companies. We do not agree with those commenters that believe that separating the 734 MSAs/RSAs from the 24 EAGs would provide greater opportunities for small businesses and rural telephone companies. Larger entities that do not qualify for bidding credits would continue to be eligible to participate in an auction of the 734 MSA/RSA licenses. In the *Lower 700 MHz Report and Order,* 67 FR 5491 (February 6, 2002), the Commission adopted MSAs/RSAs as the licensing area for a portion of the Lower 700 MHz band to promote opportunities for a wide variety of applicants, including small and rural wireless providers, to obtain spectrum. However, the Commission did not decide to restrict eligibility for these licenses to small and rural service providers. Because the Commission adopted licensing rules for the Lower 700 MHz band that provide for open eligibility, the Bureau declines to consider license groupings for the purpose of discouraging participation in the auction by any particular class of bidders. We disagree with those commenters who suggest that grouping the MSA/RSA licenses with the EAG licenses in the Lower 700 MHz band may discourage many smaller carriers from participating in Auction No. 44. The Commission has sought to provide small businesses with an opportunity to successfully compete against larger, well-financed bidders by defining three tiers of small-businesses that are eligible for bidding credits. As the Commission noted in the *Lower 700 MHz Report & Order*, the use of a third small entity definition may result in the dissemination of licenses among an even wider range of small business entities, consistent with its obligations under section 309(j)(3)(B) of the Act.

B. Rules and Disclaimers

i. Relevant Authority

10. Prospective bidders must familiarize themselves thoroughly with the Commission's rules relating to the Upper 700 MHz bands contained in title 47, part 27 of the Code of Federal Regulations, and those relating to application and auction procedures, contained in title 47, part 1 of the Code of Federal Regulations.

11. Prospective bidders also must be thoroughly familiar with the procedures, terms and conditions (collectively, ''Terms'') contained in the Commission's rulemakings regarding the Upper 700 MHz bands, including the *Reallocation and Reconsideration,* 63 FR 6669 (February 10, 1998) and 63 FR 63798 (November 17, 1998); *Upper 700 MHz First Report and Order;* the *Upper 700 MHz Memorandum Opinion and Order and Further Notice of Proposed Rulemaking,* 65 FR 42960 (July 12, 2000); the *Upper 700 MHz Third Report and Order,* 66 FR 10204 (February 14, 2001); and the *Upper 700 MHz Third Report and Order Reconsideration,* 66 FR 51594 (October 10, 2001); as well as the Commission's rulemakings regarding competitive bidding, such as the *Part 1 Fifth Report and Order*, 65 FR 52323 (August 29, 2001).

12. The terms contained in the Commission's rules, relevant orders, and public notices are not negotiable. The Commission may amend or supplement the information contained in our public notices at any time, and will issue public notices to convey any new or supplemental information to bidders. It is the responsibility of all prospective bidders to remain current with all Commission rules and with all public notices pertaining to this auction. Copies of most Commission documents, including public notices, can be retrieved from the FCC Auctions Internet site at *http://wireless.fcc.gov/auctions.* Additionally, documents are available for public inspection and copying during regular business hours at the FCC Reference Information Center, Portals II, 445 12th Street, SW, Room CY–A257, Washington, DC, 20554 or may be purchased from the Commission's duplicating contractor, Qualex International, Portals II, 445 12th Street, SW, Room CY–B402, Washington, DC 20554, telephone 202–863–2893, facsimile 202–863–2898, or via e-mail *qualexint@aol.com.* When ordering documents from Qualex, please provide the appropriate FCC number (for example, FCC 00–5 for the *700 MHz First Report & Order).*

ii. Prohibition of Collusion

13. To ensure the competitiveness of the auction process, the Commission's rules prohibit applicants for the same geographic license area from communicating with each other during the auction about bids, bidding strategies, or settlements. This prohibition begins at the short-form application filing deadline and ends at the down payment deadline after the auction. Bidders competing for licenses in the same geographic license areas are encouraged not to use the same individual as an authorized bidder. A violation of the anti-collusion rule could occur if an individual acts as the authorized bidder for two or more competing applicants, and conveys information concerning the substance of bids or bidding strategies between the bidders he or she is authorized to represent in the auction. A violation could similarly occur if the authorized bidders are different individuals employed by the same organization (*e.g.,* law firm or consulting firm). In such a case, at a minimum, applicants should certify on their applications that precautionary steps have been taken to prevent communication between authorized bidders and that applicants and their bidding agents will comply with the anti-collusion rule.

14. However, the Bureau cautions that merely filing a certifying statement as part of an application will not outweigh specific evidence that collusive behavior has occurred, nor will it preclude the initiation of an investigation when warranted. In Auction No. 31, for example, the rule would apply to any applicants bidding for the same 700 MHz Band EAG. Therefore, applicants that apply to bid for ''all markets'' are precluded from communicating with all other applicants until after the down payment deadline. However, applicants may enter into bidding agreements *before* filing their FCC Form 175, as long as they disclose the existence of the agreement(s) in their Form 175. If parties agree in principle on all material terms prior to the short-form filing deadline, those parties must be identified on the short-form application pursuant to § 1.2105(c) of the Commission's rules, even if the agreement has not been reduced to writing. If the parties have not agreed in principle by the filing deadline, an applicant would not include the names of those parties on its application, and may not continue negotiations with other applicants for licenses covering the same geographic areas. By signing their FCC Form 175 short-form applications, applicants are certifying their compliance with § 1.2105(c).

15. In addition, § 1.65 of the Commission's rules requires an applicant to *maintain* the accuracy and completeness of information furnished in its pending application and to notify the Commission within 30 days of any

substantial change that may be of decisional significance to that application. Thus, §§ 1.65 and 1.2105 require an auction applicant to notify the Commission of any violation of the anti-collusion rules upon learning of such violation. Bidders therefore are required to make such notification to the Commission immediately upon discovery.

16. A summary listing of documents from the Commission and the Bureau addressing the application of the anti-collusion rules may be found in Attachment I of the *Auction No. 31 Further Procedures Public Notice.*

iii. Interference Protection of Television Services

17. Licensees operating on the spectrum associated with Channels 60, 61, 62, 65, 66, and 67 must comply with the co-channel and adjacent channel provisions of § 27.60 of the Commission's rules. For example, a licensee operating on any portion of the 10 megahertz block (i.e., between 752 MHz and 762 MHz) that coincides with Channel 61 will have to provide co-channel protection to television stations operating on Channel 61 and adjacent channel protection to television stations operating on Channels 60 and 62 (including digital television (''DTV'') stations); and any licensee operating on any portion of the 10 megahertz block that coincides with Channel 62 will have to provide co-channel protection to television stations operating on Channel 62 and adjacent channel protection to television stations operating on Channels 61 and 63. Licensees operating on spectrum between 747 MHz and 752 MHz (Channel 60), in addition to providing co-channel protection to Channel 60 television stations, will have to provide adjacent channel protection to television stations operating on both Channel 61 and 59. New Upper 700 MHz licensees will also have to comply with any additional technical requirements or interference protection requirements that may be adopted in the future as a result of pending and future rulemaking proceedings. These interference obligations will remain in force until the end of the DTV transition period, at which time analog TV and DTV broadcasters will be required to vacate both the Upper and Lower 700 MHz bands.

(a) Negotiations With Incumbent Broadcast Licensees

18. The Commission has established a policy of facilitating voluntary clearing of the 700 MHz bands to allow for the introduction of new wireless services and to promote the transition of incumbent analog television licensees to DTV service. The Commission established its policies on voluntary clearing for the Upper 700 MHz Band in a series of orders. The Commission initially stated that it would ''consider specific regulatory requests needed to implement voluntary agreements'' between incumbent broadcasters and new licensees to clear the Upper 700 MHz Band early, if consistent with public interest. Subsequently, the Commission established a rebuttable presumption favoring the grant of requests that would both result in certain specific benefits and avoid specific detriments. These policies were later extended to ''three-way'' band clearing arrangements, in which non-Channel 59–69 broadcasters were also potential parties. Subsequently, the Commission provided certain additional flexibility to facilitate voluntary agreements for early clearing and granted a request for relief from two specific DTV-related requirements. In considering such requests, the Commission will consider whether grant of the request would result in public interest benefits, such as making new or expanded public safety or other wireless services available to consumers or deploying wireless service to rural or other underserved communities. The Commission intends to weigh these benefits against any likely public interest costs, such as the loss of any of the four stations in the designated market area with the largest audience share, the loss of the sole service licensed to the local community, the loss of a community's sole service on a channel reserved for noncommercial educational broadcast service, or a negative effect on the pace of the DTV transition in the market. For example, the Commission would consider the availability of the licensee's former analog programming within the service area, through simulcast of the programming on the licensee's DTV channel or distribution of the programming on cable or DBS, or the availability of similar broadcast services within the service area (e.g., whether the lost service is the only network service, the only source for local service, or the only source for otherwise unique broadcast service).

(b) Canadian and Mexican Border Regions

19. There are currently separate agreements with Canada and Mexico covering TV broadcast use of the UHF 470–806 MHz band. Such agreements do not reflect the additional use or services adopted in the *700 MHz First Report & Order* for 746–764 and 776–794 MHz bands. While the Commission staff has been involved in discussions with both countries regarding coordination of interference criteria for the use of these bands in the border areas for the additional services, agreements have yet to be reached. Therefore, until such agreements have been finalized, the Commission found it necessary to adopt certain interim requirements for licenses in these bands along the Canada and Mexico borders. Accordingly, licenses issued for these bands within 120 km of the borders were made subject to whatever future agreements the United States developed with those two countries. Because the existing agreements for the protection of TV stations in those countries are still in effect and must be recognized until they are replaced or modified to reflect the new uses, the Commission decided that licenses in the border areas will be granted on the condition that harmful interference may not be caused to, but must accept interference from, UHF TV transmitters in Canada and Mexico. Furthermore, the Commission pointed out that modifications may be necessary to comply with whatever provisions are ultimately specified in future agreements with Canada and Mexico regarding the use of these bands.

iv. Due Diligence

20. Potential bidders are reminded that there are a number of incumbent broadcast television licensees already licensed and operating in the 746–764 and 776–794 MHz bands (television Channels 60–62 and 65–67) that will be subject to the upcoming auction. As discussed previously in greater detail, the Commission made clear that geographic area licensees operating on the spectrum associated with Channels 60, 61, 62, 65, 66, and 67 must comply with the co-channel and adjacent channel provision of § 27.60 of the Commission's rules. In addition, geographic area licensees operating fixed stations in the 746–764 MHz band must comply with the relevant provisions for ''base stations'' in §§ 27.60 and 90.309 of the Commission's rules; and licensees operating fixed stations in the 776–794 MHz band must comply with the relevant provisions for ''control stations'' in those sections of the rules.

21. These limitations may restrict the ability of such geographic licensees to use certain portions of the electromagnetic spectrum or provide service to certain regions in their geographic license areas. To aid potential bidders, the Bureau will shortly issue a Due Diligence Announcement listing incumbent

licensees operating in these bands. The Commission makes no representations or guarantees that the matters listed in this Due Diligence Announcement are the only pending matters that could affect spectrum availability in these services.

22. Potential bidders are solely responsible for identifying associated risks and for investigating and evaluating the degree to which such matters may affect their ability to bid on, otherwise acquire, or make use of licenses available in Auction No. 31.

23. Potential bidders also should be aware that certain applications (including those for modification), petitions for rulemaking, requests for special temporary authority (''STA''), waiver requests, petitions to deny, petitions for reconsideration, and applications for review may be pending before the Commission and relate to particular applicants or incumbent licensees. In addition, certain decisions reached in this proceeding may be subject to judicial appeal and may be the subject of additional reconsideration or appeal. We note that resolution of these matters could have an impact on the availability of spectrum in Auction No. 31. In addition, although the Commission will continue to act on pending applications, requests and petitions, some of these matters may not be resolved by the time of the auction. To aid potential bidders, the Bureau will issue shortly a Due Diligence Announcement listing matters pending before the Commission that relate to licenses or applications in these services. The Commission makes no representations or guarantees that the listed matters are the only pending matters that could affect spectrum availability in these services.

24. In addition, potential bidders may research the licensing database for the Media Bureau on the Internet in order to determine which frequencies are already licensed to incumbent licensees. The Commission makes no representations or guarantees regarding the accuracy or completeness of information in its databases or any third party databases, including, for example, court docketing systems. Furthermore, the Commission makes no representations or guarantees regarding the accuracy or completeness of information that has been provided by incumbent licensees and incorporated into the database. Potential bidders are strongly encouraged to physically inspect any sites located in or near the EAG for which they plan to bid.

25. Licensing records for the Media Bureau are contained in the Media Bureau's Consolidated Data Base System (CDBS) and may be researched on the Internet at *http://wireless.fcc.gov/mb/databases/*. Potential bidders may query the database online and download a copy of their search results if desired. Detailed instructions on using Search for Station Information, Search for Ownership Report Information and Search for Application Information and downloading query results are available online by selecting the CDBS Public Access (main) button at the bottom of the Electronic Filing and Public Access list section. The database searches return either station or application data. The application search provides an application link that displays the complete electronically filed application in application format. An AL/TC search under the application search link permits searching for Assignment of License/Transfer of Control groups using the AL/TC group lead application. For further details, click on the *Help* file.

26. Potential bidders should direct questions regarding the search capabilities of CDBS to the Media Bureau help line at (202) 418–2662, or via e-mail at *mbinfo@fcc.gov.*

v. Bidder Alerts

27. All applicants must certify on their FCC Form 175 applications under penalty of perjury that they are legally, technically, financially and otherwise qualified to hold a license, and not in default on any payment for Commission licenses (including down payments) or delinquent on any non-tax debt owed to any Federal agency. Prospective bidders are reminded that submission of a false certification to the Commission is a serious matter that may result in severe penalties, including monetary forfeitures, license revocations, exclusion from participation in future auctions, and/or criminal prosecution.

28. The FCC makes no representations or warranties about the use of this spectrum for particular services. Applicants should be aware that an FCC auction represents an opportunity to become an FCC licensee in this service, subject to certain conditions and regulations. An FCC auction does not constitute an endorsement by the FCC of any particular services, technologies or products, nor does an FCC license constitute a guarantee of business success. Applicants and interested parties should perform their own due diligence before proceeding, as they would with any new business venture.

29. As is the case with many business investment opportunities, some unscrupulous entrepreneurs may attempt to use Auction No. 31 to deceive and defraud unsuspecting investors. Common warning signals of fraud include the following:

- The first contact is a ''cold call'' from a telemarketer, or is made in response to an inquiry prompted by a radio or television infomercial.
- The offering materials used to invest in the venture appear to be targeted at IRA funds, for example, by including all documents and papers needed for the transfer of funds maintained in IRA accounts.
- The amount of investment is less than $25,000.
- The sales representative makes verbal representations that: (a) The Internal Revenue Service (''IRS''), Federal Trade Commission (''FTC''), Securities and Exchange Commission (''SEC''), FCC, or other government agency has approved the investment; (b) the investment is not subject to state or federal securities laws; or (c) the investment will yield unrealistically high short-term profits. In addition, the offering materials often include copies of actual FCC releases, or quotes from FCC personnel, giving the appearance of FCC knowledge or approval of the solicitation.

30. Information about deceptive telemarketing investment schemes is available from the FTC at (202) 326–2222 and from the SEC at (202) 942–7040. Complaints about specific deceptive telemarketing investment schemes should be directed to the FTC, the SEC, or the National Fraud Information Center at (800) 876–7060. Consumers who have concerns about specific proposals regarding Auction No. 31 may also call the FCC Consumer Center at (888) CALL-FCC ((888) 225–5322).

vi. National Environmental Policy Act (''NEPA'') Requirements

31. Licensees must comply with the Commission's rules regarding the National Environmental Policy Act (NEPA). The construction of a wireless antenna facility is a federal action and the licensee must comply with the Commission's NEPA rules for each such facility. The Commission's NEPA rules require, among other things, that the licensee consult with expert agencies having NEPA responsibilities, including the U.S. Fish and Wildlife Service, the State Historic Preservation Office, the Army Corp of Engineers and the Federal Emergency Management Agency (through the local authority with jurisdiction over floodplains). The licensee must prepare environmental assessments for facilities that may have a significant impact in or on wilderness areas, wildlife preserves, threatened or endangered species or designated

critical habitats, historical or archaeological sites, Indian religious sites, floodplains, and surface features. The licensee must also prepare environmental assessments for facilities that include high intensity white lights in residential neighborhoods or excessive radio frequency emission.

C. Auction Specifics

i. Auction Date

32. The auction will begin on Wednesday, June 19, 2002. The initial schedule for bidding will be announced by public notice at least one week before the start of the auction. Unless otherwise announced, bidding on all licenses and packages will be conducted on each business day until bidding has stopped on all licenses and packages.

ii. Auction Title

33. Auction No. 31—Upper 700 MHz Band

iii. Bidding Methodology

34. The bidding methodology for Auction No. 31 will be simultaneous multiple round with package bidding (SMR–PB). The Commission will conduct this auction over the Internet. Telephonic bidding will also be available. As a contingency, the FCC Wide Area Network, which requires access to a 900 number telephone service, will be available as well for a fee of $2.30 per minute. Qualified bidders are permitted to bid telephonically or electronically.

iv. Pre-Auction Dates and Deadlines

35. These are important dates relating to Auction No. 31:

Auction Seminar—April 30, 2002
Short-Form Application (FCC FORM 175)—May 8, 2002; 6 p.m. ET
Upfront Payments (via wire transfer)—May 28, 2002; 6 p.m. ET
Mock Auction—June 13–14, 2002
Auction Begins—June 19, 2002

v. Requirements For Participation

36. Those wishing to participate in the auction must:

- Submit a short-form application (FCC Form 175) electronically by 6 p.m. ET, May 8, 2002.
- Submit a sufficient upfront payment and an FCC Remittance Advice Form (FCC Form 159) by 6 p.m. ET, May 28, 2002.
- Comply with all provisions outlined in this public notice.
- Comply with all rules set forth in the Commission's order in WT Docket No. 99–168, Service Rules for the 746–764 and 776–794 MHz Bands, and Revisions to part 27 of the Commission's Rules.

iv. General Contact Information

37. The following is a list of general contact information relating to Auction No. 31:

General Auction Information: General Auction Questions, Seminar Registration— FCC Auctions Hotline, (888) 225–5322, Press Option #2 or direct (717) 338–2888, Hours of service: 8 a.m.–5:30 p.m. ET
Auction Legal Information: Auction Rules, Policies, Regulations—Auctions and Industry Analysis Division, Legal Branch (202) 418–0660
Licensing Information: Rules, Policies, Regulations, Licensing Issues, Due Diligence, Incumbency Issues—Commercial Wireless Division (202) 418–0620
Technical Support: Electronic Filing, Automated Auction System—FCC Auctions Technical Support Hotline, (202) 414–1250 (Voice), (202) 414–1255 (TTY), Hours of service: Monday through Friday 7 a.m. to 10 p.m. ET, Saturday, 8:00 a.m. to 7p.m., Sunday, 12 noon to 6 p.m.
Payment Information: Wire Transfers, Refunds—FCC Auctions Accounting Branch, (202) 418–1995, (202) 418–2843 (Fax)
Telephonic Bidding—Will be furnished only to qualified bidders
FCC Copy Contractor: Additional Copies of Commission Documents—Qualex International, Portals II, 445 12th Street, SW, Room CY–B402, Washington, DC 20554, (202) 863–2893, (202) 863–2898 (Fax), *qualexint@aol.com* (e-mail)
Press Information—Meribeth McCarrick, (202) 418–0654
FCC Forms—(800) 418–3676 (outside Washington, DC) (202) 418–3676 (in the Washington Area)—*http://www.fcc.gov/formpage.html*
FCC Internet Sites—*http://www.fcc.gov, http://wireless.fcc.gov/auctions, http://wireless.fcc.gov/uls*

II. Short-Form (FCC Form 175) Application Requirements

38. Guidelines for completion of the short-form (FCC Form 175) are set forth in Attachment E of the *Auction No. 31 Further Procedures Public Notice.* The short-form application seeks the applicant's name and address, legal classification, status, small or very small business bidding credit eligibility, identification of the license(s) sought, the authorized bidders and contact persons. All applicants must certify on their FCC Form 175 applications under penalty of perjury that they are legally, technically, financially and otherwise qualified to hold a license and, as discussed in Section II.D (Provisions Regarding Defaulters and Former Defaulters), that they are not in default on any payment for Commission licenses (including down payments) or delinquent on any non-tax debt owed to any Federal agency.

A. Ownership Disclosure Requirements (FCC Form 175 Exhibit A)

39. All applicants must comply with the uniform part 1 ownership disclosure standards and provide information required by § 1.2105 and § 1.2112 of the Commission's rules. Specifically, in completing FCC Form 175, applicants will be required to file an ''Exhibit A'' providing a full and complete statement of the ownership of the bidding entity. The ownership disclosure standards for the short-form are set forth in § 1.2112 of the Commission's rules.

B. Consortia and Joint Bidding Arrangements (FCC Form 175 Exhibit B)

40. Applicants will be required to identify on their short-form applications any parties with whom they have entered into any consortium arrangements, joint ventures, partnerships or other agreements or understandings which relate in any way to the licenses being auctioned, including any agreements relating to post-auction market structure. Applicants will also be required to certify on their short-form applications that they have not entered into any explicit or implicit agreements, arrangements or understandings of any kind with any parties, other than those identified, regarding the amount of their bids, bidding strategies, or the particular licenses on which they will or will not bid. As previously discussed, if an applicant has had discussions, but has not reached a joint bidding agreement by the short-form deadline, it would not include the names of parties to the discussions on its applications and may not continue discussions with applicants for the same geographic license area(s) after the deadline. Where applicants have entered into consortia or joint bidding arrangements, applicants must submit an ''Exhibit B'' to the FCC Form 175.

41. A party holding a non-controlling, attributable interest in one applicant will be permitted to acquire an ownership interest in, form a consortium with, or enter into a joint bidding arrangement with other applicants for licenses in the same geographic license area provided that (i) the attributable interest holder certifies that it has not and will not communicate with any party concerning the bids or bidding strategies of more

than one of the applicants in which it holds an attributable interest, or with which it has formed a consortium or entered into a joint bidding arrangement; and (ii) the arrangements do not result in a change in control of any of the applicants. While the anti-collusion rules do not prohibit non-auction related business negotiations among auction applicants, bidders are reminded that certain discussions or exchanges could touch upon impermissible subject matters because they may convey pricing information and bidding strategies.

C. Eligibility

i. Bidding Credit Eligibility (FCC Form 175 Exhibit C)

42. Bidding credits are available to small and very small businesses, or consortia, thereof, as defined in 47 CFR 27.502. A bidding credit represents the amount by which a bidder's winning bids are discounted. The size of a 700 MHz band bidding credit depends on the average of the aggregated annual gross revenues for each of the preceding three years of the bidder, its affiliates, its controlling interests, and the affiliates of its controlling interests:

- A bidder with attributed average annual gross revenues of not more than $40 million for the preceding three years receives a 15 percent discount on its winning bids for 700 MHz band licenses (''small business'');
- A bidder with attributed average annual gross revenues of not more than $15 million for the preceding three years receives a 25 percent discount on its winning bids for 700 MHz band licenses (''very small business'').

Bidding credits are not cumulative; qualifying applicants receive either the 15 percent or the 25 percent bidding credit, but not both.

ii. Tribal Land Bidding Credit

43. To encourage the growth of wireless services in federally recognized tribal lands the Commission has implemented a tribal land bidding credit. *See* Section V.D. of the *Auction No. 31 Further Procedures Public Notice.*

iii. Applicability of Part 1 Attribution Rules

44. *Controlling interest standard.* On August 14, 2000, the Commission released the *Part 1 Fifth Report and Order,* in which the Commission, inter alia, adopted a ''controlling interest'' standard for attributing to auction applicants the gross revenues of their investors and affiliates in determining small business eligibility for future auctions. The Commission observed that the rule modifications adopted in the various part 1 orders would result in discrepancies and/or redundancies between certain of the new part 1 rules and existing service-specific rules, and the Commission delegated to the Bureau the authority to make conforming edits to the Code of Federal Regulations (CFR) consistent with the rules adopted in the part 1 proceeding. Part 1 rules that superseded inconsistent service-specific rules will control in Auction No. 31. Accordingly, the ''controlling interest'' standard as set forth in the part 1 rules will be in effect for Auction No. 31, even if conforming edits to the CFR are not made prior to the auction.

45. *Control.* The term ''control'' includes both *de facto* and *de jure* control of the applicant. Typically, *ownership of at least 50.1 percent of an entity's voting stock evidences de jure control. De facto* control is determined on a case-by-case basis. The following are some common indicia of *de facto* control:

- The entity constitutes or appoints more than 50 percent of the board of directors or management committee;
- The entity has authority to appoint, promote, demote, and fire senior executives that control the day-to-day activities of the licensee; or
- The entity plays an integral role in management decisions.

46. *Attribution for small and very small business eligibility.* In determining which entities qualify as small or very small businesses, the Commission will consider the gross revenues of the applicant, its affiliates, its controlling interests, and the affiliates of its controlling interests. The Commission does not impose specific equity requirements on controlling interest holders. Once the principals or entities with a controlling interest are determined, only the revenues of those principals or entities, the affiliates of those principals or entities, the applicant and its affiliates, will be counted in determining small business eligibility.

47. A consortium of small or very small businesses is a ''conglomerate organization formed as a joint venture between or among mutually independent business firms,'' each of which *individually* must satisfy the definition of small or very small business in §§ 1.2110(f), 27.502. Thus, each consortium member must disclose its gross revenues along with those of its affiliates, its controlling interests, and the affiliates of its controlling interests. We note that although the gross revenues of the consortium members will not be aggregated for purposes of determining eligibility for small or very small business credits, this information must be provided to ensure that each individual consortium member qualifies for any bidding credit awarded to the consortium.

iv. Supporting Documentation

48. Applicants should note that they will be required to file supporting documentation to their FCC Form 175 short-form applications to establish that they satisfy the eligibility requirements to qualify as small or very small businesses (or consortia of small or very small businesses) for this auction.

49. Applicants should further note that submission of an FCC Form 175 application constitutes a representation by the certifying official that he or she is an authorized representative of the applicant, has read the form's instructions and certifications, and that the contents of the application and its attachments are true and correct. Submission of a false certification to the Commission may result in penalties, including monetary forfeitures, license forfeitures, ineligibility to participate in future auctions, and/or criminal prosecution.

50. *Small or very small business eligibility (Exhibit C).* Entities applying to bid as small or very small businesses (or consortia of small or very small businesses) will be required to disclose on Exhibit C to their FCC Form 175 short-form applications, *separately and in the aggregate*, the gross revenues for the preceding three years of each of the following: (i) The applicant, (ii) its affiliates, (iii) its controlling interests, and (iv) the affiliates of its controlling interests. Certification that the average annual gross revenues for the preceding three years do not exceed the applicable limit is not sufficient. A statement of the total gross revenues for the preceding three years is also insufficient. The applicant must provide separately for itself, its affiliates, its controlling interests, and the affiliates of its controlling interests, a schedule of gross revenues for each of the preceding three years, as well as a statement of total average gross revenues for the three-year period. If the applicant is applying as a consortium of small or very small businesses, this information must be provided for each consortium member.

D. Provisions Regarding Defaulters and Former Defaulters (FCC Form 175 Exhibit D)

51. Each applicant must certify on its FCC Form 175 application that it is not in default on any Commission licenses and that it is not delinquent on any non-tax debt owed to any Federal agency. In

addition, each applicant must attach to its FCC Form 175 application a statement made under penalty of perjury indicating whether or not the applicant, its affiliates, its controlling interests, or the affiliates of its controlling interest have ever been in default on any Commission licenses or have ever been delinquent on any non-tax debt owed to any Federal agency. The applicant must provide such information for itself, its affiliates, its controlling interests, and the affiliates of its controlling interests, as defined by § 1.2110 of the Commission's rules (as amended in the *Part 1 Fifth Report and Order*). Applicants must include this statement as Exhibit D of the FCC Form 175. Prospective bidders are reminded that the statement must be made under penalty of perjury and, further, submission of a false certification to the Commission is a serious matter that may result in severe penalties, including monetary forfeitures, license revocations, exclusion from participation in future auctions, and/or criminal prosecution.

52. ''Former defaulters''—*i.e.*, applicants, including their attributable interest holders, that in the past have defaulted on any Commission licenses or been delinquent on any non-tax debt owed to any Federal agency, but that have since remedied all such defaults and cured all of their outstanding non-tax delinquencies—are eligible to bid in Auction No. 31, provided that they are otherwise qualified. However, as discussed *infra* in Section III.D.iii, former defaulters are required to pay upfront payments that are fifty percent more than the normal upfront payment amounts.

E. Installment Payments

53. Installment payment plans will not be available in Auction No. 31.

F. Other Information (FCC Form 175 Exhibits E and F)

54. Applicants owned by minorities or women, as defined in 47 CFR 1.2110(c)(2), may attach an exhibit (Exhibit E) regarding this status. This applicant status information is collected for statistical purposes only and assists the Commission in monitoring the participation of ''designated entities'' in its auctions. Applicants wishing to submit additional information may do so on Exhibit F (Miscellaneous Information) to the FCC Form 175.

G. Minor Modifications to Short-Form Applications (FCC Form 175)

55. After the short-form filing deadline (May 8, 2002), applicants may make only minor changes to their FCC Form 175 applications. Applicants will not be permitted to make major modifications to their applications (*e.g.*, change their license selections or proposed service areas, change the certifying official or change control of the applicant or change bidding credits). *See* 47 CFR 1.2105. Permissible minor changes include, for example, deletion and addition of authorized bidders (to a maximum of three) and revision of exhibits. Applicants should make these modifications to their FCC Form 175 electronically and submit a letter, briefly summarizing the changes, by electronic mail to the attention of Margaret Wiener, Chief, Auctions and Industry Analysis Division, at the following address: *auction31@fcc.gov*. The electronic mail summarizing the changes must include a subject or caption referring to Auction No. 31. The Bureau requests that parties format any attachments to electronic mail as Adobe® Acrobat® (pdf) or Microsoft'' Word documents.

56. A separate copy of the letter should be faxed to the attention of Kathryn Garland at (717) 338–2850. Questions about other changes should be directed to Howard Davenport of the Auctions and Industry Analysis Division at (202) 418–0660.

H. Maintaining Current Information in Short-Form Applications (FCC Form 175)

57. Applicants have an obligation under 47 CFR 1.65, to maintain the completeness and accuracy of information in their short-form applications. Amendments reporting substantial changes of possible decisional significance in information contained in FCC Form 175 applications, as defined by 47 CFR 1.2105(b)(2), will not be accepted and may in some instances result in the dismissal of the FCC Form 175 application.

III. Pre-Auction Procedures

A. Auction Seminar

58. On Tuesday, April 30, 2002, the FCC will sponsor a free seminar for Auction No. 31 at the Federal Communications Commission, located at 445 12th Street, SW., Washington, DC. The seminar will provide attendees with information about pre-auction procedures, conduct of the auction, the FCC Automated Auction System, and the 700 MHz band service and auction rules. The seminar will also provide an opportunity for prospective bidders to ask questions of FCC staff.

59. To register, complete the registration form attached as Attachment C of the *Auction No. 31 Further Procedures Public Notice* and submit it by Friday, April, 26, 2002. Registrations are accepted on a first-come, first-served basis.

B. Short-Form Application (FCC Form 175)—Due May 8, 2002

60. In order to be eligible to bid in this auction, applicants must first submit an FCC Form 175 application. This application must be submitted electronically and received at the Commission no later than 6 p.m. ET on May 8, 2002. Late applications will not be accepted.

61. There is no application fee required when filing an FCC Form 175. However, to be eligible to bid, an applicant must submit an upfront payment. *See* part III.D.

i. Electronic Filing

62. Applicants must file their FCC Form 175 applications electronically. Applications may generally be filed at any time beginning at noon ET on April 30, 2002, until 6 p.m. ET on May 8, 2002. Applicants are strongly encouraged to file early and are responsible for allowing adequate time for filing their applications. Applicants may update or amend their electronic applications multiple times until the filing deadline on May 8, 2002.

63. Applicants must press the ''SUBMIT Application'' button on the ''Submission'' page of the electronic form to successfully submit their FCC Form 175s. Any form that is not submitted will not be reviewed by the FCC. Information about accessing the FCC Form 175 is included in Attachment D of the *Auction No. 31 Further Procedures Public Notice*.

64. Technical support is available at (202) 414–1250 (voice) or (202) 414–1255 (text telephone (TTY)); the hours of service Monday through Friday, from 7 a.m. to 10 p.m. ET, Saturday, 8 a.m. to 7 p.m. ET, and Sunday, 12 noon to 6 p.m.ET. In order to provide better service to the public, *all calls to the hotline are recorded*.

65. Applicants can also contact Technical Support via e-mail at *betacomm@fcc.gov*.

ii. Completion of the FCC Form 175

66. Applicants should carefully review 47 CFR 1.2105, and must complete all items on the FCC Form 175. Instructions for completing the FCC Form 175 are in Attachment E of the *Auction No. 31 Further Procedures Public Notice*. Applicants are encouraged to begin preparing the required attachments for FCC Form 175 prior to submitting the form.

Attachments D and E to the *Auction No. 31 Further Procedures Public Notice* provide information on the required attachments and appropriate formats.

iii. Electronic Review of FCC Form 175

67. The FCC Form 175 electronic review system may be used to locate and print applicants' FCC Form 175 information. Applicants may also view other applicants' completed FCC Form 175s after the filing deadline has passed and the FCC has issued a public notice explaining the status of the applications. For this reason, it is important that applicants do not include their Taxpayer Identification Numbers (TINs) on any exhibits to their FCC Form 175 applications. There is no fee for accessing this system. Attachment D of the *Auction No. 31 Further Procedures Public Notice* provides details on accessing the review system.

C. Application Processing and Minor Corrections

68. After the deadline for filing the FCC Form 175 applications has passed, the FCC will process all timely submitted applications to determine which are acceptable for filing, and subsequently will issue a public notice identifying: (i) Those applications accepted for filing; (ii) those applications rejected; and (iii) those applications which have minor defects that may be corrected, and the deadline for filing such corrected applications.

69. As described more fully in the Commission's rules, after the May 8, 2002, short-form filing deadline, applicants may make only minor corrections to their FCC Form 175 applications. Applicants will not be permitted to make major modifications to their applications (*e.g.*, change their license selections, change the certifying official, change control of the applicant, or change bidding credit eligibility).

D. Upfront Payments—Due May 28, 2002

70. In order to be eligible to bid in the auction, applicants must submit an upfront payment accompanied by an FCC Remittance Advice Form (FCC Form 159). After completing the FCC Form 175, filers will have access to an electronic version of the FCC Form 159 that can be printed and faxed to Mellon Bank in Pittsburgh, PA. All upfront payments must be received at Mellon Bank by 6 p.m. ET on May 28, 2002.

Please note that:

- All payments must be made in U.S. dollars.
- All payments must be made by wire transfer.
- Upfront payments for Auction No. 31 go to a lockbox number different from the lockboxes used in previous FCC auctions, and different from the lockbox number to be used for post-auction payments.
- Failure to deliver the upfront payment by the May 28, 2002, deadline will result in dismissal of the application and disqualification from participation in the auction.

i. Making Auction Payments by Wire Transfer

71. Wire transfer payments must be received by 6 p.m. ET on May 28, 2002. To avoid untimely payments, applicants should discuss arrangements (including bank closing schedules) with their banker several days before they plan to make the wire transfer, and allow sufficient time for the transfer to be initiated and completed before the deadline. Applicants will need the following information:

ABA Routing Number: 043000261.

Receiving Bank: Mellon Pittsburgh.

Beneficiary: FCC/Account # 910–0171.

OBI Field: (Skip one space between each information item).

''AUCTIONPAY''

FCC Registration Number (FRN): (same as FCC Form 159, block 11 and/or 21).

Payment Type Code: (same as FCC Form 159, block 24A: A31U).

FCC Code 1: (same as FCC Form 159, block 28A: ''31'').

Payer Name: (same as FCC Form 159, block 2).

Lockbox No.: # 358430.

Note: The BNF and Lockbox number are specific to the upfront payments for this auction; do not use BNF or Lockbox numbers from previous auctions.

72. Applicants must fax a completed FCC Form 159 (Revised 2/00) to Mellon Bank at (412) 209–6045 at least one hour before placing the order for the wire transfer (but on the same business day). On the cover sheet of the fax, write ''Wire Transfer—Auction Payment for Auction Event No. 31.'' Bidders should confirm receipt of their upfront payment at Mellon Bank by contacting their sending financial institution.

iii. FCC Form 159

73. A completed FCC Remittance Advice Form (FCC Form 159, Revised 2/00) must be faxed to Mellon Bank in order to accompany each upfront payment. Proper completion of FCC Form 159 (Revised 2/00) is critical to ensuring correct credit of upfront payments. Detailed instructions for completion of FCC Form 159 are included in Attachment F of the *Auction No. 31 Further Procedures Public Notice*. An electronic version of the FCC Form 159 is available after filing the FCC Form 175. The FCC Form 159 can be completed electronically, but must be filed with Mellon Bank via facsimile.

iii. Amount of Upfront Payment

74. In the *Part 1 Order, Memorandum Opinion and Order, and Notice of Proposed Rule Making*, 62 FR 13540 (March 21, 1997), the Commission delegated to the Bureau the authority and discretion to determine appropriate upfront payment(s) for each auction. In addition, in the *Part 1 Fifth Report and Order*, the Commission ordered that ''former defaulters,'' *i.e.*, applicants that have ever been in default on any Commission license or have ever been delinquent on any non-tax debt owed to any Federal agency, be required to pay upfront payments fifty percent greater than non-''former defaulters.'' For purposes of this calculation, the ''applicant'' includes the applicant itself, its affiliates, its controlling interests, and the affiliates of its controlling interests, as defined by § 1.2110 of the Commission's rules (as amended in the *Part 1 Fifth Report and Order*).

75. The amount of the upfront payment will determine the number of bidding units on which a bidder can bid, where each license is associated with a fixed number of bidding units. A bidder's maximum eligibility will be established by translating its upfront payment to bidding units (one dollar equals one bidding unit). In order to bid on a license, otherwise qualified bidders who applied for that license on Form 175 must have an eligibility level that meets or exceeds the number of bidding units assigned to that license. At a minimum, therefore, an applicant's total upfront payment must be enough to establish eligibility to bid on at least one of the licenses applied for on Form 175, or else the applicant will not be eligible to participate in the auction. An applicant does not have to make an upfront payment to cover all licenses for which the applicant has applied on Form 175. An applicant may, on its FCC Form 175, apply for every applicable license being offered, but its actual bidding in any round will be limited by (i) its initial eligibility, the bidding units reflected in its upfront payment; and (ii) its current eligibility, the bidding units reflected in its upfront payment less the number of bidding units by which its eligibility has been reduced. As an upper bound on the upfront payment, an applicant could add together the

upfront payments for all licenses on which it seeks to bid (either individually or in a package) in any given round. Bidders should check their calculations carefully, as there is no provision for increasing a bidder's maximum eligibility after the upfront payment deadline.

76. The specific upfront payments and bidding units for each license are set forth in Attachment A of the *Auction No. 31 Further Procedures Public Notice*.

77. Former defaulters should calculate their upfront payment for all licenses by multiplying the number of bidding units they wish to purchase by 1.5. In order to calculate the number of bidding units to assign to former defaulters, the Commission will divide the upfront payment received by 1.5 and round the result up to the nearest bidding unit.

EXAMPLE: UPPER 700 MHZ BANDS UPFRONT PAYMENTS AND BIDDING FLEXIBILITY

License or package	Bidding units	Upfront payment
Package A (WX–EAG701–C and WX–EAG701–D)	42,000,000	$42,000,000
WX–EAG702–C	14,000,000	14,000,000

If a bidder wishes to bid on both Package A and license WX–EAG702–C in a round, it must have selected WX–EAG701–C, WX–EAG701–D, and WX–EAG702–C on its FCC Form 175 and purchased at least 56,000,000 bidding units (14,000,000 + 28,000,000 + 14,000,000). If a bidder only wishes to bid on either Package A or license WX–EAG702–C, but not both, purchasing 42,000,000 bidding units would meet the requirement for either Package A or license WX–EAG702–C. The bidder would be able to bid on either Package A or license WX–EAG702–C, *but not both at the same time*. If the bidder purchased only 14,000,000 bidding units, it would have enough eligibility for license WXEAG702–C or license WX–EAG701–C but not for Package A or license WX–EAG701–D.

iv. Applicant's Wire Transfer Information for Purposes of Refunds of Upfront Payments

78. The Commission will use wire transfers for all Auction No. 31 refunds. To ensure that refunds of upfront payments are processed in an expeditious manner, the Commission is requesting that all pertinent information as listed be supplied to the FCC. Applicants can provide the information electronically during the initial short-form filing window after the form has been submitted. Wire Transfer Instructions can also be manually faxed to the FCC, Financial Operations Center, Auctions Accounting Group, ATTN: Tim Dates or Gail Glasser, at (202) 418–2843 by May 28, 2002. All refunds will be returned to the payer of record as identified on the FCC Form 159 unless the payer submits written authorization instructing otherwise. For additional information, please call (202) 418–1995.

Name of Bank
ABA Number
Contact and Phone Number
Account Number to Credit
Name of Account Holder
FCC Registration Number (FRN)
Taxpayer Identification Number
Correspondent Bank (if applicable)
ABA Number
Account Number

(Applicants should also note that implementation of the Debt Collection Improvement Act of 1996 requires the FCC to obtain a Taxpayer Identification Number (TIN) before it can disburse refunds.)

Eligibility for refunds is discussed in Section V.F.

E. Auction Registration

79. Approximately ten days before the auction, the FCC will issue a public notice announcing all qualified bidders for the auction. Qualified bidders are those applicants whose FCC Form 175 applications have been accepted for filing and have timely submitted upfront payments sufficient to make them eligible to bid on at least one of the licenses for which they applied.

80. All qualified bidders are automatically registered for the auction. Registration materials will be distributed prior to the auction by two separate overnight mailings, one containing the confidential bidder identification number (BIN) required to place bids and the other containing the SecurID cards. These mailings will be sent only to the contact person at the contact address listed in the FCC Form 175.

81. Applicants that do not receive both registration mailings will not be able to submit bids. Therefore, any qualified applicant that has not received both mailings by noon on Wednesday, June 12, 2002, should contact the Auctions Hotline at (717) 338–2888. Receipt of both registration mailings is critical to participating in the auction and each applicant is responsible for ensuring it has received all of the registration material.

82. Qualified bidders should note that lost bidder identification numbers or SecurID cards can be replaced only by appearing *in person* at the FCC Auction Headquarters located at 445 12th St., SW, Washington, DC 20554. Only an authorized representative or certifying official, as designated on an applicant's FCC Form 175, may appear in person with two forms of identification (one of which must be a photo identification) in order to receive replacements. Qualified bidders requiring replacements must call technical support prior to arriving at the FCC.

F. Electronic Bidding

83. The Commission will conduct this auction over the Internet. Telephonic bidding will also be available. As a contingency, the FCC Wide Area Network, which requires access to a 900 number telephone service, will be available as well. Qualified bidders are permitted to bid telephonically or electronically, *i.e.*, over the Internet or the FCC's Wide Area Network at $2.30 per minute. In either case, each authorized bidder must have its own Remote Security Access SecurID card, which the FCC will provide at no charge. Any applicant with only one authorized bidder will be issued two SecurID cards, while applicants with two or three authorized bidders will be issued three cards. For security purposes, the SecurID cards and the FCC Automated Auction System User Manual are only mailed to the contact person at the contact address listed on the FCC Form 175. Please note that each SecurID card is tailored to a specific auction, therefore, SecurID cards issued for other auctions or obtained from a source other than the FCC will not work for Auction No. 31. The telephonic bidding phone number will be supplied in the first overnight mailing, which also includes the confidential bidder identification number. Each applicant should indicate its bidding preference'electronic or telephonic'' on the FCC Form 175.

84. Please note that the SecurID cards can be recycled, and we encourage bidders to return the cards to the FCC. We will provide pre-addressed envelopes that bidders may use to

return the cards once the auction is over.

G. Mock Auction

85. All qualified bidders will be eligible to participate in a mock auction on Thursday, June 13, 2002, and Friday, June 14, 2002. The mock auction will enable applicants to become familiar with the FCC Automated Auction System prior to the auction. Participation by all bidders is strongly recommended. Details will be announced by public notice.

IV. Auction Event

86. The first round of bidding for Auction No. 31 will begin on Wednesday, June 19, 2002. The initial bidding schedule will be announced in a public notice listing the qualified bidders, which is released approximately 10 days before the start of the auction.

A. Auction Structure

i. Simultaneous Multiple Round Auction With Package Bidding

87. We will auction the twelve Upper 700 MHz band licenses in a single, simultaneous multiple-round auction with package bidding. Unless otherwise announced, bids will be accepted on all licenses and packages in each round of the auction. This approach, we believe, will allow bidders in this auction to take advantage of any synergies that exist among licenses and will lead to the most efficient outcome consistent with our objectives under section 309(j) of the Communications Act of 1934.

88. The simultaneous multiple round auction with package bidding auction format (SMR–PB) differs in several important ways from our traditional simultaneous multiple round auction (SMR). Briefly and generally, the most important structural changes follow. Bids are allowed on groups of licenses as well as on individual licenses. All bids in the auction, not just those from the current round, are considered when determining the provisionally winning set of bids in each round. However, the bids of a bidder in one round are considered mutually exclusive of its bids from any other round '' that is, all bids from a single bidder in the provisionally winning set must be from the same round. A major implication of these changes is that bids which are not part of the provisionally winning set in a given round can become part of the provisionally winning set in later rounds.

89. As a consequence of these basic structural changes, the SMR-PB rules on activity and eligibility, minimum acceptable bids, bid withdrawals, and many other auctions specifics are very different from the rules under the traditional SMR format. In addition to the complete descriptions in this Public Notice, Attachments G and H of the Auction No. 31 Further Procedures Public Notice summarize the SMR–PB requirements.

ii. Maximum Eligibility

90. The amount of the upfront payment submitted by a bidder will determine the initial maximum eligibility (as measured in bidding units) for each bidder. Note again that each license is assigned a specific number of bidding units equal to the upfront payment listed in Attachment A of the *Auction No. 31 Further Procedures Public Notice* on a bidding unit per dollar basis. The bidding units associated with a package are defined as the sum of the bidding units associated with the individual licenses comprising the package. The total upfront payment defines the maximum number of bidding units on which the applicant will be permitted to be active during any given round. As there is no provision for increasing a bidder's maximum eligibility during the course of an auction, prospective bidders are cautioned to calculate their upfront payments carefully. The total upfront payment does not affect the dollar amount a bidder may bid on licenses.

iii. Activity and Eligibility Rules

91. In order to ensure that the auction closes within a reasonable period of time, an activity rule is in place that requires bidder participation throughout the auction. The activity rule requires each bidder to have active bids in each round that account for a specified fraction of the bidder's current eligibility, as measured in bidding units. Failure to adhere to the rule results in the use of an activity rule waiver or the reduction of current eligibility (*see* Section IV.A.iv, ''Activity Rule Waivers and Reducing Eligibility'').

92. In earlier SMR auctions, a bidder's activity in a round was determined by summing the bidding units associated with licenses on which the bidder was active. A bidder was considered active on a license in the current round if it was either the high bidder at the end of the previous bidding round (and did not withdraw the high bid in the current round), or if it submitted an acceptable bid in the current round (and did not subsequently remove the bid). In a package-bidding auction, calculating activity levels in a round is not as straightforward because a bidder can submit bids on different packages that contain one or more of the same licenses.

93. *Bidding* activity is one measure that is used to determine a bidder's activity in a round for a package-bidding auction. We define a bidder's bidding activity in a round to be the maximum number of bidding units the bidder can win considering new bids placed and provisionally winning bids renewed in that round. Thus, when a bidder submits bids in a round the system will determine the set of bids, among the bidder's new bids and renewed provisionally winning bids, that contains the most bidding units and has no overlap among the licenses. To illustrate this, suppose a bidder submits the following bids in round *t*:

BIDS PLACED IN ROUND t

License/package	Bidding units
Package A	56,000,000 bu
WX–EAG701–C (14,000,000 bu)	
WX–EAG702–C (14,000,000 bu)	
WX–EAG703–C (14,000,000 bu)	
WX–EAG704–C (14,000,000 bu)	
Package B	42,000,000 bu
WX–EAG701–C (14,000,000 bu)	
WX–EAG701–D (28,000,000 bu)	

This set of bids contains five distinct licenses. The sum of the bidding units associated with these five licenses is 84,000,000. However, since both packages contain license WX–EAG701–C, this bidder can not win both packages at the same time. The maximum number of bidding units that the bidder can win would be the 56,000,000 associated with Package A, so the bidder's bidding activity is 56,000,000 bidding units.

94. A bidder is also considered to be active if the bidder has provisionally winning bids from the previous round. Auction rules state that a bidder's bids made in different rounds will be considered mutually exclusive, so the bidding units associated with provisionally winning bids must be viewed independently from the bidding units associated with current round bids. We define a bidder's eligibility activity in a round to be the greater of (i) its bidding activity in the round and (ii) the bidding units associated with the bidder's provisionally winning bids from the prior round. To illustrate how eligibility activity will be calculated in a round we continue with our example. Suppose this bidder has the following provisionally winning bids from round *t-1*:

PROVISIONALLY WINNING BIDS FROM ROUND *t-1*

License/package	Bidding units
License: WX–EAG701–C (14,000,000 bu)	14,000,000 bu
License: WX–EAG701–D (28,000,000 bu)	28,000,000 bu

The number of bidding units associated with this bidder's provisionally winning bids is 42,000,000. Recall that the bidder's bidding activity for the round is 56,000,000 bidding units. The eligibility activity for this bidder in round t is therefore 56,000,000, the greater of its bidding activity (56,000,000 bidding units) and the bidding units associated with its bids in the provisionally winning set (42,000,000 bidding units).

95. We have established an eligibility activity requirement of one-half. Accordingly, in each round of the auction, a bidder desiring to maintain its current eligibility and not use an activity rule waiver is required to have eligibility activity equal to at least half of its current eligibility. A bidder that fails to meet this eligibility activity requirement in a given round and also has no remaining activity rule waivers will have its current eligibility reduced for the next round to a level consistent with the eligibility activity requirement. The bidder's new current eligibility will be its eligibility activity in the current round multiplied by the reciprocal of the eligibility activity requirement (1/eligibility activity requirement)—in this case, two (1/(½)). Thus, a bidder's eligibility in the current round will be the lesser of: (i) its eligibility in the previous round or (ii) the product of its eligibility activity in the previous round and the reciprocal of the eligibility activity requirement.

96. The Bureau has reserved the right, however, to increase to two-thirds the proportion of current eligibility on which bidders must be active to retain their current eligibility. The two-thirds limit will ensure that bidders retain the flexibility to switch from bidding on a 20 MHz license or package to a 30 MHz package with the equivalent population. Any such change will be announced to bidders prior to the beginning of the round in which the change takes effect. In the event that the Bureau exercises its ability to change the eligibility activity requirement to two-thirds, the new current eligibility for a bidder not meeting the requirement and having no remaining activity rule waivers will be its eligibility activity in the current round multiplied by 3/2 (the reciprocal of the eligibility activity requirement).

97. In the previous example, the bidder has eligibility activity in the current round of 56,000,000 bidding units. If this bidder's current eligibility is 168,000,000 bidding units and the eligibility activity requirement is one-half, the bidder's required activity level is 84,000,000 bidding units (168,000,000 * ½ = 84,000,000). Since the bidder's eligibility activity is less than the required activity level, and if the bidder has no remaining activity rule waivers, its current eligibility will be reduced so that the bidder will be in compliance with the activity requirement. Therefore, the bidder's current eligibility for the next round will be 112,000,000 bidding units (56,000,000 * (1/½) = 112,000,000).

98. Because a bidder's bids from all prior rounds are considered in determining provisionally winning bids, it is possible for a bidder to become a provisional winner for a license or package even though it does not have sufficient eligibility to place a new bid on that license or package. In such a case, the bidder will be awarded the license or package at the end of the auction if it has made the winning bid, but it will not be permitted to place any new bids on the license or package during the auction.

iv. Activity Rule Waivers and Reducing Eligibility

99. Each bidder in the auction will be provided five activity rule waivers that may be used in any round during the course of the auction. Use of an activity rule waiver preserves the bidder's current bidding eligibility despite the bidder's eligibility activity in the current round being below the required minimum level. An activity rule waiver applies to an entire round of bidding and not to a particular license. We are satisfied that our practice of providing five waivers over the course of the auction provides a sufficient number of waivers and flexibility to the bidders, while safeguarding the integrity of the auction.

100. In contrast to our traditional SMR auction format, bidders will not have the ability to apply waivers proactively. In our SMR auction format, proactive waivers are a means by which bidders can keep the auction open without bidding. For Auction No. 31, we have adopted a two-round simultaneous stopping rule. Thus, after one round with no new bids, the auction will not close. For more information, *see* Section IV.A.vi. ''Stopping Rules,'' *infra*.

101. The FCC Automated Auction System assumes that bidders with insufficient eligibility activity would prefer to use an activity rule waiver (if available) rather than lose bidding eligibility. Therefore, the system will automatically apply a waiver at the end of any round where a bidder's eligibility activity level is below the minimum required unless: (i) There are no activity rule waivers available; or (ii) the bidder overrides the automatic application of a waiver by reducing eligibility, thereby meeting the minimum requirements.

102. A bidder with insufficient eligibility activity that wants to reduce its bidding eligibility rather than use an activity rule waiver must affirmatively override the automatic waiver mechanism during the round by using the reduce eligibility function in the Automated Auction System. In this

case, the bidder's eligibility is permanently reduced to bring the bidder into compliance with the activity rules as described in the previous section. Once eligibility has been reduced, a bidder will not be permitted to regain its lost bidding eligibility

v. Auction Stages and Stage Transitions

103. Our SMR auctions generally are conducted in two or three stages, in which the activity requirement is increased between stages. In this SMR–PB auction, we have adopted a single stage with a one-half activity requirement, although we retain the discretion during the auction to increase to two-thirds the proportion of bidding units on which bidders must be active to retain their current eligibility. Any such change will be announced to bidders prior to the beginning of the round in which the change takes effect.

vi. Auction Stopping Rules

104. For Auction No. 31, we have adopted a two-round simultaneous stopping rule. A two-round simultaneous stopping rule means that all licenses remain open until two consecutive rounds have occurred in which no new bids are accepted. After a round with no new bids, bidders will receive a message warning that if no new bids are placed in the next round the auction will close. After the second consecutive round with no new bids, bidding closes simultaneously on all licenses and packages. Thus, unless circumstances dictate otherwise, bidding will remain open on all licenses until bidding stops on every license and package.

105. For purposes of the stopping rule, renewed bids are not considered new bids; in other words, a round in which the only bids that are placed are renewed bids is considered a round with no new bids for purposes of the stopping rule.

106. The computer software used to determine the provisionally winning set of bids is run at the end of every round of the auction but the last round (*i.e.*, the second consecutive round with no new bids). Because ties are broken randomly, this means that if there were ties for the provisionally winning set in the previous round, running the software at the conclusion of the next round may well result in a different provisionally winning set, even if there was no bidding activity in the round. Consequently, a provisionally winning bid on a license or package may not be a provisionally winning bid one round later, even if there are no bids in the intervening round. Bidders have the option of using the last and best bidding procedure in order to avoid being in a tied set (*see* Section IV.B.v, ''Last and Best Bids'').

107. As in previous auctions, the Bureau has retained the discretion to keep an auction open even if no new bids are submitted. The activity rule would apply as usual, and a bidder with insufficient eligibility activity will either lose bidding eligibility or use a remaining activity rule waiver. The Bureau has reserved the right to declare that the auction will end after a specified number of additional rounds (''special stopping rule''). The Bureau would exercise this option only in certain circumstances, such as, for example, where the auction is proceeding very slowly, there is minimal overall bidding activity, or it appears likely that the auction will not close within a reasonable period of time. Before exercising this option, the Bureau is likely to attempt to increase the pace of the auction, for example, by increasing the number of bidding rounds per day, and/or by increasing the amount of the minimum acceptable bids for the limited number of licenses where there is still a high level of bidding activity. Any such change will be announced to bidders before it takes effect.

vii. Auction Delay, Suspension, or Cancellation

108. By public notice or by announcement during the auction, the Bureau may delay, suspend, or cancel the auction in the event of natural disaster, technical obstacle, evidence of an auction security breach, unlawful bidding activity, administrative or weather necessity, or for any other reason that affects the fair and competitive conduct of competitive bidding. In such cases, the Bureau, in its sole discretion, may elect to resume the auction starting from the beginning of the current round, resume the auction starting from some previous round, or cancel the auction in its entirety. Network interruption may cause the Bureau to delay or suspend the auction. We emphasize that exercise of this authority is solely within the discretion of the Bureau, and its use is not intended to be a substitute for situations in which bidders may wish to apply their activity rule waivers.

B. Bidding Procedures

i. Round Structure

109. The Commission will use an automated auction system to conduct the simultaneous multiple round with package bidding auction format. The initial bidding schedule will be announced in the public notice listing the qualified bidders, which is released approximately 10 days before the start of the auction. The round structure for each bidding round contains a single bidding round followed by the release of the round results. Multiple bidding rounds may be conducted in a given day.

110. The Bureau will release an additional public notice by April 30, 2002, explaining the round results process and providing sufficient information on our solving and tie-breaking procedures such that participants and interested observers will be able to replicate the FCC's official round results.

111. The Bureau has discretion to change the bidding schedule in order to foster an auction pace that reasonably balances speed with the bidders' need to study round results and adjust their bidding strategies. The Bureau may increase or decrease the amount of time for the bidding rounds and review periods, or the number of rounds per day, depending upon the bidding activity level and other factors.

ii. Reserve Price and Minimum Opening Bid

112. Congress mandated that the Commission's objectives when designing competitive bidding methodologies include ''recovery for the public of a portion of the value of the public spectrum resource.'' Section 309(j) of the Communications Act, as amended, calls upon the Commission to prescribe methods by which a reasonable reserve price will be required and/or a minimum opening bid established for licenses subject to auction, unless the Commission determines that a reserve price or minimum opening bid is not in the public interest. Consistent with this mandate, the Commission directed the Bureau to seek comment on the use of a minimum opening bid and/or reserve price prior to the start of each auction. Among other factors, the Bureau must consider the amount of spectrum being auctioned, levels of incumbency, the availability of technology to provide service, the size of the geographic service areas, the extent of interference with other spectrum bands, and any other relevant factors that could have an impact on the spectrum being auctioned. The Commission concluded that the Bureau should have the discretion to employ either or both of these mechanisms for future auctions.

113. The Bureau has adopted minimum opening bids for each license in Auction No. 31, and the Bureau further established that the minimum

opening bids for packages will be the sum of the minimum opening bids for the licenses comprising the package.

114. Given the complexities resulting from the presence of incumbents and the clearance process, the Bureau specifically sought comment on an aggregate reserve in Auction No. 31 equal to $2.6 billion in gross bids. As the Bureau noted in the *Auction No. 31 Further Modifications Comment Public Notice,* Congress previously estimated that the Upper 700 MHz band licenses, which consist of the previously auctioned 700 MHz guard bands licenses and the licenses in Auction No. 31, will generate $2.6 billion in net revenue. The prior 700 MHz guard bands auctions generated nearly $541 million in net revenue. To assure that net revenues in Auction No. 31 together with prior net revenues will be commensurate with Congress's expectations, the Bureau suggested establishing an aggregate reserve price for Auction No. 31 of $2.6 billion in gross bids. The Bureau notes that there are unavoidable uncertainties in estimating the gross bids required to assure particular net revenues.

115. The Bureau adopts the suggested public aggregate reserve price equal to $2.6 billion in gross bids. The unique complexities of the spectrum clearance process make establishing an aggregate reserve price for Auction No. 31 appropriate.

116. In addition to the aggregate reserve price of $2.6 billion, we will maintain the previously-established minimum opening bids on licenses and packages. No license or package will be sold if it has not received a bid at the minimum opening bid amount. Furthermore, at the end of Auction No. 31, if the total gross revenue of the provisionally winning set does not equal or exceed $2.6 billion, there will be no winning bids and no licenses will be sold.

117. However, the aggregate reserve will be considered satisfied and licenses will be awarded to the winning bidders if total gross revenue exceeds $2.6 billion, even if some individual licenses remain unsold. The FCC will retain any unsold licenses. For the purposes of calculating the total gross revenue of the winning set, any FCC-held licenses will be treated as having received a bid at a small amount below the minimum opening bid amount. Therefore, in the event that there are unsold licenses while the aggregate reserve is met, actual gross payments to the Treasury from winning bidders will be less than total gross revenues, since the latter figure includes FCC ''bid'' amounts for the unsold licenses. During the course of the auction, the Bureau will not entertain any requests to reduce the aggregate reserve price.

118. The specific minimum opening bids for each license are set forth in Attachment A of the *Auction No. 31 Further Procedures Public Notice.* The minimum opening bids that we have adopted are reducible at the discretion of the Bureau. The Bureau emphasizes, however, that such discretion will be exercised, if at all, sparingly and early in the auction, *i.e.*, before bidders lose all waivers and begin to lose substantial eligibility. During the course of the auction, the Bureau will not entertain any requests to reduce the minimum opening bid on specific licenses.

iii. Minimum Acceptable Bids and Bid Increments

119. In the *Auction No. 31 Further Modifications Comment Public Notice,* the Bureau sought comment on two potential changes, Options 1 and 2, to the previously-adopted procedures for calculating minimum acceptable bids. In the previously-adopted procedures, the minimum acceptable bid for any particular license or package would be the greatest of: (i) The applicable minimum opening bid; (ii) the bidder's previous high bid on that license/package plus x%, where the Bureau would specify the value of x in each round; and (iii) the bidder's previous high bid on that particular license/package plus an amount based on the increase in the bidder's previous high bid needed to create a tie with the provisional winners. If the bidder has not bid on a license or an already constructed package, the bidder's previous high bid for purposes of calculating part (iii) would be the applicable minimum opening bid. As Option 1, the Bureau proposed completely replacing part (iii) of the minimum acceptable bid calculation with a formula based on ''current price estimates.'' In addition, as a second part of Option 1, the Bureau proposed considering all bids submitted during the auction both when calculating current price estimates and when determining the provisionally winning set of bids. The Bureau proposed a much more modest change to part (iii) as Option 2. The Bureau proposed changing the mathematical formula applicable only when determining minimum acceptable bids on packages created and bid on in the same round.

120. The ''current price estimate'' is a measure, developed by the Bureau, which utilizes information from all current and past bids on a license and packages containing that license, to approximate a ''price'' for each license in every round of the auction. The precise methodology used to calculate price estimates is described in Attachment B of the *Auction No. 31 Further Procedures Public Notice.* Until a bid is placed on a license *or* on a package containing that license, by any bidder in any round, the current price estimate is the FCC bid amount, which is slightly below the minimum opening bid. If a bid on a single license is part of the provisionally winning set of bids in a round, then the current price estimate for that license in that round will be equal to the provisionally winning bid. Generally, however, if a license is part of a package bid in the provisionally winning set, the current price estimate for an individual license is calculated using all of the bids placed that involve that license, since those bids together yield information on how bidders value that license. The set of current price estimates, one for each license, is then used as the basis for determining minimum acceptable bids for the next round, under part (iii) of the minimum acceptable bid rule. Specifically, for individual licenses, the part (iii) minimum acceptable bid amount is the current price estimate of the license plus z%. For packages, it is the sum of the current price estimates for the licenses comprising that package, plus z% of the sum. Initially, the Bureau will set z at five, but retains the discretion to adjust the amount during the course of the auction, including setting z at less than zero, in order to control the pace of the auction.

121. The Bureau adopts Option 1. Thus, the minimum acceptable bid for any license or package will be the greatest of: (i) The minimum opening bid; (ii) the bidder's own previous high bid on a license or package plus x%, where the Bureau will specify the value of x in each round; and (iii) the current price estimate of the license plus z%, or for a package, the sum of the current price estimates for the licenses in the package plus z%, where the Bureau will specify the value of z in each round. The result will be rounded to the nearest thousand dollars. Initially, the Bureau will set x at ten, but retains the discretion to adjust the amount during the course of the auction.

122. The Bureau retains an exception to part (iii) for calculating the minimum acceptable bid for a ''global'' package—a package consisting of all of the licenses available in the auction. After the first round of the auction, part (iii) of the minimum acceptable bid rule for a global package will always be the revenue generated by the provisionally winning bid set in the previous round plus w%, rounded to the nearest

thousand dollars. The Bureau makes this distinction in order to retain the ability to ensure that bids for the global package will continue to increase even if we employ a percentage z that does not guarantee that outcome. Initially, the Bureau will set w at five, but retains the discretion to adjust the amount during the course of the auction.

123. Under our normal SMR auction design, we define a bid increment for a license as the difference between the minimum acceptable bid and the standing high bid. Under these package bidding procedures, we do not have standing high bids. Therefore, bid increments cannot be defined and used in the same manner. Minimum acceptable bids will be calculated as previously set forth. To maintain consistency with our simultaneous multiple round auction design, we will still sometimes refer to the minimum acceptable bid as being a bid of one bid increment.

124. For bids higher than the minimum acceptable bid—*i.e.*, multi-increment bids—we are defining the amount of the additional bid increments as v% of the minimum acceptable bid, rounded to the nearest thousand dollars, where the minimum acceptable bid is determined as previously discussed. Initially, the Bureau will set v at ten, but retains the discretion to adjust the amount during the course of the auction. Thus, when v equals ten, bidders will be able to place multi-increment bids of the minimum acceptable bid plus approximately 10%, 20%, etc., with the maximum bid being approximately equal to the minimum acceptable bid plus 80%.

125. We retain the discretion to change the minimum acceptable bid, and to do so on a license-by-license and package-by-package basis, if circumstances so dictate. We will notify bidders of any such change before it takes effect.

126. As described in the *Auction No. 31 Further Modifications Comment Public Notice,* the adoption of Option 1 also involves a change in the number of rounds of bids being considered when determining the provisionally winning set. In contrast to the prior procedures in which two rounds of bids were considered, we now will consider every bid made in every round of the auction (except for bids that are placed and subsequently removed during the same round). Additionally, a set of ''FCC'' bids on each license in the auction at some small dollar amount less than the respective minimum opening bid will also be considered.

iv. Renewed Bids

127. For each bidder, we will treat the bids it makes in different rounds as mutually exclusive. If a bidder does not want a bid from the previous round (including a provisionally winning bid) to be considered mutually exclusive with bids made in the current round, it can renew the bid in the current round.

128. Without regard to the minimum acceptable bid requirement, a bidder may ''renew'' in the current round the highest previous bid it made on any license or package; that is, it may resubmit the bid without increasing the amount bid. Renewed bids will be treated as being made in the current round.

129. Renewed provisionally winning bids confer bidding activity, while non-renewed provisional winners count toward eligibility activity. No eligibility or bidding activity will be conferred for renewing a non-provisionally winning bid. All bidding, including renewals of non-provisionally winning bids, is limited by initial eligibility, however.

v. Last and Best Bids

130. Bidders that wish to drop out of the auction or that believe they are about to lose their bidding eligibility will have the opportunity before they drop out to make ''last and best'' bids on any licenses or packages for which they remain eligible. This is a limited exception to the minimum acceptable bid rule and to click box bidding. If a bidder chooses this option, it will not be permitted to make any further bids during the auction.

131. A bidder may make up to two sets of last and best bids. The two sets of last and best bids must be submitted in a single round, but will be treated as mutually exclusive, as are bids placed in separate rounds. Once last and best bids are placed, the bidder will not be permitted to place new bids or renew previous bids in any subsequent round. If a bidder chooses to submit last and best bids, then, for the remainder of the auction, those bids will be considered, as will all of the bidder's previous rounds of bidding.

132. The last and best bid amount for any license or package is any amount, in thousand dollar increments, greater than or equal to the bidder's previous high bid on the license or package and less than or equal to the eighth increment above the minimum acceptable bid for that license or package in the current round. Also, if the bidder has never placed a bid on a package or license, the lower bound on the last and best bid amount is equal to the minimum opening bid for that package or license.

133. Each set of last and best bids may consist of bids on any or all of the licenses selected on the Form 175 and any or all of the packages created by the bidder, consistent with the activity and eligibility rules and the twelve package limitation. Bidding activity for each of the sets of last and best bids must not exceed current eligibility, as determined at the beginning of the round in which these bids are placed. In other words, eligibility for the second set of last and best bids will not be recalculated based on eligibility activity associated with the first set of bids. Last and best bids are considered to be new bids in the round in which they are placed. However, a last and best bid equal to the bidder's previous high bid will be considered as a renewed bid.

vi. Winning and Provisionally Winning Bids

134. The winning bids are the set of ''consistent'' bids (bids that (i) do not overlap and (ii) are made or renewed by an individual bidder in the same round) that maximizes total revenue when the auction closes, provided that the aggregate reserve has been met. The provisionally winning bids are the set of consistent bids that maximizes total revenue in a particular round. When determining winning and provisionally winning bids, all bids made in every round throughout the course of the auction (except for bids that are placed and subsequently removed during the same round) will be considered. In addition, each license is treated as having a bid placed by the FCC at some small amount less than the minimum opening bid. This procedure will ensure that a bid on a license or package at the minimum opening bid always beats the FCC bid.

135. Since there can be more than one set of consistent bids that produces the maximum revenue, a procedure for randomly selecting among these tied sets is used when determining the provisionally winning bids. This tie breaking procedure involves two steps: The assignment of a selection number to each bid, and the determination of, among all tied bid sets, the set that produces the maximum sum of selection numbers.

136. A bid's selection number is the sum of n pseudo-random numbers where n is the number of licenses comprising the bid's package. Each pseudo-random number is generated by invoking a well-documented and well-tested routine developed by Pierre L'Ecuyer. A bid's selection number as well as the beginning seed numbers used to produce it will be released at the close of each round.

137. Once the selection numbers have been generated for each bid, the second step of the tie breaking procedure will decide the provisionally winning bids. Computer software is used to determine, among all tied bid sets, the set that produces the maximum sum of selection numbers. Thus, the set of provisionally winning bids is the set of consistent bids that maximizes revenue and maximizes the sum of selection numbers. Each bid will be assigned a new selection number in every round. The solver will not be run after the last round of the auction. *See* Section IV.A.vi, ''Auction Stopping Rules,'' for more information on the close of the auction.

138. The procedure we are adopting for last and best bids, described in Section IV.B.v, allows bidders to reduce the likelihood that their final bid on a license or package will be part of a randomly broken tied set. Generally, in the case of a tie, the bidder(s) whose bid is not chosen has the opportunity in the next round to continue bidding. However, if the bidder believes that the minimum acceptable bid is too high and so would ordinarily cease bidding on that license or package, it may use the last and best bid(s) procedure to make final bids on licenses and packages, which may be as little as $1,000 more than the bidder's highest previous bid on each license or package.

vii. Packages

139. In addition to bidding on individual licenses, bidders will be permitted to create and bid on up to twelve different packages of their own choosing during the course of the auction. Bidders will not be required to identify or create their packages before the start of the auction, but may create their packages as the auction progresses. A bidder may modify or delete a package it has created up until the point where it has bid on the package and the round has closed. If the bidder submits a bid on a package and subsequently removes the bid during the same round, the bidder has the option of also deleting or modifying the package. However, once a bidder bids on a package and the round closes, the package may not be modified or deleted and counts as one of the bidder's twelve allowable packages. A bid on an individual license does not count as a bid on a package; packages consist of two or more licenses.

viii. Bidding

140. During a bidding round, a bidder may submit new bids or renewed bids for as many licenses and packages as it wishes, subject to its eligibility, its FCC Form 175 license selection, and the twelve package limitation; remove bids placed in the current bidding round; or permanently reduce eligibility. Bidders also have the option of making multiple submissions in each bidding round. If a bidder submits multiple bids for a single license or package in the same round, the system overwrites any previous bid with the last bid entered as that bidder's bid for the round. Bidders should note that the bidding units associated with licenses for which the bidder has removed its bid do not count towards the bidder's bidding activity at the close of the round.

141. Bidding is constrained by the eligibility and activity rules, which determine both minimum and maximum permissible levels of bidding, as measured in bidding units. As previously discussed, minimum bidding, as measured in bidding units, is constrained by the activity rules. In each round, a bidder desiring to maintain its current eligibility and not use an activity rule waiver must be active, based on eligibility activity, on licenses associated with enough bidding units to meet the activity requirement for the current round. For more details, please refer to Section IV.A.iii. ''Activity and Eligibility Rules.''

142. Maximum bidding, as measured in bidding units, is constrained by the eligibility rules. Bidding activity for a round, defined as the maximum number of bidding units a bidder can win considering new bids and renewed provisionally winning bids placed in that round, cannot exceed current eligibility. That is, when a bidder submits a set of bids in a round, the system will not accept the set of bids if it determines that the bidding activity generated by those bids exceeds the bidder's current eligibility. Bidding in a round is further limited by the requirement that a bidder's *bidding exposure* in a round must be less than or equal to its initial eligibility. Bidding exposure is the maximum number of bidding units a bidder can win considering all the bids (new, renewed provisionally winning or non-provisionally winning) placed in the round. Similarly, when a bidder submits a set of bids in a round, the system will not accept the set of bids if it determines that the bidding exposure generated by those bids exceeds the bidder's initial eligibility. In either case, if a set of bids is rejected, the system will notify the bidder that its bids have not been accepted and report which rule is in violation.

143. Bidders are permitted only to bid on the specific licenses they selected on their FCC Form 175. Any packages they create must be comprised entirely of licenses selected on their Form 175. The bid submission screens are customized using the bidder's Form 175 information, and will not permit bidding on non-selected licenses (or packages of those licenses).

144. Please note that all bidding will take place remotely either through the FCC Automated Auction System or by telephonic bidding. (Telephonic bid assistants are required to use a script when entering bids placed by telephone. Telephonic bidders are therefore reminded to allow sufficient time to bid by placing their calls well in advance of the close of a round.) There will be no on-site bidding during Auction No. 31.

145. The Automated Auction System requires each bidder to be logged in during the bidding round using the bidder identification number provided in the registration materials, and the generated SecurID code. Bidders are strongly encouraged to print bid confirmations *after* they submit their bids.

146. In each round, eligible bidders will be able to place new bids on a given license or package in any of nine different amounts. Bidders must use the drop-down box to select bids from among the nine acceptable new bid amounts; to renew any bids (if applicable); or to remove any bids made within that same round.

147. Finally, bidders are cautioned in selecting their bid amounts because, as explained in the following section, bidders are not permitted to withdraw bids from prior rounds, even if mistakenly or erroneously made. As explained previously, when determining winning and provisionally winning bids, we consider all bids made throughout the course of the auction.

ix. Bid Removal and Bid Withdrawal

148. Bid ''removal'' is the voiding of a bid made in the current round. For the reasons set forth, we permit only the removal of bids placed in the current round. The withdrawal or cancellation of bids made in previous rounds is prohibited.

149. At any time before the close of a bidding round, a bidder has the option of removing any bids placed in that round. By using the remove bid function in the bidding system, a bidder may effectively ''unsubmit'' any bid placed within the current round. This is not the same as withdrawing a bid, which, in our SMR system, can occur in rounds subsequent to the round in which the high bid was placed. A bidder removing a bid placed in the same round is not subject to withdrawal payments. Once a

round closes, a bidder may no longer remove a bid.

150. At the close of the auction, if a bid is declared the winner and the bidder does not pay the amount due, it is liable for a default payment as set forth in the Commission's Rules.

151. We stated the following in the *Auction No. 31 Package Bidding Procedures Public Notice,* and it still holds true.

> We believe that by making bids placed in different rounds mutually exclusive, we have limited a bidder's exposure risk when changing strategies. Moreover, the bid withdrawal procedure was designed to allow bidders to back out of failed aggregations—to avoid winning some licenses that are worth less to them than the amount bid without the other licenses they need to implement their business plan. Therefore, since bidders may make package bids on all combinations of licenses with significant complementarities, the use of withdrawals to mitigate such risk is no longer necessary. Moreover, while there is no offsetting benefit from allowing bid withdrawals, there would still be potential harm. Withdrawals may be used strategically to provide incorrect price signals during the auction and lead other bidders to place inefficient bids. Also, when withdrawals are permitted, one cannot ensure that the auction will proceed at an acceptable pace. Moreover, the harm associated with withdrawals is likely to be more severe in auctions with package bidding since a single withdrawal of a bid (on either an individual license or a package) can affect the entire provisionally winning set. Accordingly, we will *not* permit bidders to withdraw their provisionally winning bids.

x. Round Results

152. Bids placed during a round will not be published until the conclusion of that bidding period. After a round closes, the Bureau will compile reports of all bids made in that round, the set of bids considered when determining the current provisionally winning bids, current price estimates, new minimum acceptable bids for all bidders, current provisionally winning bids, and bidder eligibility status (bidding eligibility and activity rule waivers), and post the reports for public access. Reports reflecting bidders' identities and bidder identification numbers for Auction No. 31 will be available before and during the auction. Thus, bidders will know in advance of this auction the identities of the bidders against which they are bidding.

153. The Bureau will release an additional public notice by April 30, 2002, detailing round results reports formats, explaining the round results process and providing sufficient information on our solving and tie-breaking procedures such that participants and interested observers will be able to replicate the FCC's official round results.

154. *In the Auction No. 31 Package Bidding Procedures Public Notice,* the Bureau stated in a footnote that we would ''make available a bidder aid for bidders to be able to determine for themselves what bid amount would have been necessary to beat the other bids and become a provisional winner in the prior round.'' This bidder's aid tool was intended to calculate the ''shortfall and deficit'' amounts which have been superceded by current price estimates in part (iii) of the minimum acceptable bid rule. The Bureau will not provide such a bidder aid, nor will it provide the FCC Auction Tracking Tool software.

xi. Auction Announcements

155. The FCC will use auction announcements to announce items such as schedule changes. All FCC auction announcements will be available by clicking on a link in the Automated Auction System.

xii. Default

156. The Commission adopted a special rule for calculating default payments in connection with package bidding in the Upper 700 MHz band. In the event a winning bidder defaults on payments due after an auction closes or is disqualified after the auction, a default payment will be assessed. The default payment will consist of a deficiency portion and an additional 25% payment. The special default rule is modeled on the default rule used in other auctions. However, there are substantial differences, perhaps most significantly in the amount of the additional payment. The default rule used in other auctions sets the additional payment at three percent (3%) of the lesser of the subsequent winning bid and the defaulted bid. In contrast, the default rule for use with package bidding in the Upper 700 MHz bands sets the additional payment at twenty-five percent (25%) of the lesser of the subsequent winning bid and the defaulted bid.

157. The deficiency portion will make up any loss to the Commission that results when defaulted bid(s) are replaced by subsequent winning bid(s). If the subsequent winning bid(s) exceed the defaulted bid(s), no deficiency portion will be assessed. Even in the absence of a deficiency portion, however, an additional 25% payment will be due. Where a defaulting bidder held winning bids on individual licenses (*i.e.,* not as part of a package), and in a subsequent auction the licenses are also won individually, the deficiency portion will be calculated by subtracting the subsequent winning bid from the defaulted bid. The deficiency portion for such bids will be calculated on a license-by-license basis (*i.e.,* in the event of defaults on multiple bids, the differences between the amounts originally bid and the amounts subsequently bid will not be aggregated to determine a net amount owed).

158. Where a defaulting bidder won licenses in package(s), and in a subsequent auction the licenses are won either (a) in the same package(s), or (b) in smaller packages or as individual licenses that correlate to the defaulted package(s), the deficiency portion will be determined on a package-by-package basis. In the event a defaulting bidder defaults on more than one such bid, the differences between the amount originally bid and the amount(s) subsequently bid will not be aggregated to determine a net amount owed. Thus, in this situation, the deficiency portion will be calculated in a manner analogous to where the licenses are sold individually. However, with regard to each individual package, where the licenses are subsequently sold individually or as part of smaller packages, the amounts received in the subsequent auction will be aggregated in order to determine any deficiency.

159. Where a defaulting bidder or bidders won licenses either individually or as part of packages, and in a subsequent auction the licenses are won as larger packages or different packages (not including the situation described in the preceding paragraph), the deficiency portion will be calculated by subtracting the aggregate amount originally bid for the licenses from the aggregate amount bid in the subsequent auction for the licenses. Thus, in this situation, the deficiency portion will not be calculated on a bid-by-bid basis.

160. If, in a situation requiring that bids be aggregated in order to determine the deficiency portion of the default payments for the bids, there are multiple defaulting bidders, the default payment (both the deficiency portion and the additional 25% payment portion) will be allocated to the defaulting bidders in proportion to their share of the aggregated default bids.

161. In the event that a bidding credit applies to any applicable bid(s), the Bureau will assess the deficiency portion of the default payment using the lesser of the difference between gross bids and the difference between net bids. (In the event that a bidder does not have a bidding credit, the bidder's gross bid and net bid are the same.) In other words, the Bureau will compare (i) the

sum of the gross defaulted Auction No. 31 bid(s) minus the gross subsequent winning bid(s) and (ii) the sum of the net defaulted Auction No. 31 bid(s) minus the net subsequent winning bid(s). The Bureau will impose the lesser of (i) and (ii) as the deficiency portion.

162. As noted at the outset, the default payment consists of the deficiency portion and an additional 25% payment. The additional payment will be 25% of the lesser of the subsequent winning bid(s) and the defaulted bid(s). The Bureau will use the same gross or net bid(s) that it used to calculate the deficiency portion when assessing the additional 25% payment. That is, the Bureau will compare the defaulted and subsequent bid(s) according to the methods described for calculation of the deficiency portion of the default payment when determining whether the defaulted bid(s) or the subsequent winning bid(s) is the lesser amount. Should there be no difference between the gross or net bid(s) for purposes of assessing the deficiency portion, the Bureau will assess the additional 25% payment using the lesser of the gross or net bid(s).

V. Post-Auction Procedures

A. Down Payments

163. After bidding has ended, the Commission will issue a public notice declaring the auction closed, identifying winning bidders and down payments due.

164. Within ten business days after release of the auction closing notice, each winning bidder must submit sufficient funds (in addition to its upfront payment) to bring its total amount of money on deposit with the Government to 20 percent of its net winning bids (actual bids less any applicable small and very small business bidding credits). *See* 47 CFR 1.2107(b).

B. Auction Discount Voucher

165. On June 8, 2000, the Commission awarded Qualcomm, Inc. a transferable Auction Discount Voucher (''ADV'') in the amount of $125,273,878.00. This ADV may be used by Qualcomm or its transferee, in whole or in part, to adjust a winning bid in any spectrum auction prior to June 8, 2003, subject to terms and conditions set forth in the Commission's Order. Qualcomm transferred $10,848,000.00 of the ADV to a winning bidder in FCC Auction No. 35 and the transferee used its portion of the ADV to adjust one of its winning bids in Auction No. 35. The remaining portion of Qualcomm's ADV could be used to adjust winning bids in another FCC auction, including Auction No. 31.

C. Long-Form Application

166. Within ten business days after release of the auction closing notice, winning bidders must electronically submit a properly completed long-form application (FCC Form 601) and required exhibits for each license won through Auction No. 31. Winning bidders that are small or very small businesses must include an exhibit demonstrating their eligibility for small and very small business bidding credits. *See* 47 CFR 1.2112(b). Further filing instructions will be provided to auction winners at the close of the auction.

D. Tribal Land Bidding Credit

167. A winning bidder that intends to use its license(s) to deploy facilities and provide services to federally-recognized tribal lands that are unserved by any telecommunications carrier or that have a telephone service penetration rate equal to or below 70 percent is eligible to receive a tribal land bidding credit as set forth in 47 CFR 1.2107 and 1.2110(f). A tribal land bidding credit is in addition to, and separate from, any other bidding credit for which a winning bidder may qualify.

168. Unlike other bidding credits that are requested prior to the auction, a winning bidder applies for the tribal land bidding credit after winning the auction when it files its long-form application (FCC Form 601). When filing the long-form application, the winning bidder will be required to advise the Commission whether it intends to seek a tribal land bidding credit, for each market won in the auction, by checking the designated box(es). After stating its intent to seek a tribal land bidding credit, the applicant will have 90 days from the close of the long-form filing window to amend its application to select the specific tribal lands to be served and provide the required tribal government certifications. Licensees receiving a tribal land bidding credit are subject to performance criteria as set forth in 47 CFR 1.2110(f).

169. For additional information on the tribal land bidding credit, including how the amount of the credit is calculated, applicants should review the Commission's rule making proceeding regarding tribal land bidding credits and related public notices. Relevant documents can be viewed on the Commission's auctions Web site at *http://wireless.fcc.gov/auctions* by clicking on the *Tribal Land Credits* link.

E. Default and Disqualification

170. Any high bidder that defaults or is disqualified after the close of the auction (*i.e.,* fails to remit the required down payment within the prescribed period of time, fails to submit a timely long-form application, fails to make full payment, or is otherwise disqualified) will be subject to the payments described in 47 CFR 27.501(b). In addition, if a default or disqualification involves gross misconduct, misrepresentation, or bad faith by an applicant, the Commission may declare the applicant and its principals ineligible to bid in future auctions, and may take any other action that it deems necessary, including institution of proceedings to revoke any existing licenses held by the applicant. *See* Section IV.B.xii for more detail on the default rule for this auction.

F. Refund of Remaining Upfront Payment Balance

171. All applicants that submitted upfront payments but were not winning bidders for a license in Auction No. 31 may be entitled to a refund of their remaining upfront payment balance after the conclusion of the auction. All refunds will be returned to the payer of record, as identified on the FCC Form 159, unless the payer submits written authorization instructing otherwise.

172. At the end of the auction, those bidders who are eligible for a refund must submit a written refund request. If you have completed the refund instructions electronically, then only a written request for the refund is necessary. If not, the request must also include wire transfer instructions, Taxpayer Identification Number (TIN), and FCC Registration Number (FRN). Send refund request to: Federal Communications Commission, Financial Operations Center, Auctions Accounting Group, Gail Glasser or Tim Dates, 445 12th Street, SW, Room 1–C863, Washington, DC 20554.

173. Bidders are encouraged to file their refund information electronically using the refund information portion of the FCC Form 175, but bidders can also fax their information to the Auctions Accounting Group at (202) 418–2843. Once the information has been approved, a refund will be sent to the party identified in the refund information.

Note: Refund processing generally takes up to two weeks to complete. Bidders with questions about refunds should contact Tim Dates or Gail Glasser at (202) 418–1995.

Federal Communications Commission.

Magaret Wiener,

Chief, Auctions and Industry Analysis Division, WTB.

[FR Doc. 02–9988 Filed 4–23–02; 8:45 am]

BILLING CODE 6712–01–P

FEDERAL MARITIME COMMISSION

Notice of Agreement(s) Filed

The Commission hereby gives notice of the filing of the following agreement(s) under the Shipping Act of 1984. Interested parties can review or obtain copies of agreements at the Washington, DC offices of the Commission, 800 North Capitol Street, NW., Room 940. Interested parties may submit comments on an agreement to the Secretary, Federal Maritime Commission, Washington, DC 20573, within 10 days of the date this notice appears in the **Federal Register**.

Agreement No.: 011677–005.

Title: United States Australasia Agreement.

Parties:

Australia New Zealand Direct Line

Contship Containerlines

Hamburg-Sud, d/b/a Columbus Line

P&O Nedlloyd Limited

Wallenius Wilhelmsen Lines AS

CMA CGM, S.A.

Synopsis: The proposed agreement modification extends the current share period for the parties' Trade Participation Arrangement through December 31, 2002, and revises the overcarriage and undercarriage thresholds.

Agreement No.: 011785–001.

Title: The COSCON/KL/YMUK Asia/U.S. East and Gulf Coast/Mediterranean Vessel Sharing Agreement.

Parties:

COSCO Container Lines Company, Limited

Kawasaki Kisen Kaisha, Ltd.

Yangming (U.K.) Ltd.

Synopsis: The proposed agreement modification adds ports in North Europe in the Hamburg/Gibraltar range, the United Kingdom, and Scandinavia to the geographic scope of the agreement.

Dated: April 19, 2002.

By Order of the Federal Maritime Commission.

Bryant L. VanBrakle,

Secretary.

[FR Doc. 02–10063 Filed 4–23–02; 8:45 am]

BILLING CODE 6730–01–P

FEDERAL MARITIME COMMISSION

Ocean Transportation Intermediary License Applicants

Notice is hereby given that the following applicants have filed with the Federal Maritime Commission an application for license as Non-Vessel Operating Common Carrier and Ocean Freight Forwarder—Ocean Transportation Intermediary pursuant to section 19 of the Shipping Act of 1984 as amended (46 U.S.C. app. 1718 and 46 CFR 515).

Persons knowing of any reason why the following applicants should not receive a license are requested to contact the Office of Transportation Intermediaries, Federal Maritime Commission, Washington, DC 20573.

Non-Vessel Operating Common Carrier Ocean Transportation Intermediary Applicants

Greating Marine Inc., 2225 W. Commonwealth Ave., Suite #316, Alhambra, CA 91803, Officers: Eugene Yu Chiang, Operation Manager (Qualifying Individual), Ho The Chang, President

Hana Logistics, Inc. 1123 E. Dominguez Street Carson, CA 90746 Officers: Jung Hyun Oh, President (Qualifying Individual), Helen Jun, Secretary

Skythech International, Inc., 145–38 157th Street, Jamaica, NY 11434, Officer: Yun Seok Lee, President, Qualifying Individual

West Point International Shipping Co., 509 Summerbreeze Drive, Newark, DE 19702, Mary O. Atupulazi, Sole Proprietor

Dart Express (NYC) Inc., 177–14 149th Road, Jamaica, NY 11434, Officers: Kwok Keung Wong, Vice President (Qualifying Individual), Joseph Pang, Director

Kasy Logistics Co., Ltd., 8050 Florence Avenue, Suite 30, Downey, CA 90240, Officers: Paul Kee-Nui Leung, Chief Financial Officer (Qualifying Individual), Ying Chen, CEO

Willmar International, Inc., 975 Navajo Drive, Bluffton, OH 45817, Officer: William T. Martin, President (Qualifying Individual)

Crescent Ocean Services, LLC dba Crescent Ocean Services, 5100 South Dawson Street, Suite 200, Seattle, WA 98118, Officer: Christopher J. Clark, General Manager (Qualifying Individual)

Worldwide Logistics Partner Inc. dba WWLP Inc., 720 Industrial Drive, Suite 109, Cary, IL 60013, Officers: Mitesh P. Kamdar, Director (Qualifying Individual), Jim Ehrbar, Vice President of Sales

A.N.I. Cargo Services Inc., 6931 NW 87th Avenue, Miami, FL 33178, Officers: Stephen Chang, President (Qualifying Individual), Allan Grant, Vice President

DLS Freight Services (SFO) Ltd. dba DLS Logistic Service, 840 Hinckley Road, Suite #110, Burlingame, CA 94010, Officers: Elaine Pan, CFO (Qualifying Individual), Iris Meng, President

Global Brilliant Logistics Corp., 343 N. Wood Dale, Suite 102, Wood Dale, IL 60191, Officer: Veronica Knycha, President (Qualifying Individual)

Non-Vessel Operating Common Carrier and Ocean Freight Forwarder Transportation Intermediary Applicants

R.S. Logistics Inc., 700 Plaza Drive, Secaucus, NJ 07094, Officers: Gregory Shiu, Vice President (Qualifying Individual), Ling Wan, Director

A Customs Brokerage, Inc., 656 South Drive, Miami Springs, FL 33166, Officers: Gilda Castillo, Vice President (Qualifying Individual), Gabriel T. Rodriguez, President

GPS Logistics, Inc., 175–18 147th Avenue, Jamaica, NY 11434, Officers: Paul Fitzpatrick, President (Qualifying Individual), Peter T.C. Chow, Secretary

Annex Global Logistics Inc., 808 South Hindry Avenue, Suite E, Inglewood, CA 90301, Officer: Charles Wong, President (Qualifying Individual)

Klasman-Varnak USA, Inc., 14 Laurel Hill Terrace, Kearny, NJ 07032, Officers: Kemal M. Guler, Vice President (Qualifying Individual), Vilmaz Nalcakar, President

Trans Caribbean Cargo International, Inc., 1601 NW 70th Avenue, Suite 101, Miami, FL 33126, Officers: Lt. Col. Lawrence H. London, CEO (Qualifying Individual), Ian Davis, President

Dated: April 19, 2002.

Bryant L. VanBrakle,

Secretary.

[FR Doc. 02–10062 Filed 4–23–02; 8:45 am]

BILLING CODE 6730–01–P

FEDERAL RESERVE SYSTEM

Formations of, Acquisitions by, and Mergers of Bank Holding Companies

The companies listed in this notice have applied to the Board for approval, pursuant to the Bank Holding Company Act of 1956 (12 U.S.C. 1841 *et seq.*) (BHC Act), Regulation Y (12 CFR Part 225), and all other applicable statutes and regulations to become a bank holding company and/or to acquire the

assets or the ownership of, control of, or the power to vote shares of a bank or bank holding company and all of the banks and nonbanking companies owned by the bank holding company, including the companies listed below.

The applications listed below, as well as other related filings required by the Board, are available for immediate inspection at the Federal Reserve Bank indicated. The application also will be available for inspection at the offices of the Board of Governors. Interested persons may express their views in writing on the standards enumerated in the BHC Act (12 U.S.C. 1842(c)). If the proposal also involves the acquisition of a nonbanking company, the review also includes whether the acquisition of the nonbanking company complies with the standards in section 4 of the BHC Act (12 U.S.C. 1843). Unless otherwise noted, nonbanking activities will be conducted throughout the United States. Additional information on all bank holding companies may be obtained from the National Information Center website at www.ffiec.gov/nic/.

Unless otherwise noted, comments regarding each of these applications must be received at the Reserve Bank indicated or the offices of the Board of Governors not later than May 17, 2002.

A. Federal Reserve Bank of Boston (Richard Walker, Community Affairs Officer) 600 Atlantic Avenue, Boston, Massachusetts 02106-2204:

1. Port Financial Corp, Brighton, Massachusetts; to retain shares and acquire up to 9.9 percent of the voting shares of Cambridge Bancorp, Cambridge, Massachusetts, and thereby indirectly acquire shares of Cambridge Trust Company, Cambridge, Massachusetts.

Board of Governors of the Federal Reserve System, April 18, 2002.

Robert deV. Frierson,

Deputy Secretary of the Board.

[FR Doc. 02–9937 Filed 4–23–02; 8:45 am]

BILLING CODE 6210–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 01N–0319]

Agency Information Collection Activities; Announcement of OMB Approval; Health and Diet Survey

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that a collection of information entitled ''Health and Diet Survey'' has been approved by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995.

FOR FURTHER INFORMATION CONTACT: Peggy Schlosburg, Office of Information Resources Management (HFA–250), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–1223.

SUPPLEMENTARY INFORMATION: In the **Federal Register** of November 30, 2001 (66 FR 59794), the agency announced that the proposed information collection had been submitted to OMB for review and clearance under 44 U.S.C. 3507. An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number. OMB has now approved the information collection and has assigned OMB control number 0910–0489. The approval expires on March 31, 2005. A copy of the supporting statement for this information collection is available on the Internet at http://www.fda.gov/ohrms/dockets.

Dated: April 5, 2002.

Margaret M. Dotzel,

Associate Commissioner for Policy.

[FR Doc. 02–9986 Filed 4–23–02; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Cancer Institute; Notice of Closed Meeting

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. Appendix 2), notice is hereby given of the following meeting.

The meeting will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: National Cancer Institute Special Emphasis Panel, Spores in Breast Cancer.

Date: June 17–19, 2002.

Time: 8 a.m to 6 p.m.

Agenda: To review and evaluate grant applications.

Place: Washington Terrace Hotel, 1515 Rhode Island Avenue, NW, Washington, DC 20005.

Contact Person: Brian E. Wojcik, PhD, Scientific Review Administrator, Grants Review Branch, Division of Extramural Activities, National Cancer Institute, 6116 Executive Boulevard, Room 8019, Bethesda, MD 20892. 301/402–2785.

(Catalogue of Federal Domestic Assistance Program Nos. 93.392, Cancer Construction; 93.393, Cancer Cause and Prevention Research; 93.394, Cancer Detection and Diagnosis Research; 93.395, Cancer Treatment Research; 93.396, Cancer Biology Research; 93.397, Cancer Centers Support; 93.398, Cancer Research Manpower; 93.399, Cancer Control, National Institutes of Health, HHS)

Dated: April 17, 2002.

LaVerne Y. Stringfield,

Director, Office of Federal Advisory Committee Policy.

[FR Doc. 02–9975 Filed 4–23–02; 8:45 am]

BILLING CODE 4140–01–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Cancer Institute; Notice of Closed Meeting

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. Appendix 2), notice is hereby given of the following meeting.

The meeting will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: National Cancer Institute Initial Review Group, Subcommittee G—Education.

Date: June 19–21, 2002.

Time: 9 am to 5 pm.

Agenda: To review and evaluate grant applications.

Place: Georgetown Holiday Inn, 2101 Wisconsin Ave., NW, Washington, DC 20007.

Contact Person: Harvey P. Stein, PhD, Scientific Review Administrator, Grants Review Branch, Division of Extramural Activities, National Cancer Institute, National Institutes of Health, 6116 Executive Boulevard, Room 8107, Bethesda, MD 20892. (301) 496–7841.

(Catalogue of Federal Domestic Assistance Program Nos. 93.392, Cancer Construction; 93.393, Cancer Cause and Prevention

Research; 93.394, Cancer Detection and Diagnosis Research; 93.395, Cancer Treatment Research; 93.396, Cancer Biology Research; 93.397, Cancer Centers Support; 93.398, Cancer Research Manpower; 93.999, Cancer Control, National Institutes of Health, HHS)

Dated: April 17, 2002.

LaVerne Y. Stringfield,

Director, Office of Federal Advisory Committee Poilicy.

[FR Doc. 02–9976 Filed 4–23–02; 8:45 am]

BILLING CODE 4140–01–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute of Dental & Craniofacial 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.

The meetings will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: National Institute of Dental and Craniofacial Research Special Emphasis Panel, 02–77, Review of R13 Grants.

Date: May 2, 2002.

Time: 2 p.m. to 4 p.m.

Agenda: To review and evaluate grant applications.

Place: 45 Center Drive, Natcher Building, Conference Room H, Bethesda, MD 20892. (Telephone Conference Call).

Contact Person: H. George Hausch, PhD, Acting Director, 4500 Center Drive, Natcher Building, Rm. 4AN44F, National Institutes of Health, Bethesda, MD 20892. (301) 594–2372.

Name of Committee: National Institute of Dental and Craniofacial Research Special Emphasis Panel, 02–73, Review of R13 Grants.

Date: May 14, 2002.

Time: 1 p.m. to 3 p.m.

Agenda: To review and evaluate grant applications.

Place: 45 Center Drive, Natcher Bldg., Conf. Rms. A & D, Bethesda, MD 20892.

Contact Person: H. George Hausch, PhD, Acting Director, 4500 Center Drive, Natcher Building, Rm. 4AN44F, National Institutes of Health, Bethesda, MD 20892. (301) 594–2372.

Name of Committee: National Institute of Dental and Craniofacial Research Special Emphasis Panel, 02–71, Loan Repayment Grants.

Date: May 23, 2002.

Time: 1 p.m. to 4 p.m.

Agenda: To review and evaluate grant applications.

Place: Natcher Building, Bethesda, MD 20892. (Telephone Conference Call).

Contact Person: H. George Hausch, PhD, Acting Director, 4500 Center Drive, Natcher Building, Rm. 4AN44F, National Institutes of Health, Bethesda, MD 20892. (301) 594–2372.

(Catalogue of Federal Domestic Assistance Program Nos. 93.121, Oral Diseases and Disorders Research, National Institutes of Health, HHS)

Dated: April 17, 2002.

LaVerne Y. Stringfield,

Director, Office of Federal Advisory Committee Policy.

[FR Doc. 02–9973 Filed 4–23–02; 8:45 am]

BILLING CODE 4140–01–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute of Child Health and Human Development; Notice of Closed Meeting

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. Appendix 2), notice is hereby given of the following meeting.

The meeting will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The contract proposals and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the contract proposals, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: National Institute of Child Health and Human Development Special Emphasis Panel, NICHD International Pediatric and Perinatal HIV Studies Network Coordinating Center.

Date: June 17, 2002.

Time: 8:30 a.m. to 3 p.m.

Agenda: To review and evaluate contract proposals.

Place: Bethesda Marriott Hotel 5151 Pooks Hill Road, Bethesda, MD 20814.

Contact Person: Hameed Khan, Phd., Scientific Review Administrator, Division of Scientific Review, National Institute of Child Health and Human Development, National Institutes of Health, 6100 Executive Blvd., Room 5E01, Bethesda, MD 20892. (301) 496–1485.

(Catalogue of Federal Domestic Assistance Program Nos. 93.209, Contraception and Infertility Loan Repayment Program; 93.864, Population Research; 93.865, Research for Mothers and Children; 93.929, Center for Medical Rehabilitation Research, National Institutes of Health, HHS)

Dated: April 17, 2002.

LaVerne Y. Stringfield,

Director, Office of Federal Advisory Committee Policy.

[FR Doc. 02–9974 Filed 4–23–02; 8:45 am]

BILLING CODE 4140–01–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Center for Scientific Review; Notice of Closed Meetings

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. Appendix 2), notice is hereby given of the following meetings.

The meetings will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: Center for Scientific Review Special Emphasis Panel.

Dated: April 24, 2002.

Time: 1 p.m. to 2 p.m.

Agenda: To review and evaluate grant applications.

Place: NIH, Rockledge 2, Bethesda, MD 20892, (Telephone Conference Call).

Contact Person: Weijia Ni, PHD, Scientific Review Administrator, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 3190, MSC 7848, Bethesda, MD 20892, (301) 435–1507, *niw@csr.nih.gov.*

This notice is being published less than 15 days prior to the meeting due to the timing limitations imposed by the review and funding cycle.

Name of Committee: Center for Scientific Review Special Emphasis Panel.

Date: May 2–3, 2002.

Time: 8 am to 4 p.m.

Agenda: To review and evaluate grant applications.

Place: The Churchill Hotel, 1914 Connecticut Avenue, NW., Washington, DC 20009.

Contact Person: Ranga V. Srinivas, PhD, Scientific Review Administrator, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 5108, MSC 7852, Bethesda, MD 20892, (301) 435–1167, *srinivar@csr.nih.gov.*

This notice is being published less than 15 days prior to the meeting due to the timing limitations imposed by the review and funding cycle.

(Catalogue of Federal Domestic Assistance Program Nos. 93.306, Comparative Medicine, 93.306; 93.333, Clinical Research, 93.333, 93.337, 93.393–93.396, 93.837–93.844, 93.846–93.878, 93.892, 93.893, National Institutes of Health, HHS)

Dated: April 16, 2002.

LaVerne Y. Stringfield,

Director, Office of Federal Advisory Committee Policy.

[FR Doc. 02–9972 Filed 4–23–02; 8:45 am]

BILLING CODE 4140–01–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Substance Abuse and Mental Health Services Administration

Fiscal Year (FY) 2002 Funding Opportunities

AGENCY: Substance Abuse and Mental Health Services Administration, HHS.

ACTION: Notice of funding availability.

SUMMARY: The Substance Abuse and Mental Health Services Administration (SAMHSA) Center for Substance Abuse Treatment (CSAT) announces the availability of FY 2002 funds for grants for the following activity. This notice is not a complete description of the activity; potential applicants must obtain a copy of the Guidance for Applicants (GFA), including Part I, Grants to Improve the Quality and Availability of Residential Treatment and Its Continuing Care Component for Adolescents (TI 02–007), and Part II, General Policies and Procedures Applicable to all SAMHSA Applications for Discretionary Grants and Cooperative Agreements, before preparing and submitting an application.

Activity	Application deadline	Est. funds FY 2002	Est. no. of awards	Project period years
Grants to Improve the Quality and Availability of Residential Treatment and its Continuing Care Component for Adolescents.	June 19, 2002 ..	$8,000,000	16	3

The actual amount available for the award may vary, depending on unanticipated program requirements and the number and quality of applications received. FY 2002 funds for the activity discussed in this announcement were appropriated by the Congress under Public Law 106–310. SAMHSA's policies and procedures for peer review and Advisory Council review of grant and cooperative agreement applications were published in the **Federal Register** (Vol. 58, No. 126) on July 2, 1993.

General Instructions: Applicants must use application form PHS 5161–1 (Rev. 7/00). The application kit contains the two-part application materials (complete programmatic guidance and instructions for preparing and submitting applications), the PHS 5161–1 which includes Standard Form 424 (Face Page), and other documentation and forms. Application kits may be obtained from: National Clearinghouse for Alcohol and Drug Information (NCADI), P.O. Box 2345, Rockville, MD 20847–2345, Telephone: 1–800–729–6686.

The PHS 5161–1 application form and the full text of the activity are also available electronically via SAMHSA's World Wide Web Home Page: *http://www.samhsa.gov*

When requesting an application kit, the applicant must specify the particular activity for which detailed information is desired. All information necessary to apply, including where to submit applications and application deadline instructions, are included in the application kit.

Purpose: The Substance Abuse and Mental Health Services Administration (SAMHSA), Center for Substance Abuse Treatment (CSAT) announces the availability of Fiscal Year 2002 funds for up to 16 grants to enhance and/or expand residential treatment services for youth (aged 21 and under) referred for treatment of a drug or alcohol problem.

Eligibility: Public and domestic private non-profit entities are eligible to apply, including units of State and local government, Native Alaskan entities, Indian tribes and tribal organizations, and community-based organizations, including faith based organizations.

All direct providers of substance abuse treatment services involved in the proposed project, including the applicant organization, if applicable, must have been providing treatment services for adolescents for a minimum of two years prior to the date of this application. If the applicant organization is not a direct provider of substance abuse treatment services, the applicant must document a commitment from one or more experienced, licensed substance abuse treatment providers to participate in the proposed project. All direct providers of substance abuse services involved in the proposed project, including the applicant organization, if applicable, must be in compliance with any and all applicable local, city, county and/or State requirements for licensing, accreditation, and certification.

Availability of Funds: Approximately $8.0 million will be available for up to 16 awards. The average annual award is expected to range from $400,000 to $500,000 in total costs (direct and indirect). Annual continuation awards are subject to the continued availability of funds and progress achieved by the grantee.

Period of Support: Awards may be requested for up to 3 years.

Criteria for Review and Funding

General Review Criteria: Competing applications requesting funding under this activity will be reviewed for technical merit in accordance with established PHS/SAMHSA peer review procedures. Review criteria that will be used by the peer review groups are specified in the application guidance material.

Award Criteria for Scored Applications: Applications will be considered for funding on the basis of their overall technical merit as determined through the peer review group and the appropriate National Advisory Council review process. Availability of funds will also be an award criteria. Additional award criteria specific to the programmatic activity may be included in the application guidance materials.

Catalog of Federal Domestic Assistance Number: 93.243.

Program Contact: For questions concerning program issues, contact: Randolph D. Muck, M.Ed., CSAT/SAMHSA, Rockwall II, 7th Floor, 5600 Fishers Lane, Rockville, MD 20857, (301) 443–6574, E-Mail: *rmuck@samhsa.gov.*

For questions regarding grants management issues, contact: Steve Hudak, Division of Grants Management, OPS/SAMHSA, Rockwall II, 6th floor, 5600 Fishers Lane, Rockville, MD 20857, (301) 443–9666, E-Mail: *shudak@samhsa.gov.*

Public Health System Reporting Requirements: The Public Health System Impact Statement (PHSIS) is intended to keep State and local health

officials apprised of proposed health services grant and cooperative agreement applications submitted by community-based nongovernmental organizations within their jurisdictions.

Community-based nongovernmental service providers who are not transmitting their applications through the State must submit a PHSIS to the head(s) of the appropriate State and local health agencies in the area(s) to be affected not later than the pertinent receipt date for applications. This PHSIS consists of the following information:

a. A copy of the face page of the application (Standard form 424).

b. A summary of the project (PHSIS), not to exceed one page, which provides:

(1) A description of the population to be served.

(2) A summary of the services to be provided.

(3) A description of the coordination planned with the appropriate State or local health agencies.

State and local governments and Indian Tribal Authority applicants are not subject to the Public Health System Reporting Requirements. Application guidance materials will specify if a particular FY 2002 activity is subject to the Public Health System Reporting Requirements.

PHS Non-use of Tobacco Policy Statement: The PHS strongly encourages all grant and contract recipients to provide a smoke-free workplace and promote the non-use of all tobacco products. In addition, Public Law 103–227, the Pro-Children Act of 1994, prohibits smoking in certain facilities (or in some cases, any portion of a facility) in which regular or routine education, library, day care, health care, or early childhood development services are provided to children. This is consistent with the PHS mission to protect and advance the physical and mental health of the American people.

Executive Order 12372: Applications submitted in response to the FY 2002 activity listed above are subject to the intergovernmental review requirements of Executive Order 12372, as implemented through DHHS regulations at 45 CFR part 100. E.O. 12372 sets up a system for State and local government review of applications for Federal financial assistance. Applicants (other than Federally recognized Indian tribal governments) should contact the State's Single Point of Contact (SPOC) as early as possible to alert them to the prospective application(s) and to receive any necessary instructions on the State's review process. For proposed projects serving more than one State, the applicant is advised to contact the SPOC of each affected State. A current listing of SPOCs is included in the application guidance materials. The SPOC should send any State review process recommendations directly to: Division of Extramural Activities, Policy, and Review, Substance Abuse and Mental Health Services Administration, Parklawn Building, Room 17–89, 5600 Fishers Lane, Rockville, Maryland 20857.

The due date for State review process recommendations is no later than 60 days after the specified deadline date for the receipt of applications. SAMHSA does not guarantee to accommodate or explain SPOC comments that are received after the 60-day cut-off.

Dated: April 18, 2002.

Richard Kopanda,

Executive Officer, Substance Abuse and Mental Health Services Administration.

[FR Doc. 02–9987 Filed 4–23–02; 8:45 am]

BILLING CODE 4162–20–P

DEPARTMENT OF THE INTERIOR

Fish and Wildlife Service

Notice of Availability, Draft Restoration Plan and Environmental Assessment

AGENCY: Fish and Wildlife Service, Department of the Interior.

ACTION: Notice of Availability.

SUMMARY: The U.S. Fish and Wildlife Service (Service), on behalf of the Department of the Interior and the State of Rhode Island, announces the release for public review of the draft Restoration Plan and Environmental Assessment (RP/EA) for the Landfill and Resource Recovery, Inc Superfund Site. The RP/EA describes the trustees' proposal to restore natural resources injured as a result of the release of hazardous substances from the site.

DATES: Written comments must be submitted on or before May 30, 2002.

ADDRESSES: Requests for copies of the RP/EA may be made to the U.S. Fish and Wildlife Service, New England Field Office, 70 Commercial Street, Suite 300, Concord, New Hampshire 03301.

Written comments or materials regarding the RP/EA should be sent to the same address.

FOR FURTHER INFORMATION CONTACT: Molly B. Sperduto or Kenneth C. Carr, Environmental Contaminants Program, U.S. Fish and Wildlife Service, 70 Commercial Street, Suite 300, Concord, New Hampshire 03301.

Interested parties may also call 603–223–2541 for further information.

SUPPLEMENTARY INFORMATION: The Landfill and Resource Recovery, Inc. Superfund Site, located in North Smithfield, Rhode Island was an active landfill until 1986, when the landfill was closed and approximately three-fourths of the site was covered with a synthetic cap. Due to erosion and re-grading associated with capping the landfill, approximately 1 acre of palustrine emergent and scrub-shrub wetland habitat was destroyed in perpetuity.

In 1997, the United States of America and the State of Rhode Island settled claims for natural resource damages associated with the Landfill and Resource Recovery, Inc. Superfund Site under the authority of the Comprehensive Environmental Response, Compensation, and Liability Act (CERCLA) of 1980. The settlement proceeds will be used to compensate for loss of natural resources under trusteeship of the Department of the Interior and the State of Rhode Island. The RP/EA is being released in accordance with CERCLA of 1980 as amended, commonly known as Superfund, (42 U.S.C. 9601 et seq.), the Natural Resource Damage Assessment Regulations found at 43 CFR, part 11, and the National Environmental Policy Act. It is intended to describe the trustees' proposals to restore natural resources injured at the site and evaluate the impacts of each.

The RP/EA describes a number of habitat restoration and protection alternatives and discusses the environmental consequences of each. Restoration efforts which have the greatest potential to restore wetlands and the services those wetlands provide to wetland-dependant wildlife are preferred. Based on an evaluation of the various restoration alternatives, the restoration of wetland habitat at the former Lonsdale Drive-In is proposed. This alternative maximizes the benefit to wetland-dependent wildlife, restoring over 20 acres of riparian habitat, including 7 acres of wetland.

Interested members of the public are invited to review and comment on the RP/EA. Copies of the RP/EA are available for review at the U.S. Fish and Wildlife Service's New England Field Office in Concord, New Hampshire (70 Commercial Street, Suite 300, Concord, New Hampshire). Additionally, the RP/EA will be available for review at the North Smithfield Municipal Annex Building. Written comments will be considered and addressed in the final RP/EA at the conclusion of the restoration planning process.

Author: The primary author of this notice is Molly Sperduto, U.S. Fish &

Wildlife Service, New England Field Office, 70 Commercial Street, Suite 300, Concord, New Hampshire 03301.

Authority: The authority for this action is CERCLA of 1980 as amended, commonly known as Superfund, (42 U.S.C. 9601 et seq.) and the Natural Resource Damage Assessment Regulations found at 43 CFR, part 11.

Dated: April 11, 2002.

Mamie A. Parker,

Regional Director, Region 5, U.S. Fish and Wildlife Service, DOI Designated Authorized Official.

[FR Doc. 02–9982 Filed 4–23–02; 8:45 am]

BILLING CODE 4310–55–P

DEPARTMENT OF THE INTERIOR

Bureau of Land Management

[CO–174–1820–DG]

Canyons of the Ancients National Monument Advisory Committee; Notice of Intent To Establish and Call for Nominations

AGENCY: Bureau of Land Management (BLM), San Juan Public Lands Center, Durango, Colorado.

ACTION: Notice of intent to establish and call for nominations for the Canyons of the Ancients National Monument Advisory Committee, as directed by the Secretary of the Interior on June 28, 2000, to ''establish an advisory committee to advise BLM on issues related to the Monument''.

SUMMARY: BLM is publishing this notice under section 9(a)(2) of the Federal Advisory Committee Act. Pursuant to the instructions of the Secretary of the Interior dated June 28, 2000, BLM gives notice that the Secretary of the Interior intends to establish the Canyons of the Ancients National Monument Advisory Committee (Committee). The notice requests the public to submit nominations for membership on the Committee. The Committee is necessary to advise the Secretary and BLM on resource management issues associated with the Canyons of the Ancients National Monument (CANM).

DATES: Submit a completed nomination form and nomination letters to the address listed below no later than May 24, 2002.

ADDRESSES: Send nominations to: Manager, Canyons of the Ancients National Monument, Bureau of Land Management, 27501 Highway 184, Dolores, Colorado 81323.

FOR FURTHER INFORMATION CONTACT: Gary Thrash, Planner, 970–385–1371, LouAnn Jacobson, Manager, 970–882–4811, or e-mail *Colorado_CANM@co.blm.gov* or visit the monument Web site at *http://www.co.blm.gov/canm/index.html*.

SUPPLEMENTARY INFORMATION: Any individual or organization may nominate one or more persons to serve on the Canyons of the Ancients National Monument Advisory Committee. Individuals may nominate themselves for Committee membership. You may obtain nomination forms from the Canyons of the Ancients National Monument Manager, Bureau of Land Management (see **ADDRESSES**, above) or from *http://www.co.blm.gov/canm/index.html*. To make a nomination, you must submit a completed nomination form, letters of reference from the represented interests or organizations, as well as any other information that speaks to the nominee's qualifications, to the Canyons of the Ancients National Monument Manager. You may make nominations for the following categories of interest:

- A representative of the Montezuma County Commission (appointed from nominees submitted by the Montezuma County Commission);
- A representative of the Dolores County Commission (appointed from nominees submitted by the Dolores County Commission);
- Two persons from any of the following tribes and pueblos representing Native American interests: The Ute Mountain Ute Tribe, The Uintah-Ouray Ute Tribe, The Southern Ute Tribe, The Navajo Nation, The Hopi Tribe, The Pueblo of Acoma, The Pueblo of Cochiti, The Pueblo of Isleta, The Pueblo of San Felipe, The Pueblo of Santa Ana, The Pueblo of Santo Domingo, The Pueblo of Jemez, The Pueblo of Laguna, The Pueblo of Sandia, The Pueblo of Zia, The Pueblo of Zuni, The Pueblo of Nambe, The Pueblo of San Juan, The Pueblo of Picuris, The Pueblo of Pojoaque, The Pueblo of San Ildefonso, The Pueblo of Santa Clara, The Pueblo of Taos, The Pueblo of Tesuque (appointed from nominees submitted by the Bureau of Land Management);
- Two persons who are recognized cultural resource representatives, one of whom represents regional interests and one of whom is from the local area (appointed from nominees submitted by the Bureau of Land Management);
- One person who is a grazing permittee on Federal lands in the CANM (appointed from nominees submitted by the Bureau of Land Management);
- A person who represents fluid minerals development (appointed from nominees submitted by the Bureau of Land Management);
- *Three people representing any of the following:* private landowners in or adjacent to the CANM, recognized national or regional environmental or resource conservation organizations, off-road vehicle use, commercial recreation, and/or representing statewide perspectives with no financial interest in the CANM (appointed from nominees submitted by the Bureau of Land Management).

The specific category the nominee would like to represent should be identified in the letter of nomination and in the nomination form. The Canyons of the Ancients National Monument Manager will collect the nomination forms and letters of reference and distribute them to the officials responsible for submitting nominations (Montezuma County Commission, Dolores County Commission, and the Bureau of Land Management). The Bureau of Land Management will then forward recommended nominations to the Secretary, who has responsibility for making the appointments.

The purpose of the Canyons of the Ancients National Monument Advisory Committee is to advise the Bureau of Land Management concerning development and implementation of a management plan for public lands within Canyons of the Ancients National Monument. Each member will be a person who, as a result of training and experience, has knowledge or special expertise which qualifies him or her to provide advice from among the categories of interest listed above.

Members will serve without monetary compensation, but will be reimbursed for travel and per diem expenses at current rates for Government employees. The membership term will be for four years.

Elaine Marquis-Brong,

Director, National Landscape Conservation System, Bureau of Land Management.

[FR Doc. 02–9590 Filed 4–23–02; 8:45 am]

BILLING CODE 4310–JB–P

DEPARTMENT OF THE INTERIOR

Bureau of Land Management

[CA 160–1220–PG]

Carrizo Plain Advisory Committee; Notice of Intent to Establish and Call for Nominations

AGENCY: Bureau of Land Management (BLM), Bakersfield Field Office, California.

ACTION: Notice of intent to establish and call for nominations for the Carrizo Plain Advisory Committee under the Federal Land Policy and Management Act (Pub. L. 94–579).

SUMMARY: BLM is publishing this notice under the authority of the Federal Land Policy and Management Act (Pub. L. 94–579). BLM gives notice that the Secretary of the Interior intends to establish the Carrizo Plain Advisory Committee (Committee). The notice requests the public to submit nominations for membership on the Committee. The Committee is necessary to advise the Secretary and BLM on resource management issues associated with the Carrizo Plain National Monument (Monument).

DATES: Submit a completed nomination form and nomination letters to the address listed below no later than May 24, 2002.

ADDRESSES: Send nominations to: Bakersfield Field Manager, Bakersfield Field Office, Bureau of Land Management, 3801 Pegasus Avenue, Bakersfield, California 93308.

FOR FURTHER INFORMATION CONTACT: Ron Fellows, Bakersfield Field Manager, (661) 301–6000, or *Ronald_Fellows@ca.blm.gov* or from the following Web site, *http://www.ca.blm.gov/bakersfield/carrizoplain.html.*

SUPPLEMENTARY INFORMATION: Any individual or organization may nominate one or more persons to serve on the Carrizo Plain Advisory Committee. Individuals may nominate themselves for Committee membership. Nomination forms can be obtained from the Bakersfield Field Office, Bureau of Land Management (see **ADDRESSES**, above). To make a nomination, you must submit a completed nomination form, letters of reference from the interests or organizations the nominee intends to represent, as well as any other information that speaks to the nominee's qualifications, to the Bakersfield Field Office. You may make nominations for the following categories of interest:

(1) A member of, or nominated by, the San Luis Obispo Board of Supervisors.

(2) A member of, or nominated by, the Kern County Board of Supervisors.

(3) A member of, or nominated by, the Carrizo Native American Advisory Council.

(4) A member of, or nominated by, the Central California Resource Advisory Council.

(5) A member representing individuals or companies authorized to graze livestock within the National Monument.

(6) Four members with recognized backgrounds reflecting—

(A) the purposes for which the Monument was established and

(B) the interests of other stakeholders, including the general public, that are affected by or interested in the planning and management of the National Monument.

The specific category the nominee would like to represent should be identified in the letter of nomination and in the nomination form. The Bakersfield Field Office will collect the nomination forms and letters of reference and, in the case of categories 1–4 (above) distribute them to the officials responsible for submitting nominations. The Bureau of Land Management will then forward recommended nominations to the Secretary of the Interior, who has responsibility for making the appointments.

The purpose of the Carrizo Plain Advisory Committee is to advise the Bureau of Land Management on the management of the Monument. Each member will be a person who, as a result of training and experience, has knowledge or special expertise which qualifies him or her to provide advice from among the categories of interest listed above.

Members will serve without monetary compensation, but will be reimbursed for travel and per diem expenses at current rates for Government employees.

Elaine Marquis-Brong,

Director, National Landscape Conservation System, Bureau of Land Management.

[FR Doc. 02–9592 Filed 4–23–02; 8:45 am]

BILLING CODE 4310–33–P

DEPARTMENT OF THE INTERIOR

Bureau of Land Management

[AZ 020–01–1610–D0–081A–002A]

Agua Fria National Monument

AGENCY: Bureau of Land Management, Phoenix Field Office, Phoenix, AZ

ACTION: Notice of Intent to prepare (1) a Resource Management Plan (RMP) for Agua Fria National Monument, designated on January 11, 2000, and (2) an RMP for lands collectively known as the Bradshaw Foothills. These two actions will require a single Environmental Impact Statement (EIS).

Location: The planning area encompasses the public lands managed by the BLM north of Phoenix, Arizona, including the Agua Fria National Monument and the Bradshaw Foothills. The Bradshaw Foothills include the Black Canyon Corridor and the areas around Lake Pleasant and Wickenburg. For more information, a map can be viewed in the Public Room of the Bureau of Land Management (BLM) Phoenix Field Office.

SUMMARY: The BLM provides notice that it intends to prepare two RMPs with one associated EIS for lands north of Phoenix, Arizona, managed by the Phoenix Field Office. One RMP will be developed for the lands referred to as the Bradshaw Foothills, and a separate RMP will be developed for the Agua Fria National Monument. This area is currently managed under the Lower Gila North Management Framework Plan (MFP) (1983) and the Phoenix RMP (1989). These plans will fulfill the needs and obligations set forth by the National Environmental Policy Act (NEPA), the Federal Land Policy and Management Act (FLPMA), the Agua Fria National Monument proclamation, and BLM regulations and policies. The BLM will work closely with interested parties to identify management decisions best suited to the needs of the public. This collaborative process will take into account local, regional, and national needs and concerns. This notice begins the public scoping process to examine proposed issues and planning criteria.

DATES: The scoping comment period will commence with the publication of this notice. Formal scoping will last a minimum of 60 days. Comments on issues and criteria should be received on or before the end of the scoping period at the address listed below. To ensure diverse local community participation and input, meeting locations will include the following communities: Wickenburg, Phoenix, Peoria, Prescott, Cave Creek, New River, Black Canyon City, Cordes Junction and Castle Hot Springs. At least 15 days public notice will be given for activities where the public is invited to attend. Meetings and comment deadlines will be announced through the local news media, newsletters, and the BLM web site (*www.az.blm.gov*). Public meetings will be held throughout the plan scoping and preparation period. Early participation by all those interested is encouraged and will help determine future management of the public lands.

ADDRESSES: To send written comments, obtain further information and/or to have your name added to our mailing list, contact: Chris Horyza, Bureau of Land Management, Phoenix Field Office, 21605 North 7th Avenue,

Phoenix, AZ 85027; Telephone (623) 580–5628; Fax (623) 580–5580; e-mail: *chris__horyza@blm.gov.* Documents pertinent to this proposal may be examined at the Phoenix Field Office at the address listed above. Comments, including names and street addresses of respondents, will be available for public review at the Phoenix Field Office during regular business hours, 7:45 a.m. to 4:15 p.m., Monday through Friday, except holidays, and may be published as part of the EIS. Individual respondents may request confidentiality. If you wish to withhold your name or street address from public review or from disclosure under the Freedom of Information Act, you must state this prominently at the beginning of your written comment. Such requests will be honored to the extent allowed by law. All submissions from organizations and businesses, and from individuals identifying themselves as representatives or officials of organizations or businesses, will be available for public inspection in their entirety.

SUPPLEMENTARY INFORMATION: The extraordinary population growth in Arizona, and especially the Greater Phoenix Metropolitan Area, as well as the creation of Agua Fria National Monument, requires reconsideration of previous land use plan decisions. This planning activity will develop management plans for Agua Fria National Monument and the Bradshaw Foothills through one planning effort. These actions require a single EIS with two records of decision.

The BLM will develop these plans using a community-based collaborative approach. The BLM will work with local communities to develop creative ways to resolve community issues and BLM management issues and establish a sense of ownership for BLM activities. BLM will work cooperatively with Federal agencies and State, tribal, and local governments in developing the plans. The planning area is within the planning jurisdiction of the Arizona State Land Department, Yavapai County, Maricopa County, Peoria, and Phoenix. Other agencies involved in the planning process may include Arizona Department of Transportation, Arizona Game and Fish Department, Arizona Public Service, and Yavapai and Maricopa County Departments of Transportation and Parks and Recreation. In addition, Tonto and Prescott National Forests adjoin the planning area and contain similar cultural, historic, recreational, and natural resources that should be managed in concert with the BLM-managed lands. The collaborative planning approach will encourage long-term support for BLM land use plan decisions and continued community involvement in BLM projects.

Preliminary issues and management concerns have been raised by BLM employees, other agencies, and through contacts with individuals and user groups. BLM will address the following major issues in the plans: (1) Meeting public needs and achieving a healthy, thriving environment in the face of rapidly increasing urban population; (2) identifying actions necessary to provide for visitor use and safety in the Agua Fria National Monument; and (3) identifying actions necessary to protect the monument's natural and cultural resources consistent with the proclamation. These are the issues that have been raised to date.

After gathering public comments on what issues the plan should address, BLM will place the suggested issues into one of four categories:

1. Issues to be resolved in the plan.
2. Issues to be resolved through policy or administrative action.
3. Issues to be resolved independent of this planning effort.
4. Issues beyond the scope of this plan.

BLM will address category one issues in the land use plan process and give a rationale in the plan for each issue placed in category two or four. Issues falling under category three will be passed to, and addressed by, the appropriate management agency or entity.

In addition to the preceding major issues, management questions and concerns to be addressed in the plans include, but are not limited to, the following: ecosystem health, riparian condition, threatened and endangered species habitat, wildlife habitat, reintroduction of native species, cultural resource protection and interpretation, recreation and visitor use, access and transportation, rangeland management, and minerals management. The following disciplines will be represented on the BLM planning team: wilderness, recreation, wildlife, rangeland management, botany, fire ecology, geology, realty, cultural resources, soils, hydrology, and geographic information systems (GIS). Where necessary, outside expertise may be used.

Background Information: Agua Fria National Monument was created on January 11, 2000, with the signing by the President of Proclamation 7263. The Monument contains one of the most significant systems of late prehistoric sites in the American Southwest. At least 450 prehistoric sites are known to exist within the monument. In addition to its rich record of human history, the monument contains other objects of scientific interest, including a diversity of vegetation communities, a wide array of sensitive wildlife species, and native fish populations.

The purpose of the monument designation is to protect these sensitive natural and cultural resources. The proclamation designated more than 71,000 acres to be managed by the BLM for this purpose. Establishment of the national monument necessitates development of a land use plan.

The area in and around Phoenix, Arizona, has experienced significant population growth in recent years. Since 1990, Maricopa County's population has increased nearly 35 percent. During this same time period, the City of Peoria has annexed more than 59,000 acres, including more than 16,000 acres of BLM land, and the City of Phoenix has added more than 19,000 acres, including nearly 700 acres of BLM land. These are only two of the growing cities and towns expanding their borders toward and into the Bradshaw Foothills Planning Area. The increased pressure on public lands for recreation, rights-of-way, mineral materials, and other purposes resulting from population increases requires BLM to readdress its land use plan decisions.

Elaine Marquis-Brong,

Director, National Landscape Conservation System, Bureau of Land Management.

[FR Doc. 02–9595 Filed 4–23–02; 8:45 am]

BILLING CODE 4310–32–P

DEPARTMENT OF THE INTERIOR

Bureau of Land Management

[CA–939–1610–DO]

California Coastal National Monument

AGENCY: Bureau of Land Management; California State Office.

ACTION: Notice of Intent to prepare a Resource Management Plan (RMP) for the California Coastal National Monument, designated January 11, 2000. This action will require a single Environmental Impact Statement (EIS). The planning area includes all counties which border the California Coast.

SUMMARY: This document provides notice that the Bureau of Land Management (BLM) intends to prepare an RMP with an associated EIS for the California Coastal National Monument Area. The monument includes all unappropriated and unreserved islands,

rocks, exposed reefs, and pinnacles owned by the United States along the Pacific coastline of California located above high mean tide. This area overlaps the Arcata, Ukiah, Hollister, Bakersfield, and the Palm Springs—South Coast Field Offices. This planning activity encompasses approximately 883 acres of public land or approximately 11,500 islands. The plan will fulfill the needs and obligations set forth by the National Environmental Policy Act (NEPA), the Federal Land Policy and Management Act (FLPMA), the monument proclamation, and BLM management policies. The BLM will work collaboratively with interested parties to identify the management decisions that are best suited to local, regional, and national needs and concerns. Partners in the plan will include all major coastal management agencies and local governments. The public scoping process will identify planning issues and develop planning criteria, including an evaluation of the existing RMPs and Management Framework Plans (MFPs) in the context of the needs and interests of the public and protection of the objects of historic and scientific interest specified in the proclamation.

DATES: The publication of this notice initiates the public scoping process. Formal scoping will last a minimum of 60 days. The Draft California Coastal National Monument Plan is scheduled for completion in September 2003. Comments on issues and planning criteria can be submitted in writing to the addresses listed below. All public meetings will be announced through the local news media, newsletters, and the BLM Web site (*www.ca.blm.gov*) at least 15 days prior to the event. The minutes and list of attendees for each meeting will be available to the public and open for 30 days to any participant who wishes to clarify the views they expressed.

Public Participation: Public meetings will be held throughout the plan scoping and preparation period. In order to ensure local community participation and input, open houses will be held in locations most closely affiliated with the monument. Probable locations include the towns of Eureka, Mendicino, Guala, San Francisco, Monterey, San Luis Obispo, Santa Barbara, Sacramento, and Los Angeles. Early participation is encouraged and will help determine the future management of the California Coastal National Monument. In addition to the ongoing public participation process, formal opportunities for public participation will be provided through comment on the alternatives and upon publication of the BLM draft RMP/EIS. In addition, written comments will be accepted throughout the entire planning process.

ADDRESSES: Written comments should be sent to California State Office, Bureau of Land Management, Division of Resources, 2800 Cottage Way, Sacramento, California 95825; Fax 916–978–4657. Documents pertinent to this proposal may be examined at that office, the Arcata Field Office in Arcata California, the Ukiah Field Office in Ukiah, California, the Hollister Field Office in Hollister, California, the Bakersfield Field Office in Bakersfield, California, and the Palm Springs/South Coast Field Office in Palm Springs, California. Comments, including names and street addresses of respondents, will be available for public review at those above listed offices during regular business hours 7:45 a.m. to 4 p.m., Monday through Friday, except holidays, and may be published as part of the EIS. Individual respondents may request confidentiality. If you wish to withhold your name or street address from public review or from disclosure under the Freedom of Information Act, you must state this prominently at the beginning of your written comment. Such requests will be honored to the extent allowed by law. All submissions from organizations and businesses, and from individuals identifying themselves as representatives or officials of organizations or businesses, will be available for public inspection in their entirety.

FOR FURTHER INFORMATION: For further information and/or to have your name added to our mailing list, contact Tony Danna, telephone 916 978–4630, or Paul Brink, telephone 916 978–4641.

SUPPLEMENTARY INFORMATION: The creation of the California Coastal National Monument necessitates a maintenance action to the Arcata RMP, the Clear Lake MFP, the Hollister RMP, the Caliente RMP, and the South Coast RMP in order to revise the boundaries of these plans to exclude the new Monument.

Preliminary issues and management concerns have been identified by BLM personnel, other agencies, and in meetings with individuals and user groups. They represent the BLM's knowledge to date on the existing issues and concerns with current management. The major issue themes that will be addressed in the planning effort include, but are not limited to: management and protection of shore birds and pinnepeds; management and protection of the area's cultural, historic, and prehistoric values; management integration with other agencies along the coastal zone; management of recreation/visitor use and safety; facilities and infrastructures needed to provide visitor interpretation/appreciation and administration of the monument; and integrating monument management with community, tribal, and other agency needs. After gathering public comments on what issues the plan should address, the suggested issues will be placed in one of three categories:

1. Issues to be resolved in the plan;
2. Issues resolved through policy or administrative action; or
3. Issues beyond the scope of this plan.

Rationale will be provided in the plan for each issue placed in category two or three. In addition to these major issues, a number of management questions and concerns will be addressed in the plan. The public is encouraged to help identify these questions and concerns during the scoping phase. An interdisciplinary approach will be used to develop the plan in order to consider the variety of resource issues and concerns identified. Disciplines involved in the planning process will include specialists with expertise in wildlife/fisheries/marine sciences management, minerals and geology, outdoor recreation, archaeology, paleontology, lands and realty, botany, soils, information technology, sociology, and economics. Where necessary, outside expertise may be sought to advise BLM staff.

Background Information

On January 11, 2000, the President signed the Proclamation creating the California Coastal National Monument. The monument encompasses approximately 883 acres or approximately 11,500 islands along the entire coast of California. This monument does not include submerged lands or territorial waters that are owned by the State of California. The Proclamation recognizes the biological, geological, and cultural significance that warrant protection as a national monument. In particular, gulls, the endangered California least tern, the endangered brown pelican, and the snowy plover reside in and establish their nests on the islands, rocks, exposed reefs, and pinnacles that comprise the national monument. Studies as early as 1970 have noted that the rookeries on which these birds breed are unprotected and threatened. The number of breeding pairs for some of the species continues to decline. The monument also provides forage and breeding habitat for several mammal

species, including a number of threatened pinnepeds. Recognizing their ecological importance, the Secretary of the Interior designated these islands, rocks, exposed reefs, and pinnacles as the ''California Islands Wildlife Sanctuary'' on April 11, 1983 (Public Land Order 6369). On February 5, 1990, the BLM designated these islands, rocks, exposed reefs, and pinnacles an Area of Critical Environmental Concern pursuant to the Federal Land Policy and Management Act of 1976 (FLPMA, 43 U.S.C. 1701 *et seq.*). While the BLM retains legal responsibility for the Sanctuary, the State of California's Department of Fish and Game currently handles day-to-day management under a 2000 Memorandum of Understanding (MOU).

Elaine Marquis-Brong,

Director, National Landscape Conservation System, Bureau of Land Management.

[FR Doc. 02–9591 Filed 4–23–02; 8:45 am]

BILLING CODE 4310–32–P

DEPARTMENT OF THE INTERIOR

Bureau of Land Management

[CO–174–02–1610–DO–083A]

Notice of intent to Prepare a Resource Management Plan (RMP)

AGENCY: Bureau of Land Management, San Juan Public Lands Center, Canyons of the Ancients National Monument, Dolores, Colorado, Interior.

ACTION: Notice of Intent to prepare a Resource Management Plan (RMP) for the Canyons of the Ancients National Monument, designated June 9, 2000. This action will require a single Environmental Impact Statement (EIS). These lands are located in Montezuma and Dolores Counties, Colorado.

SUMMARY: This document provides notice that the Bureau of Land Management (BLM) intends to prepare an RMP with an associated EIS for the Canyons of the Ancients National Monument. This planning activity encompasses approximately 164,000 acres of public land. The plan will fulfill the needs and obligations set forth by the National Environmental Policy Act (NEPA), the Federal Land Policy and Management Act (FLPMA), the monument proclamation, and BLM management policies. The BLM will work collaboratively with interested parties to identify the management decisions that are best suited to local, regional, and national needs and concerns. The public scoping process will identify planning issues and develop planning criteria, including an evaluation of the existing RMP in the context of the needs and interests of the public and protection of the objects of historic and scientific interest specified in the proclamation.

DATES: The publication of this notice initiates the public scoping comment process. Formal scoping will last a minimum of 60 days. Comments on issues and planning criteria can be submitted in writing to the address listed below. All public meetings will be announced through the local news media, newsletters, and the BLM web site (*www.co.blm.gov/canm/index.html*) at least 15 days prior to the event.

The minutes and list of attendees for each meeting will be available to the public and open for 30 days to any participant who wishes to clarify the views they expressed.

Public Participation: Public meetings will be held throughout the plan scoping and preparation period. In order to ensure local community participation and input, public meeting locations will be rotated between the towns of Cortez and Durango, Colorado. Early participation is encouraged and will help determine the future management of the Canyons of the Ancients National Monument. In addition to the ongoing public participation process, formal opportunities for public participation will be provided through comment on the alternatives and upon publication of the BLM draft RMP/EIS. In addition, written comments will be accepted throughout the entire planning process.

ADDRESSES: Written comments should be sent to Canyons of the Ancients Planning, Bureau of Land Management, Anasazi Heritage Center, 27501 Highway 184, Dolores, Colorado 81323; *Colorado_CANM@co.blm.gov*; Fax 970.882.7035. Documents pertinent to this proposal may be examined at the Anasazi Heritage Center, located 3 miles west of Dolores, Colorado. Comments, including names and street addresses of respondents, will be available for public review at the Anasazi Heritage Center, during regular business hours 9 a.m. to 5 p.m., Monday through Friday, except holidays, and may be published as part of the EIS. Individual respondents may request confidentiality. If you wish to withhold your name or street address from public review or from disclosure under the Freedom of Information Act, you must state this prominently at the beginning of your written comment. Such requests will be honored to the extent allowed by law. All submissions from organizations and businesses, and from individuals identifying themselves as representatives or officials of organizations or businesses, will be available for public inspection in their entirety.

FOR FURTHER INFORMATION CONTACT: For further information and/or to have your name added to our mailing list, contact Gary Thrash, Telephone 970.385.1371, or Marilynn Eastin, Telephone 970.882.4811, or *Colorado_CANM@co.blm.gov*.

SUPPLEMENTARY INFORMATION: The creation of the Canyons of the Ancients National Monument along with the changing needs and interests of the public necessitates a completion of a new RMP for the monument. This action will require a single EIS with one Record of Decision (ROD). Preliminary issues and management concerns have been identified by BLM personnel, other agencies, individuals and user groups, and by the Southwest Resource Advisory Council in public meetings held prior to monument designation. They represent the BLM's knowledge to date on the existing issues and concerns with current management. The major issue themes that will be addressed in the plan include, but are not limited to: preservation of cultural and natural resources; balancing multiple uses such as recreation, livestock grazing, energy development, traditional and Native American activities; integrating monument management with community, tribal, and other agency needs; visitor services; and access and transportation on the public lands.

After gathering public comments on what issues the plan should address, the suggested issues will be placed in one of three categories:

1. Issues to be resolved in the plan;
2. Issues resolved through policy or administrative action; or
3. Issues beyond the scope of this plan.

Rationale will be provided in the plan for each issue placed in category two or three. In addition to these major issues, a number of management questions and concerns will be addressed in the plan. The public is encouraged to help identify these questions and concerns during the scoping phase. An interdisciplinary approach will be used to develop the plan in order to consider the variety of resource issues and concerns identified. Disciplines involved in the planning process will include specialists with expertise in archaeology, paleontology, rangeland management, minerals and geology, outdoor recreation, wilderness, wildlife, lands and realty, hydrology, ecology, fire, geographic information systems, sociology, and economics. Where

necessary, outside expertise may be used.

Background Information: On June 9, 2000, the President signed Proclamation 7317, creating the Canyons of the Ancients National Monument. The monument encompasses approximately 164,000 acres of public lands in Montezuma and Dolores Counties, Colorado, borders the State of Utah and the Navajo Reservation to the west, and the Ute Mountain Ute Reservation is located to the south. The National Park Service, Hovenweep National Monument, manages 400 acres inside the boundaries of Canyons of the Ancients National Monument. Mesa Verde National Park is 12 miles east of Canyons of the Ancients National Monument.

The San Juan/San Miguel RMP completed in 1985 encompassed the monument (Anasazi ACEC at that time) and has been amended four times. Two of these amendments affected management within the area now designated as Canyons of the Ancients National Monument: an amendment for Oil and Gas Leasing and Development (1991) and an amendment to implement the Standards for Public Land Health and Guidelines for Livestock Grazing Management (1997).

Information from the existing plan and amendments may be incorporated into this plan.

LouAnn Jacobson,

Canyons of the Ancients National Monument Manager.

[FR Doc. 02–9588 Filed 4–23–02; 8:45 am]

BILLING CODE 4310–32–P

DEPARTMENT OF THE INTERIOR

Bureau of Land Management

[CA 169–02–1610–DO]

Carrizo Plain National Monument

AGENCY: Bureau of Land Management; Bakersfield Field Office.

ACTION: Notice of Intent to (1) prepare a Resource Management Plan (RMP) for the Carrizo Plain National Monument, designated January 17, 2001, and (2) amend the Caliente RMP, approved on May 5, 1997. This action will require a single Environmental Assessment (EA). The planning area is located in San Luis Obispo, Santa Barbara, and Kern Counties, in California.

SUMMARY: This document provides notice that the Bureau of Land Management (BLM) intends to prepare an RMP and RMP amendment with an associated EA for the Bakersfield Field Office. This planning activity encompasses approximately 204,000 acres of public land. The plan will fulfill the needs and obligations set forth by the National Environmental Policy Act (NEPA), the Federal Land Policy and Management Act (FLPMA), the monument proclamation, and BLM management policies. The Carrizo Plain National Monument RMP will be created by combining the existing Carrizo Plain Natural Area Management Plan with pertinent decisions within the Caliente RMP, and amending those decisions as needed to bring them into conformance with the monument proclamation. Those decisions within the Caliente RMP that pertain only to Carrizo will then be removed from the Caliente RMP by amendment. Both the Caliente RMP and the Carrizo Plain Natural Area Management Plan were prepared by the BLM in collaboration with a broad cross-section of interested parties. The BLM will again work collaboratively with interested parties to review the management decisions that are best suited to local, regional, and national needs and concerns. The environmental review process includes an evaluation of the pertinent RMP decisions in the context of the needs and interests of the public and protection of the objects of historic and scientific interest specified in the proclamation.

DATES: This notice initiates the planning process. General scoping will last a minimum of 60 days. The Draft Carrizo RMP and Draft Caliente RMP Amendment/EA are expected to be completed in December 2002. A Notice of Availability will be published in the **Federal Register**, beginning a 60 day public comment period. Public meetings will be held during the 60 day comment period. A decision on the Carrizo Plain National Monument RMP and Caliente RMP Plan Amendment is expected by May 2003.

ADDRESSES: Written comments should be sent to Carrizo Plain National Monument RMP, Bureau of Land Management, Bakersfield Field Office, 3801 Pegasus Drive, Bakersfield, California 93308; Fax 661 391–6040. Documents pertinent to this proposal may be examined at the Bakersfield Field Office located in Bakersfield, California. Comments, including names and street addresses of respondents, will be available for public review at the Bakersfield Field Office during regular business hours 7:30 a.m. to 4:15 p.m., Monday through Friday, except holidays, and may be published as part of the EA. Individual respondents may request confidentiality. If you wish to withhold your name or street address from public review or from disclosure under the Freedom of Information Act, you must state this prominently at the beginning of your written comment. Such requests will be honored to the extent allowed by law. All submissions from organizations and businesses, and from individuals identifying themselves as representatives or officials of organizations or businesses, will be available for public inspection in their entirety.

FOR FURTHER INFORMATION: For further information and/or to have your name added to our mailing list, contact Chris Ryan, Telephone 661 391–6107.

SUPPLEMENTARY INFORMATION: The Carrizo Plain National Monument is currently managed under the recently completed Carrizo Plain Natural Area Management Plan and the Caliente RMP. Together, these existing plans provide a comprehensive management program which is believed to be appropriate for the new monument. While BLM will review this existing management program in light of current issues associated with the new monument, a full scale planning effort is not considered necessary. However, BLM will evaluate any public comments as to the adequacy of the existing management program prior to making a final determination on the scope of the monument plan and related NEPA document. (1) The new Carrizo RMP will be comprised of those goals, decisions, and allocations within the Caliente RMP that pertain to the Carrizo Plain National Monument, combined with the primary goals and decisions identified within the Carrizo Plain Natural Area Management Plan. Activity plan direction from the Carrizo Plain Natural Area Management Plan will be carried forward and appended to the Carrizo Plain National Monument RMP. Modification of existing land use planning decisions is not anticipated except where necessary to conform to the monument proclamation. (2) The Caliente RMP will be amended by removing those decisions and allocations that pertain only to public lands within the Carrizo Plain National Monument, and clarifying that the remaining direction excludes the monument from that point forward. This will eliminate any overlap and potential conflict between the two land use plans.

Public Participation: Public meetings will be held during the EA public comment period. In order to ensure local community participation and input, public meeting locations will be rotated among the towns of San Luis

Obispo, California Valley, and Bakersfield, California. Participation is encouraged and will help determine the future management of the Carrizo Plain National Monument and the Bakersfield Field Office public lands. All public meetings will be announced through the local news media, newsletters, and the BLM web site (*www.ca.blm.gov*) at least 15 days prior to the event. Any notes generated and the list of attendees for each meeting will be available to the public and open for 30 days to any participant who wishes to clarify the views they expressed. In addition to public meetings, formal opportunities for public participation will be provided through comment upon publication of the draft Carrizo RMP, and Caliente RMP Plan Amendment/EA. In addition, written comments will be accepted throughout the entire planning process.

Background Information: On January 17, 2001, the President signed a proclamation creating the Carrizo Plain National Monument. The monument encompasses approximately 204,000 acres of public lands primarily in San Luis Obispo County, with smaller portions within Kern and Santa Barbara Counties, all in California. Located midway between the cities of Bakersfield and San Luis Obispo, the monument links Bittercreek National Wildlife Refuge to the southeast with privately conserved lands and the Los Padres National Forest to the northwest. The Caliente RMP was completed in 1997 and encompassed all BLM managed public lands within San Luis Obispo, Santa Barbara, Ventura, Kings, Tulare, and western Kern counties. Public involvement in preparation of the Caliente RMP was solicited through announcements in the **Federal Register**, the mailing of a notice to 1,300 people and organizations, six scoping meetings, the mailing of a draft plan to 1,000 interested publics, and 6 public open houses. The Carrizo Plain Natural Area Management Plan was completed between 1996 and 1999. This plan was jointly prepared and signed by The Nature Conservancy, California Department of Fish and Game, and BLM, following public involvement that included a mailing to 1,000 people and organizations, 7 public meetings, and an additional mailing to a list of 200 people and organizations before the final plan was compiled. Neither plan has been amended previously, and both continue to provide clear and broadly supported direction for public lands now within the Carrizo Plain National Monument.

Elaine Marquis-Brong,

Director, National Landscape Conservation System, Bureau of Land Management.

[FR Doc. 02–9593 Filed 4–24–02; 8:45 am]

BILLING CODE 4310–32–P

DEPARTMENT OF THE INTERIOR

Bureau of Land Management

[OR113–6310–AA; HAG02–0018]

Cascade-Siskiyou National Resource Management; Notice of Availability of Cascade-Siskiyou National Monument Draft Resource Management Plan and Draft Environmental Impact Statement

AGENCY: Bureau of Land Management, Cascade-Siskiyou National Monument, Medford District.

ACTION: Notice of availability of Cascade-Siskiyou National Monument Draft Resource Management Plan and Environmental Impact Statement (DRMP/DEIS).

SUMMARY: Pursuant to section 202 of the Federal Land Policy and Management of 1976 and section 102(2)(c) of the National Environmental Policy Act of 1969 and 40 CFR 1506.6(2), the Bureau of Land Management (BLM) has prepared a Draft Resource Management Plan (DRMP) and associated Draft Environmental Impact Statement (DEIS) for the Cascade-Siskiyou National Monument located in Jackson County, Oregon. The DRMP will provide a range of alternatives, including identification of a preferred alternative, for management direction for the Cascade-Siskiyou National Monument. The DRMP addressed management on approximately 52,947 acres of public land. Final decisions through this planning process will supercede planning guidance presented in the Medford District Resource Management Plan. The Plan will provide direction for management of these public lands for a period of approximately 10 years. The DRMP/DEIS considers all issues raised during plan scoping that are within the decision space allowed by the Presidential Proclamation 7318 which designated the Monument and other non-discretionary programs and policies. Issues addressed in the DRMP/DEIS include vegetation management, access, prescribed fire, recreation, visitor use, and facilities/rights-of-way. The DRMP/DEIS describes four alternatives for management of the CSNM, including a ''No Action'' Alternative A. Each ''action'' alternative has a different emphasis, primarily defined in terms of the amount of management intervention necessary to meet the primary goal of protecting, maintaining, restoring or enhancing relevant and important ecological, biological, geological, and archaeological objects. Alternative B promotes natural ecosystem processes in the management of plant communities. Alternative C incorporates active management for protection and maintenance of the conifer communities while limiting some ground disturbing management tools that may be used in maintaining and restoring the other plant communities. Alternative D promotes aggressive management for protection, maintenance and restoration of Monument resources through the use of all management tools available. The alternatives defer proposing land use allocations or management directions that are precluded by the need for the livestock grazing study required by the Proclamation. The action alternatives were prepared in accordance with applicable planning procedures and are designed to protect, maintain, restore or enhance Monument objects, resources and ecological processes.

DATES: The public has the opportunity to review and comment on the CSNM DRMP/DEIS. It is anticipated that this document will be available for review around May 2002. Per BLM Planning Regulations, 43 CFR 1610.2(e), ninety (90) days shall be provided for review of the draft plan and draft environmental impact statement. The 90-day period shall formally begin when the Environmental Protection Agency publishes a notice of the filing of the draft environmental impact statement in the **Federal Register**. During this time period, written comments on the contents of the DRMP/DEIS will be solicited, particularly comments that address one or more of the following: (1) New information that would affect the analysis; (2) possible improvements in the analysis; and (3) suggestions for improving or clarifying the proposed management direction. Specific comments are most useful. BLM will respond to comments addressing the adequacy of the DRMP/DEIS in the Proposed Resource Management Plan/Final Environmental Impact Statement. Comments on the DEIS, including names and addresses of respondents, will be available for public review at the Medford District Office during regular business hours (8 a.m. to 4:30 p.m. Monday through Friday, except holidays). Individuals may request confidentiality. If you wish to withhold your name or address from public

review or from disclosure under the Freedom of Information Act, you must state this promptly at the beginning of your written comment. Such requests will be honored to the extent allowed by law. All submissions from organizations or businesses, and from individuals identifying themselves as representatives or officials or organizations or businesses, will be made available for public inspection in their entirety.

BLM will discuss the various management alternatives and answer questions pertaining to the Monument at an open-house type public meeting to be held at Southern Oregon University in Ashland, Oregon during the comment period. If there is sufficient public interest, the BLM may have additional public meetings. All public meetings will be announced in the Medford and Ashland newspapers and on the BLM Medford District's web site, *http://www.or.blm.gov/Medford/* under ''Planning Documents'' at least 15 days prior to the event.

ADDRESSES: Written comments should be sent to Richard J. Drehobl, Monument Manager, Medford District Bureau of Land Management, 3040 Biddle Road, Medford, Oregon 97504.

FOR FURTHER INFORMATION CONTACT: Ted Hass, Planning and Environmental Coordinator at 3040 Biddle Road, Medford, Oregon, 97504, telephone 541–618–2253. Single copies of the DRMP/DEIS will be available at the BLM Medford District Office around May 2002. Interested persons not already on the mailing list may review the DRMP/DEIS via the internet at *http://www.or.blm.gov/Medford/* under ''Planning Documents.'' A hard copy or a CD–ROM of the DRMP/DEIS may be requested from the Medford District Office.

SUPPLEMENTARY INFORMATION: The Cascade-Siskiyou National Monument (CSNM) consists of 52,947 acres of federal land located in southern Jackson County, Oregon. These federal lands are managed by the Bureau of Land Management's Medford District Office. Although there are approximately 32,222 acres of non-federal lands interspersed among the federal land within the Presidential Proclamation boundary, the CSNM is comprised of only federal land.

The CSNM is located in the Klamath and Rogue River basins and four watersheds that have a combined total of approximately 780 miles of streams. There are three ecoregions identified in the CSNM having particular biological significance in terms of species richness, endemism, and unique evolutionary/ecological phenomenon.

Archaeological evidence indicates that people have lived in the region for at least 10,000 years. Various native peoples inhabited or used the CSNM area including the Shasta, the Klamath and Modoc tribes. Euro-American settlement in the Rogue and Shasta valleys from the 1850s on spurred the development of a new way of life in the region.

The BLM controls approximately 251 miles of road that access the 52,947 acres of public land designated as the Monument. These roads provide access for recreation, private property and management activities such as wildfire suppression.

Dated: January 3, 2002.

Ron Wenker,

District Manager.

[FR Doc. 02–9598 Filed 4–23–02; 8:45 am]

BILLING CODE 4310–33–P

DEPARTMENT OF THE INTERIOR

Bureau of Land Management

National Park Service

[ID 070–02–1610–DO–051D]

Craters of the Moon National Monument; Land Use Plan and Associated Environmental Impact Statement

AGENCY: Upper Snake River District, Bureau of Land Management, Idaho Falls, Idaho; National Park Service, Craters of the Moon National Monument.

ACTION: Issuance of a Notice of intent to prepare a Resource Management Plan (RMP)/General Management Plan (GMP), and Environmental Impact Statement (EIS) for the Craters of the Moon National Monument. The Monument is located in Blaine, Butte, Lincoln, Minidoka, and Power Counties, Idaho.

SUMMARY: This document announces that the Bureau of Land Management (BLM) and the National Park Service (NPS) intend to jointly prepare a land use plan and associated EIS for the Craters of the Moon National Monument. This planning activity encompasses approximately 739,682 acres of federally managed land. The plan will fulfill the requirements of the National Environmental Policy Act (NEPA), the Federal Land Policy and Management Act (FLPMA, the National Park Service Organic Act, other pertinent statutes, the Presidential Proclamations establishing and expanding the Monument, and the NPS and BLM management policies. The BLM and NPS will work closely with interested parties to identify the management decisions that are best suited to the needs of the public. This collaborative process will take into account local, regional, and national needs and concerns. Publication of this notice initiates the public scoping process to identify planning issues and to develop planning criteria. Formal scoping will last a minimum of 60 days. The scoping process will include an evaluation of the existing land use plans in the context of the needs and interests of the public and protection of the values for which the Monument was established and expanded.

Comments: Open-house public meetings will be held throughout the plan scoping and preparation period. In order to ensure local community participation and input, public meeting locations will be rotated among nearby towns, especially those within a one-hour drive of the Monument. The dates and locations of these meetings will be announced through mailings and local and regional media releases. The notices will also be posted on the National Park Service (*www.nps.gov/crmo*) and Bureau of Land Management (*www.id.blm.gov/planning*) web sites. At least 15 days public notice will be given for activities where the public is invited to attend. Early participation by all those interested is encouraged and will help determine the future management of the Craters of the Moon National Monument. The BLM and NPS are interested in public comment regarding issues to be addressed by this planning effort. Issues identified by the public will help define the alternative management strategies to be analyzed in this conservation planning/environmental impact analysis process. To receive full consideration during alternative formulation, written comments identifying issues to be addressed must be postmarked or transmitted not later than 60 days after the publication of this notice in the **Federal Register**.

Informal public participation is encouraged throughout this process. Open-house meetings will be held to explain the planning/environmental impact analysis process and receive public input. Formal opportunity for public review and comment will be provided upon publication of the joint draft plan and EIS. Documents pertinent to this proposal may be examined at the Craters of Moon National Monument Headquarters, eighteen miles southwest of Arco on U.S. Highway 93, and at the

Shoshone Field Office of the BLM, 400 W F Street, Shoshone, Idaho.

Comments, including names and street addresses of respondents, will be available for public review at the Shoshone Field Office of the BLM, in Shoshone, Idaho, during regular business hours, 7:45 a.m. to 4:30 p.m., Monday through Friday, except holidays, and may be published as part of the EIS. Individual respondents may request confidentiality. If you wish to withhold your name or street address from public review or from disclosure under the Freedom of Information Act, you must state this prominently at the beginning of your written comment. Such requests will be honored to the extent allowed by law. All submissions from organizations and businesses, and from individuals identifying themselves as representatives or officials of organizations or businesses, will be available for public inspection in their entirety.

ADDRESSES: For further information and/or to add your name to our mailing list, contact Rick VanderVoet, BLM Shoshone Field Office, PO Box 2–B, Shoshone, Idaho 83352, telephone (208) 732–7200, or James Morris, NPS, Craters of the Moon National Monument, PO Box 29, Arco, ID 83213, telephone (208) 527–3257.

SUPPLEMENTARY INFORMATION: The expansion of the Craters of the Moon National Monument and the changing needs and interests of the public necessitates development of a new plan for the Monument. Preliminary issues and management concerns have been identified by BLM and NPS personnel, other agencies, and in meetings with individuals and user groups. They represent BLM's and NPS's knowledge to date on the existing issues and concerns with current management. The issue themes that will be addressed in the plan include, but are not limited to: protection of geologic features, cave management, fire and fuels management, cultural resource management, transportation management, recreation management, livestock grazing, land tenure adjustments, wilderness resource management, and designation of management zones. After gathering public comments on what issues the plan should address, the suggested issues will be placed in one of three categories:

1. Issues to be resolved in the plan.

2. Issues resolved through policy or administrative action.

3. Issues beyond the scope of this plan.

Rationale will be provided in the plan for each issue placed in category 2 or 3. An interdisciplinary approach will be used to develop the plan in order to consider the variety of resource issues and concerns identified. Disciplines involved in the planning process will include specialists with expertise in minerals and geology, archaeology, rangeland management, outdoor recreation, wildlife, wilderness, lands and realty, hydrology, soils, sociology, and economics. Where necessary, outside expertise may be used.

Background Information: Presidential Proclamation 1694 established the Craters of the Moon National Monument on May 2, 1924 for the purpose of protecting the unusual landscape of the Craters of the Moon lava field. This ''lunar'' landscape was thought to resemble that of the moon and was described in the Proclamation as a ''weird and scenic landscape peculiar to itself.'' Since 1924, Monument has been expanded and boundary adjustments made through four Presidential Proclamations issued pursuant to the Antiquities Act (34 Stat. 225, 16 U.S.C. 431). Presidential Proclamation 1843 of July 23, 1928, expanded the monument to include certain springs for water supply and additional features of scientific interest. Presidential Proclamation 1916 of July 9, 1930, Presidential Proclamation 2499 of July 18, 1941, and Presidential Proclamation 3506 of November 19, 1962, made further adjustments to the boundaries. In 1996, a minor boundary adjustment was made by section 205 of the Omnibus Parks and Public Lands Management Act of 1996 (Pub. L. 104–333, 110 Stat. 4093, 4106). Presidential Proclamation (7373) of November 9, 2000 is the fifth proclamation affecting the Monument. This latest proclamation directed the National Park Service and Bureau of Land Management to manage the Monument cooperatively. The BLM and NPS propose to use a combined Resource Management Plan (RMP)/General Management Plan (GMP) process to replace portions of five existing BLM Land Use Plans and one NPS General Management Plan. This single, interagency RMP/GMP will establish management objectives for the entire Craters of the Moon National Monument. The proposed, new land use plan will be a stand-alone, comprehensive plan for the recently expanded Monument, and will serve as ''blueprint'' for joint management of these lands during the next 10–15 years.

Dated: April 16, 2002.

Patricia L. Neubacher,

Acting Regional Director, Pacific West Region.

Dated: April 17, 2002.

Elaine Marquis-Brong,

Director, National Conservation Landscape System, Bureau of Land Management.

[FR Doc. 02–9794 Filed 4–23–02; 8:45 am]

BILLING CODE 4310–32–M

DEPARTMENT OF THE INTERIOR

Bureau of Land Management

National Park Service

[AZ 100–02–1610–DO–083A]

Grand Canyon Parashant National Monument

AGENCY: Bureau of Land Management, Arizona Strip Field Office, St. George, Utah; National Park Service, Lake Mead National Recreation Area, Boulder City, Nevada.

ACTION: Notice of Intent to (1) prepare a Resource Management Plan (RMP) for the Grand Canyon Parashant National Monument, designated January 11, 2000, (2) prepare a RMP for the Vermilion Cliffs National Monument, designated November 9, 2000, and (3) revise the 1992 Arizona Strip RMP. These three actions will require a single Environmental Impact Statement (EIS). These lands are located in Mohave and Coconino Counties, Arizona.

SUMMARY: This document provides notice that the Bureau of Land Management (BLM) intends to prepare a RMP with an associated EIS for the Arizona Strip Field Office. BLM will work in cooperation with the National Park Service (NPS) for lands administered by the NPS Lake Mead National Recreation Area in the Grand Canyon Parashant National Monument. Separate plans will be developed for the Vermilion Cliffs National Monument and the Grand Canyon Parashant National Monument. This planning activity encompasses approximately 2,800,000 acres of public land, including 1,052,000 acres in the Grand Canyon Parashant Monument and 293,000 acres in the Vermilion Cliffs National Monument. The plan will fulfill the needs and obligations set forth by the National Environmental Policy Act (NEPA), the Federal Land Policy and Management Act (FLPMA), the National Park Service Organic Act, the Lake Mead National Recreation Area Enabling Legislation, the two monument proclamations, and the NPS and BLM management policies. The BLM will work closely with interested parties to

identify the management decisions that are best suited to the needs of the public. This collaborative process will take into account local, regional, and national needs and concerns. This notice initiates the public scoping process to identify planning issues and to develop planning criteria. The scoping process will include an evaluation of the existing RMP in the context of the needs and interests of the public and protection of the objects of historic and scientific interest specified in the proclamations.

Comments: Public meetings will be held throughout the plan scoping and preparation period. In order to ensure local community participation and input, public meeting locations will be rotated among towns, which could include St. George and Kanab, Utah; Flagstaff, Kingman, Page, and Phoenix, Arizona; and Mesquite and Las Vegas, Nevada. Early participation by all those interested is encouraged and will help determine the future management of the Grand Canyon Parashant and Vermilion Cliffs National Monuments and the Arizona Strip Field Office public lands. The publication of this notice will initiate the BLM and NPS scoping comment period. Scoping will last a minimum of 90 days. At least 15 days public notice will be given for activities where the public is invited to attend. Written comments will be accepted throughout the planning process at the addresses shown below. Meetings and comment deadlines will be announced through the local news media, newsletters and the BLM web site (*www.az.blm.gov*). In addition to the ongoing public participation process, formal opportunities for public participation will be provided through comment on the alternatives and upon publication of the joint BLM draft RMP/EIS and NPS draft General Management Plan (GMP)/EIS. Documents pertinent to this proposal may be examined at the Arizona Strip Field Office located in St. George, Utah. Comments, including names and street addresses of respondents, will be available for public review at the Arizona Strip Field Office located in St. George, Utah, during regular business hours 7:45 a.m. to 4:15 p.m., Monday through Friday, except holidays, and may be published as part of the EIS. Individual respondents may request confidentiality. If you wish to withhold your name or street address from public review or from disclosure under the Freedom of Information Act, you must state this prominently at the beginning of your written comment. Such requests will be honored to the extent allowed by law. All submissions from organizations and businesses, and from individuals identifying themselves as representatives or officials of organizations or businesses, will be available for public inspection in their entirety.

ADDRESSES: For further information and/or to have your name added to our mailing list, contact Dennis Curtis, Telephone 435 688–3202, or Diana Hawks, Telephone 435 688–3266, Bureau of Land Management, Arizona Strip Field Office, 345 E. Riverside Drive, St. George, Utah 84790; Fax 435 688–3388; or Jim Holland, Telephone 702 293–8986, National Park Service, Lake Mead National Recreation Area, 601 Nevada Highway, Boulder City, Nevada 89005; Fax 702 293–8967.

SUPPLEMENTARY INFORMATION: The designation of Grand Canyon Parashant and Vermilion Cliffs National Monuments and the changing needs and interests of the public necessitates a revision of the Arizona Strip RMP, 1992, and Lake Mead National Recreation Area GMP, 1986. Two monument plans and a revised RMP for the remaining BLM Arizona Strip area will be combined into one planning effort. These actions require three separate Records of Decision (ROD)within a single EIS.

Preliminary issues and management concerns have been identified by BLM and NPS personnel, other agencies, and in meetings with individuals and user groups. They represent BLM's and NPS's knowledge to date on the existing issues and concerns with current management. The major issue themes that will be addressed in the plan effort are: management and protection of public land resources, recreation/visitor use and safety; access and transportation on the public lands; integrating monument management with community, tribal, and other agency needs; and balancing multiple uses. After gathering public comments, the suggested issues will be placed in one of three categories:

1. Issues to be resolved in the plan.
2. Issues resolved through policy or administrative action.
3. Issues beyond the scope of this plan.

Rationale will be provided in the plan for each issue placed in category 2 or 3. In addition to the preceding major issues, management questions and concerns to be addressed in the plan include, but are not limited to: ecosystem health, riparian condition, threatened and endangered species habitat, wildlife habitat, reintroduction of native species, cultural resource protection and interpretation, recreation/visitor use, rangeland management, woodland product harvest, and minerals management. The following disciplines will be represented on the BLM/NPS planning team: wilderness, recreation, wildlife, range management, botany, fire ecology, forestry, geology, realty, cultural resources, soils, hydrology, Geographic Information Systems (GIS), and engineering. Where necessary and available, outside expertise will be used.

Background Information: On January 11, 2000, the President signed Proclamation 7265, creating the Grand Canyon Parashant National Monument. The monument encompasses approximately 1,052,000 acres of public lands in Mohave County, Arizona. It borders Nevada to the west and Grand Canyon National Park to the south and BLM managed public lands to the east and north. The Vermilion Cliffs National Monument was established by Presidential Proclamation on November 9, 2000, and is under the administration of the BLM. The monument is located on the Colorado Plateau in northern Arizona. It borders the Kaibab National Forest to the west, Glen Canyon National Recreation Area to the east, and the state of Utah to the north.

The Grand Canyon Parashant National Monument proclamation states that the NPS and the BLM shall manage the monument cooperatively and shall prepare an agreement to share, consistent with applicable laws, whatever resources are necessary to properly manage the monument; however, the NPS shall continue to have primary management authority over the portion of the monument within the Lake Mead National Recreation Area, and the BLM shall have primary management authority over the remaining portion of the monument. The plan will need to address and incorporate, to the extent possible, NPS policies, regulations and management directives.

The Arizona Strip RMP was completed in 1992 and amended in 1998 to implement the Mohave Desert Tortoise Recovery Plan. Several significant multi-discipline plans have recently been completed, including the Mt. Trumbull Resource Conservation Area Plan in 1995 and the Parashant Resource Conservation Area Plan in 1997. The Lake Mead National Recreation Area GMP was completed in 1986, and the Shivwits portion of this plan was revised as part of Parashant Interdisciplinary Plan completed cooperatively by the two agencies in 1997. We anticipate incorporating much

of the information in the existing plans into this plan revision.

Roger G. Taylor,

Arizona Strip Field Manager.

William K. Dickinson,

Lake Mead National Recreation Area, Superintendent.

[FR Doc. 02–9597 Filed 4–23–02; 8:45 am]

BILLING CODE 4310–32–P

DEPARTMENT OF THE INTERIOR

Bureau of Land Management

[AZ 069–01–1610–DO–241E]

Ironwood Forest National Monument

AGENCY: Tucson Field Office, Bureau of Land Management, Tucson, Arizona.

ACTION: Notice of Intent to (1) prepare a Resource Management Plan (RMP) for the Ironwood Forest National Monument, designated on June 9, 2000, and (2) amend the 1989 Phoenix RMP to consider land tenure adjustments in support of the Pima County Sonoran Desert Conservation Plan. These two actions will require a single Environmental Impact Statement (EIS). These lands are located northwest of Tucson in Pima and Pinal Counties, Arizona.

SUMMARY: This document provides notice that the Bureau of Land Management (BLM) intends to prepare a RMP for the Ironwood Forest National Monument and an amendment to the Phoenix RMP to consider land tenure adjustments with one EIS prepared for both plans. The plan development will continue and expand the planning approach in the Tucson Field Office, which means working closely with interested parties to identify the management decisions that are best suited to the needs of the public. This collaborative process will take into account local, regional, and national needs and concerns. The planning effort will include the Ironwood Forest National Monument and other lands managed by the Tucson Field Office. The planning effort will fulfill the needs and obligations set forth by the National Environmental Policy Act (NEPA), the Federal Land Policy and Management Act (FLPMA), the National Monument proclamation, and BLM management policies. This notice also initiates the public scoping process to examine issues and develop planning criteria to guide the planning process. Formal scoping will last a minimum of 60 days. The scoping process will include an evaluation of the existing RMP in the context of the needs and interests of the public and protection of the objects of scientific and historic interest in the National Monument.

ADDRESSES: For further information and/or to have your name added to our mailing list, contact Tony Herrell, Telephone 520–258–7203, Bureau of Land Management, Tucson Field Office, 12661 East Broadway, Tucson, Arizona 85748; Fax 520–258–7238. Comments, including names and street addresses of respondents, will be available for public review at the above address during regular business hours 7:45 a.m. to 4:15 p.m., Monday through Friday, except holidays, and may be published as part of the EIS. Individual respondents may request confidentiality. If you wish to withhold your name or street address from public review or from disclosure under the Freedom of Information Act, you must state this prominently at the beginning of your written comment. Such requests will be honored to the extent allowed by law. All submissions from organizations or businesses, and from individuals identifying themselves as representatives or officials of organizations or businesses, will be made available for public inspection in their entirety.

SUPPLEMENTARY INFORMATION: The designation of the Ironwood Forest National Monument and the changing needs and interests of the public necessitate the development of a RMP for the Ironwood Forest National Monument. In addition, the Phoenix RMP will be amended to address land tenure adjustments in support of the Pima County Sonoran Desert Conservation Plan. These two actions require a single EIS. Public meetings will be held throughout the scoping and preparation period. In order to ensure local community participation and input, meeting locations will occur in local communities in the Tucson area, including Marana, Eloy, Casa Grande, and Picture Rocks, as well as in the Phoenix area. At least 15 days public notice will be given for activities where the public is invited to attend. The minutes and list of attendees for each meeting will be available to the public and open for 30 days to any participants who wish to clarify the views they expressed. Written comments will also be accepted throughout the planning process at the address shown above. Meetings and comment deadlines will be announced through the local news media, newsletters and the BLM web site (*www.az.blm.gov*). Additional opportunities for public participation will be provided through comment on the alternatives and upon publishing the draft RMP/Draft EIS. Documents pertinent to this proposal may be examined at the Tucson Field Office located in Tucson, Arizona. Early participation by all those interested is encouraged and will help determine the future management of the Ironwood Forest National Monument.

Preliminary issues and management concerns have been identified by BLM personnel and other agencies and in meetings with individuals and user groups. They represent BLM's knowledge to date on the existing issues and concerns with current management. The major issue themes that will be addressed in the plan effort are: Management and protection of Monument resources; appropriate scientific research activities; visitor use and safety; identification of protection measures for cultural resources, sensitive plant and animal species and other special resources; public access and transportation within the Monument; commercial and industrial uses; integrating Monument management with tribal, other agency and community needs; and addressing urban interface and land tenure issues. Other issues may be identified by interested parties during the public scoping phase of the planning. After gathering public comments on what issues the plan should address, the suggested issues will be placed in one of three categories:

1. Issues to be resolved in the plan.
2. Issues resolved through policy or administrative action.
3. Issues beyond the scope of this plan.

Rationale will be provided for each issue placed in category 2 or 3. In addition to the preceding major issues, management questions and concerns to be addressed in the plan effort include, but are not limited to: Native American consultation; rangeland management; watershed management; wildlife management; soil, water, and vegetation management; air quality; and hazardous materials. Disciplines corresponding to these issue areas will be represented and used during the planning process. Where necessary, outside expertise may be used.

Background Information: The Ironwood Forest National Monument was created to protect the resources of the Sonoran Desert. The Ironwood Forest National Monument Presidential Proclamation of June 9, 2000, designated about 129,068 acres of land in Pima and Pinal Counties, Arizona, managed by the BLM as the Ironwood Forest National Monument.

Before designation, management of the area was guided by the Phoenix RMP, completed in 1989. Previously

completed wildlife habitat plans, such as the Silverbell Habitat Management Plan, allotment management plans, as well as other activity level plans provide specific management direction and actions on lands within and immediately adjacent to the Ironwood Forest National Monument. As these plans address many significant issues, those decisions that are still valid will be incorporated into the new plan. Pima County, in cooperation with the U.S. Fish and Wildlife Service and with the unanimous endorsement of the Board of Supervisors, spearheaded the planning effort that addressed growth issues in the county, largely related to construction delays because of the identification of threatened and endangered species. This local, collaborative effort involved all interested parties in developing the Sonoran Desert Conservation Plan. This collaborative approach will continue to be used in the planning for the Ironwood Forest National Monument. Among the management prescriptions included in the Sonoran Desert Conservation Plan are the identification of lands critical to threatened and endangered species throughout Pima County, including the recommendation to designate the Ironwood Forest National Monument.

Elaine Marquis-Brong,

Director, National Landscape Conservation System, Bureau of Land Management.

[FR Doc. 02–9594 Filed 4–23–02; 8:45 am]

BILLING CODE 4310–32–P

DEPARTMENT OF THE INTERIOR

Bureau of Land Management

[AZ 400–02–1610–DO–089A]

Sonoran Desert National Monument

AGENCY: Bureau of Land Management, Phoenix Field Office, Phoenix, AZ, Interior.

ACTION: Notice of intent to prepare a Resource Management Plan (RMP) and Environmental Impact Statement (EIS) for the Sonoran Desert National Monument, designated January 17, 2001. These lands are located in Maricopa and Pinal Counties, Arizona.

SUMMARY: This document provides notice that the Bureau of Land Management (BLM), Phoenix Field Office intends to prepare a RMP with an associated EIS. This planning activity encompasses approximately 486,603 acres of public land in the Sonoran Desert National Monument. The plan will fulfill the needs and obligations set forth by the National Environmental Policy Act (NEPA), the Federal Land Policy and Management Act (FLPMA), the monument proclamation, and BLM management policies. The BLM will work closely with interested parties to identify the management decisions that are best suited to the needs of the public. This collaborative process will take into account local, regional, and national needs and concerns. The first phase of the planning process is scoping which includes an evaluation of the existing RMP in the context of the needs and interests of the public and protection of the objects of historic and scientific interest specified in the proclamation, the identification of issues that should be addressed in the planning process, and development of planning criteria.

DATES: The scoping comment period will commence with the publication of this notice. Formal scoping will last a minimum of 60 days.

Public Participation: Public meetings will be held throughout the plan scoping and preparation period. In order to ensure local community participation and input, public meeting locations will be rotated among the towns of Gila Bend, Casa Grande, Yuma, Phoenix, and Tucson, Arizona. Early participation by all those interested is encouraged and will help determine the future management of the Sonoran Desert National Monument. At least 15 days public notice will be given for activities where the public is invited to attend. Written comments will be accepted throughout the planning process. Meetings and comment deadlines will be announced through the local news media, newsletters, and the BLM web site (www.az.blm.gov). In addition to the ongoing public participation process, formal opportunities for public participation will be provided upon publication of the draft RMP/EIS.

ADDRESSES: Sonoran Desert NM Planning, Bureau of Land Management, Phoenix Field Office, 21605 N. 7th Avenue, Phoenix, AZ 85027; Fax 623–580–5580. For further information and/or to have your name added to our mailing list, contact Mike Brown, Telephone 623–580–5503, or Karen Kelleher, Telephone 623–580–5566.

SUPPLEMENTARY INFORMATION: Preliminary issues and management concerns have been identified by BLM personnel, other agencies, and in meetings with individuals and user groups. They represent the BLM's knowledge to date on the existing issues and concerns with current management. Additional issues and modifications to known issues will be identified during public scoping. The major issues that will be addressed in the plan effort include, but are not limited to management and protection of public land resources, including wildlife management and wilderness; recreation/visitor use and safety; access and transportation on the public lands; location and management of utility corridors; suitability and management of grazing; and integration of monument management with state, local community, tribal, and other agency needs and plans.

After gathering public comments on what issues the plan should address, the suggested issues will be placed in one of three categories:

1. Issues to be resolved in the plan;
2. Issues resolved through policy or administrative action; or
3. Issues beyond the scope of this plan.

Rationale will be provided in the plan for each issue placed in category two or three. In addition to these major issues, a number of management questions and concerns will be addressed in the plan. The public is encouraged to help identify these questions and concerns during the scoping phase.

An interdisciplinary approach will be used to develop the plan in order to consider the variety of resource issues and concerns identified. Disciplines involved in the planning process will include rangeland management, minerals and geology, outdoor recreation, archaeology, wildlife, wilderness, lands and realty, hydrology, soils, sociology, and economics. Where necessary, outside expertise may be used.

Elaine Marquis-Brong,

Director, National Landscape Conservation System.

[FR Doc. 02–9587 Filed 4–23–02; 8:45 am]

BILLING CODE 4310–32–P

DEPARTMENT OF THE INTERIOR

Bureau of Land Management

[MT 060–02–1610–DO]

Upper Missouri River Breaks National Monument

AGENCY: Bureau of Land Management, Interior.

ACTION: Notice of Intent to prepare a Resource Management Plan (RMP) for the Upper Missouri River Breaks National Monument, designated January 17, 2001. This action will require a single Environmental Impact Statement (EIS). The planning area is located in Chouteau, Blaine, Phillips and Fergus

Counties. The Monument RMP will be a new management plan and amend a portion of two plans affected by the designation; (1) the West HiLine RMP and (2) Judith-Valley-Phillips RMP.

SUMMARY: This document provides notice that the Bureau of Land Management (BLM) intends to prepare an RMP with an associated EIS for the Upper Missouri River Breaks National Monument. This planning activity encompasses approximately 375,000 acres of public land. The plan will fulfill the needs and obligations set forth by the National Environmental Policy Act (NEPA), the Federal Land Policy and Management Act (FLPMA), the monument proclamation, and BLM management policies. The BLM will work collaboratively with interested parties to identify the management decisions that are best suited to local, regional, and national needs and concerns. The public scoping process will identify planning issues and develop planning criteria, including an evaluation of the West HiLine and Judith-Valley-Phillips RMPs in the context of the needs and interests of the public and protection of the objects of historic and scientific interest specified in the proclamation.

DATES: The publication of this notice will initiate the public scoping comment process which will end after 120 days.Comments on issues and planning criteria can be submitted in writing to the address listed below. All public meetings will be announced through the local news media, newsletter, and the BLM web site (www.mt.blm.gov) at least 15 days prior to the event. The minutes and list of attendees for each meeting will be available to the public and open for 30 days to any participant who wishes to clarify the views they expressed.

Public Participation: Public meetings will be held during the plan scoping and preparation period. In order to ensure local community participation and input, public meeting locations will be in Winifred, Lewistown, Great Falls, Fort Benton, Havre, Chinook, and Malta, Montana. Early participation is encouraged and will help determine the future management of the Upper Missouri River Breaks National Monument public lands. In addition to the ongoing public participation process, formal opportunities for public participation will be provided through comment on the alternatives and upon publication of the BLM draft RMP/EIS. In addition, written comments will be accepted throughout the entire planning process.

ADDRESSES: Written comments should be sent to Gary Slagel, Monument Manager, Bureau of Land Management, Lewistown Field Office, P.O. Box 1160, Lewistown, MT 59457–1160. Documents pertinent to this proposal may be examined at the Lewistown Field Office located in Lewistown, Montana. Comments, including names and street addresses of respondents, will be available for public review at the Lewistown Field Office located in Lewistown, Montana, during regular business hours 7:45 a.m. to 4:30 p.m., Monday through Friday, except holidays, and may be published as part of the EIS. Individual respondents may request confidentiality. If you wish to withhold your name or street address from public review or from disclosure under the Freedom of Information Act, you must state this prominently at the beginning of your written comment. Such requests will be honored to the extent allowed by law. All submissions from organizations and businesses, and from individuals identifying themselves as representatives or officials of organizations or businesses, will be available for public inspection in their entirety.

FOR FURTHER INFORMATION: For further information and/or to have your name added to our mailing list, contact Jerry Majerus, Project Manager, 406–538–1924.

SUPPLEMENTARY INFORMATION: The creation of the Upper Missouri River Breaks National Monument, along with the changing needs and interests of the public, necessitates creation of an RMP for the Monument and an amendment to the West HiLine and Judith-Valley-Phillips RMPs to address some decisions affected by the Monument designation. These actions require a single EIS and one Record of Decision (ROD).

Preliminary issues and management concerns have been identified by BLM personnel, other agencies, and in meetings with individuals and user groups. They represent the BLM's knowledge to date on the existing issues and concerns with current management. The major issue themes that will be addressed in the plan effort include, but are not limited to: Management and protection of public land resources; recreation/visitor use, interpretation and safety; integrating monument management with community, tribal, and other agency needs; and access and transportation on the public lands.

After gathering public comments on what issues the plan should address, the suggested issues will be placed in one of three categories:

1. Issues to be resolved in the plan;

2. Issues resolved through policy or administrative action; or

3. Issues beyond the scope of this plan.

Rationale will be provided in the plan for each issue placed in category two or three. In addition to these major issues, a number of management questions and concerns will be addressed in the plan. The public is encouraged to help identify these questions and concerns during the scoping phase.

An interdisciplinary approach will be used to develop the plan in order to consider the variety of resource issues and concerns identified. Disciplines involved in the planning process will include specialists with expertise in rangeland management, minerals and geology, forestry, outdoor recreation, archaeology, paleontology, wildlife and fisheries, lands and realty, hydrology, soils, sociology and economics. Where necessary and available, outside expertise may be sought to help advise BLM.

Background Information: On January 17, 2001, the President signed a Proclamation creating the Upper Missouri River Breaks National Monument. The monument encompasses approximately 375,000 acres of public land located in north-central Montana in Chouteau, Blaine, Phillips and Fergus Counties, Montana. The area generally corresponds with the Upper Missouri National Wild and Scenic River from Fort Benton downstream to approximately Arrow Creek where it begins to widen out from five to sixteen miles on either side of the Missouri River to the Charles M. Russell National Wildlife Refuge.

A portion of the West HiLine RMP was approved in 1988 and the remainder in 1992 and the Judith-Valley-Phillips RMP was completed in 1994. Several multi-discipline plans have recently been completed, including the Two Calf Watershed Plan (1998), Woodhawk Watershed Plan (1998), and Armells Watershed Plan (2000). The Upper Missouri National Wild and Scenic River Management Plan Update was completed in 1993 and the Missouri River Facility Maintenance/Replacement EA was completed in 1997. Information from these existing plans may be incorporated into the Monument RMP.

Elaine Marquis-Brong,

Director, National Landscape Conservation System, Bureau of Land Management.

[FR Doc. 02–9589 Filed 4–23–02; 8:45 am]

BILLING CODE 4310–32–P

DEPARTMENT OF THE INTERIOR

National Park Service

Draft Supplemental Environmental Impact Statement, General Management Plan Amendment for Visitor & Learning Center Great Basin National Park, White Pine County, NV; Notice of Availability

SUMMARY: Pursuant to § 102(2)(c) of the National Environmental Policy Act of 1969 (Pub. L. 91–190, as amended), the National Park Service, Department of the Interior, has prepared a draft supplemental environmental impact statement to amend the General Management Plan assessing the potential impacts of a proposal to construct a new Visitor/Learning Center on National Park Service administered lands north of the town of Baker, Nevada. The existing General Management Plan called for the construction of a visitor center within the park on Baker Ridge. This conservation planning and environmental impact analysis effort to date has identified and analyzed three alternatives (and appropriate mitigation strategies) for the location of the park's Visitor/Learning Center. The park announced the initiation of the scoping process for this DSEIS on December 2, 1999 in the **Federal Register**.

Proposal and Alternatives: The draft supplemental environmental impact statement (DSEIS) includes three alternatives, including the ''no action'' (existing conditions) alternative. The No Action Alternative assumes that the location of the Visitor/Learning Center would remain unchanged from the existing General Management Plan. The Preferred Alternative amends the General Management Plan to allow locating the new Visitor/Learning Center outside of the main park area, in the town of Baker, Nevada. The Third Alternative amends the General Management Plan to eliminate the Baker Ridge Visitor Center and to maintain the current Lehman Caves Visitor Center as the only orientation facility.

Comments: Printed or CD–ROM copies of the DSEIS are available for public review; in addition the document is posted on the park website at *www.nps.gov/grba*. Inquiries may be directed to: Superintendent, Great Basin National Park, Baker, Nevada, 89311, or telephone (775) 234–7331. Interested individuals, organizations, and agencies wishing to provide comments are encouraged to address these to the Superintendent, Great Basin National Park. All written comments must be postmarked not later than 60 days from the date the EPA publishes its notice of filing of the DSEIS in the **Federal Register** (as soon as this date has been determined it will be announced on the park web site).

If individuals submitting comments request that their name or/and address be withheld from public disclosure it will be honored to the extent allowable by law. Such requests must be stated prominently in the beginning of the comments. There may also be circumstances wherein the NPS will withhold a respondent's identity as allowable by law. As always: NPS will make available to public inspection all submissions from organizations and businesses; and, anonymous comments may not be considered.

Public Meetings: One public meeting will be held in Baker, Nevada. Confirmed details as to specific date and time will be announced in the local newspaper, available at the internet site identified above, or can be obtained by calling the park at (775) 234–7331.

Decision: After the formal DSEIS review period has concluded, all comments and suggestions received will be considered in preparing the final SEIS. Currently the final SEIS is anticipated in the Summer of 2002; its availability will be similarly announced in the **Federal Register**. Subsequently a Record of Decision would be executed no sooner than 30 (thirty) days after the release of the final SEIS. As a delegated EIS, the official responsible for approval is the Regional Director, Pacific West Region; subsequently the official responsible for implementation will be the Superintendent, Great Basin National Park.

Dated: March 21, 2002.

Patricia L. Neubacher,

Acting Regional Director, Pacific West Region.

[FR Doc. 02–10023 Filed 4–23–02; 8:45 am]

BILLING CODE 4310–70–M

DEPARTMENT OF THE INTERIOR

National Park Service

Draft Environmental Impact Statement for the Lake Management Plan; Lake Mead National Recreation Area, Mohave County, AZ and Clark County, NV; Notice of Availability

SUMMARY: Pursuant to section 102(2)(C) of the National Environmental Policy Act of 1969 (Public Law 91–190, as amended), and the Council on Environmental Quality Regulations (40 CFR part 1500–1508), the National Park Service (NPS), Department of the Interior, has prepared a draft environmental impact statement (DEIS) assessing the potential impacts of the proposed Lake Management Plan for Lake Mead National Recreation Area. The DEIS describes and analyzes four alternatives to improve the management of Lakes Mead and Mohave to provide for the long-term protection of park resources while allowing a range of recreational opportunities to support visitor needs.

Specifically, this environmental impact statement evaluates four alternatives for managing the waters and associated shoreline areas of Lake Mead National Recreation Area. Each alternative identifies proposed actions related to recreational opportunity zoning and shoreline zoning, developed areas, facilities and recreational services, recreational conflicts, sanitation and litter, resource protection, and park operations.

This document also is used to make reasoned decisions about whether to continue personal watercraft use at Lake Mead NRA. NPS will make the determination based on the unit's enabling statute, mission, management objectives, resources, values, and other uses, as well as impacts from personal watercraft on the unit (65 FR 15,078—2000). In addition, this DEIS evaluates personal watercraft use within Lake Mead National Recreation Area. Consistent with *Bluewater Network* v. *Stanton,* No. CV02093 (D.D.C. 2000) and the settlement agreement approved by the court on April 11, 2001, the DEIS includes an evaluation of various personal watercraft use alternatives to determine their effects on water quality, air quality, soundscapes, wildlife, wildlife habitat, shoreline vegetation, visitor conflicts, safety, and other appropriate topics.

Scoping

Public meetings were initiated in January, 1993 to solicit early input into the scope and range of issues to be analyzed. A notice of intent announcing the decision to prepare the Lake Management Plan and Environmental Impact Statement was published in the **Federal Register** on May 3, 1993. Between January 1993 and September 2000, a series of public scoping meetings were held throughout the area to solicit early input into the scope and range of issues to be analyzed. Scoping comments continued to be accepted and considered until December 2001.

During this comment period, the NPS facilitated over 100 discussions and briefings to park staff, congressional delegations, elected officials, tribal representatives, public service organizations, educational institutions, and other interested members of the

public. Nearly 1,000 letters concerning the DEIS planning process were received. The major issues raised during this period are summarized in Chapter 1, Purpose and Need for the Action.

Proposed Plan and Alternatives

The DEIS includes three ''action'' alternative and one ''no action'' (existing conditions) alternative. Under all the action alternatives, a Special Regulation would be promulgated to address the continued use of personal watercraft in the recreation area, in accordance with settlement agreement signed by the United States District Court for the District of Columbia on April 12, 2001. This agreement between the NPS and Bluewater Network requires all park units wishing to continue personal watercraft use to promulgate special regulations after an environmental analysis is conducted in accordance with the 1969 National Environmental Policy Act.

Alternative A: No Action, evaluates the impacts from the continuation of the present management direction, as established by the 1986 General Management Plan for Lake Mead NRA. Under this alternative, the lakes would be managed for rural and urban recreational settings, with no restrictions on motorized use except where specifically marked by buoys. Management zoning of recreational activities would continue in the Boulder Beach (Lake Mead) and Katherine Landing (Lake Mohave) areas. Facility expansion authorized under the General Management Plan would occur as funding and resources become available. No new measures to improve water quality and shoreline sanitation would be implemented. No special regulations related to personal watercraft use would be promulgated, therefore, personal watercraft use would be prohibited after September 15, 2002. No regulation would be promulgated to restrict the use of two-stroke engines.

Alternative B emphasizes the primitive recreational opportunity for visitors, imposing the most limits on motorized water recreation, and furnishing the greatest opportunity for solitude. Development would be capped at existing levels, and some uses, such as overnight camping, may be reduced or eliminated from some areas. A boat carrying capacity would be established for both lakes and a 100-foot wakeless zone would be established along the shoreline of the lakes. Boater education would be offered, but not required. The use of portable toilets would be voluntary. The Environmental Protection Agency regulation requiring the marine industry to improve the efficiency of engines by the year 2006 would be adopted at Lake Mead NRA. The NPS would develop a new regulation requiring the exclusive use of the new direct-injection two-stroke engines, or the equivalent, for motorized vessels within one year of the approval of this plan.

Alternative C, the *preferred alternative,* slightly increases the overall level of boating activity. Primitive and semi-primitive areas would comprise about 2 percent of the water surface area. Facility expansion could occur at several existing developed areas: Cottonwood Cove on Lake Mohave and Overton Beach, Echo Bay, Callville Bay and Temple Bar on Lake Mead. Additional public launch facilities could be constructed at Eldorado Canyon along Lake Mohave, and at Stewarts Point on Lake Mead. This alternative also proposes the construction of an access road to improve lake access from Northshore Road. Carrying capacities would be used to reduce crowding. Shoreline zoning to separate recreational uses would be further developed at the Boulder Basin and Katherine Landing areas and a 100-foot wakeless zone would be established along the shoreline of the lakes. The NPS would work with the states to develop uniform boating laws and mandatory boater education programs. Alcohol consumption while operating a boat would be prohibited. Sanitation and public education requirements would be implemented and a clean-up program initiated. Glass containers and styrofoam would be prohibited within the park. The Environmental Protection Agency regulation requiring the marine industry to improve the efficiency of engines by the year 2006 would be adopted at Lake Mead NRA. The NPS would develop a new regulation requiring the exclusive use of the new direct-injection two-stroke engines, or the equivalent, for motorized vessels starting in 2012.

Alternative D, proposes managing the waters of the recreation area for concentrated use. A greater percentage of the lakes would be designated as urban park, with no areas designated as primitive or semi-primitive. Facility expansion could occur at several existing developed areas: Cottonwood Cove on Lake Mohave and Overton Beach, Echo Bay, Callville Bay and Temple Bar on Lake Mead. Additional public launch facilities could be constructed at Eldorado Canyon along Lake Mohave, and at Stewarts Point on Lake Mead. Marina expansion would increase the number of slips proposed in Alternative C. Shoreline zoning would be mandatory and exclusive. A 300-foot wakeless zone would be established along the shoreline of the lakes. This alternative would have the same boater education and shoreline sanitation requirements as the proposed action. Alcohol and glass containers would be banned from the recreation area. No regulation would be promulgated to restrict the use of two-stroke engines.

Comments

The DEIS is now available for public review. Interested persons and organizations wishing to express any concerns or provide relevant information are encouraged to contact the Superintendent, Lake Mead National Recreation Area, 601 Nevada Way, Boulder City, Nevada 89005, or via telephone at (702) 293–8986. A postcard will be sent to agencies and individuals notifying them of the availability of the DEIS. The document may be obtained from the park (printed copy or CD copy); it is also available at area libraries, or electronically via the Lake Mead National Recreation Area Web site *www.nps.gov/lame/LMPdraft/home.htm.*

All written comments must be postmarked no later than 60 days from the date the Environmental Protection Agency posts its notice of filing in the **Federal Register**. The end date for the comment period is not known at this time. Immediately upon determination of this end date, a postcard will be sent to agencies and individuals on the mailing list, and it will be announced on the park Web site.

If individuals submitting comments request that their name or/and address be withheld from public disclosure, it will be honored to the extent allowable by law. Such requests must be stated prominently in the beginning of the comments. There also may be circumstances wherein the NPS will withhold a respondent's identity as allowable by law. As always: NPS will make available to public inspection all submissions from organizations and business; and, anonymous comments may not be considered.

Public Meetings

The NPS will conduct several public meetings to facilitate public review and comment on the DEIS. Although the logistics for these meetings are not yet confirmed, NPS will make this information available in the near future through press releases and via the park Web site. Current details on meeting locations, times, and dates can also be obtained by contacting Park Planner, Jim Holland, at the above address, or by telephone at (702) 293–8986.

Decision

Following the formal DEIS review period, comments received will be considered in preparing the Final EIS (FEIS). The FEIS is anticipated to be completed during summer 2002—its availability will be similarly announced in the **Federal Register**. As this is a delegated EIS, the official responsible for the final decision is the Regional Director, Pacific West Region. The Record of Decision may be approved by the Regional Director not sooner than 30 days after the release of the FEIS; subsequently the official responsible for implementation would be the Superintendent, Lake Mead National Recreation Area.

Dated: April 17, 2002.

Holly Bundock,

Acting Regional Director, Pacific West Region.

[FR Doc. 02–10027 Filed 4–23–02; 8:45 am]

BILLING CODE 4310–70–P

DEPARTMENT OF THE INTERIOR

National Park Service

Biscayne National Park; Notice of Intent To Prepare a Fisheries Management Plan With Environmental Impact Statement

AGENCY: National Park Service, Interior.

ACTION: Notice of Intent to prepare a Fisheries Management Plan with Environmental Impact Statement for Biscayne National Park.

SUMMARY: Notice is hereby given that in accordance with the National Environmental Policy Act of 1969, the U.S. Department of the Interior, National Park Service (NPS) will prepare a Fisheries Management Plan (FMP) with Environmental Impact Statement for Biscayne National Park. The plan will identify the current status of the fishery, describe desired future conditions, develop fisheries management objectives and present a range of alternatives that will directly contribute to the long-term protection and perpetuation of the Park's marine resources. Specific issues to be addressed include commercial and recreational harvest limits, park visitor use/access, availability of educational opportunities about fisheries resources within the Park, conservation and preservation of natural aquatic habitats, and the overall health and vitality of the fishery community. The plan will also address current tackle, techniques, methods, and practices pertaining to the recreational and commercial fisheries.

DATES: To determine the scope of issues to be addressed in the FMP and to identify significant issues related to the project, the NPS will hold three public scoping meetings. The first public meeting will be held in Miami, Florida on May 14, 2002. The second meeting will be held in Homestead, Florida on May 15, 2002, and the third will be held in Key Largo on May 16, 2002. An additional meeting will be held in Miami, Florida on May 13, 2002, to provide an opportunity for the NPS to respond to issues and concerns raised by commercial fishermen. A press release and advance mailing will be sent out providing details about the exact times and locations of each meeting. Representatives of the NPS will be available to discuss issues, resource concerns, and the planning process at each of the public meetings.

ADDRESSES: Any comments or requests for information should be addressed to Rick Clark, Chief, Resource Management, Biscayne National Park, 9700 SW 328th Street, Homestead, FL 33033–5634.

FOR FURTHER INFORMATION CONTACT: (1) Monika Mayr, Assistant Superintendent, Biscayne National Park, 9700 SW 328th Street, Homestead, FL 33033–5634, by telephone at 305–230–1144, ext. 3004 or by e-mail at *Monika_Mayr@nps.gov.* (2) Rick Clark, Chief, Resource Management, Biscayne National Park, 9700 SW 328th Street, Homestead, FL 33033–5634, by telephone at 305–230–1144, ext. 3007 or by e-mail at *Rick_Clark@nps.gov.*

SUPPLEMENTARY INFORMATION: Biscayne National Monument was established by Congress in 1968 (Pub. L. 90–606). The Monument was later expanded in 1974 (PL 93–477), and again in 1980 (Pub. L. 96–287) to its current size of 173,000 acres (270 square miles), when it was also redesignated Biscayne National Park to ''preserve and protect for the education, inspiration, recreation, and enjoyment of present and future generations a rare combination of terrestrial, marine, and amphibious life in a tropical setting of great natural beauty.'' As part of the enabling legislation, Congress recognized ''the unique and special values'' of the resources within the Park as well as the ''vulnerability of these resources to destruction or damage due to easy human access by water.'' Congress therefore directed the NPS to ''manage this area in positive and scientific way in order to protect the area's natural resource integrity.'' With respect to fisheries management, Congress provided additional direction by stipulating in the enabling legislation (Pub. L. 96–287) that ''The Secretary shall preserve and administer the park in accordance with the provisions of the Act of August 25, 1916 (39 Stat. 535; U.S.S. 1–4), as amended and supplemented. The waters within the park shall continue to be open to fishing in conformity with the laws of the State of Florida except as the Secretary, after consultation with appropriate officials of said State, designates species for which, areas and times within which, and methods by which fishing is prohibited, limited, or otherwise regulated in the interest of sound conservation to achieve the purposes for which the park is established.''

Biscayne National Park is predominantly made up of submerged lands (95%), and may generally be divided into three major environments: coral reef, estuarine and terrestrial. The boundaries of the Park are from the mangrove shoreline to the west, extend east to Biscayne Bay (including seagrass communities and shoals), the keys (including hardwood hammocks, mangrove wetlands, sandy beaches and rocky inter-tidal areas), the reef, and continue to a contiguous 60-foot depth contour to the east. The northern boundary for the Park is near the southern extent of Key Biscayne, while the southern boundary is near the northern extent of Key Largo, adjacent to the Barnes Sound and Card Sound areas. This fisheries planning effort will evaluate a range of management recommendations to provide a quality visitor experience while maximizing the protection of the Park's resources.

Public comments received in writing and from the public meetings, including names and home addresses of respondents will be available for public review at the Park office during regular business hours. If you wish to withhold your name and/or address, please state this prominently at the beginning of your comment. Anonymous comments will be included in the public record, however, the NPS is not legally required to consider or respond to anonymous comments. All submissions from organizations or businesses, and from individuals identifying themselves as representatives or officials of organizations or businesses, will also be made available for public inspection in their entirety.

The draft and final fisheries management plans will be distributed to all known interested parties and appropriate agencies. Full public participation by federal, state, and local agencies, as well as other concerned organizations and private citizens, is invited during the scoping process and

after the draft Fisheries Management Plan is prepared.

The responsible official for this environnmental impact statement is Jerry Belson, Regional Director, National Park Service, Southeast Region, 100 Alabama Street S.W., Atlanta, Georgia 30303.

Dated: April 2, 2002.

Patricia A. Hooks,

Acting Regional Director, Southeast Region.

[FR Doc. 02–10024 Filed 4–23–02; 8:45 am]

BILLING CODE 4310–70–M

DEPARTMENT OF THE INTERIOR

National Park Service

Draft Environmental Impact Statement/ General Management Plan Minidoka Internment National Monument Jerome County, ID; Notice of Intent To Prepare an Environmental Impact Statement

SUMMARY: In accord with § 102(c) of the National Environmental Policy Act of 1969 (42 U.S.C. 4321, *et seq.*), the National Park Service is undertaking a conservation planning and environmental impact analysis process for the first General Management Plan (GMP) for the Minidoka Internment National Monument, Idaho. An Environmental Impact Statement (EIS) will be prepared concurrently with the GMP. The GMP is intended to set forth the basic management philosophy for this new unit of the National Park System and provide strategies for addressing issues and achieving identified management objectives for that unit, thus serving as a ''blueprint'' to guide management of natural and cultural resources and visitor use during the next 15–20 years. Development Concept Plans, which guide more detailed, site-specific preservation and development actions may be included with the GMP.

Background

The Minidoka Relocation Center (an area also known as Hunt) was authorized in August 1942 and operated by the War Relocation Authority until October 1945. The Center included over 33,000 acres of land with administrative and residential facilities. There were more than 600 buildings with a peak population of approximately 10,000 Japanese Americans from Washington State, Oregon, and Alaska. Established January 17, 2001, as the 385th unit of the National Park System, the purposes of Minidoka Internment National Monument, which is to be managed by the National Park Service, are to: (a) Protect the historic structures and objects of historic interest on 72.75 acres; and (b) Provide opportunities for public education and interpretation of the internment of Japanese Americans during World War II. This site is located approximately 25 northeast of Twin Falls, Idaho, surrounded by a rural, sparsely populated agricultural community. The site has many ground features that are the remnants of the camp, dominated by the basalt stone masonry foundations of the original entrance area.

Scoping Process

In preparing the EIS/GMP, the National Park Service (NPS) will formulate a range of alternatives to define distinct management strategies for the park, including visitor use and appreciation, and cultural and natural resource protection. Public comment is a key component of this conservation planning process, which will also include identification and evaluation of potential environmental impacts, and appropriate mitigation measures, of each alternative.

Some of the major issues we anticipate addressing in the Minidoka Internment National Monument EIS/GMP are:

—Interpretation and educational activities at the site;
—Educational and interpretation activities pertaining to the site in context with other related themes and sites;
—Natural and cultural resource management;
—Cultural resources research;
—Restoration and protection of the site and its historic structures;
—Park maintenance and sustainability;
—Public access to the Monument and on-site circulation;
—Development of the model visitor experience;
—The desired future conditions of the site;
—Park operations and administration;
—Identification and development of partnerships to effect NPS management strategies, including partnering with adjacent southern Idaho communities and organizations, the Japanese-American communities on the West Coast and throughout the Nation, and all other interested citizens in general; and
—Cooperation with other federal agencies, state, local and tribal governments.

Comments

All interested persons, organizations, agencies, and American Indian tribes wishing to express concerns or provide information about management issues which should be addressed in the upcoming conservation planning and environmental impact analysis process are encouraged to contact the Superintendent. Comments are also sought in regards to a suitable range of alternatives which should be considered in the EIS/GMP, the nature and extent of potential environmental impacts, and appropriate mitigating measures.

All comments received will become part of the public record. If individuals submitting comments request that their name or/and address be withheld from public disclosure, it will be honored to the extent allowable by law. Such requests must be stated prominently in the beginning of the comments. There also may be circumstances wherein the NPS will withhold a respondent's identity as allowable by law. As always, NPS will make available to public inspection all submissions from organizations or businesses and from persons identifying themselves as representatives or officials of organizations and businesses; and, anonymous comments may not be considered.

DATES: We anticipate holding public scoping meetings during the summer or early fall of 2002. Details will be announced widely in local and regional news media and via direct park mailings. All written comments regarding the preparation of the EIS/GMP must be postmarked not later than September 30, 2002, and these should be submitted directly to the Superintendent, Minidoka Internment National Monument, P.O. Box 570, 221 North State Street, Hagerman, Idaho 83332. Current information will be available at (208) 837–4793.

Decision

We expect the draft EIS/GMP to be available for public review during the fall of 2003, with the final document completed in the fall of 2004. Formal announcement of the availability of both documents will be published in the **Federal Register**, as well as publicized via local and regional media. The responsibility for approving the EIS/GMP has been delegated to the National Park Service, and the official responsible for the final decision is the Regional Director, Pacific West Region. Subsequently the official responsible for implementation of the GMP is the Superintendent, Minidoka Internment National Monument.

Dated: April 19, 2002.

P. Daniel Smith,

Acting Director, National Park Service.

[FR Doc. 02–10127 Filed 4–23–02; 8:45 am]

BILLING CODE 4310–70–P

DEPARTMENT OF THE INTERIOR

National Park Service

National Register of Historic Places; Notification of Pending Nominations

Nominations for the following properties being considered for listing in the National Register were received by the National Park Service before April 6, 2002. Pursuant to § 60.13 of 36 CFR part 60 written comments concerning the significance of these properties under the National Register criteria for evaluation may be forwarded by United States Postal Service, to the National Register of Historic Places, National Park Service, 1849 C St. NW., NC400, Washington, DC 20240; by all other carriers, National Register of Historic Places, National Park Service, 800 N. Capitol St. NW., Suite 400, Washington DC 20002; or by fax, 202–343–1836. Written or faxed comments should be submitted by May 9, 2002.

Carol D. Shull,

Keeper of the National Register Of Historic Places.

Alabama

Colbert County

Sheffield Downtown Commercial District, Roughly bounded by Sixth St., Austin Ave, Fourth St., Pittsburg St., First St., and Columbia Ave., Sheffield, 02000483

Sheffield Residential Historic District, Roughly bounded by Riverside Pk, River Bluff Dr., Wood, Third, Second Sts., 15th Ave., 27th St., and 19th Ave., Sheffield, 02000481

Etowah County

Alabama City Wall Street Historic District, Roughly along Wall St., from Norris Ave. to Meighan Blvd., Gadsden, 02000484

Jackson County

Bridgeport Historic District, Roughly bounded by Bridgeport City Limits, Enrich Ave., Bridgeport, 5th Ave., Broadway Ave., 8th St., and 11th Ave., Bridgeport, 02000479

Jefferson County

Downtown Bessemer Historic District (Boundary Increase), Roughly along 19th St., 4th Ave., and Carolina Ave., Bessemer, 02000480

Hollywood Historic District, Roughly bounded by Al 31, AL 280 and Lakeshore Dr., Homewood, 02000482

Marshall County

Kate Duncan Smith Daughters of the American Revolution School, 6077 Main St., Grant, 02000478

Arkansas

Jefferson County

Sherrill Methodist Episcopal Church, South, 301 Main St., Sherrill, 02000487

Montgomery County

Caddo Valley Academy Complex, 234 Hettie St., Norman, 02000485

Randolph County

Pocahontas Post Office, 109 Van Bibber St., Pocahontas, 02000488

Scott County

Scott City County Jail, (Old), 125 W. 2nd St., Waldron, 02000486

California

Sacramento County

Sandy Cove, Address Restricted, Sacramento, 02000489

Florida

Gulf County

USCG Cutter DUANE, 1 mi. S of Molasses Reef, Key Largo, 02000494

Volusia County

Orange City Town Hall, 205 E. Graves Ave., Orange City, 02000493

Illinois

Cook County

Raymond Park Apartments, (Suburban Apartment Buildings in Evanston TR) 1501 Hinman and 425 Grove, Evanston, 02000503

Iowa

Van Buren County

Goodin Building, North 106 Front St., Farmington, 02000505

Kansas

Marion County

Schaeffler, William F. and Ida G., House, 312 E. Grand, Hillsboro, 02000490

Osborne County

IOOF Lodge, Jct. of Nicholas and Mill Sts., Alton, 02000491

Shawnee County

Union Pacific Railroad Passenger Depot, (Railroad Resources of Kansas MPS) 701 N. Kansas Ave., Topeka, 02000492

North Carolina

Duplin County

Utley—Council House, (Wake County MPS) NC 1390, near jct. with NC 1387, Apex, 02000498

Wake County

Bloomsbury Historic District, (Five Points Neighborhoods, Raleigh, North Carolina MPS) Roughly bounded by Fairview Rd., St. Mary's St., Byrd St., Sunset Dr. and Whitaker Mill Rd., Raleigh, 02000497

Fuquay Springs High School, (Wake County MPS) 112 N. Ennis St., Fuquay-Varina, 02000495

Graves, Willis M., House, (Oberlin, North Carolina MPS) 802 Oberlin Rd., Raleigh, 02000500

Hall, Rev. Plummer T., House, (Oberlin, North Carolina MPS) 814 Oberlin Rd., Raleigh, 02000501

Hayes Barton Historic District, (Five Points Neighborhoods, Raleigh, North Carolina MPS) Roughly bounded by St. Mary's St., Fairview Rd., Aycock St., Scales St. and Williamson Dr., Raleigh, 02000496

Latta, Rev. M.L., House, (Oberlin, North Carolina MPS) 1001 Parker St., Raleigh, 02000502

Turner, John T. and Mary, House, (Oberlin, North Carolina MPS) 1002 Oberlin Rd., Raleigh, 02000499

Pennsylvania

Luzerne County

Wyoming Monument, US 11, Wyoming Ave. and Susquehanna St., Wyoming Borough, 02000509

Utah

Cache County

Richmond Interurban Depot, Address Restricted, Richmond, 02000508

Carbon County

Bruno, Giacomo and Maria, House and Farmstead, 524 N. Main St., Helper, 02000506

Sanpete County

Fairview Amusement Hall, 75 S. State St., Fairview, 02000507

Summit County

Watson, Patrick B., House, (Residences of Mining Boom Era Park City MPS) 962 Norfolk Ave., Park City, 02000504

Virginia

Appomattox County

Appomattox Historic District, Roughly along High, Church, Highland, VA 131, Linden, Lee Grant, Oakleigh and Evergreen, Appomattox, 02000510

Arlington County

Lyon Village Historic District, Roughly bounded by Lee Hwy, N. Veitch St., N. Franklin Rd., N. Highland St., N. Fillmore St., and N. Kirkwood Rd., Arlington, 02000512

Campbell County

Oak Grove, 7378 Gladys Rd., Altavista, 02000516

Carroll County

Hillsville Historic District, 300–500 Blks of Main St., Hillsville, 02000522

Pless, A.G., Jr. House, 942 Glendale Rd., Galax, 02000526

Floyd County

Glenanna, 204 W. Main St., Floyd, 02000523

Frederick County

Opequon Historic District, Jct. of VA 622 and VA 620, Winchester, 02000515

Fredericksburg Independent city Washington Avenue Historic District, 1200–1500 blks of Washington Ave., and 620 Lewis St., Fredericksburg (Independent City), 02000518

Hanover County

Montpelier Historic District, Roughly along Mountain Rd., Montpelier, 02000517

Henrico County

Rocky Mills, 211 Ross Rd., Richmond, 02000513

Mecklenburg County

Boydton Historic District, Roughly the Boydton corporate limits except for section including and NW of VA 58, Boydton, 02000511

Richmond Independent city Manchester Residential and Commercial Historic District, Roughly bounded by 9th St., McDonough St., Cowardin Ave., and Stockton St. Richmond (Independent City), 02000521

Union Hill Historic District, Roughly bounded by 25th, Carrington, and Mosby Sts., and Jefferson Ave., Richmond (Independent City), 02000520

Tazewell County

Tazewill Historic District, Main, Church, Tower, and Pine Sts., and Central Ave., Tazewell, 02000519

Warren County

Riverton Historic District, Roughly along Crisman Dr., Duck St., Old Winchester Pike, Queens Hwy., Riverside Dr., Rugby St., and Strasburg Rd., Front Royal, 02000514

Washington County

Grove, The, 14071 Lee Hwy, Bristol, 02000525

Wise County

Hotel Norten, 798 Park Ave., Norton, 02000524

[FR Doc. 02–10025 Filed 4–23–02; 8:45 am]

BILLING CODE 4310–70–P

DEPARTMENT OF THE INTERIOR

National Park Service

National Register of Historic Places; Notification of Pending Nominations

Nominations for the following properties being considered for listing in the National Register were received by the National Park Service before April 13, 2002. Pursuant to § 60.13 of 36 CFR part 60 written comments concerning the significance of these properties under the National Register criteria for evaluation may be forwarded by United States Postal Service, to the National Register, National Park Service, 1849 C St. NW., NC400, Washington, DC 20240; by all other carriers, National Register of Historic Places, National Park Service, 800 N. Capitol St. NW., Suite 400, Washington, DC 20002; or by fax, 202–343–1836. Written or faxed comments should be submitted by May 9, 2002.

Carol D. Shull,

Keeper of the National Register of Historic Places.

Alaska

Nome Borough-Census Area, Bureau of Indian Affairs Unalakleet School, Unalakleet Native Reservation, Unalakleet, 02000536

California

Del Norte County

BROTHER JONATHAN (Shipwreck Site), About 4.5 mi. W of Pt. St. George, Crescent City, 02000535

San Bernardino County

El Garces, 950 Front St., Needles, 02000537

Colorado

Routt County

Routt County National Bank Building, 802–806 Lincoln Ave., Steamboat Springs, 02000538

Georgia

Fulton County

Southern Railway North Avenue Yards Historic District, 539 John St. NW, Atlanta, 02000539

Laurens County

Dublin Commercial Historic District, Roughly centered on Jackson Ave. and Lawrence St., Dublin, 02000540

Illinois

Cook County

Wooden Alley, 1535 N bet. Astor and State Sts., Chicago, 02000543

Henry County

Music Pavilion, 1208 5th St., Orion, 02000544

Kane County

Elgin Tower Building, 100 E. Chicago St., Elgin, 02000542

Iowa

Polk County

Fleming Building, 218 6th Ave., Des Moines, 02000541

Kansas

Reno County

Soldiers and Sailors Memorial, First Ave. and Walnut St., Hutchinson, 02000557

Sedgwick County

Gelbach House, 1721 Park Place, Wichita, 02000545

Wyandotte County

Quindaro Townsite, Address Restricted, Kansas City, 02000547

Massachusetts

Middlesex County

Goodnow Library, 21 Concord Rd., Sudbury, 02000549

Suffolk County

Bennington Street Burying Ground, Bennington St., bet. Swift and Harmony Sts., Boston, 02000548

Montana

Park County

North Entrance Road Historic District, (Yellowstone National Park MPS) Yellowstone National Park, Yellowstone National Park, 02000529

New York

Delaware County

New Kingston Presbyterian Church, CR 6, New Kingston, 02000554

Erie County

Williamsville Christian Church, 5658 Main St., Williamsville, 02000546

New York County

Building at 19 Rector St., 19 Rector St., 88 Greenwich St., New York, 02000551

Otsego County

Oneonta Theatre, 47 Chestnut St., Oneonta, 02000555

Warren County

CADET (Shipwreck), Address Restricted, Bolton, 02000553

Westchester County

Philipsburgh Building, 2–8 Hudson St., Yonkers, 02000552

Ohio

Cuyahoga County

Harvard School, 6900 Harvard Ave., Cleveland, 02000550

Pennsylvania

Allegheny County

Fulton Building, 107 Sixth St., Pittsburgh, 02000556

South Carolina

Aiken County

Warrenville Elementary School, 115 Timmerman St., Warrenville, 02000560

Hampton County

Stoney Creek Independent Presbyterian Chapel of Prince William Parish, McPhersonville, McPhersonville, 02000559

Horry County

Socastee Historic District, SC 544, 0.5 mi. N of Indtracoastal Waterway, Socastee, 02000558

Texas

Hays County

Kyle City Hall, 109 Burleson Rd., Kyle, 02000528

Winters—Wimberley House, 14070 Ranch Road 12, Wimberley, 02000527

Virginia

Loudoun County

Leesburg Historic District (Boundary Increase), Roughly bounded by North,

Union Sts., Morven Park Rd., and Harrison St., Leesburg, 02000531

Louisa County

Harris—Poindexter House and Store, 81 Tavern Rd., Mineral, 02000534

Mecklenburg County

Oakley, 10,000 Corbin Ln., Spotsylvania, 02000533

Norfolk Independent city Colonial Place, Roughly bounded by the Lafayette R., Knitting Mill Creek, East Haven Creek and 38th St., Norfolk, 02000532

Wyoming

Park County

North Entrance Road Historic District, (Yellowstone National Park MPS) Yellowstone National Park, Yellowstone National Park, 02000530

[FR Doc. 02–10026 Filed 4–23–02; 8:45 am]

BILLING CODE 4310–70–P

DEPARTMENT OF LABOR

Employment and Training Administration

Notice of Determinations Regarding Eligibility To Apply for Worker Adjustment Assistance and NAFTA Transitional Adjustment Assistance

In Accordance with section 223 of the Trade Act of 1974, as amended, the Department of Labor herein presents summaries of determinations regarding eligibility to apply for trade adjustment assistance for workers (TA–W) issued during the period of April, 2002.

In order for an affirmative determination to be made and a certification of eligibility to apply for worker adjustment assistance to be issued, each of the group eligibility requirements of section 222 of the Act must be met.

(1) That a significant number or proportion of the workers in the workers' firm, or an appropriate subdivision thereof, have become totally or partially separated,

(2) That sales or production, or both, of the firm or subdivision have decreased absolutely, and

(3) That increases of imports of articles like or directly competitive with articles produced by the firm or appropriate subdivision have contributed importantly to the separations, or threat thereof, and to the absolute decline in sales or production.

Negative Determinations for Worker Adjustment Assistance

In each of the following cases the investigation revealed that criterion (3) has not been met. A survey of customers indicated that increased imports did not contribute importantly to worker separations at the firm.

TA–W–40,282; Key Plastic, LLC, Felton, PA

TA–W–40,649; Bank Manufacturing Co., Havelock, NC

TA–W–40,781; Creative Leather and Vinyl, Milwaukee, WI

TA–W–40,829; Scientific Molding Corp., Brownsville, TX

TA–W–41,079; Exide Technologies transportation Business Group, Florence, MS

TA–W–41,203; Midwest International, Inc. d/b/a Midwest Manufacturing Co., Stanberry, MO

In the following cases, the investigation revealed that the criteria for eligibility have not been met for the reasons specified.

Increased imports did not contribute importantly to worker separations at the firm.

TA–W–41,086; Abbott Laboratories, Laurinburg, NC

TA–W–39,912 & A; Allen Edmonds Shoe Corp., d/b/a/ Maine Shoe, Lewiston, ME and Wilton, ME

TA–W–40,312; Timex Corp., Little Rock, AR

TA–W–40,890; Hutchinson Technology, Inc., Hutchinson, MN

TA–W–40,366; Mike Dent Enterprises, Burns, OR

TA–W–40,076 & A,B,C,D,F; Rockwell Automation, Components and Packaged Application Group, Department 214, Department 238, Department 240, Department 245, Department 250/270, Department 260, Milwaukee, WI

The workers firm does not produce an article as required for certification under Section 222 of the Trade Act of 1974.

TA–W–40,628; Erickson Air-Crane Co., Central Point, OR

TA–W–41,145; US Ecology-Idaho, A Div. of American Ecology Corp., Sterling, IL

TA–W–40,677; Purcell Tire Co., Silver City, NM

TA–W–40,732; LM Services, Cumberland, MD

Affirmative Determinations for Worker Adjustment Assistance

The following certifications have been issued; the date following the company name and location of each determination references the impact date for all workers of such determination.

TA–W–40,364; Nutec Tooling Systems, Inc., Meadville, PA: October 15, 2000.

TA–W–40,399; Hermes Floral, Becker, MN: October 17, 2002.

TA–W–41,180; Johnston and Murphy Manufacturing, a Div. of Genesco, Inc., Nashville, TN: February 20, 2001.

TA–W–40,076E; Rockwell Automation, Components and Packaged Application Group, Department 255, Milwaukee, WI: September 6, 2000.

TA–W–40,076F; Rockwell Automation, Components and Packaged Application Group, Department 260, Milwaukee, WI: September 6, 2000. ''All workers engaged in the production of NEMA disconnects and IEC contactors are certified''.

TA–W–41,229; Precision Kidd Steel Co., Inc., Aliquippa, PA: April 1, 2001.

TA–W–41,190; TRW, Inc., TRW Automotive, Cookville, TN: February 22, 2001.

TA–W–41,060; Brooks Instruments, a Div. of Emerson Process Management, Hatfield, PA: February 7, 2001.

TA–W–41,008; Mars Footwear, Inc., Elizabethville, PA: February 11, 2001.

TA–W–40,834; Levolor Kirsch Window Fashions, Wood and Faux Wood Custom Window Coverings Department, Westminster, CA: January 28, 2001.

TA–W–40,822; Emerson Electric Co., Daniel Measurement and Control, Statesboro, GA: January 21, 2001.

TA–W–40,819; Schumacher Electric Corp., Hoopeston 001, Hoopeston, IL: January 28, 2001.

TA–W–40,694; Commercial Warehouse and Cartage, Inc., El Paso, TX: November 18, 2000.

TA–W–39,710 & A; Ogden Manufacturing Co., Orfordville, WI and Albany, WI: July 12, 2000.

Also, pursuant to Title V of the North American Free Trade Agreement Implementation Act (Pub. L. 103–182) concerning transitional adjustment assistance hereinafter called (NAFTA–TAA) and in accordance with section 250(a), Subchapter D, Chapter 2, Title II, of the Trade Act as amended, the Department of Labor presents summaries of determinations regarding eligibility to apply for NAFTA–TAA issued during the month of April, 2002.

In order for an affirmative determination to be made and a certification of eligibility to apply for NAFTA–TAA the following group eligibility requirements of section 250 of the Trade Act must be met:

(1) That a significant number or proportion of the workers in the workers' firm, or an appropriate subdivision thereof, (including workers in any agricultural firm or appropriate subdivision thereof) have become totally or partially separated from employment and either–

(2) That sales or production, or both, of such firm or subdivision have decreased absolutely,

(3) That imports from Mexico or Canada of articles like or directly competitive with articles produced by such firm or subdivision have increased, and that the increases imports contributed importantly to such workers' separations or threat of separation and to the decline in sales or production of such firm or subdivision; or

(4) That there has been a shift in production by such workers' firm or subdivision to Mexico or Canada of articles like or directly competitive with articles which are produced by the firm or subdivision.

Negative Determinations NAFTA–TAA

In each of the following cases the investigation revealed that criteria (3) and (4) were not met. Imports from Canada or Mexico did not contribute importantly to workers' separations. There was no shift in production from the subject firm to Canada or Mexico during the relevant period.

NAFTA–TAA–05559; Mike Dent Enterprises, Burns, OR
NAFTA–TAA–05627; Freightliner, Parts Manufacturing Plant, Gastonia, NC
NAFTA–TAA–05834; Brooks Instruments, a Div. Of Emerson Process Management, Hatfield, PA
NAFTA–TAA–05347; Polyone Corp., Plastic Compounds and Colors Group, Corona, CA
NAFTA–TAA–05404; Glad Rags, Inc., Buchanan, VA
NAFTA–TAA–05866; Exide Technologies, Transportation Business Group, Florence, MS
NAFTA–TAA–05915; Gunderson, Inc., Portland, OR

The investigation revealed that criteria (2) has not been met. Sales or production did not decline during the relevant period as required for certification.

NAFTA–TAA–5931; Howmet Castings of Wichita Falls, Wichita Falls, TX

Affirmative Determinations NAFTA–TAA

NAFTA–TAA–05842; Schumacher Electric Corp., Hoopeston 001, Hoopeston, IL: January 28, 2001.
NAFTA–TAA–05900; Johnston and Murphy Manufacturing, A Division of Genesco, Inc., Nashville, TN: February 25, 2001.
NAFTA–TAA–05906; Laclede Steel Co., Alton, IL: February 14, 2001.
NAFTA–TAA–5098 & A; Ogden Manufacturing Co., Orfordville, WI and Albany, WI: July 17, 2000.
NAFTA–TAA–05790; Owens Illinois, Plastic Containers Div., Newburyport, MS: January 9, 2001.
NAFTA–TAA–05794; Emerson Electric Co., Daniel Measurement and Control, Statesboro, GA: January 21, 2001.
NAFTA–TAA–05849; Levolor Kirsch Window Fashions, Wood and Faux Wood Custom Window Coverings Department, Westminster, CA: February 4, 2001.
NAFTA–TAA–05986; Nice Ball Bearing Co., A Subsidiary of Roller Bearing Corp., Kulpsville, PA: February 27, 2001.

I hereby certify that the aforementioned determinations were issued during the month of April, 2002. Copies of these determinations are available for inspection in Room C–5311, U.S. Department of Labor, 200 Constitution Avenue, NW., Washington, DC 20210 during normal business hours or will be mailed to persons who write to the above address.

Dated: April 12, 2002.

Edward A. Tomchick,

Director, Division of Trade Adjustment Assistance.

[FR Doc. 02–10051 Filed 4–23–02; 8:45 am]

BILLING CODE 4510–30–M

DEPARTMENT OF LABOR

Employment and Training Administration

[TA–W–40,476]

A.S. Haight & Company, Inc. Cartersville, GA; Notice of Termination of Investigation

Pursuant to section 221 of the Trade Act of 1974, an investigation was initiated on December 21, 2001, in response to a worker petition which was field by the UNITE! Southern Regional Joint Board, Local 308, on behalf of workers at Haight & Company, Inc., Cartersville, Georgia.

The petitioning group of workers are subject to an ongoing investigation for which a determination has not yet been issued (TA–W–40,392). Consequently, further investigation in this case would serve no purpose, and the investigation has been terminated.

Signed at Washington, DC, this 12th day of April, 2002.

Linda G. Poole,

Certifying Officer, Division of Trade Adjustment Assistance.

[FR Doc. 02–10050 Filed 4–23–02; 8:45 am]

BILLING CODE 4510–30–M

DEPARTMENT OF LABOR

Employment and Training Administration

Investigations Regarding Certifications of Eligibility To Apply for NAFTA Transitional Adjustment Assistance

Petitions for transitional adjustment assistance under the North American Free Trade Agreement-Transitional Adjustment Assistance Implementation Act (Pub. L. 103–182), hereinafter called (NAFTA–TAA), have been filed with State Governors under Section 250(b)(1) of Subchapter D, Chapter 2, Title II, of the Trade Act of 1974, as amended, are identified in the Appendix to this Notice. Upon notice from a Governor that a NAFTA–TAA petition has been received, the Director of the Division of Trade Adjustment Assistance (DTAA), Employment and Training Administration (ETA), Department of Labor (DOL), announces the filing of the petition and takes action pursuant to paragraphs (c) and (e) of Section 250 of the Trade Act.

The purpose of the Governor's actions and the Labor Department's investigations are to determine whether the workers separated from employment on or after December 8, 1993 (date of enactment of Pub.L. 103–182) are eligible to apply for NAFTA–TAA under Subchapter D of the Trade Act because of increased imports from or the shift in production to Mexico or Canada.

The petitioners or any other persons showing a substantial interest in the subject matter of the investigations may request a public hearing with the Director of DTAA at the U.S. Department of Labor (DOL) in Washington, DC provided such request if filed in writing with the Director of DTAA not later than May 6, 2002.

Also, interested persons are invited to submit written comments regarding the subject matter of the petitioners to the Director of DTAA at the address shown below not later than May 6, 2002.

Petitions filed with the Governors are available for inspection at the Office of the Director, DTAA, ETA, DOL, Room 5311, 200 Constitution Avenue, NW., Washington, DC 20210.

Signed at Washington, DC this 16th day of April, 2002.

Edward A. Tomchick,

Director, Division of Trade Adjustment Assistance.

APPENDIX

Subject	Location	Date received at Governor's office	Petition	Articles produced
DY Marketing—SML Label (USA) (Wkrs).	San Francisco, CA	04/10/2002	NAFTA–6,064	Clothing labels.
American Tramways (Wkrs)	Waterstown, NY	10/03/2002	NAFTA–6,065	Trams, ski-lift components.
Motorola (Wkrs)	Mesa, AZ	03/25/2002	NAFTA–6,066	Radio tranceivers.
Ericsson, Inc. (Wkrs)	Lynchburg, VA	04/01/2002	NAFTA–6,067	Cellular phones.
Jahil Circuits (Wkrs)	Auburn Hills, MI	03/18/2002	NAFTA–6,068	Electronic circuit boards.
Flex Print (Wkrs)	Moonestown, NJ	04/15/2002	NAFTA–6,069	Foil packaging.
Williamson Dickie (Wkrs)	McAllen, TX	04/15/2002	NAFTA–6,070	Work pants.
Jervia B. Wabb (USWA)	New Hudson, MI	04/12/2002	NAFTA–6,071	Switches, roller turns, drives, etc.
Germantown USA (Co.)	West Chester, PA	04/08/2002	NAFTA–6,072	Stablizers, dry blending.
American Tissue Mill (PACE)	Menasha, WI	04/13/2002	NAFTA–6,073	Napkins, tissue, bath, facial etc.
American Dawn (Wkrs)	Compton, CA	04/08/2002	NAFTA–6,074	Pillows and restaurant wear.
Lockheed Martin Distribution Technologie (Wkrs).	Tulsa, OK	04/10/2002	NAFTA–6,075	Assembly of postal pre-sort machines.
Shiloh Industries (Wkrs)	Canton, MI	04/08/2002	NAFTA–6,076	Built dies for the auto.
Boeing Company (The) (Wkrs)	El Paso, TX	04/10/2002	NAFTA–6,077	Electronic components.
Conring, Inc. (Wkrs)	Wilmington, NC	04/09/2002	NAFTA–6,078	Optical fiber.
Sterling Fluid Systems (IBT)	White Pigeon, MI	04/08/2002	NAFTA–6,079	Pump castings.
Wellon, Inc. (Co.)	Marion, SC	04/09/2002	NAFTA–6,080	Polyester fiber, resin and nylon resin.
Cummins Power Generation (Wkrs).	Fridley, MN	04/11/2002	NAFTA–6,081	Alternators.
Pleatz LLC (Wkrs)	New York, NY	08/30/2001	NAFTA–6,082	Sportswear.
MJM Knitwear (Wkrs)	Brookly, NY	08/23/2001	NAFTA–6,083	Ladies and men sweaters.
Pohlman Foundry—Lionheart Industries (Wkrs).	Buffalo, NY	09/12/2001	NAFTA–6,084	Iron castings.
London Harness and Cable (Wkrs)	Trenton, NJ	03/06/2002	NAFTA–6,085	Cable.
Scapa North America (Wkrs)	Watertown, NY	08/12/2001	NAFTA–6,086	Pressure sensitive tapes.
International Paper (Co.)	Corinth, NY	07/27/2001	NAFTA–6,087	Coated papers.
Zinc Corporation of American (Wkrs).	Hailesboro, NY	08/13/2001	NAFTA–6,088	Zinc concentrate.
Delphi Harrison Thermal Systems (Wkrs).	Lockport, NY	08/21/2002	NAFTA–6,089	Thermal systems products.
VC Sportswear (Wkrs)	New York, NY	08/20/2001	NAFTA–6,090	Children's apparel.
Cooper's Industries (IBEW)	Syracuse, NY	08/28/2001	NAFTA–6,091	Sealing fitting.
Levcor International (Wkrs)	New York, NY	09/18/2001	NAFTA–6,092	Fabrics.
RHO Industries (Co.)	Buffalo, NY	04/09/2002	NAFTA–6,093	Parts of men's suits.
L.G. Philips Display (Co.)	Ottawa, OH	04/12/2002	NAFTA–6,094	Picture tubes.
Levi Strauss and Co. (Co.)	Brownsville, TX	04/15/2002	NAFTA–6,095	Jeans and khaki casual dress pants.
Intimate Touch (Co.)	New York, NY	03/21/2002	NAFTA–6,096	Lace.
Amloid (Co.)	Saddle Brook, NJ	03/02/2002	NAFTA–6,097	Toys.
Leviton Manufacturing (Wkrs)	El Paso, TX	04/13/2002	NAFTA–6,098	Electrical wiring devices.

[FR Doc. 02–10059 Filed 4–23–02; 8:45 am]

BILLING CODE 4510–30–M

DEPARTMENT OF LABOR

Employment and Training Administration

[TA–W–40,600]

Fiber Tech Group Inc., Landisville, New Jersey; Notice of Termination of Investigation

Pursuant to section 221 of the Trade Act of 1974, an investigation was initiated on January 22, 2002, in response to a worker petition which was filed by a company official on behalf of workers at Fiber Tech Group Inc., Landisville, New Jersey.

The petitioner has requested that the petition be withdrawn. Consequently, further investigation in this case would serve no purpose, and the investigation has been terminated.

Signed in Washington, DC this 16th day of April, 2002.

Linda G. Poole,

Certifying Officer, Division of Trade Adjustment Assistance.

[FR Doc. 02–10048 Filed 4–23–02; 8:45 am]

BILLING CODE 4510–30–M

DEPARTMENT OF LABOR

Employment and Training Administration

Investigations Regarding Certifications of Eligibility To Apply for Worker Adjustment Assistance

Petitions have been filed with the Secretary of Labor under Section 221(a) of the Trade Act of 1974 (''the Act'') and are identified in the Appendix to this notice. Upon receipt of these petitions, the Director of the Division of Trade Adjustment Assistance, Employment and Training Administration, has instituted investigations pursuant to Section 221(a) of the Act.

The purpose of each of the investigations is to determine whether the workers are eligible to apply for

adjustment assistance under Title II, Chapter 2, of the Act. The investigations will further relate, as appropriate, to the determination of the date on which total or partial separations began or threatened to begin and the subdivision of the firm involved.

The petitioners or any other persons showing a substantial interest in the subject matter of the investigations may request a public hearing, provided such request is filed in writing with the Director, Division of Trade Adjustment Assistance, at the address shown below, not later than May 6, 2002.

Interested persons are invited to submit written comments regarding the subject matter of the investigations to the Director, Division of Trade Adjustment Assistance, at the address shown below, not later than May 6, 2003.

The petitions filed in this case are available for inspection at the Office of the Director, Division of Trade Adjustment Assistance, Employment and Training Administration, U.S. Department of Labor, Room C–5311, 200 Constitution Avenue, NW., Washington, DC 20210.

Signed at Washington, DC, this 4th day of March, 2002.

Edward A. Tomchick,

Director, Division of Trade Adjustment Assistance.

APPENDIX

[Petitions Instituted on 03/04/2002]

TA–W	Subject Firm (Petitioners)	Location	Date of petition	Product(s)
40,873	Genalite Corp (Wrks)	Jessup, PA	01/18/2002	Christmas Trees.
40,874	3M Corp (Comp)	Bedford Park, IL	01/25/2002	Pressure Sensitive Tape.
40,875	Graham Tech, Inc. (Comp)	Cochranton, PA	11/26/2002	Tool Maker.
40,876	Springfield Precision (Wrks)	Woodridge, NJ	10/25/2002	Thermometers, Timers and Barometers.
40,877	ESP/Jocassee Trading Co (Comp)	Easley, SC	09/24/2001	Sheetsets comforters and pillows.
40,878	JTD, Inc. (Comp)	Tigard, OR	08/09/2001	Cast Molds.
40,879	Sheldahl Northfield (Wrks)	Northfield, MN	10/31/2001	Flexible Circuity.
40,880	Madill Equipment (Wrks)	Eugene, OR	11/27/2001	Yarders Loaders Limbers Logs.
40,881	Choctaw Electronics (Wrks)	Philadelphia, MS	10/05/2001	Car speakers.
40,882	Bassett Mirror Co (Wrks)	Bassett,	10/29/2001	Bassett Mirrors Occasional Tables.
40,883	Iomega Corp (Wrks)	Roy, UT	10/23/2002	Zip Drives Jaz Drives.
40,884	Tracy Minntronix Corp (Wrks)	Tracy, MN	01/29/2002	Magnetic Transformers and Components.
40,885	O.P. Schuman & Sons, Inc (MT&D)	Warrington, PA	11/12/2001	Lycra.
40,886	Otis Elevator Co (IUE)	Bloomington, IN	11/27/2001	Elevators.
40,887	Spicer Driveshaft (Comp)	Lima, OH	11/28/2001	Companion Flanges for Automobiles.
40,888	Carling Technologies (Wrks)	Brownsville, TX	10/18/2001	Switches and Magnetic Circuit Breakers.
40,889	Nordic Delight/Maine (Comp)	Lubec, ME	11/08/2001	Salmon.
40,890	Hutchinson Technology (Wrks)	Hutchinson, MN	10/12/2001	Suspension Assemblies—Disk Drives.
40,891	Von Hoffman Press (Wrks)	Owensville, MO	11/06/2001	Educational Textbook.
40,892	JDS Uniphase (Wrks)	Bloomfield, CT	01/25/2002	SN Switch Products.
40,893	Danbury Fabrics Ltd (Comp)	Ridgewood, NY	10/25/2001	Knitting Cloth—Apparel.
40,894	Detroit Tool and Engineer (Wrks)	Lebanon, MO	11/08/2001	Automatic Manuf. Equipment Machines.
40,895	Ushio Oregon, Inc. (Comp)	Newberg, OR	10/22/2001	High tech halogen lamps.
40,896	Them's Fine Apparel (Comp)	Bethel Springs, TN	09/06/2001	Hospital Apparel.
40,897	National Steel Pellet (USWA)	Keewatin, MN	10/29/2002	Tacunite Pellets.
40,898	St. Clair Technologies (Wrks	Charlotte, MI	11/02/2001	Wiring Harnesses.
40,899	E.J. Footwear (Wrks)	Blairsville, GA	10/24/2001	Work and Occupational Footwear.
40,900	Holland Binkley Co (Comp)	Delphos, OH	11/03/2001	Semi-trailer Axle & Break System.
40,901	Integrated Logistics (Wrks)	New Hyde Park, NY	09/25/2001	Fasteners.
40,902	Forecaster of Boston (UNITE)	New Bedford, MA	10/15/2001	Ladies Winter Coat.
40,903	Monona Wire Corp (Comp)	Livingston, WI	12/19/2001	Wire Harness Assemblies.
40,904	ANR Pipeline Co (Wrks)	Detroit, MI	11/29/2001	Pipe Transportation—Natural Gas.
40,905	Coastal Lumber Co (Wrks)	Dailey, WV	12/14/2001	Wood Products.
40,906A	Quark Enterprise Systems (Wrks)	Downers Grove, IL	12/11/2001	Software Development.
40,906	Quark, Inc. (Wrks)	Denver, CO	12/11/2001	Software Development.
40,907	Pak-Mor Manufacturing Co (Wrks)	San Antonio, TX	12/20/2001	Truck Bodies and Components.
40,908	Tumi, Inc. (Comp)	Vidalia, GA	01/29/2002	Luggages, Business Cases and Accessories.
40,909	Bowater Coosa Pines (PACE)	Coosa Pines, AL	12/03/2001	Pulp & Paper.
40,910	Stein Steel Mills Service (USWA)	Broadview Hghts, OH	12/28/2001	Steel.
40,911	Rhodia, Inc. (Comp)	New Brunswick, NJ	12/12/2001	Coumarin and Salicyladehyde.
40,912	Kennametal Industrial (Comp)	Pine Bluff, AR	12/07/2001	Drill Bits.
40,913	Emsig Manufacturing Corp (UNITE)	Hudson, NY	12/21/2001	Plastic Buttons.
40,914	Harsco Track Technologies (UAW)	Ludington, MI	12/21/2001	China Grinder.
40,915	Trend Technologies (Wrks)	Round Rock, TX	12/30/2001	Hardware for Computers.
40,916	EDS (Wkrs)	Camp Hill, PA	12/24/2001	Ixplus Customer Care Software.
40,917	Hunter Sadler (Comp)	Tupelo, MS	12/13/2001	Men's Suits.
40,918	Goldman Industrial Group (UE)	N. Springfield, VT	01/21/2002	Machine Tools.
40,919	Sovereign Specialty (Wrks)	Ewing, NJ	12/06/2001	Adhesives.
40,920	Honeywell International (Wrks)	Elyria, OH	12/21/2001	Truck Brakes.

APPENDIX—Continued

[Petitions Instituted on 03/04/2002]

TA–W	Subject Firm (Petitioners)	Location	Date of petition	Product(s)
40,921	Gulf Fibers, Inc. (Comp)	Axis, AL	12/18/2001	15 Denier Mono Filament Nylon.
40,922	Emerson Electric Co. (Comp)	Hazlehurst, GA	12/17/2001	Refrigeration Filter Driers.
40,923	Tele Cruz Technology (Wrks)	San Jose, CA	01/31/2002	Electronic Componets.
40,924	MCMS, Inc. (Comp)	Durham, NC	12/26/2002	Printed Circuits.
40,925	BH Electronics (Wrks)	Marshall, MN	01/29/2002	Transformer & Electronic Componets.
40,926	EVTAC Mining LLC (USWA)	Eveleth, MN	01/09/2002	Mine and Process Taconite.
40,927	Teleflex, Inc. (UAW)	Waterbury, CT	01/02/2002	Automative Cables.
40,928	Ramtex, Inc. (Comp)	Ramseur, NC	01/18/2002	Spin & Weave Yarn.
40,929	Loranger Manufacturing (Comp)	Warren, PA	01/15/2002	Molded Connectors and Metal Inserts.
40,930	Prudential Steel, Inc. (Wrks)	Longview, WA	02/25/2002	Welded Steel Tubular Goods, Line Pipe.
40,931	Cone Blanchard Corp. (UE)	Windsor, VT	01/24/2002	Machine Tools.
40,932	Allegro Microsystems (Wrks)	Willow Grove PA	01/24/2002	Integrated Circuits.
40,933	Oxford Slacks (Comp)	Monroe, GA	01/29/2002	Men's Slacks.
40,934	Tyco Electronics (Wrks)	Jacobus, PA	01/24/2002	Electrical Connectors.
40,935	Nice Ball Bearing Co (USWA)	Kulpsville, PA	01/22/2002	Ground Ball Bearings.
40,936	LTV Steel Corp. (Wrks)	Grand River, OH	01/28/2002	Lime Pebbles.
40,937	IBM Corp. (Wrks)	Rochester, MN	01/21/2002	Glass Substrates
40,938	Marathon Electric (Wrks)	West Plains, MO	01/24/2002	Electric Motors.
40,939	P.S.W. Industries Inc. (Wrks)	Chicago, IL	01/11/2002	Magnetc Lamanations.
40,940	Trinity Rail Operations (BRC)	Clinton, IL	01/31/2002	Rail Chips.
40,941	Wheland Automotive (Comp)	Warrenton, GA	01/14/2002	Gray Iron Casting for Braking System.
40,942	Biltrite Corp. (The) (Comp)	Ripley, MS	01/24/2002	Shoe Soles and Heels.
40,943	Ormet Mill Products (Wrks)	Jackson, TN	01/14/2002	Light Guage/Aluminum Foil.
40,944	Zeeland Chemical (Wrks)	Zeeland, MI	01/16/2002	Chemicals.
40,945	Barry of Laredo (Comp)	Laredo, TX	01/28/2002	Slippers.
40,946	KBA North America, Inc. (Wrks)	York, PA	01/28/2002	Painting Presses/Related Equipment.
40,947	BASF Corp. (Wrks)	Wyandotte, MI	01/14/2002	Vitamin E Powder.
40,948	Boero, Inc. (Comp)	Oakland, CA	01/29/2002	Ladies' Sportswear.
40,949	DuPont—Beaumont Works (Wrks)	Beaumont, TX	01/14/2002	Ammonia.
40,950	Opton, Inc. (Wrks)	Newport News, VA	01/29/2002	Glass/Mirrow.
40,951	Geschmay Corp. (Comp)	Greenville, SC	01/28/2002	Paper.

[FR Doc. 02–10057 Filed 4–23–02; 8:45 am]

BILLING CODE 4510–30–M

DEPARTMENT OF LABOR

Employment and Training Administration

[TA–W–40,780]

O–Z/Gedney Company, Division of EGS Electrical Group, Brooklyn, New York; Notice of Termination of Investigation

Pursuant to section 221 of the Trade Act of 1974, an investigation was initiated on February 11, 2002, in response to a worker petition which was filed on behalf of workers at O–Z/Gedney Company, Division of EGS Electrical Group, Brooklyn, New York.

The petitioners were separated from the subject firm more than a year prior to the petition dated January 9, 2002. Section 223(b)(1) of the Trade Act of 1974 specifies that no certification may apply to any worker whose last separation occurred more than a year before the date of the petition. Consequently, further investigation in this case would serve no purpose, and the investigation has been terminated.

Signed at Washington, DC this 15th day of April, 2002.

Linda G. Poole,

Certifying Officer, Division of Trade Adjustment Assistance.

[FR Doc. 02–10049 Filed 4–23–02; 8:45 am]

BILLING CODE 4510–30–M

DEPARTMENT OF LABOR

Employment and Training Administration

[SGA/DFA 02–108]

Solicitation for Grant Applications (SGA); Grants for Small Faith-Based and Community-Based Non-Profit Organizations

AGENCY: Employment and Training Administration (ETA), Labor.

ACTION: Notice; corrections.

SUMMARY: The Employment and Training Administration published a document in the **Federal Register** of April 17, 2002, concerning the availability of grant funds to award a grant to ''grass-roots'' organizations or small faith-based and community-based non-profit organizations with the ability to connect to the nation's workforce development system. The document contained incorrect criteria information.

FOR FURTHER INFORMATION CONTACT: Linda Forman, Grants Management Specialist, Division of Federal Assistance, Fax (202) 693–2879.

Corrections

In the **Federal Register** of April 17, 2002, in FR Doc. 02–9259, on page 18931, in the first column, correct to read:

FOR FURTHER INFORMATION CONTACT: Questions should be faxed to Linda Forman, Grants Management Specialist, Division of Federal Assistance, Fax (202) 693–2879.

On page 18933, in the second column, correct to read:

Performance History With Grants Management (10 points)

The applicant must provide a statement of its capability/performance history in providing the services proposed in its Statement of Work. The Department will be evaluating applications based on scope, strength, and record of achievement. Applicant may provide a recent history of any involvement as a partner or provider in the Workforce Development system.

Signed at Washington, DC, this 19th day of April, 2002.

James W. Stockton,

Grant Officer.

[FR Doc. 02–10047 Filed 4–23–02; 8:45 am]

BILLING CODE 4510–30–P

DEPARTMENT OF LABOR

Employment and Training Administration

[NAFTA–05625]

Alcatel USA Marketing, Inc., Andover, MA; Notice of Negative Determination Regarding Application for Reconsideration

By application dated January 28, 2002, the workers requested administrative reconsideration of the Department's negative determination regarding eligibility to apply for North American Free Trade Agreement-Transitional Adjustment Assistance (NAFTA–TAA), applicable to workers and former workers of the subject firm. The denial notice was signed on December 31, 2001, and was published in the **Federal Register** on January 11, 2002 (67 FR 1511).

Pursuant to 29 CFR 90.18(c) reconsideration may be granted under the following circumstances:

(1) If it appears on the basis of facts not previously considered that the determination complained of was erroneous;

(2) If it appears that the determination complained of was based on a mistake in the determination of facts not previously considered; or

(3) If in the opinion of the Certifying Officer, a misinterpretation of facts or of the law justified reconsideration of the decision.

The NAFTA–TAA petition, filed on behalf of workers at Alcatel USA Marketing, Inc., Andover, Massachusetts engaged in activities related to the engineering and development of a network switch for computers was denied because the workers of the subject firm did not produce an article within the meaning of Section 250(a) of the Trade Act, as amended.

The petitioners allege that the firm did not end the development of the 7420 IP Edge Router before the product was manufactured. They further indicated that the router shipped from Andover to outside sources was long before the decision was made to transfer the program to Canada. They further indicated that the program was ultimately canceled. The petitioners attached statements from various workers as testimony.

Information supplied during initial investigation show that workers were engaged in activities related to the engineering and development of a computer network switch, referred to as the 7420 IP Edge Router. ALCATEL USA decided to consolidate some of their North American facilities, including transferring the engineering and development of the 7420 IP Edge Router to Kanata, Canada. After further evaluation, the company decided to completely discontinue development of the 7420 IP Edge Router. The product was never fully developed. The Andover facility shipped the 7420 IP Edge Router to internal and outside sources for beta testing only. The router was never produced for sale to outside sources. The subject plant workers engaged in activities related to engineering and development of the 7420 IP EDGE ROUTER at the subject firm did not produce an article within the meaning of Section 250(a) of the Trade Act, as amended. Therefore, the shifts in functions performed at the subject plant related to the 7420 IP Edge Router to Canada are irrelevant.

Conclusion

After review of the application for reconsideration and investigative findings, I conclude that there has been no error or misinterpretation of the law or of the facts which would justify reconsideration of the Department of Labor's prior decisions. Accordingly, the application is denied.

Signed at Washington, DC, this day of April, 2002.

Edward A. Tomchick,

Director, Division of Trade Adjustment Assistance.

[FR Doc. 02–10054 Filed 4–23–02; 8:45 am]

BILLING CODE 4510–30–M

DEPARTMENT OF LABOR

Employment and Training Administration

Investigations Regarding Certifications of Eligibility To Apply For NAFTA Transitional Adjustment Assistance

Petitions for transitional adjustment assistance under the North American Free Trade Agreement-Transitional Adjustment Assistance Implementation Act (Pub. L. 103–182), hereinafter called (NAFTA–TAA), have been filed with State Governors under Section 250(b)(1) of Subchapter D, Chapter 2, Title II, of the Trade Act of 1974, as amended, are identified in the Appendix to this Notice. Upon notice from a Governor that a NAFTA–TAA petition has been received, the Director of the Division of Trade Adjustment Assistance (DTAA), Employment and Training Administration (ETA), Department of Labor (DOL), announces the filing of the petition and takes action pursuant to paragraphs (c) and (e) of Section 250 of the Trade Act.

The purpose of the Governor's actions and the Labor Department's investigations are to determine whether the workers separated from employment on or after December 8, 1993 (date of enactment of Pub. L. 103–182) are eligible to apply for NAFTA–TAA under Subchapter D of the Trade Act because of increased imports from or the shift in production to Mexico or Canada.

The petitioners or any other persons showing a substantial interest in the subject matter of the investigations may request a public hearing with the Director of DTAA at the U.S. Department of Labor (DOL) in Washington, DC, provided such request if filed in writing with the Director of DTAA not later than May 6, 2002.

Also, interested persons are invited to submit written comments regarding the subject matter of the petitions to the Director of DTAA at the address shown below not later than May 6, 2002.

Petitions filed with the Governors are available for inspection at the Office of the Director, DTAA, ETA, DOL, Room C–5311, 200 Constitution Avenue, NW., Washington, DC 20210.

Signed at Washington, DC this 10th day of April 2002.

Edward A Tomchick,

Director, Division of Trade Adjustment Assistance.

APPENDIX

Subject firm	Location	Date received at Governor's Office	Petition No.	Articles produced
Ametek Specialty Motors (Co.)	Hudson, WI	03/20/2002	NAFTA–5,997	electric motors.
Ibiden Graphite of America (Wkrs)	Portland, OR	03/19/2002	NAFTA–5,998	ovens.
Flextronics Enclosure Systems (Wkrs)	Kingston, PA	03/14/2002	NAFTA–5,999	enclosure cabinets.
General Electric (Wkrs)	Owensboro, KY	03/20/2002	NAFTA–6,000	motors.
South Coast Lumber (Co.)	Brookings, OR	03/19/2002	NAFTA–6,001	lumber.
Burlington Chemical (Co.)	Burlington, NC	03/19/2002	NAFTA–6,002	textile products.
Joseph Timber (Wkrs)	Joseph, OR	03/18/2002	NAFTA–6,003	lumber.
Bill Levkoff (Wkrs)	New York, NY	01/02/2002	NAFTA–6,004	dresses and evening gowns.
Kayby Mills (Wkrs)	Thomasville, NC	03/25/2002	NAFTA–6,005	tights and socks.
Braden Manufacturing (Co.)	Ft. Smith, AR	03/25/2002	NAFTA–6,006	fabricated steel components.
Schneider Mills—Alexander Mills (Co.)	Forest City, NC	03/25/2002	NAFTA–6,007	woven unfinished material.
Howmet Castings (Co.)	City of Industry, CA	03/21/2002	NAFTA–6,008	aluminum castings.
Dana Corp.—Perfect Circle (UAW)	Richmond, IN	03/25/2002	NAFTA–6,009	cylinder liners.
Nature's Art (Co.)	Albemarle, NC	03/26/2002	NAFTA–6,010	t-shirts.
McCain Foods—Anchor Appetiser Group (Wkrs).	Appleton, WI	04/01/2002	NAFTA–6,011	appetiser.
Dayton Pattern (Co.)	Dayton, OH	03/28/2002	NAFTA–6,012	castings.
Amstead Corp.—American Steel Foundry (Co.).	Alliance, OR	03/28/2002	NAFTA–6,013	wood/metal pattern.
Welland Chemical (Wkrs)	Newell, PA	03/19/2002	NAFTA–6,014	nitric acid.
Camfil Farr (Co.)	Jonesboro, AR	03/29/2002	NAFTA–6,015	eco clamps.
Wheelabrator Air Pollution Control (Co.)	Pittsburgh, PA	03/28/2002	NAFTA–6,016	pollution control equipment.
Ashland Chemical (USWA)	Pittsburgh, PA	03/28/2002	NAFTA–6,017	chemicals.
Johnson Controls (Wkrs)	Fulleron, CA	03/27/2002	NAFTA–6,018	automotive batteries.
Lucent Technologies (IBEW)	Oklahoma City, OK	01/03/2002	NAFTA–6,019	telephone switching equipment.
A. Stucki Company (USWA)	Pittsburgh, PA	03/28/2002	NAFTA–6,020	rail cars.
Aspen Trailer (Wkrs)	Litchfield, MN	03/19/2002	NAFTA–6,021	heavy haul trailers.
Mototola (Wkrs)	Mesa, AZ	03/25/2002	NAFTA–6,022	pressure sensors.
Aerocell Structures Adirison (Wkrs)	Hot Springs, AR	03/26/2002	NAFTA–6,023	airplane parts.
ITT Industries—ITT Cannon Switch (Wkrs)	Eden Prairie, MN	03/26/2002	NAFTA–6,024	electronic control, panels and switches.
Imation—Kodak Polychrome Grapics (Wkrs).	Oakdale, MN	03/22/2002	NAFTA–6,025	data storage.
Portland Pattern (Co.)	Portland, OR	03/05/2002	NAFTA–6,026	aluminum molds.
ILD Lantis-Container Pallent Loader (Wkrs).	Salinas, CA	03/26/2002	NAFTA–6,027	container pallent loaders.
L and A Molding (Co.)	Lewiston, ME	03/28/2002	NAFTA–6,028	injection molded footwear.
T and T Land and Timber (Co.)	Rexford, MT	04/02/2002	NAFTA–6,029	timber.
Schlumberger Limited (Wkrs)	Sugarland, TX	04/01/2002	NAFTA–6,030	oil and gas.
H.J. Seagroa (Co.)	Berlin, NY	03/19/2002	NAFTA–6,031	cut roses and flowers.
Ameripol Synpol (Wkrs)	Odessa, TX	04/08/2002	NAFTA–6,032	synthetic rubber.
Sanmina (Co.)	Carrollton, TX	04/05/2002	NAFTA–6,033	electronic cable assemblies.
Alcatel (Wkrs)	Ogdensburg, NY	02/27/2002	NAFTA–6,034	customer service.
Motorola-ACES Group (Co.)	Elma, NY	02/21/2002	NAFTA–6,035	printed circuit boards.
Siemens VDO Automotive (Wkrs)	Auburn, IN	04/05/2002	NAFTA–6,036	automotive instrument.
Toro Company (The)(Co.)	Riverside, CA	04/04/2002	NAFTA–6,037	irrigation equipment.
Birdair (Co.)	Amherst, NY	03/13/2002	NAFTA–6,038	tensioned membrane roof systems.
Tredegar Film Products (Wkrs)	Carbondale, PA	04/08/2002	NAFTA–6,039	plastic film.
Kaijay (UNITE)	Nesquehoning, PA	04/08/2002	NAFTA–6,040	jeans.
Rohm and Haas (Wkrs)	Philadelphia, PA	04/08/2002	NAFTA–6,041	water purification products.
American Fashion (UNITE)	Chula Vista, CA	04/01/2002	NAFTA–6,042	men's suits.
Contract Embroidery (Wkrs)	El Paso, TX	04/08/2002	NAFTA–6,043	embroidery.
Hontsman Petro Chemicals (Wkrs)	Odessa, TX	04/08/2002	NAFTA–6,044	shipping and receiving rail cars.
BBA Nonwovens Simpsonville (PACE)	Lewisburg, PA	04/08/2002	NAFTA–6,045	apparel materials.
Mid Western Machinery (Co.)	Joplin, MO	04/05/2002	NAFTA–6,046	pneumatic rock drills.
TRW, Inc. (Co.)	Cleveland, OH	04/04/2002	NAFTA–6,047	engine values.
McKechnie Tooling and Engineering (Co.)	Staples, MN	04/04/2002	NAFTA–6,048	plastic injection molds.
Jacobs Sverdrup (Co.)	Amherst, NY	02/15/2002	NAFTA–6,049	automotive air conditioner.
NAS Interplex (Wkrs)	Flushing, NY	02/28/2002	NAFTA–6,050	electronics connectors.
Mac Specialties (Co.)	Oceanside, NY	02/11/2002	NAFTA–6,051	foam.
Burrows Paper (Wkrs)	Little Falls, NY	04/04/2002	NAFTA–6,052	food containers.
Federal Pipe and Steel (Wkrs)	Blytheville, AR	04/01/2002	NAFTA–6,053	steel.
Guilford Mills (Wkrs)	Cobleskill, NY	01/14/2002	NAFTA–6,054	apparel fabric.
C and W Fabrication (Wkrs)	Gardner, MA	04/05/2002	NAFTA–6,055	gas tubrines.
Oetiker (Co.)	Livingston, NJ	03/25/2002	NAFTA–6,056	hose clamps.
Chicago Mold and Engineering (Co.)	St. Charles, IL	04/01/2002	NAFTA–6,057	plastic injection machines.
Walls Industrial (Wkrs)	Cleburne, TX	04/03/2002	NAFTA–6,058	outerwear, jackets and overalls.
New Images (Wkrs)	Reidsville, NC	04/01/2002	NAFTA–6,059	clothing.
Mitsubishi Silicon (Wkrs)	Dallas, OR	03/29/2002	NAFTA–6,060	silicon wafers.
Owens Brigam Medical (Wkrs)	Morganton, NC	04/01/2002	NAFTA–6,061	disposable anesthesia & respiratory.

APPENDIX—Continued

Subject firm	Location	Date received at Governor's Office	Petition No.	Articles produced
Parkdale America (Wkrs)	Kings Mountain, NC	04/01/2002	NAFTA–6,062	yarn.
Celestica (Co.)	Westminster, Co	04/03/2002	NAFTA–6,063	printed circuit asemblies.

[FR Doc. 02–10058 Filed 4–23–02; 8:45 am]

BILLING CODE 4510–30–M

DEPARTMENT OF LABOR

Employment and Training Administration

[NAFTA–5913]

JDS Uniphase, Electro-Optic Products Division, Bloomfield, Connecticut; Amended Certification Regarding Eligibility To Apply for NAFTA-Transitional Adjustment Assistance

In accordance with Section 250(a), Subchapter D, Chapter 2, Title II, of the Trade Act of 1974, as amended (19 U.S.C. 2273), the Department of Labor issued a Certification of Eligibility to Apply for NAFTA Transitional Adjustment Assistance on March 19, 2002, applicable to all workers of JDS Uniphase, Electro-Optic Products Division, located in Bloomfield, Connecticut. The notice was published in the **Federal Register** on March 29, 2002. (67 FR 15227).

At the request of the State agency, the Department reviewed the certification for workers of the subject firm. The certification covering all workers JDS Uniphase, Electro-Optic Products Division, Bloomfield, Connecticut, was based on the finding that production of SN switches was shifted from that plant to Canada, and workers were not separately identifiable from those producing other articles at the plant.

An official of the company reports that workers producing the SN switches are separately identifiable by product.

The intent of the Department's certification is to include only those workers of JDS Uniphase, Elector-Optic Products Division, Bloomfield, Connecticut, adversely affected by the shift in production of SN switches to Canada. Accordingly, the Department is amending the certification to limit the worker group coverage to those engaged in activities related to the production of SN switches.

The amended notice applicable to NAFTA–5913 is hereby issued as follows:

All workers engaged in activities related to the production of SN switches at JDS Uniphase, Electro-Optic Products Division, Bloomfield, Connecticut, who became totally or partially separated from employment on or after February 12, 2001 through March 19, 2004, are eligible to apply for NAFTA–TAA under Section 250 of the Trade Act of 1974.

Signed in Washington, DC, this 5th day of April, 2002.

Linda G. Poole,

Certifying Officer, Division of Trade Adjustment Assistance.

[FR Doc. 02–10053 Filed 4–23–02; 8:45 am]

BILLING CODE 4510–30–M

DEPARTMENT OF LABOR

Employment and Training Administration

[NAFTA–05319]

Motorola, Inc., Personal Communications Sector, Wireless Messaging Division, Including Leased Workers of Adecco Employment, Boynton Beach, FL; Amended Certification Regarding Eligibility To Apply for NAFTA-Transitional Adjustment Assistance

In accordance with Section 250(a), Subchapter D, Chapter 2, Title II, of the Trade Act of 1974, as amended (19 U.S.C. 2273), the Department of Labor issued a Certification of Eligibility to Apply for NAFTA Transitional Adjustment Assistance on February 11, 2002, applicable to workers of Motorola, Inc., Personal Communications Sector, Wireless Messaging Division, Boynton Beach, Florida. The notice was published in the **Federal Register** on February 28, 2002 (67 FR 9328).

At the request of the State agency, the Department reviewed the certification for workers of the subject firm. Information provided by the State shows that leased workers of Adecco Employment, Boca Raton, Florida were employed at Motorola, Inc., Personal Communications Sector, Wireless Messaging Division to produce electronic paging and cellular products at the Boynton Beach, Florida location of the subject firm.

Based on these findings, the Department is amending the certification to include leased workers of Adecco Employment, Boca Raton, Florida employed at Motorola, Inc., Personal Communications Sector, Wireless Messaging Division, Boynton Beach, Florida.

The intent of the Department's certification is to include all workers of Motorola, Inc., Personal Communications Sector, Wireless Messaging affected by employment declines and a shift in the production of electronic paging and cellular products to Mexico.

The amended notice applicable to NAFTA–05319 is hereby issued as follows:

All workers of Motorola, Inc., Personal Communications Sector, Wireless Messaging Division, Boynton Beach, Florida including leased workers of Adecco Employment, Boca Raton, Florida engaged in employment related to the production of electronic paging and cellular products at Motorola, Inc., Personal Communications Sector, Wireless Messaging Division, Boynton Beach, Florida who became totally or partially separated from employment on or after August 17, 2000, through December 7, 2003, are eligible to apply for NAFTA–TAA under Section 250 of the Trade Act of 1974.

Signed in Washington, DC this 9th day of April, 2002.

Linda G. Poole,

Certifying Officer, Division of Trade Adjustment Assistance.

[FR Doc. 02–10052 Filed 4–23–02; 8:45 am]

BILLING CODE 4510–30–M

DEPARTMENT OF LABOR

Employment and Training Administration

[NAFTA–5471]

SYST–A–MATIC Tool & Design, Inc., Meadville, PA; Notice of Negative Determination Regarding Application for Reconsideration

By application dated January 10, 2002, the company requested administrative reconsideration of the Department's negative determination of the Department's negative determination regarding eligibility to apply for North American Free Trade Agreement-Transitional Adjustment Assistance (NAFTA–TAA), applicable to workers and former workers of the

subject firm. The denial notice was signed on December 26, 2001, and was published in the **Federal Register** on January 11, 2002 (67 FR 1513).

Pursuant to 29 CFR 90.18(c) reconsideration may be granted under the following circumstances:

(1) If it appears on the basis of facts not previously considered that the determination complained of was erroneous;

(2) If it appears that the determination complained of was based on a mistake in the determination of facts not previously considered; or

(3) If in the opinion of the Certifying Officer, a misinterpretation of facts or of the law justified reconsideration of the decision.

The denial of NAFTA–TAA for workers engaged in activities related to the production of connector holders at SYST–A–MATIC Tool & Design, Meadville, Pennsylvania, was based on the finding that criteria (3) and (4) of the group eligibility requirements of paragraph (a)(1) of Section 250 of the Trade Act, as amended, were not met. There were no company imports of connector holders from Mexico or Canada, nor did SYST–A–MATIC Tool & Design shift production from Meadville, Pennsylvania to Mexico or Canada. Major customers did not import from Canada or Mexico during the relevant period.

The petitioner alleges that a customer of the subject firm that produced automotive wire harnesses shifted their production to Mexico. As a result of the shift, the customer is now purchasing their connector holders from a company is now purchasing their connector holders from a company located in El Paso, Texas, rather than purchasing the connector holders from the subject firm. The connector holder is a component part that is incorporated into the wire harness.

The loss of a customer to another domestic producer, a shift in production by the customer to Mexico and exports of connector holders to Mexico by the customer's new supplier do not meet the eligibility requirements of the group eligibility requirements of paragraph (a)(1) of Section 250 of the Trade Act, as amended.

Conclusion

After review of the application and investigative findings, I conclude that there has been no error or misinterpretation of the law or of the facts which would justify reconsideration of the Department of Labor's prior decision. Accordingly, the application is denied.

Signed at Washington, DC, this 4th day of April, 2002.

Edward A. Tomchick,

Director, Division of Trade Adjustment Assistance.

[FR Doc. 02–10056 Filed 4–23–02; 8:45 am]

BILLING CODE 4510–30–M

DEPARTMENT OF LABOR

Employment and Training Administration

[NAFTA–05470]

Tyco International, Ltd, A Division of Tyco Electronic Power Systems, Formerly Lucent Technologies Including Leased Workers of Adecco Employment, Mesquite TX; Amended Certification Regarding Eligibility To Apply for NAFTA—Transitional Adjustment Assistance

In accordance with Section 250(a), Subchapter D, Chapter 2, Title II, of the Trade Act of 1974, as amended (19 U.S.C. 2273), the Department of Labor issued a Certification of Eligibility to Apply for NAFTA Transitional Adjustment Assistance on January 2, 2002, applicable to workers of Tyco International, LTD, A Division of Tyco Electronic Power Systems, Formerly Lucent Technologies, Mesquite, Texas. The notice was published in the **Federal Register** on January 11, 2002 (67 FR 1512).

At the request of the State agency, the Department reviewed the certification for workers of the subject firm. Information provided by the State shows that leased workers of Adecco Employment, Garland, Texas were employed at Tyco International, LTD, A Division of Tyco Electronic Power Systems to produce power supplies at the Mesquite, Texas location of the subject firm.

Based on these findings, the Department is amending the certification to include leased workers of Adecco Employment, Garland, Texas employed at Tyco International, Ltd, A Division of Tyco Electronic Power Systems, Mesquite, Texas.

The intent of the Department's certification is to include all workers of Tyco International, Ltd, A Division of Tyco Electronic Power Systems affected by a shift in the production of power supplies to Mexico.

The amended notice applicable to NAFTA–05470 is hereby issued as follows:

All workers of Tyco International, Ltd, A Division of Tyco Electronic Power Systems, Mesquite, Texas including leased workers of Adecco Employment, Garland, Texas engaged in employment related to the production of power supplies at Tyco International, Ltd, A Division of Tyco Electronic Power Systems, Mesquite, Texas who became totally or partially separated from employment on or after October 22, 2000, through January 2, 2004, are eligible to apply for NAFTA–TAA under Section 250 of the Trade Act of 1974.

Signed in Washington, DC, this 9th day of April, 2002.

Linda G. Poole,

Certifying Officer, Division of Trade Adjustment Assistance.

[FR Doc. 02–10055 Filed 4–23–02; 8:45 am]

BILLING CODE 4510–30–M

NATIONAL AERONAUTICS AND SPACE ADMINISTRATION

[Notice (02–053)]

Notice of Information Collection

AGENCY: National Aeronautics and Space Administration (NASA).

ACTION: Notice of information collection.

SUMMARY: The National Aeronautics and Space Administration, 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 (Pub. L. 104–13, 44 U.S.C. 3506(c)(2)(A)). The information obtained in this collection will assist NASA in assessing the effectiveness of aviation safety programs.

DATES: All comments should be submitted within 60 calendar days from the date of this publication.

ADDRESSES: All comments should be addressed to Ms. Linda Connell, NASA Ames Research Center, MS 262–7, Moffett Field, CA 94035–1000.

FOR FURTHER INFORMATION CONTACT: Ms. Nancy Kaplan, NASA Reports Officer, (202) 358–1372.

Title: National Aviation Operations Monitoring Service: General Aviation Pilots.

OMB Number: 2700-.

Type of review: New collection.

Need and Uses: The information collected will be analyzed and used by NASA Aviation Safety Program managers to evaluate their progress in improving aviation over the next decade.

Affected Public: Individuals or households.

Number of Respondents: 10,000.

Responses Per Respondent: 1.

Annual Responses: 10,000.

Hours Per Request: Approx. ½ hour.
Annual Burden Hours: 6,280.
Frequency of Report: Quarterly; Annually.

David B. Nelson,

Deputy Chief Information Officer, Office of the Administrator.

[FR Doc. 02–10045 Filed 4–23–02; 8:45 am]

BILLING CODE 7510–01–P

NUCLEAR REGULATORY COMMISSION

Agency Information Collection Activities: Submission for the Office of Management and Budget (OMB) Review; Comment Request

AGENCY: U.S. Nuclear Regulatory Commission (NRC).

ACTION: Notice of the OMB review of information collection and solicitation of public comment.

SUMMARY: The NRC has recently submitted to OMB for review the following proposal for the collection of information under the provisions of the Paperwork Reduction Act of 1995 (44 U.S.C. Chapter 35). The NRC hereby informs potential respondents that an agency may not conduct or sponsor, and that a person is not required to respond to, a collection of information unless it displays a current valid OMB control number.

1. *Type of submission, new, revision, or extension:* Extension.
2. *The title of the information collection:* IAEA N–71, ''Design Information Questionnaire.''
3. *The form number if applicable:* IAEA N–71.
4. *How often the collection is required:* It is estimated that this collection is required approximately 1 time per year.
5. *Who will be required or asked to report:* Licensees of facilities on the U.S. eligible list who have been notified in writing by the Commission to submit the form.
6. *An estimate of the number of responses:* 1.
7. *The estimated number of annual respondents:* 1.
8. *An estimate of the total number of hours needed annually to complete the requirement or request:* 360 hours.
9. *An indication of whether Section 3507(d), Public Law 104–13 applies:* Not applicable.
10. *Abstract:* Licensees of facilities that appear on the U.S. eligible list, pursuant to the US/IAEA Safeguards Agreement, and who have been notified in writing by the Commission, are required to complete and submit a Design Information Questionnaire, IAEA Form N–71 (and the appropriate associated IAEA Form), to provide information concerning their installation for use of the International Atomic Energy Agency.

A copy of the final supporting statement may be viewed free of charge at the NRC Public Document Room, One White Flint North, 11555 Rockville Pike, Rockville, MD. OMB clearance requests are available at the NRC worldwide Web site *http://www.nrc.gov/public-involve/doc-comment/OMB/index/html.* The document will be available on the NRC home page site for 60 days after the signature date of this notice.

Comments and questions should be directed to the OMB reviewer listed below by May 24, 2002. Comments received after this date will be considered if it is practical to do so, but assurance of consideration cannot be given to comments received after this date. Bryon Allen, Office of Information and Regulatory Affairs (3150–0158), NEOB–10202, Office of Management and Budget, Washington, DC 20503.

Comments can also be submitted by telephone at (202) 395–3087.

The NRC Clearance Officer is Brenda Jo. Shelton, 301–415–7233.

Dated at Rockville, Maryland, this 17th day of April, 2002.

For the Nuclear Regulatory Commission.

Brenda Jo. Shelton,

NRC Clearance Officer, Office of the Chief Information Officer.

[FR Doc. 02–9990 Filed 4–23–02; 8:45 am]

BILLING CODE 7590–01–P

NUCLEAR REGULATORY COMMISSION

[Docket Nos. 50–247–OLA; ASLBP No. 02–798–01–OLA]

Entergy Nuclear Indian Point 2, LLC, and Entergy Nuclear Operations, Inc., Indian Point Nuclear Generating Unit No. 2; Establishment of Atomic Safety and Licensing Board

Pursuant to delegation by the Commission dated December 29, 1972, published in the **Federal Register**, 37 FR 28,710 (1972), and §§ 2.105, 2.700, 2.702, 2.714, 2.714a, 2.717, 2.721, and 2.772(j) of the Commission's regulations, all as amended, an Atomic Safety and Licensing Board is being established to preside over the following proceeding:

Entergy Nuclear Indian Point 2, LLC, and

Entergy Nuclear Operations, Inc.

Indian Point Neclear Generating Unit No. 2

This Board is being established pursuant to a notice of consideration of issuance of operating license amendment, proposed no significant hazards consideration determination, and opportunity for a hearing published in the **Federal Register** (66 FR 44,161, 44,165 (Aug. 22, 2001)). The proceeding involves a petition for leave to intervene and request for a hearing submitted March 18, 2002, by Riverkeeper, Inc., challenging a July 13, 2001 request by then-licensee Consolidated Edison Company of New York, Inc., to amend the operating license for the Indian Point Nuclear Generating Unit No. 2. (By order dated August 27, 2001, the agency approved a license transfer request regarding Indian Point Nuclear Generating Unit No. 2 that made Entergy Nuclear Indian Point 2, LLC, the facility owner and Entergy Nuclear Operations, Inc., its licensed operator.) The amendment would make a change to the facility technical specifications to increase the interval for the Type A containment integrated leak rate test from at least once per ten years to once per fifteen years, albeit applicable only to the interval following the last Type A test, which was satisfactorily performed in June 1991.

The Board is comprised of the following administrative judges:

Michael C. Farrar, Chair, Atomic Safety and Licensing Board Panel, U.S. Nuclear Regulatory Commission Washington, DC 20555–0001.

Dr. Richard F. Cole, Atomic Safety and Licensing Board Panel, U.S. Nuclear Regulatory Commission, Washington, DC 20555–0001.

Dr. Charles N. Kelber, Atomic Safety and Licensing Board Panel, U.S. Nuclear Regulatory Commission, Washington, DC 20555–0001.

All correspondence, documents, and other materials shall be filed with the administrative judges in accordance with 10 CFR 2.701.

Issued at Rockville, Maryland, this twelfth day of April, 2002.

G. Paul Bollwerk III,

Chief Administrative Judge, Atomic Safety and Licensing Board Panel.

[FR Doc. 02–9994 Filed 4–23–02; 8:45 am]

BILLING CODE 7590–01–P

NUCLEAR REGULATORY COMMISSION

[Docket No. 50–368]

Entergy Operations, Inc., Arkansas Nuclear One, Unit 2; Environmental Assessment and Finding of No Significant Impact Related to a Proposed License Amendment to Increase the Maximum Thermal Power Level

The U.S. Nuclear Regulatory Commission (NRC) is considering issuance of an amendment to Facility Operating License No. NPF–6, issued to Entergy Operations, Inc. (Entergy or the licensee), for the operation of Arkansas Nuclear One, Unit 2 (ANO–2), located in Pope County, Arkansas. Therefore, as required by 10 CFR 51.21, the NRC is issuing this environmental assessment and finding of no significant impact.

Environmental Assessment

Identification of the Proposed Action

The proposed action would allow Entergy, the operator of ANO–2, to increase its electrical generating capacity at ANO–2 by raising the maximum reactor core power level from 2815 MWt to 3026 MWt. This change is approximately 7.5 percent above the current maximum licensed power level for ANO–2. The change is considered an extended power uprate (EPU) because it would raise the reactor core power level at least 7 percent above the original licensed power level. ANO–2 has not submitted a previous power uprate application. The EPU is accomplished by increasing the heat output of the reactor, thereby increasing the steam flow to the turbine for which increased feedwater flow is needed. As a result, more heat will be rejected to the circulating water and cooling tower complex. Increased heat load to the cooling tower will cause evaporative losses to increase. Therefore, cooling tower makeup, supplied from Lake Dardanelle, will increase due to the increased evaporative losses.

The proposed action is in accordance with Entergy's application for amendment dated December 19, 2000, as supplemented by letters dated May 30, June 20, 26 (two letters), 27, and 28, July 3 and 24 (two letters), August 7, 13, 21, 23, and 30, September 14, October 1, 12 (two letters), 17, 30 (two letters), and 31, November 9, 16 (three letters), and 17, and December 5, 6 (two letters), 10, and 20, 2001, and January 14, 15, and 31, February 7 (two letters), and March 1, 2002.

The Need for the Proposed Action

The proposed action is to provide an option that allows for power generation capability beyond the current nuclear power plant operating license to meet future system generating needs, as such needs may be determined by State, utility, and where authorized, Federal (other than NRC) decisionmakers. The ANO–2 steam generators were replaced in 2000 due to primary water stress corrosion cracking. In evaluating the options for the replacement steam generators (RSGs), Entergy determined that the RSGs would be capable of supporting a 7.5 percent thermal uprate which would increase the licensed core thermal power level to 3026 MWt. The proposed action to increase the licensed core thermal power level to 3026 MWt is based on Entergy's operational goal of increasing electrical generating capacity. According to Entergy, summer peak temperatures in the South challenge the ability of Entergy and other power producers to meet peak load demands, and nuclear power has been shown to be a reliable energy source during these peak periods.

In addition, Entergy states that there is an ongoing need for existing Entergy system generating capacity, including that provided by ANO–2. Entergy also states that load growth is expected to further increase the system's resource requirements. In view of the foregoing, Entergy determined that the EPU for ANO–2 would provide an economically sound choice with no significant impact to the environment.

Environmental Impacts of the Proposed Action

The NRC has completed its evaluation of the proposed action and concludes that the increase in the rated core thermal power can be accomplished without significant impact on the environment.

The environmental impacts of ANO–2 have been described in (1) the Final Environmental Statement (FES), dated June 1977 (NUREG–0254); (2) the Power Uprate Licensing Report (PULR), which is Enclosure 5 to the EPU application dated December 19, 2000, as supplemented; and (3) the June 26 and December 10, 2001, and January 15, 2002, responses to NRC requests for additional information (RAI). On January 31, 2000, Entergy submitted a supplement to its environmental report supporting the license renewal of Arkansas Nuclear One, Unit 1 (ANO–1), which resides adjacent to ANO–2. Responses to NRC RAIs regarding the environmental report for license renewal were submitted on June 26, July 31, and September 21, 2000. The staff evaluation of that action was documented in NUREG–1437, Supplement 3, ''Generic Environmental Impact Statement for License Renewal of Nuclear Plants, Regarding Arkansas Nuclear One, Unit 1,'' September 2000 (Supplement 3). Supplement 3 addresses many balance-of-plant site features that are common to ANO–1 and ANO–2. Supplement 3 was cited in Enclosure 5 of the December 19, 2000, license application in instances where site characteristics common to both ANO–1 and ANO–2 are unchanged by the EPU.

The original operating license for ANO–2 allowed a maximum reactor power level of 2815 MWt. Based upon on its independent analyses of the non-radiological and radiological impacts, as described in more detail below, the staff has determined that the environmental impacts of the proposed EPU are essentially unchanged from the environmental impacts previously evaluated in the staff's FES and, as common to both units, Supplement 3. The EPU does not involve extensive changes to plant systems that directly or indirectly interface with the environment. Additionally, no changes are necessary to the National Pollutant Discharge Elimination System (NPDES) permit issued by the Arkansas Department of Environment Quality (ADEQ), formerly the Arkansas Department of Pollution Control and Ecology.

Non-Radiological Impacts

The following contains the NRC staff's analysis of the non-radiological environmental impacts of the proposed EPU on land use, water use, waste discharges, terrestrial and aquatic biota, transmission facilities, and social and economic conditions at ANO–2.

Land Use Impacts

The proposed EPU would not modify land use at the site or have impacts on lands with historic or archeological significance. The licensee states that it has no plans to construct any new facilities or alter the land around existing facilities, including buildings, access roads, parking facilities, laydown areas, onsite transmission and distribution equipment, or power line rights-of-way in conjunction with the proposed EPU. The EPU would not significantly affect the storage of materials, including chemicals, fuels, and other materials stored above or under the ground. The EPU would not alter the aesthetics of the site. Therefore, the conclusions in Supplement 3 for impacts on land use that are common to

ANO–1 and ANO–2, and the conclusions on land use impacts in FES Section 5–2, augmented by information in the PULR and the June 26 and December 10, 2001, and January 15, 2002, RAI responses, will remain valid under the proposed EPU conditions.

Noise was not addressed in the FES. However, FES Section 5.2 notes that Arkansas Nuclear One (ANO) is located on 1,164 acres and FES Section 2.2.2 states that the ''* * * station has altered the land use in Pope County, primarily through the conversion of 430 acres to an industrial site. Only 150 acres actually are being disturbed * * * The total acreage of the land affected by the construction and operation of ANO is extremely small. Most of the changes in land use have occurred with the construction and operation of Unit 1. * * *'' Supplement 3, Section 2.1 states that ''[t]he ANO site is located on a peninsula formed by Lake Dardanelle, and three sides of the site are surrounded by lake water.'' The two nearest residences are ''* * * approximately 3 and 1.2 miles, respectively, from the Unit 2 containment building centerline* * *'' (ANO–2 Environmental Report (ER) Section 2.2.3.2. The ANO–2 ER was submitted on March 1, 1974, and amended on July 11 and December 13, 1974, June 13, October 6 and December 19, 1975, and June 21 and September 8, 1976.) The EPU will not change the character, sources, or energy of noise generated at ANO–2. Modified structures, systems, and components necessary to implement the proposed EPU will be installed within existing plant buildings and no noticeable increase in ambient noise levels within the plant is expected.

Water Use Impacts

The following is the NRC staff's evaluation of ground and surface water use as environmental impacts of water usage at ANO–2. Ground and surface water use impacts are also discussed in the ''Radiological Impacts'' section below.

Groundwater Use

As stated in the RAI response to the NRC staff dated June 26, 2001, ANO–1 and ANO–2 do not use any groundwater. Therefore, the EPU will have no non-radiological effects on groundwater.

Surface Water Use

The EPU is accomplished by increasing the heat output of the reactor, thereby increasing the steam flow to the turbine for which increased feedwater flow is needed. The licensee has stated that, as a result, more heat will be rejected to the circulating water and cooling tower complex. Increased heat load to the cooling tower will cause a slight increase in evaporative losses. Therefore, cooling tower makeup, supplied from Lake Dardanelle, will slightly increase due the increased evaporative losses.

While the EPU will require increased water use, the licensee has stated that ANO–2 will not use more water from the lake than permitted. ANO–2 has a contract with the U.S. Corps of Engineers that allows water to be withdrawn from the lake at an average rate of 22 ft^3/sec; withdrawals can exceed this average without an adverse environmental impact. An average evaporation rate of 22 ft^3/sec (9,900 gpm) and maximum evaporation rate of 27 ft^3/sec (11,900 gpm) was analyzed in FES Section 5.3.4. PULR Section 10.4.1.2, stated that the maximum cooling tower make-up for evaporation will increase from 12,180 (27.1 ft^3/sec) to 13,020 gpm (29.0 ft^3/sec) under EPU conditions. However, by allowing the cooling tower cycles of concentration to increase from 3.5 to 3.8, still a low concentration value, cooling tower evaporation at design conditions will be about 11,600 gpm (25.8 ft^3/sec). (While water will also be withdrawn from the lake at a rate of 4,150 gpm (9.2 ft^3/sec) to satisfy blowdown needs, this water is returned to the lake.) Cooling tower design conditions continue to be 81.0 °F wet bulb temperature (Wbt) and 37.0 percent relative humidity. These are conservative values. The meteorological worst day on record, July 17, 1934, reflects a worst average 4-hour Wbt and relative humidity of 82.4 °F and 59.20 percent, respectively. The Wbt during this worst 4-hour period exceeds the tower design temperature by only 1.4 °F and the relative humidity was 22.2 percent higher than design.

The limits on withdrawal (i.e., consumption via evaporation) from Lake Dardanelle are based on economics. By withdrawing from the lake, less stream flow is available to flow through Corps of Engineers' hydroelectric generation plants. The licensee compensates the Corps of Engineers for reduction of the flow of the stream (Lake Dardanelle), and the resultant power generation losses to its hydroelectric projects (see FES Section 5.3.4), and will continue to do so for any additional water withdrawal from Lake Dardanelle as a result of the EPU under the terms of the contract.

Surface water hydrology is discussed in ER Sections 2.5.1 and 5.1.3, and FES Section 2.3.2. The EPU results in no increase in the water use permitted. In addition, any changes would be subject to approval by the ADEQ and subject to the NPDES permit. Accordingly, the NRC staff finds that the licensee's conclusions that ANO–2 ''cooling water facilities will have no adverse effects on the local environment, agriculture, housing, roads, airports, and other facilities,'' and that ''* * * measures are being provided to control the formation of slime and algae in the circulating water system, without causing unnecessary harm to aquatic life and biota,'' remains true for the EPU. In addition, FES Section 2.3.2 statements remain unaffected by the EPU. See the discussion below on drift regarding replacing chlorination with bromination at ANO–2.

Waste Discharge Impacts

The NRC staff evaluated the environmental impacts such as cooling tower fogging, icing, drift, noise, chemical discharges to surface water, sanitary waste discharges, blowdown, thermal plume spread, temperature of the lake, cold shock to aquatic biota, hazardous waste effluents, and air emissions that were presented in the FES. The NRC staff, as set forth below, finds that the proposed EPU causes no significant change to the FES evaluations and conclusions relating to waste discharge.

Cooling Tower Fogging, Icing, Drift

The ANO–2 cooling tower is discussed extensively in FES Section 5.4. Entergy's predecessor prepared the ANO–2 ER and submitted its seventh and final amendment attached to a September 8, 1976, letter. As stated in Section 10.1 of the ER, several types of cooling systems such as a cooling pond, a spray pond, a mechanical draft cooling tower, and dry cooling towers were evaluated before a natural draft cooling tower was selected as the best option.

Fogging, Icing and Drift

The licensee has stated in ER Section 10.1.6.3.C, that based on studies done at the Keystone Station in Pennsylvania, ''[f]logging and icing were not problems in the area surrounding these towers.'' This ER section also noted that ''* * * the physical conditions at the Arkansas Nuclear One site were comparable to the installation at Pennsylvania, and the winters less severe.'' The NRC staff found that fogging and icing caused by cooling tower evaporation and drift has either a ''minimal'' or no effect on ground transportation, air transportation, and water transportation, and is not affected by the EPU.

In Section 10.4.1.2 of the PULR, the increase in circulating water makeup

rate is approximately 840 gpm (1.87 ft^3/sec) due to increased evaporation. As stated above, makeup due to evaporation will increase. However, PULR Section 10.4.1.4 states that the circulating water flow rate actually decreased slightly after the condenser was refurbished during a recent refueling outage (2R13). Since drift is a function (i.e., is some fractional amount) of circulating water flow rate, the NRC staff finds that the drift due to the proposed EPU will not exceed that evaluated in the FES.

FES Section 5.4.1.1 assesses cooling tower drift. In this section, the licensee states that ''[c]hlorides were selected by the staff as the primary component of TDS [total dissolved solids] which may cause potential vegetation damage above certain deposition rates.'' The chlorination system for biological control was revised to include a bromination process for the circulating water systems on both ANO–1 and ANO–2 in early 1990. Chlorination was abandoned in 1991 in lieu of the preferred bromination process. This approach was discussed in a follow-up ANO response to Generic Letter 89–13, ''Service Water System Problems Affecting Safety-Related Equipment,'' in 1992.

Since drift has not increased and the evaporation increase is relatively small, the NRC staff finds that the conclusions of the ER and FES regarding fogging, icing, and drift are not altered due to the proposed EPU.

Chemical and Sanitary Discharges

Surface water and wastewater discharges are regulated by the ADEQ. The NPDES permit is periodically reviewed and reissued by the ADEQ. The present NPDES permit for ANO–2 authorizes discharges from nine outfalls, only one of which will be affected by the EPU. The one affected outfall is the cooling tower blowdown that is addressed below.

The use of chemicals and their subsequent discharge to the environment will not change significantly as a result of the EPU. The cooling tower concentration cycle will remain a low concentration value (3.8). Therefore, the NRC staff concludes that concentration of pollutants in the effluent stream will remain low.

Sanitary wastes are described in ER Section 3.7.1 and ANO–2 Safety Analysis Report Section 9.2.4.2. Sanitary wastes from ANO–2 are discharged directly to the ANO–2 sewage treatment plant in accordance with a permit issued by the ADEQ. Since there is no increase in the ANO staff as a result of the EPU, there is no increase in sanitary waste. Therefore, the EPU requires no changes to the sanitary waste systems or to the parameters regulated by the NPDES permit.

Blowdown

The NRC staff evaluated blowdown, which is discussed in PULR Section 10.4.1.2. As discussed in the ANO–2 Safety Analysis Report Section 10.4.5, Circulating Water, the cooling tower blowdown system, which discharges through the Unit 1 discharge flume, maintains the concentration of the circulating water below the solubility limit of calcium sulfate, thereby preventing condenser tube scale precipitation.

FES Section 5.3.2 evaluated the concentrating effect of evaporation of cooling tower water. The FES states that ''[s]ubstances brought into the circulating water system with the makeup will be concentrated by a factor which will range from 3 to 14 due to evaporation of the water in the cooling tower.'' The licensee states that the EPU will not increase the number of cooling tower concentration cycles beyond this range. Cycles of concentration will remain at the lower end of the range cited, as discussed below. Therefore, the NRC staff concludes that current water appropriation limits are maintained and the conclusions in the FES will remain valid under the EPU conditions.

As stated in the section above, additional cooling tower evaporation will require a small (1.87 ft^3/sec) increase in cooling tower makeup rate. However the blowdown rate will only increase slightly or be kept at the current rate. With blowdown rate at the current rate, cooling tower cycles of concentration will increase by about 0.3 from approximately 3.5 to 3.8. The effect is negligible with either maintaining the current blowdown rate by increasing cycles of concentration or with increasing blowdown. This is because the blowdown is normally mixed with the ANO–1 circulating water system discharge, which has a flow rate of 383,000 gpm (853 ft^3/sec) with two of the four circulating water pumps in operation. Mixing of the blowdown with the Unit 1 circulating water is discussed in FES summary and conclusion paragraph 3.b and Section 5.3.2.

There are no blowdown flow limitations established in ANO NPDES Permit Number AR0001392, issued by ADEQ. Other parameters such as pH, free available chlorine, and total zinc will continue to be monitored in accordance with the permit to ensure that State water quality standards are met.

Thermal Plume Spread and Temperature of Lake Dardanelle

These two topics are discussed in PULR Section 10.4.1.3. As stated above, the ANO–2 cooling tower makeup rate will increase by 840 gpm (1.87 ft^3/sec) from 12,180 (27.1 ft^3/sec) to 13,020 gpm (29.0 ft^3/sec), but blowdown will remain at essentially the current rate. As stated above, this blowdown is normally mixed into the ANO–1 circulating water system discharge, which has a greater flow rate. Since the blowdown temperature will increase by less than 1 °F due to the EPU, the effect of the EPU on thermal plume spread and Lake Dardanelle temperature is negligible.

Cold Shock

Cold shock to an aquatic biota occurs when the warm water discharge from a plant abruptly stops because of an unplanned shutdown, resulting in a rapid temperature drop of the discharge water to the lake and possible adverse impact on aquatic biota. The FES does not discuss cold shock caused by an unplanned trip of ANO–2, and the likelihood of an unplanned shutdown is independent of a power uprate. As stated above, the ANO–2 blowdown is normally mixed with the much larger ANO–1 circulating water discharge. An unplanned shutdown of ANO–1 can cause cold shock as evaluated in Supplement 3. However, even if the ANO–1 circulating water pumps are not in service, the amount of ANO–2 blowdown flow into Lake Dardanelle at the ANO–1 circulating water discharge, even at EPU conditions, is too small to cause cold shock. The NRC staff concludes that the risk of aquatic biota mortality by cold shock is not applicable to ANO–2 even at the proposed EPU conditions. Therefore, the discussion in FES Section 5.4.2 regarding winter lake water temperature effects on shad (FES pages 5–8 and 5–9) remains unchanged.

Hazardous Waste Generation and Air Emissions

As stated in PULR Section 10.4.1.4, ANO holds an Air Permit that was issued and is monitored by the ADEQ Air Division. This permit identifies emission sources at ANO. These sources include, but are not limited to, emergency diesel generators, plant heating boilers, cooling tower, start-up boiler, and bulk storage tanks.

ANO generates hazardous waste from routine plant operations. ANO has a hazardous waste generator's identification number assigned by the

ADEQ Solid Waste Division. ANO files Annual Hazardous Waste Reports to the ADEQ.

The EPU has no impact on the quality or quantity of effluents from these sources, and operation under EPU conditions will not reduce the margin to the limits established by the applicable permits.

Terrestrial Biota Impacts

The licensee states that the EPU will not change the previously evaluated land use at ANO and will not disturb the habitat of any terrestrial plant or animal species. There are no significant increases in previously evaluated environmental impacts from cooling tower operation at EPU conditions.

According to a 1999 review by the Arkansas National Heritage Commission, documented in Supplement 3, Section 4.6, there are no known rare or endangered plant species within the area of the site boundary. As stated in Supplement 3, Section 4.6, the Arkansas Natural Heritage Commission and the U.S. Fish and Wildlife Service have recently stated (June 2000) that no endangered species have been identified at the ANO site or along the transmission rights-of-way. This is consistent with the subsection on ''Fishes'' in FES Section 2.5.1. (See the first paragraph after FES Table 2.4.)

As stated in the June 2001 environmental impact RAI response, the EPU will not disturb land, and land use will remain unchanged. The EPU will not adversely impact the habitat of any terrestrial plant or animal species. There are no deleterious effects on the diversity of biological systems or the sustainability of species due to the EPU, and it does not involve additional changes to the stability or integrity of ecosystems. Therefore, the NRC staff has concluded that the description of the impact on terrestrial ecology, including endangered and threatened plant and animal species, will remain valid for the EPU.

Aquatic Biota Impacts

ANO–1 has a traveling water screen system that protects the suction to both its large circulating water pumps and the much smaller safety-related service water pumps. This same traveling water screen system is used for ANO–2, only for its safety-related service water pumps. The licensee indicates that the EPU does not require larger service water pumps, and the pumps were evaluated at their permitted flowrate as part of the NPDES permit. Therefore, the EPU will have no increased impact on the traveling water screen system. The effect of the proposed EPU on the impingement and entrainment of organisms is unchanged and, therefore, remains insignificant. Therefore, the NRC staff conclusions regarding impingement, entrainment, and endangered and threatened aquatic species as discussed in FES Sections 2.5.1 and 5.4.2, and Supplement 3 Section 4.1.1 will remain valid for the EPU. The EPU does not affect ANO's compliance with Sections 316(a) or 316(b) of the Federal Water Pollution Control Act.

Transmission Facility Impacts

Environmental impacts, such as exposure to electromagnetic fields (EMFs) and shock, could result from a major modification to transmission line facilities. However, the licensee states that no change is being made to the existing transmission line design or operation as a result of the EPU. As stated in one of the licensee's supplemental letters dated October 30, 2001, main transformer capacity is adequate to deliver the additional power to the offsite grid. Grid stability is addressed in PULR Section 2.2.1, which cites ANO procedure changes to avoid grid instability with either the Mablevale or Pleasant Hill 500 kV line out of service or during minimum load conditions. These modifications are consistent with Entergy's program of maintaining grid stability. Therefore, the NRC staff concludes that no significant environmental impacts from any changes in transmission facility design and equipment are expected, and the conclusions of FES Sections 3.3, 4.2, and 5.2 remain valid.

The generator output associated with the EPU will slightly increase the current and the EMFs in the onsite transmission line between the main generator and the plant substation. The line is located entirely within the fenced, ANO-controlled boundary of the plant, and neither members of the public nor wildlife are expected to be affected. Exposure to EMFs from the offsite transmission system is not expected to increase significantly, and any such increase is not expected to change any conclusion in FES Section 5.4.1.3 that no significant biological effects are attributable to EMFs from high voltage transmission lines.

ANO–2 transmission lines are designed and constructed in accordance with the applicable shock prevention provisions of the National Electric Safety Code and the EPU will not cause the transmission line design to deviate from these provisions. Therefore, the NRC staff concludes that the expected increase in current attributable to the EPU does not change the conclusion in FES Section 5.4.1.3 (i.e., adequate protection is provided against hazards from electrical shock).

Social, Economic, and Physical Impacts

The NRC staff has reviewed information provided by the licensee regarding the social, economic, and physical impacts associated with the EPU. ANO employs more than 1,000 people and is a major contributor to the local tax base. The EPU will not significantly affect the size of the ANO workforce and will have no material effect on the labor force required for future outages. Because the plant modifications needed to implement the EPU will be minor, any increase in sales taxes and local and national business revenues will be negligible relative to the large amount of taxes paid by ANO. It is expected that improving the economic performance of ANO–2 through cost reductions and lower total bus bar costs per kilowatt hour will enhance the value of ANO–2 as a generating asset and lower the probability of early plant retirement.

Early plant retirement would have a negative, long-term impact upon the local economy and the community as a whole by reducing public services, employment, income, business revenues, and property values. Conclusions in FES Section 10 and Supplement 3 regarding social and economic impacts and benefits from ANO remain valid under EPU conditions for ANO–2.

The potential for direct physical impacts of the EPU, such as vibration and dust from construction activities, has been considered. The EPU will be accomplished primarily by changes in station operation and few physical modifications to the facility. These limited modifications will be accomplished without physical changes to transmission corridors, access roads, other offsite facilities, or additional project-related transportation of goods or materials. Therefore, the NRC staff concludes that no significant additional construction disturbances causing noise, odors, vehicle exhaust, dust, vibration, or shock from blasting are anticipated, and the conclusions in FES Sections 4.1 and 5.2 remain valid.

Summary

In summary, the NRC staff has concluded that the EPU will not result in a significant change in non-radiological impacts on land use, water use, waste discharges, terrestrial and aquatic biota, transmission facilities, or social and economic factors, and will have no non-radiological environmental impacts other than those evaluated in

the FES. Table 1 provides a tabular summary of the non-radiological results.

TABLE 1.—SUMMARY OF NON-RADIOLOGICAL ENVIRONMENTAL IMPACTS OF POWER UPRATE

Land Use Impacts	No change in land use or aesthetics; will not impact lands with historic or archeological significance. No significant impact due to noise.
Water Use Impacts:	
Groundwater Use	No groundwater use.
Surface Water Use	There is only a small increase in water withdrawal (i.e., for consumption) rate from the lake. The maximum consumption rate will remain at 27ft^3/sec which is within permitted levels.
Waste Discharge Impacts:	
Cooling Tower Fogging, Icing, Drift	Fogging, evaluated as minimal in ER Table 10.1–2. Remains minimal for EPU. No significant change in icing. Icing, evaluated as minimal in ER Table 10.1–2. Remains minimal for EPU. No significant change in cooling tower drift per PULR 10.4.1.4.
Chemical and Sanitary Discharges	No expected change to chemical use and subsequent and discharge, or sanitary waste systems; cooling towers will operate in the current cycle range. No changes to sanitary waste discharges.
Blowdown	Increase in blowdown discussed in PULR Section 10.4.1.2. Maximum 9.2 ft^3/sec blowdown normally mixed with 853 ft^3/sec circulating water system discharge from ANO–1's once-through cooling system. Blowdown remains within permitted limits.
Thermal Plume Spread and Temperature of Lake Dardanelle.	Negligible and unnoticeable increase in thermal plume size. No discharge temperature increase; lake temperature primarily affected by ANO–1 once-through cooling system; remains in NPDES limit.
Cold Shock	Risk of aquatic biota mortality by cold shock is not applicable to ANO–2; discussed in FES Section 5.4.2.
Hazardous Waste Generation and Air Emissions.	No changes to hazardous waste sources or air emissions.
Terrestrial Biota Impacts	No change in terrestrial biota impacts; no known threatened or endangered species within the site boundary.
Aquatic Biota Impacts	No change in aquatic biota impacts; no known threatened or endangered species in the area of surface water intake or discharge.
Transmission Facility Impacts	No change to transmission line design or operation; main transformer capacity to deliver additional power is unchanged; no significant change in exposure to EMFs.
Social, Economic, and Physical Impacts	No significant change in the local economy. Few modifications to physical station facility.

Radiological Impacts

The NRC staff has evaluated radiological environmental impacts on waste streams, in-plant and offsite doses, accident analyses, and fuel cycle and transportation factors. The following is a general description of the waste treatment streams at ANO–2 and an evaluation of the environmental impacts. The NRC finds that the proposed EPU will not cause any radiological effects to surface water in the station environs. Even though there is no discussion in the ANO–2 FES regarding radiological impacts on surface water, ER Table 10.1–2 states that the impact on groundwater due to chemical, radionuclides, or ''other'' impacts is ''NA'' (i.e., not applicable). As stated in ER Section 2.5.2, Ground Water Hydrology, ''[c]ontamination of underground water by radioactivity presupposes the discharge of radioactive liquids from a leaking or ruptured tank into the general environs of the plant site.''

As discussed in ER Section 7.1, the liquid released by the rupture of any tank in the Boron Management System or Waste Management System will be contained within the Auxiliary Building and safely processed. This statement remains true for the EPU as does the FES statements regarding the refueling water tank.

Radiological Waste Stream Impacts

ANO–2 uses waste treatment systems designed to collect, process, and dispose of radioactive gaseous, liquid, and solid waste in accordance with the requirements of 10 CFR Part 20 and 10 CFR Part 50, Appendix I, ''Numerical Guides for Design Objectives and Limiting Conditions for Operation to Meet the Criterion ''As Low As Is Reasonably Achievable'' for Radioactive Material in Light-Water-Cooled Nuclear Power Reactor Effluents.'' These radioactive waste treatment systems are discussed in the FES. The proposed EPU will not affect the environmental monitoring of these waste streams or the radiological monitoring requirements contained in licensing basis documents. The proposed EPU does not result in any changes in operation or design of equipment in the gaseous, liquid, or solid waste systems. The proposed EPU will not introduce new or different radiological release pathways and will not increase the probability of an operator error or equipment malfunction that will result in an uncontrolled radioactive release. The NRC staff evaluated the changes in the gaseous, liquid, and solid waste streams for radiological environmental impact of the proposed EPU, which are set forth below.

Gaseous Radioactive Waste Impacts

During normal operation, the gaseous effluent systems control the release of gaseous radioactive effluents to the site environs, including small quantities of noble gases, halogens, particulates, and tritium. Routine offsite releases from station operation remain below the limits of 10 CFR Part 20 and Appendix I to 10 CFR Part 50 (10 CFR Part 20 includes the requirements of 40 CFR Part 190, ''Environmental Radiation Protection Standards for Nuclear Power Operations''). The gaseous waste management systems include the offgas system and various building ventilation systems. The EPU results in an increase in the release rate that is assumed to be linearly proportional to the power increase. An increase in gaseous effluents is, therefore, assumed to occur. The resultant effluent increases in noble gas and iodine-131 activity are 4.98E–02 μCi per second and 0.00E+00 μCi per second, respectively. A release rate of zero is assumed for iodine because no iodine has been released over the past three years. The estimated dose values will be below 10 CFR Part 50, Appendix I requirements after the EPU. These dose

levels are very small and have no significant impact on human health.

Averaging ANO–2's dose for the three most recent years and adding the effect of the EPU on gamma in air and beta in air, results in EPU dose rates of 6.92E–04 and 2.15E–03 millirad per year (mrad/yr), respectively. Comparing these dose rates to same-type dose rates in FES Table 5.7 demonstrates that ANO–2 is not only far below the RM–50–2 [1] design objective values of 10 mrad/yr and 20 mrad/yr for gamma and beta, respectively, but that the EPU dose rates for gamma and beta are about 86 and 884 times lower, respectively, than the calculated dose for gamma (0.06 mrad/yr) and beta (1.9 mrad/yr) listed in the FES table. A 3-year average allows averaging with and without refueling outages.

Similarly, the 3-year average plus projected EPU dose rate for iodine, tritium, and particules (ITP) is 1.56E–02 millirem per year (mrem/yr). Again, this EPU ITP dose rate is not only far below the RM–50–2 design objective dose rate of 15 mrem/yr, but is also about 192 times lower in dose consequence than the 3.0 mrem/yr calculated dose for ITP in the FES table.

These low dose rates projected for the EPU, when combined with the most recent 3-year average, clearly demonstrate that ANO–2 has been successful in maintaining a very low exposure to plant personnel and the public of both gaseous and liquid (see below) effluent doses. The NRC staff has evaluated the information provided by the licensee and concludes that the estimated dose values for gaseous radioactive wastes will be below Appendix I requirements after the EPU.

Liquid Radioactive Waste Impacts

The liquid radwaste system is designed to process and recycle, to the extent practicable, the liquid waste collected. Annual radiation doses to individuals are maintained below the guidelines in 10 CFR Part 20 and 10 CFR Part 50, Appendix I. As set forth below, the NRC staff expects that there will be no change in the release policy as a result of the EPU.

The licensee has stated that EPU conditions will not result in significant increases in the volume of fluid from sources flowing into the liquid radwaste system. The reactor will continue to be operated within its present pressure control band. Valve packing leakage volume into the liquid radwaste system is not expected to increase. There will be no changes in reactor cooling pump seal flow or the flow of any other normal equipment drain path. In addition, there will be no impact on the dirty radwaste or chemical waste subsystems of the liquid radwaste system as a result of the EPU, since the operation and the inputs to these subsystems are independent of the power uprate. No significant dose increase from the liquid pathway will result from the EPU. Therefore, the conclusions in the FES are expected to remain valid under EPU conditions, as demonstrated by the following comparison.

Averaging ANO–2's dose for the three most recent years and adding the effect of the EPU on the liquid effluents dose rate to the total body, or any organ, for all pathways results in a calculated dose of 1.04E–2 mrem/yr. Comparing this dose to the liquid effluent doses in FES Table 5.7 demonstrates that ANO–2 is not only far below the RM–50–2 design objective of 5 mrem/year but that the EPU dose rate is about 30 times lower than the calculated dose of 0.31 mrem/yr listed in the FES.

Solid Radioactive Waste Impacts

The solid radioactive waste system collects, monitors, processes, packages, and provides temporary storage facilities for radioactive solid wastes prior to offsite shipment and permanent disposal. Entergy has implemented procedures to assure that the processing and packaging of wet and dry solid radioactive waste and irradiated reactor components at ANO–2 are accomplished in compliance with regulations. Entergy continually tracks the volume of solid radioactive waste generated at ANO; however, the total is not isolated by unit (i.e., ANO–1 or ANO–2). From 1995 to the present, ANO–1 and ANO–2 generated 78,787 ft^3 of low-level radioactive waste for an average of about 12,097 ft^3 per year. In 2000, ANO generated a peak volume of 25,107 ft^3 of low-level radioactive waste. The majority of the waste was generated as a result of the ANO–2 outage involving replacement of the steam generator.

Wet Waste: The largest volume contributors to radioactive solid wet waste are low-specific-activity spent secondary resins. Historically, this has accounted for more than 50 percent of the total volume of wet radioactive waste generated annually. Since the completion of the ANO–2 steam generator replacement outage, no secondary resin has been found to be radioactive. This should not change appreciably with the EPU. The remainder of the wet waste is primary resins, filters, and oil and sludge from various contaminated systems. The EPU will not involve changes in either reactor water cleanup flow rates or filter performance. Therefore, the NRC staff concludes that implementation of the proposed EPU will not have a significant impact on the volume or activity of wet radioactive solid waste at ANO–2.

Dry Waste: Entergy states that it continually tracks the volume of dry radioactive waste generated and continually looks for new ways to minimize the volume of waste generated. Dry waste consists primarily of air filters, contaminated paper products and rags, contaminated clothing, tools and equipment parts that cannot be effectively decontaminated, and solid laboratory wastes. The activity of much of this waste is low enough to permit manual handling. Dry waste is collected in containers located throughout the plant, packaged, and removed to a controlled area for temporary storage. Because of its low activity, dry waste can be stored until enough is accumulated to permit economical transportation to an offsite processing facility for volume reduction or a burial ground for final disposal.

The licensee has stated that the majority of waste generated at ANO is compactible dry active waste. In light of Entergy's continuing efforts to reduce radioactive wastes at ANO, any projected increase in solid waste generation under the EPU conditions described above would not be significant and is not sufficient to reverse the continuing downward trend in the production and activity of dry wastes. Moreover, due to the nature of the materials in this waste stream, it is not expected to change significantly as a result of the EPU.

Irradiated Reactor Components: Irradiated reactor components such as in-core detectors and fuel assemblies, must be disposed of after the life of the component. The volume and activity of waste generated from spent control element assemblies and in-core detectors may increase slightly under the higher flux conditions associated with EPU conditions.

Entergy plans to load 80 fresh fuel bundles in the initial refueling of ANO–2 to commence operation under the proposed EPU. This is 12 fresh bundles more than required for the current refueling cycle. The number of irradiated fuel assemblies discharged from the reactor should not increase during subsequent reloads for

[1] Guides on Design Objectives proposed by the NRC staff on February 20, 1974; considers doses to individuals from all units on site. From ''Concluding Statement of Position of the Regulatory Staff,'' Docket No. RM–50–2, February 20, 1974, pp. 25–30, U.S. Atomic Energy Commission, Washington, D.C.

comparable energy requirements. Accordingly, the NRC staff concludes that implementation of the EPU will not have a significant impact on the volume or activity of the irradiated reactor components at ANO.

Given the information above, NRC staff concludes that the environmental impact due to generation of solid reactor system waste from the proposed EPU is not significant.

Dose Impacts

The NRC staff evaluated in-plant and offsite radiation levels as part of the environmental impacts of the proposed EPU.

In-plant Radiation

Increasing the rated power at ANO–2 may increase the radiation levels in the reactor coolant system (RCS). However, ongoing physical plant improvements and administrative controls, such as shielding, RCS chemistry, and the plant radiation protection program, compensate for these potential increases. Over the past 7 years, Entergy has continued to decrease the occupational dose to workers at ANO–2. In years with refueling outages, the total dose decreased by 55 percent from 175 rem in 1995 to 79 rem in 1999. As a result of the length and scope of the steam generator replacement outage in 2000, doses were higher than in a typical year. Non-outage year doses at ANO–2 illustrate a downward trend from 49 rem in 1996 to 35 rem in 1998 to 9 rem in 2001. The licensee stated that it expects to continue this trend while operating under the EPU conditions.

The plant radiation protection program will maintain individual doses consistent with as-low-as reasonably achievable (ALARA) requirements and well below the established limits of 10 CFR Part 20. Routine plant radiation surveys required by the radiation protection program will identify increased radiation levels in accessible areas of the plant and radiation zone postings, and job planning will be adjusted, if necessary. Time within radiation areas is monitored and controlled under the radiation protection program. Administrative limits are provided for occupational dose at levels well below the 10 CFR Part 20 limits.

These administrative limits provide a significant margin to regulatory dose limits under normal operating and outage conditions. Administrative dose limits at ANO–2 have not been routinely exceeded under present power conditions.

Offsite Doses

The slight increase in normal operational gaseous activity levels under the EPU will not significantly affect the large margin below the offsite dose limits established by 10 CFR Part 20. In addition, doses from liquid effluents, currently low, will remain low under EPU conditions.

The ANO–2 Technical Specifications implement the guidelines of 10 CFR Part 50, Appendix I, which are within the 10 CFR Part 20 limits. Adjusting current values for projected EPU increases, the offsite dose at EPU conditions is estimated to be 6.92E–04 millirads for noble gas gamma air, 2.15E–03 millirads for noble gas beta air, and 1.56E–02 millirem to the thyroid for particulates and iodine. Appendix I limits are 10 millirads, 20 millirads, and 15 millirem to the thyroid, respectively. The licensee stated that the offsite dose will continue to be within the technical specification dose limits.

The EPU will not involve significant increases in an offsite dose from noble gases, airborne particulates, iodine, or tritium. Radioactive liquid effluents are not routinely discharged from ANO–2. In addition, as stated by the Radiological Environmental Monitoring Program for ANO–2, radiation exposure from shine dose is not now a significant exposure pathway, and it will not be significantly affected by the EPU.

Therefore, the NRC staff concludes that the estimated doses from both the liquid and gaseous release pathways resulting from EPU conditions are within the design objectives specified by 10 CFR Part 50, Appendix I, and the limits of 10 CFR Part 20.

Accident Analysis Impacts

The NRC staff reviewed the licensee's analyses and performed confirmatory calculations to verfy the acceptability of the licensee's calculated doses under accident conditions. Based on these calculations, the staff concludes that the proposed EPU would not significantly increase the probability or consequences of accidents and would not result in a significant increase in the radiological environmental impact of ANO–2 under accident conditions. If the license amendment request is approved, the result of the staff's analyses will be presented in the safety evaluation issued with the license amendment.

Severe Accidents: The environmental effects of severe accidents outside the design basis of protection and engineered safety systems were not evaluated in the ANO–2 ER. The NRC staff finds that the EPU will not significantly increase the probability or consequences of accidents and will not result in a significant increase in the radiological environmental impact of ANO–2 under accident conditions.

Fuel Cycle and Transportation Impacts

The EPU will involve an increase in the average enrichment of the fuel bundle. The environmental impacts of the fuel cycle and of transportation of fuel and wastes are described in 10 CFR Part 51, Tables S–3 and S–4, specifically at 10 CFR 51.51 and 10 CFR 51.52, respectively. ANO–2 FES Section 5.5.3 discusses the uranium fuel cycle and transportation impact of the fuel at original issuance of the operating license. An NRC assessment (53 FR 30355, dated August 11, 1988, as corrected by 53 FR 32322, dated August 24, 1988) evaluated the applicability of Tables S–3 and S–4 to higher burnup cycles. The assessment concluded that there is no significant change in environmental impacts for fuel cycles with uranium enrichments up to 5.0 weight-percent U–235 and burnups up to 60 gigawatt-days per metric ton of uranium (GWd/MTU) from the parameters evaluated in Tables S–3 and S–4. In Operating License Amendment 178 dated January 14, 1997, the NRC granted Entergy's request to increase the fuel enrichment from 4.1 percent to 5.0 percent at ANO–2. The environmental effects of this fuel enrichment increase were considered at that time. Since the fuel enrichment for the EPU will not exceed 5.0 weight-percent U–235, and the rod average discharge exposure will not exceed 60 GWd/MTU, the environmental impacts of the proposed EPU will remain bounded by these conclusions and is not expected to be significant.

Summary

The NRC staff concludes that the proposed EPU will not significantly increase the probability or consequences of an accident, will not introduce any new radiological release pathways, will not result in a significant increase in occupational or public radiation exposures, and will not result in significant additional fuel cycle environmental impacts. Accordingly, the NRC staff concludes that no significant radiological environmental impacts are associated with the proposed action. Table 2 summarizes the radiological environmental impacts of the EPU.

TABLE 2.—SUMMARY OF RADIOLOGICAL ENVIRONMENTAL IMPACTS OF POWER UPRATE

Surface Water	No change in radiological impact to surface water.
Groundwater	No change in radiological impact to ground water.
Radiological Waste Stream Impacts	No changes in design or operation of waste streams.
Gaseous Radioactive Waste Impacts	An increase in release rate that is linearly proportional to the power increase will be expected.
Liquid Radioactive Waste Impacts	No change in ANO–2 liquid release policy.
Solid Radioactive Waste Impacts:	
Wet Waste	No appreciable change in radioactive secondary resins expected due to EPU.
Dry Waste	No significant changes in dry waste foreseen.
Irradiated Reactor Components	No significant changes in irradiated components forseen.
Dose Impacts:	
In-plant Radiation	Even though some RCS activity levels are elevated, in-plant exposures are controlled to mitigate worker exposures.
Offsite Doses	Slight increase in gaseous activity levels possible, but doses will remain ALARA and within 10 CFR Part 20 limits.
Accident Analysis Impacts	No increase in the probability of an accident. Some increase in consequences of an accident, but still within NRC acceptance limits.
Fuel Cycle and Transportation Impacts	Increase in bundle average enrichment; impacts will remain within the conclusions of Table S–3 and Table S–4 of 10 CFR Part 51.

Alternatives to the Proposed Action

As an alternative to the proposed action, the NRC staff considered denial of the proposed action (i.e., the ''no-action'' alternative). Denial of the application would result in no change in current environmental impacts. The environmental impacts of the proposed action and the alternative action are similar.

The estimated cost of the increase in generating capacity is approximately half the cost projected for purchasing the power and one-third the cost of producing the power by constructing a new combined-cycle, natural-gas-fueled facility with the attendant environmental impacts of construction and operation. The licensee concluded that increasing ANO–2 capacity would be an economical and environmentally sound option for increasing power supply. Furthermore, unlike fossil fuel plants, ANO–2 does not routinely emit sulfur oxides, nitrogen oxides, particulate, matter carbon dioxide, or other atmospheric pollutants that contribute to greenhouse gases or acid rain.

Alternative Use of Resources

This action does not involve the use of any resources different than those previously considered in the FES for ANO–2, dated June 1977 (NUREG–0254).

Agencies and Persons Consulted

In accordance with its stated policy, on April 15, 2002, the NRC staff consulted with Division of Radiation Control and Emergency Management of the Arkansas Department of Health, regarding the environmental impact of the proposed action. The State official had no comment.

Finding of No Significant Impact

On the basis of the environmental assessment, the NRC concludes that the proposed action will not have a significant effect on the quality of the human environment. Accordingly, the NRC has determined not to prepare an environmental impact statement for the proposed action.

For further details with respect to the proposed action, see the following: The environmental impacts of ANO–2 have been described in (1) the FES, dated June 1977 (NUREG–0254), (2) the PULR, which is Enclosure 5 to the EPU application dated December 19, 2000, and (3) the June 26 and December 10, 2001, and January 15, 2002, RAI responses. On January 31, 2000, as supplemented by letters dated June 26, July 31, and September 21, 2000, Entergy submitted its ER supporting the license renewal of ANO–1. The staff Environmental Impact Statement has been issued as NUREG–1437, Supplement 3. Supplement 3 addresses many balance-of-plant site features that are common to ANO–1 and ANO–2. Supplement 3 was cited in Enclosure 5 of the December 19, 2000, license application in instances where site characteristics common to both ANO–1 and ANO–2 are unchanged by the EPU. Documents may be examined and/or copied for a fee at the NRC's Public Document Room, at One White Flint North, 11555 Rockville Pike (first floor), Rockville, Maryland. Publicly available records will be accessible electronically from the ADAMS Public Library component on the NRC Web site, *http://www.nrc.gov* (the Electronic Reading Room). Persons who do not have access to ADAMS or who encounter problems in accessing the documents located in ADAMS should contact the NRC Public Document Room Reference staff by telephone at 1–800–397–4209, or 301–415–2737, or by e-mail at *pdr@nrc.gov.*

Dated at Rockville, Maryland, this 19th day of April 2002.

For the Nuclear Regulatory Commission.

William D. Reckley,

Acting Chief, Section 1, Project Directorate IV, Division of Licensing Project Management, Office of Nuclear Reactor Regulation.

[FR Doc. 02–9989 Filed 4–23–02; 8:45 am]

BILLING CODE 7590–01–P

NUCLEAR REGULATORY COMMISSION

Notice of Delay in Issuance of the Draft and Final Environmental Impact Statements for the Mixed Oxide Fuel Fabrication Facility

AGENCY: United States Nuclear Regulatory Commission.

ACTION: Notice of change in schedule.

SUMMARY: On March 7, 2001, pursuant to the National Environmental Policy Act (NEPA), the U.S. Nuclear Regulatory Commission (NRC) published a Notice of Intent (NOI) to Prepare an Environmental Impact Statement (EIS) for a proposed Mixed Oxide (MOX) Fuel Fabrication Facility (66 FR 13794). NRC staff subsequently held scoping meetings, and issued a Scoping Summary Report in connection with preparing the EIS. NRC staff planned to issue a Draft Environmental Impact Statement (DEIS) on February 27, 2002. NRC staff decided this schedule needed to be changed when, in January 2002, the U.S. Department of Energy (DOE) announced its decision to alter its planned hybrid approach for surplus weapons plutonium disposition [65 FR 1608]. The Plutonium Immobilization Plant (PIP) that DOE had planned to build and operate as part of its hybrid

approach will not be built. Instead, DOE decided that 34 metric tons of surplus weapons plutonium would be converted into MOX fuel at the proposed MOX facility. During the scoping process, immobilization of plutonium was identified as one of the No Action Alternatives to be evaluated in the EIS for the proposed MOX facility. DOE's decision not to build the PIP and convert all of the plutonium into MOX fuel requires design changes to the proposed MOX facility. These design changes were generally described in a February 13, 2002, public meeting between the NRC staff and the applicant, Duke COGEMA Stone & Webster (DCS). The NRC staff found that due to these changes, DCS would be required to submit a supplemental Environmental Report (ER), and that the DEIS should not be issued until after the supplemental ER is received and reviewed. The supplemental ER is expected to be submitted in July 2002, and the NRC staff anticipates issuing the DEIS in February 2003.

FOR FURTHER INFORMATION CONTACT: For general or technical information associated with the proposed MOX facility, please contact: Tim Johnson at (301) 415–7299, or Drew Persinko at (301) 415–6522. For general information on the NRC NEPA process, please contact: Tim Harris at (301) 415–6613.

Availability of Documents for Review: Information and documents associated with the MOX project are available for public review through our electronic reading room: *http://www.nrc.gov/reading-rm.html.* Documents may also be obtained from NRC's Public Document Room at U.S. Nuclear Regulatory Commission, Public Document Room, Washington, DC 20555.

SUPPLEMENTARY INFORMATION:

Background: In January 2000, DOE issued its Record of Decision (ROD) for the Surplus Plutonium Disposition Final EIS (65 FR 1608). The fundamental purpose of the DOE program is to ensure that plutonium produced for nuclear weapons and declared excess to national security needs is converted to forms that are inaccessible and unattractive for nuclear weapons. In its ROD, DOE announced that it had decided to use a hybrid approach for the disposition of surplus weapons plutonium, and that the facilities would be located at DOE's Savannah River Site (SRS) in South Carolina. The first approach described in the ROD was immobilization of approximately 17 metric tons of surplus plutonium. Immobilization would involve placing the weapons plutonium into canisters at the PIP, and filling the canisters with vitrified waste from the SRS high-level waste (HLW) tanks. The second approach would have converted up to 33 metric tons of surplus plutonium into MOX fuel at the proposed MOX facility.

DOE selected DCS to design, build, and operate the proposed MOX fuel fabrication facility. DCS submitted its ER for the MOX facility to NRC on December 19, 2000, and submitted its construction authorization request (CAR) to NRC on February 28, 2001. The NRC staff has been reviewing the CAR and ER to determine whether DCS should be authorized to begin constructing the proposed MOX facility.

NRC staff held scoping meetings to gather comments from members of the public in April and May 2001, and issued a Scoping Summary Report of those comments in August 2001. However, because of the changes in the project (summarized above and discussed below), NRC has decided to delay issuance of the DEIS.

Cancellation of Plutonium Immobilization Plant: In DOE's 2003 Fiscal Year budget, it stated that the immobilization approach will not be pursued. The Plutonium Immobilization Plant (PIP) was one of the three facilities planned as part of DOE's hybrid approach for surplus weapons plutonium disposition (65 FR 1608). Under DOE's new plan, approximately 6 metric tons of plutonium previously destined for immobilization would be processed in the re-designed proposed MOX facility. Plutonium that is too costly to convert to MOX fuel would be disposed of as waste by DOE.

During EIS scoping, immobilization of all surplus plutonium was identified as one of the No Action Alternatives for the MOX facility EIS. DOE's cancellation of the PIP requires that discussions of this No Action Alternative in the DEIS be reconsidered.

The NRC staff believes that it would be difficult for the public to comment effectively on the DEIS if it were issued in its current form, since the immobilization No Action Alternative arose from public comments received during the scoping process. The NRC is reviewing how it will present the second No Action Alternative in the DEIS.

Additional Changes in the Proposed DOE Action: As a result of the PIP cancellation, 6 metric tons of plutonium, originally slated for immobilization (designated as alternate feedstock), and 2 metric tons from additional sources, would now be processed in a re-designed proposed MOX facility. The alternate feedstock includes impurities that would require more processing than the plutonium already scheduled for conversion into MOX fuel. In addition, the amount of high-alpha waste produced from the MOX facility would be greater, due to processing of the alternate feedstock. The current MOX facility design will be updated to include new or additional equipment and processing steps to accommodate the additional plutonium.

In addition to the changes in the proposed MOX fuel fabrication facility prompted by the PIP cancellation, DOE plans to construct and operate a new waste processing building at the SRS to solidify the MOX waste streams (high-alpha and uranium) that were originally planned to go to DOE's HLW tanks at the SRS.

Resulting Changes in the Proposed NRC MOX DEIS: The DEIS will be revised to include and evaluate the proposed changes to the MOX fuel fabrication facility, including new and/or altered equipment plans, additional processing steps and the consequent hazards, and the additional waste generated. The DEIS will also evaluate the changes to the waste processing plans, including construction and operation of a new DOE facility. Finally, the DEIS will be revised to evaluate the impacts of transporting and using the additional MOX fuel. The impacts related to reactor use of MOX fuel, as described in the ER, consider only fuel converted from 25.5 metric ton of surplus plutonium, and not the 34 metric ton now scheduled to be converted into MOX fuel at the proposed MOX facility.

Your Comments are Requested: The NRC is hereby soliciting comments on our plans for the DEIS to accommodate the changes in the DOE and DCS programs. We would specifically like you to comment on:

(1) How the immobilization of surplus plutonium as a No Action Alternative should be discussed in the DEIS, since DOE has canceled plans to build the Plutonium Immobilization Plant.

(2) Whether there are additional reasonable alternatives not identified during scoping that should be considered in the DEIS, in light of the changes described above. As discussed in the Scoping Summary Report, NRC is considering the environmental impacts of the proposed action (construction and operation of the proposed MOX fuel fabrication facility), continued storage of surplus plutonium at existing DOE sites, and immobilization of surplus plutonium. If the immobilization alternative is not considered, then the DEIS would only evaluate the proposed action and one No Action Alternative.

Please submit your comments on or before August 30, 2002. Written comments should be mailed to Mike Lesar, Chief, Rules and Directives Branch, Division of Administrative Services, Office of Administration, Mail Stop T–6D59, U.S. Nuclear Regulatory Commission, Washington, DC 20555. Comments will also be accepted by e-mail. Interested parties may e-mail their comments to *teh@nrc.gov.* Comments will also be accepted by fax at (301) 415–5398, Attention: Tim Harris.

Tentative Schedule: Based on available information, and assuming DCS submits a supplemental ER in July 2002, NRC has revised the EIS schedule as follows:

Conduct Acceptance Review of DCS Supplemental Environmental Report—August 2002
Conduct Informational Meetings—September 2002
Issue Draft Environmental Impact Statement—February 2003
Public Comment on DEIS—February–April 2003
Issue Final Environmental Impact Statement—August 2003

Signed in Rockville, MD, this 17th day of April, 2002.

For the Nuclear Regulatory Commission.

Thomas H. Essig,

Chief, Environmental and Performance Assessment Branch, Division of Waste Management, Office of Nuclear Material Safety and Safeguards.

[FR Doc. 02–9991 Filed 4–23–02; 8:45 am]

BILLING CODE 7590–01–P

NUCLEAR REGULATORY COMMISSION

Advisory Committee on Reactor Safeguards; Meeting Notice

In accordance with the purposes of sections 29 and 182b. of the Atomic Energy Act (42 U.S.C. 2039, 2232b), the Advisory Committee on Reactor Safeguards (ACRS) will hold a meeting on May 2–4, 2002, in Conference Room T–2B3, 11545 Rockville Pike, Rockville, Maryland. The date of this meeting was previously published in the **Federal Register** on Monday, November 26, 2001 (66 FR 59034).

Thursday, May 2, 2002

8:30 a.m.–8:35 a.m.: Opening Remarks by the ACRS Chairman (Open)—The ACRS Chairman will make opening remarks regarding the conduct of the meeting.

8:35 a.m.–10:30 a.m.: Brunswick Steam Electric Plant, Units 1 & 2 Core Power Uprate (Open/Closed)—The Committee will hear presentations by and hold discussions with representatives of the NRC staff and the Carolina Power and Light Company regarding the license amendment to increase core power level by approximately 15% for the Brunswick Steam Electric Plant, Units 1 & 2, pursuant to the General Electric Nuclear Energy Extended Power Uprate Program.

[**Note:** A portion of this session may be closed to discuss General Electric proprietary information.]

10:45 a.m.–11:45 a.m.: Expert Panel Recommendations on Source Term for High Burnup and Mixed Oxide (MOX) Fuel (Open)—The Committee will hear presentations by and hold discussions with representatives of the NRC staff regarding the Expert Panel's recommendations on source term for high burnup and MOX fuel and on revising NUREG–1465, ''Accident Source Terms for Light-Water Nuclear Power Plants.''

12:45 p.m.–1:45 p.m.: Confirmatory Research Program on High Burnup Fuel (Open)—The Committee will hear presentations by and hold discussions with representatives of the Office of Nuclear Reactor Regulation and the Office of Nuclear Regulatory Research regarding their views on the need for the confirmatory research program on high burnup fuel.

1:45 p.m.–2:45 p.m.: Subcommittee Report (Open)—Report by the Chairman of the ACRS Subcommittee on Reactor Fuels regarding the staff's draft Safety Evaluation Report on the Duke Cogema Stone & Webster application for a construction authorization for a proposed MOX Fuel Fabrication Facility that was discussed during the April 10, 2002 Subcommittee meeting, and other related matters.

3 p.m.–6:15 p.m.: Safeguards and Security Activities (Closed)—The Committee will hear presentations by and hold discussions with representatives of the NRC staff regarding ongoing and planned NRC activities in the safeguards and security areas.

[**Note:** The entire session will be closed to protect national security information and safeguards information.]

6:30 p.m.–7:15 p.m.: Proposed ACRS Reports (Open)—The Committee will discuss proposed ACRS reports on matters considered during this meeting.

Friday, May 3, 2002

8:30 a.m.–8:35 a.m.: Opening Remarks by the ACRS Chairman (Open)—The ACRS Chairman will make opening remarks regarding the conduct of the meeting.

8:35 a.m.–11:30 A.M. : PHEBUS–FP, PHEBUS–2K and PHEBUS–LOCA International Projects (Open)—The Committee will hear presentations by and hold discussions with representatives of the French PHEBUS–FP Project regarding the recent results of the PHEBUS–FP Project and plans for the PHEBUS–2K and PHEBUS–LOCA Projects.

11:45 a.m.–12:30 p.m.: Future ACRS Activities/Report of the Planning and Procedures Subcommittee (Open)—The Committee will discuss the recommendations of the Planning and Procedures Subcommittee regarding items proposed for consideration by the full Committee during future meetings. Also, it will hear a report of the Planning and Procedures Subcommittee on matters related to the conduct of ACRS business, and organizational and personnel matters relating to the ACRS.

1:30 p.m.–1:45 p.m.: Reconciliation of ACRS Comments and Recommendations (Open)—The Committee will discuss the responses from the NRC Executive Director for Operations (EDO) to comments and recommendations included in recent ACRS reports and letters. The EDO responses are expected to be made available to the Committee prior to the meeting.

1:45 p.m.–7:00 p.m.: Proposed ACRS Reports (Open)—The Committee will discuss proposed ACRS reports.

Saturday, May 4, 2002

8:30 a.m.–12:30 p.m.: Proposed ACRS Reports (Open)—The Committee will continue its discussion of proposed ACRS reports.

12:30 p.m.–1:00 p.m.: Miscellaneous (Open)—The Committee will discuss matters related to the conduct of Committee activities and matters and specific issues that were not completed during previous meetings, as time and availability of information permit.

Procedures for the conduct of and participation in ACRS meetings were published in the **Federal Register** on October 3, 2001 (66 FR 50462). In accordance with those procedures, oral or written views may be presented by members of the public, including representatives of the nuclear industry. Electronic recordings will be permitted only during the open portions of the meeting and questions may be asked only by members of the Committee, its consultants, and staff. Persons desiring to make oral statements should notify Dr. Sher Bahadur, ACRS, five days before the meeting, if possible, so that appropriate arrangements can be made to allow necessary time during the meeting for such statements. Use of still,

motion picture, and television cameras during the meeting may be limited to selected portions of the meeting as determined by the Chairman. Information regarding the time to be set aside for this purpose may be obtained by contacting Dr. Sher Bahadur prior to the meeting. In view of the possibility that the schedule for ACRS meetings may be adjusted by the Chairman as necessary to facilitate the conduct of the meeting, persons planning to attend should check with Dr. Sher Bahadur if such rescheduling would result in major inconvenience.

In accordance with Subsection 10(d) Public Law 92–463, I have determined that it is necessary to close portions of this meeting noted above to discuss proprietary information per 5 U.S.C. 552b(c)(4), to protect national security information per 5 U.S.C. 552b(c)(1), and to protect safeguards information per 5 U.S.C. 552b(c)(3).

Further information regarding topics to be discussed, whether the meeting has been canceled or rescheduled, the Chairman's ruling on requests for the opportunity to present oral statements, and the time allotted therefor can be obtained by contacting Dr. Sher Bahadur (telephone 301–415–0138), between 7:30 a.m. and 4:15 p.m., EDT.

ACRS meeting agenda, meeting transcripts, and letter reports are available through the NRC Public Document Room at *pdr@nrc.gov*, or by calling the PDR at 1–800–397–4209, or from the Publicly Available Records System (PARS) component of NRC's document system (ADAMS) which is accessible from the NRC Web site at *http://www.nrc.gov/NRC/ADAMS/index.html.*

Videoteleconferencing service is available for observing open sessions of ACRS meetings. Those wishing to use this service for observing ACRS meetings should contact Mr. Theron Brown, ACRS Audio Visual Technician (301–415–8066), between 7:30 a.m. and 3:45 p.m., EDT, at least 10 days before the meeting to ensure the availability of this service. Individuals or organizations requesting this service will be responsible for telephone line charges and for providing the equipment and facilities that they use to establish the videoteleconferencing link. The availability of videoteleconferencing services is not guaranteed.

Dated: April 18, 2002.

Andrew L. Bates,

Advisory Committee Management Officer.

[FR Doc. 02–9993 Filed 4–23–02; 8:45 am]

BILLING CODE 7590–01–P

NUCLEAR REGULATORY COMMISSION

Report to Congress on Abnormal Occurrences Fiscal Year 2001 Dissemination of Information

Section 208 of the Energy Reorganization Act of 1974 (Pub. L. 93–438) identifies an abnormal occurrence (AO) as an unscheduled incident or event that the U.S. Nuclear Regulatory Commission (NRC) determines is significant from the standpoint of public health or safety. The Federal Reports Elimination and Sunset Act of 1995 (Pub. L. 104–66) requires that AOs be reported to Congress annually. During fiscal year 2001, two events, one at a facility licensed by the NRC and the other at a facility licensed by an Agreement State were determined to be AOs. These events are discussed below. As required by Section 208, the discussion for each event includes the date and place, the nature and probable consequences, the cause or causes, and the action taken to prevent recurrence. Each event is also being described in NUREG–0090, Vol. 24, ''Report to Congress on Abnormal Occurrences, Fiscal Year 2001.'' This report will be available electronically at the NRC Web site *http://www.nrc.gov/reading-rm/doc-collections/nuregs/staff/.*

Nuclear Power Plants

None of the events that occurred at U.S. nuclear power plants during this reporting period was significant enough to be reported as an AO.

Fuel Cycle Facilities (Other Than Nuclear Power Plants)

None of the events that occurred at fuel cycle facilities during this reporting period was significant enough to be reported as an AO.

Other NRC Licensees (Industrial Radiographers, Medical Institutions, etc.)

01–1 Occupational Overexposure at Southeast Missouri State University in Cape Girardeau, Missouri

Date and Place—June 13–16, 2000, Southeast Missouri State University (the university), Cape Girardeau, Missouri. The information available to the staff prior to the publication of the FY 2000 report was not sufficient to determine if this event met the AO criteria.

Nature and Probable Consequences—In 1970, the university was licensed by the Atomic Energy Commission, NRC's predecessor, to possess and use up to 185 megabecquerel (MBq) [5 millicurie (5 mCi)] of americium-241 (Am-241) in unsealed form. The authorized user of the Am-241 died in 1980. In 1991, the university requested and received an amendment to its NRC license to remove authorization to possess and use certain radionuclides, including Am-241. The university disposed of some radionuclides in its possession but inadvertently kept the unsealed Am-241.

On February 16, 2000, a routine NRC inspection at the university found that the radiation program had deteriorated significantly. Specifically, since August 1, 1999, the university had been without a radiation safety officer (RSO), and the university officials were not sure whether they had radioactive materials in their possession or what materials they were authorized to possess. They did not know the general terms and conditions of their license. During the inspection, the licensee and an NRC inspector found an apparently empty vial labeled as containing 185 MBq (5 mCi) of Am-241 in a safe, located in the basement of the university, along with additional unauthorized material.

After the discovery of the unauthorized material, the university hired a consultant to characterize the material in the safe, and assess contamination in and around the area. On April 19, 2000, the consultant inventoried the contents of the safe and found elevated radiation levels in the room where the safe was located. On June 13, 2000, the consultant began to perform surveys and decontamination activities and identified loose Am-241 contamination.

Inadequate radiological surveys and poor handling techniques used by the consultant resulted in contamination in a number of areas in the basement.

On June 21, 2000, the NRC initiated a special inspection in response to a report from the university on loose Am–241 contamination. NRC surveys independently confirmed the Am–241 contamination.

The licensee restricted access to all contaminated areas, interrupted the decontamination process, and performed internal dose assessments of individuals potentially exposed to Am–241 contamination. These assessments indicated that the consultant received a calculated committed dose equivalent to the bone surface of 2630 millisievert (263 rem). The consultant has seen a doctor, had one therapeutic medical treatment, and no adverse health effects are expected. The licensee hired a second consultant to complete the decontamination process.

Cause or Causes—The licensee possessed radioactive material not authorized by the NRC license and failed to perform adequate radiation

surveys, including air sampling to measure airborne radioactivity present during the inventory and decontamination activities. The survey instruments were incapable of detecting alpha activity which is needed to identify the presence of Am–241. In addition, from August 1, 1999, to July 10, 2000, the licensee had no RSO to oversee and ensure implementation of an effective radiation protection program.

Actions Taken To Prevent Recurrence

Licensee—The licensee appointed a new RSO and revised its radiation safety program, with an emphasis on inventory control. Specifically, the university implemented new property control and surplus inventory policies and procedures that included: (1) Review and approval by the RSO of property transfers of potentially contaminated equipment, (2) surveys of surplused equipment for contamination control, and (3) training of personnel in the correct procedures for surplusing equipment containing radioactive material.

NRC—On September 13, 2001, the NRC issued a Notice of Violation and Proposed Imposition of Civil Penalty against the university for the violation associated with the June 2000 radiation overexposure to the consultant. The fine was $11,000. The NRC also issued Information Notice 2001–01 to emphasize the importance of accurate inventory controls to prevent unauthorized possession of radioactive material.

This event is closed for the purpose of this report.

* * * * *

Agreement State Licensees

AS 01–1 Industrial Radiography Occupational Overexposure at Quality Inspection Services, Inc., in Jacksonville, Florida

Date and Place—February 16, 2001, Quality Inspection Services, Inc., Jacksonville, Florida.

Nature and Probable Consequences—Based on discussions with the involved individuals, it was determined that a radiographer retracted a 2.15 terabecquerel (58 curie) iridium-192 source into what was thought to be a locked, shielded, and fully retracted position inside the radiography camera. In setting up for the next shot, the radiographers noticed that the source had not been secured in the off position after the previous shot and that their survey meters and their pocket dosimeters were off scale. The radiographers immediately retracted the source to its fully shielded position and exited the working area. Film badges belonging to the radiographers indicated exposures of 29 mSv (2.9 rem) and 392 mSv (39.2 rem). For the radiographer with the highest exposure, blood tests were normal and he declined further testing. No adverse health effects are expected.

Cause or Causes—The radiographers failed to perform an adequate survey of the radiography camera after performing radiographic operations. In addition, the alarming ratemeter worn by one of the radiographers was not turned on during radiography. The alarming ratemeter for the second radiographer had a low battery and did not produce an audible alarm.

Actions Taken To Prevent Recurrence

Licensee—The licensee conducted a reenactment of the event and, based on lessons learned, the training procedures were revised to prevent future incidents.

State Agency—The State of Florida Bureau of Radiation Control determined that the radiographer failed to follow procedures and took enforcement action against the licensee. The State reviewed and accepted the licensee's corrective actions, which included refresher training.

This event is closed for the purpose of this report.

* * * * *

Dated at Rockville, Maryland this 18th day of April, 2002.

For the Nuclear Regulatory Commission.

Annette L. Vietti-Cook,

Secretary of the Commission.

[FR Doc. 02–9995 Filed 4–23–02; 8:45 am]

BILLING CODE 7590–01–P

NUCLEAR REGULATORY COMMISSION

[NUREG–1600]

NRC Enforcement Policy; Modification, Medical Use

AGENCY: Nuclear Regulatory Commission.

ACTION: Policy statement: Modification.

SUMMARY: In conjunction with a major revision of 10 CFR part 35, published in today's **Federal Register**, the Nuclear Regulatory Commission is amending its ''General Statement of Policy and Procedure for NRC Enforcement Actions,'' NUREG–1600 (Enforcement Policy). This change to the Enforcement Policy revises the examples of severity levels for violations associated with the requirements to use written directives for certain medical uses of byproduct material; and to develop, implement, and maintain certain procedures for medical uses that require a written directive (10 CFR 35.40 and 35.41). These examples are used in the enforcement process to provide guidance for determining the significance of a particular violation.

DATES: Consistent with the rulemaking to revise 10 CFR part 35, this action is effective November 25, 2002. Comments on this change to the NRC's Enforcement Policy should be submitted not later than 30 days following the effective date and will be considered by the NRC before the next revision of the Enforcement Policy.

ADDRESSES: Submit written comments to: Michael T. Lesar, Chief, Rules and Directives Branch, Division of Administrative Services, Office of Administration, Mail Stop: T6D59, U.S. Nuclear Regulatory Commission, Washington, DC 20555–0001. Hand deliver comments to: 11555 Rockville Pike, Rockville, Maryland, between 7:30 a.m. and 4:15 p.m., Federal workdays. Copies of comments received may be examined at the NRC Public Document Room, Public File area O–1F21, 11555 Rockville Pike, Rockville, Maryland.

FOR FURTHER INFORMATION CONTACT: Frank Congel, Director, Office of Enforcement, (301) 415–2741, E-mail: *fjc@nrc.gov* or John Lubinski, Office of Enforcement, (301) 415–2740, E-mail: *jwl@nrc.gov.*

SUPPLEMENTARY INFORMATION:

Background

In a separate action published in today's **Federal Register**, the NRC is revising its regulations in 10 CFR part 35 governing the medical use of byproduct material to make the requirements risk-informed and more performance-based. Before this revision, 10 CFR 35.32 required a quality management program to provide high confidence that byproduct material or radiation from byproduct material would be administered as directed by the physician who is the authorized user of the material under the NRC license. Among other things, the quality management program had to assure that, for certain medical uses, a written directive was prepared and signed by the authorized user. Before this revision to the regulations, the term ''misadministration'' was used to denote certain errors in administering byproduct material, or the radiation from byproduct material, to humans. The terms ''written directive'' and ''misadministration'' were defined in 10 CFR 35.2.

In the revision of 10 CFR part 35 published today, the requirement to use written directives has been moved to § 35.40. The terms ''quality management program'' and ''misadministration'' are no longer used. The term ''medical event'' is used to denote certain errors in administering byproduct material, or the radiation from byproduct material, to humans. This term is now defined in 10 CFR 35.2. The new § 35.41 requires that the licensee develop, implement, and maintain written procedures for medical uses that require a written directive. Among other things, the written procedures must provide high confidence that each administration of byproduct material, or radiation from byproduct material, is in accordance with the written directive.

Minor conforming changes are being made to the examples in the NRC Enforcement Policy that formerly referred to the terms ''quality management program'' and ''misadministration.'' The examples are being changed to reflect the new terms ''written procedures for administrations requiring a written directive'' and ''medical event.''

The last substantive change to the examples in the NRC Enforcement Policy that relate to errors in medical uses was published at 58 FR 17321 (April 2, 1993). At that time, the examples were changed to provide greater emphasis, and attach greater importance, to violations that are indicative of, or flow from, deficiencies of a programmatic nature. Programmatic deficiencies have, as their root cause, an underlying weakness in some part of the licensee's program for preventing medical events that is more widespread than simple occasional human error (e.g., failure to develop and implement adequate written procedures for administrations that require a written directive, failure to train personnel on the procedures, or failure to follow procedures). Programmatic deficiencies are correctable, and pose the risk of additional occurrence if effective corrective action is not taken.

Conversely, the 1993 changes reflected a reduced severity level for individual violations that represent isolated mistakes involving human error made in the diagnosis or treatment of individual patients with byproduct material. The Commission continues to believe that the examples established in 1993 are appropriate, with minor modifications to conform to the terminology used in the newly revised 10 CFR part 35.

The examples use the terms ''substantial programmatic failure'' and ''programmatic weakness.'' To differentiate between these two terms, ''substantial programmatic failure'' applies in cases where the licensee fails to establish or effectively implement one or more of the requirements in 10 CFR 35.40 or 35.41. The failure could be due to a serious omission in the procedures required under 10 CFR 35.41 or to a failure to train employees to follow procedures. ''Programmatic weakness'' indicates that the failure is more widespread than simple occasional human error. For example, the term ''programmatic weakness'' would apply in a situation where licensee employees are trained to check the calculation of radiation dose to be administered for a certain treatment and normally do so; however, there have been failures to meet this requirement on a number of occasions because of staffing shortages, and one of those occasions results in a medical event.

Paperwork Reduction Act

This final change to the NRC Enforcement Policy does not contain new or amended information collection requirements subject to the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 et seq.).

Public Protection Notification

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

Small Business Regulatory Enforcement Fairness Act

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

Accordingly, the NRC Enforcement Policy is amended to read as follows:

General Statement of Policy and Procedure for NRC Enforcement Actions

* * * * *

SUPPLEMENT VI—FUEL CYCLE AND MATERIALS OPERATIONS

* * * * *

A. Severity Level I—Violations involving for example:

* * * * *

4. Failure to use a properly prepared written directive as required by 10 CFR 35.40; or failure to develop, implement, or maintain procedures for administrations requiring a written directive as required by 10 CFR 35.41; that results in a death or serious injury (e.g., substantial organ impairment).

B. Severity Level II—Violations involving for example:

* * * * *

3. A substantial programmatic failure to implement written directives or procedures for administrations requiring a written directive, such as a failure of the licensee's procedures to address one or more of the elements in 10 CFR 35.40 or 35.41, or a failure to train personnel in those procedures, that results in a medical event.

C. Severity Level III—Violations involving for example:

* * * * *

5. A substantial programmatic failure to implement written directives or procedures for administrations requiring a written directive, such as a failure of the licensee's procedures to address one or more of the elements in 10 CFR 35.40 or 35.41, or a failure to train personnel in those procedures, that does not result in a medical event. Failure to report a medical event. A programmatic weakness in the implementation of written directives or procedures for administrations requiring a written directive, whether or not a medical event occurs.

D. Severity Level IV—Violations involving for example:

* * * * *

3. Failure to use a properly prepared written directive as required by 10 CFR 35.40 or failure to follow procedures for administrations requiring a written directive as required by 10 CFR 35.41, whether or not a medical event occurs, provided that the failures: (1) Are isolated; (2) do not demonstrate programmatic weakness in implementation; and (3) have limited consequences if a medical event is involved.

Dated at Rockville, Maryland, this 18th day of April, 2001.

For the Nuclear Regulatory Commission.

Annette Vietti-Cook,

Secretary of the Commission.

[FR Doc. 02–9992 Filed 4–23–02; 8:45 am]

BILLING CODE 7590–01–P

OFFICE OF PERSONNEL MANAGEMENT

Proposed Collection; Comment Request for Review of an Expiring Information Collection: RI 25–49

AGENCY: Office of Personnel Management.

ACTION: Notice.

SUMMARY: In accordance with the Paperwork Reduction Act of 1995 (Pub. L. 104–13, May 22, 1995), this notice announces that the Office of Personnel Management (OPM) intends to submit to the Office of Management and Budget a request for review of an information collection. RI 25–49, Verification of Full-Time School Attendance, is used to verify that adult student annuitants are entitled to payments. OPM must confirm that a full-time enrollment has been maintained.

Approximately 10,000 RI 25–49 forms are completed annually. Each form takes approximately 60 minutes to complete. The annual estimated burden is 10,000 hours.

Comments are particularly invited on:

—Whether this collection of information is necessary for the proper performance of functions of the Office of Personnel Management, and whether it will have practical utility;

—Whether our estimate of the public burden of this collection of information is accurate, and based on valid assumptions and methodology; and

—Ways in which we can minimize the burden of the collection of information on those who are to respond, through the use of appropriate technological collection techniques or other forms of information technology.

For copies of this proposal, please contact Mary Beth Smith-Toomey at (202) 606–8358, FAX (202) 418–3251 or via E-mail at *mbtoomey@opm.gov*. Please include a mailing address with your request.

DATES: Comments on this proposal should be received within 60 calendar days from the date of this publication.

ADDRESSES: Send or deliver comments to Ronald W. Melton, Chief, Operations Support Division, Retirement and Insurance Service, U.S. Office of Personnel Management, 1900 E Street, NW, Room 3349A, Washington, DC 20415.

FOR INFORMATION REGARDING ADMINISTRATIVE COORDINATION CONTACT: Donna G. Lease, Team Leader, Desktop Publishing & Printing Team, Budget and Administrative Services Division, (202) 606–0623.

Office of Personnel Management.

Kay Coles James,

Director.

[FR Doc. 02–9955 Filed 4–23–02; 8:45 am]

BILLING CODE 6325–50–P

OFFICE OF PERSONNEL MANAGEMENT

Submission for OMB Review; Comment Request for Reclearance of a Revised Information Collection: RI 25–37

AGENCY: Office of Personnel Management.

ACTION: Notice.

SUMMARY: In accordance with the Paperwork Reduction Act of 1995 (Pub. L. 104–13, May 22, 1995), this notice announces that the Office of Personnel Management (OPM) has submitted to the Office of Management and Budget a request for review of an information collection. RI 25–37, Evidence to Prove Dependency of a Child, is designed to collect sufficient information for OPM to determine whether the surviving child of a deceased federal employee is eligible to receive benefits as a dependent child.

Approximately 250 forms are completed annually. We estimate it takes approximately 60 minutes to assemble the needed documentation. The annual estimated burden is 250 hours.

For copies of this proposal, please contact Mary Beth Smith-Toomey at (202) 606–8358, FAX (202) 418–3251 or via E-mail at *mbtoomey@opm.gov*. Please include a mailing address with your request.

DATES: Comments on this proposal should be received within 30 calendar days from the date of this publication.

ADDRESSES: Send or deliver comments to

Ronald Melton, Chief, Operations Support Division, Retirement and Insurance Service, U.S. Office of Personnel Management, 1900 E Street, NW, Room 3349A, Washington, DC 20415; and

Joseph Lackey, OPM Desk Officer, Office of Information & Regulatory Affairs, Office of Management & Budget, New Executive Office Building, NW, Room 3002, Washington, DC 20503.

FOR INFORMATION REGARDING ADMINISTRATIVE COORDINATION CONTACT: Donna G. Lease, Team Leader, Forms Analysis and Design, Budget and Administrative Services Division, (202) 606–0623.

Office of Personnel Management.

Kay Coles James,

Director.

[FR Doc. 02–9954 Filed 4–23–02; 8:45 am]

BILLING CODE 6325–50–P

OFFICE OF PERSONNEL MANAGEMENT

Excepted Service

AGENCY: Office of Personnel Management.

ACTION: Notice.

SUMMARY: This gives notice of positions placed or revoked under Schedule C in the excepted service, as required by Civil Service Rule VI, Exceptions from the Competitive Service.

FOR FURTHER INFORMATION CONTACT: Pam Shivery, Director, Washington Service Center, Employment Service (202) 606–1015.

SUPPLEMENTARY INFORMATION: Individual authorities established under Schedule C between March 1, 2002, and March 31, 2002, appear in the listing below. Future notices will be published on the fourth Tuesday of each month, or as soon as possible thereafter. A consolidated listing of all authorities as of June 30 will also be published.

Schedule C

The following Schedule C authorities were established during March 2002:

Council on Environmental Quality

Environmental Research Assistant to the Chief of Staff. Effective March 4, 2002.

Department of Agriculture

Director of Advance to the Deputy Chief of Staff, Communications. Effective March 7, 2002.

Staff Assistant to the Administrator, Foreign Agriculture Service. Effective March 12, 2002.

Director, Legislative and Public Affairs Staff to the Deputy Under Secretary, Rural Development. Effective March 12, 2002.

Confidential Assistant to the Administrator, Foreign Agricultural Service. Effective March 12, 2002.

Confidential Assistant to the Administrator, Rural Business and Cooperative Service. Effective March 19, 2002.

Director of Speech Writing to the Director of Communications. Effective March 19, 2002.

Confidential Assistant to the Assistant Secretary for Congressional Relations. Effective March 21, 2002.

Confidential Assistant to the Director, Planning and Coordination. Effective March 21, 2002.

Special Assistant to the Administrator, Risk Management Agency. Effective March 28, 2002.

Department of the Air Force (DOD)

Special Assistant for Community Relations to the Special Assistant for Policy and Planning. Effective March 6, 2002.

Department of Commerce

Special Assistant to the Executive Director, Office of Export Assistance and Business. Effective March 8, 2002.

Senior Policy Advisor to the Under Secretary for Oceans and Atmosphere. Effective March 8, 2002.

Press Secretary to the Director of Public Affairs. Effective March 19, 2002.

Senior Counsel to the General Counsel. Effective March 19, 2002.

Director of Communications to the Assistant Secretary for Trade Development, International Trade Administration. Effective March 22, 2002.

Special Assistant to the Chief Financial Officer and Assistant Secretary for Administration. Effective March 22, 2002.

Congressional Affairs Specialist to the Director, Office of Legislative Affairs, National Oceanic and Atmospheric Administration. Effective March 22, 2002.

Policy Advisor to the Chief of Staff. Effective March 22, 2002.

Public Affairs Specialist to the Deputy Director of Public Affairs for Strategy. Effective March 22, 2002.

Deputy Communications Director to the Director of Communications, International Trade Administration. Effective March 25, 2002.

Deputy Director to the Director, Office of Business Liaison. Effective March 28, 2002.

Department of Defense

Confidential Assistant to the Executive Secretary, Senior Executive Council. Effective March 4, 2002.

Special Assistant (Communications) to the Principal Deputy Assistant Secretary of Defense (Legislative Affairs). Effective March 5, 2002.

Public Affairs Specialist to the Assistant Secretary of Defense (Public Affairs). Effective March 12, 2002.

Personal and Confidential Assistant to the Assistant to the Secretary of Defense for Nuclear and Chemical and Biological Defense Programs. Effective March 13, 2002.

Confidential Assistant to the Assistant Secretary of Defense (Force Management Policy). Effective March 20, 2002.

Public Affairs Specialist to the Assistant Secretary of Defense (Public Affairs). Effective March 21, 2002.

Personal and Confidential Assistant to the Under Secretary of Defense (Comptroller). Effective March 21, 2002.

Special Assistant to the Principal Deputy Assistant Secretary of Defense (Legislative Affairs). Effective March 27, 2002.

Personal and Confidential Assistant to the Assistant Secretary of Defense for International Security Affairs. Effective March 27, 2002.

Special Assistant to the Director, Defense Research and Engineering. Effective March 27, 2002.

Special Assistant to the Principal Deputy Under Secretary of Defense, Office of the Comptroller. Effective March 29, 2002.

Public Affairs Specialist to the Deputy Assistant Secretary of Defense for Public Affairs. Effective March 29, 2002.

Department of Education

Special Assistant (Executive Assistant) to the Assistant Secretary, Office of Intergovernmental and Interagency Affairs. Effective March 5, 2002.

Confidential Assistant to the Assistant Secretary for Vocational and Adult Education. Effective March 5, 2002.

Confidential Assistant to the Chief of Staff. Effective March 6, 2002.

Special Assistant to the Assistant Secretary for Vocational and Adult Education. Effective March 6, 2002.

Secretary's Regional Representative, Region X to the Deputy Assistant Secretary for Regional Services. Effective March 15, 2002.

Special Assistant to the Assistant Secretary for Postsecondary Education. Effective March 15, 2002.

Deputy Secretary's Regional Representative, Region I to the Deputy Assistant Secretary for Regional Services. Effective March 19, 2002.

Special Assistant to the Chief of Staff. Effective March 19, 2002.

Confidential Assistant to the Deputy Assistant Secretary, Office of Special Education and Rehabilitative Services. Effective March 26, 2002.

Special Assistant to the Deputy Secretary. Effective March 27, 2002.

Department of Energy

Policy Advisor to the Director, Office of Worker and Community Transition. Effective March 1, 2002.

Special Assistant to the Secretary of Energy. Effective March 1, 2002.

Special Assistant to the Assistant Secretary for Policy and International Affairs. Effective March 5, 2002.

Special Assistant to the Assistant Secretary for Energy and Renewable Energy. Effective March 5, 2002.

Senior Advisor to the Executive Director for the Secretary of Energy Advisory Board. Effective March 11, 2002.

Chief of Staff to the Director, Office of Economic Impact and Diversity. Effective March 11, 2002.

Deputy Assistant Secretary, Senate Liaison to the Assistant Secretary for Congressional and Intergovernmental Affairs. Effective March 27, 2002.

Special Assistant for Intergovernmental Affairs to the Assistant Secretary for Environmental Management. Effective March 27, 2002.

Senior Advisor to the Assistant Secretary for Congressional and Intergovernmental Affairs. Effective March 29, 2002.

Advance and Trip Coordinator to the Director, Office of Scheduling and Advance. Effective March 29, 2002.

Department of Health and Human Services

Deputy Director of Intergovernmental Affairs (Operations) to the Director, Office of Intergovernmental Affairs. Effective March 20, 2002.

Deputy Director to the Director of the Center for Faith-Based and Community Initiatives. Effective March 26, 2002.

Secretary's Regional Representative to the Director of Intergovernmental Affairs. Effective March 27, 2002.

Special Assistant to the Executive Secretary, Office of the Secretary. Effective March 27, 2002.

Confidential Assistant (Advance) to the Director of Scheduling. Effective March 27, 2002.

Secretary's Regional Representative for Intergovernmental Affairs to the Director of Intergovernmental Affairs. Effective March 28, 2002.

Department of Housing and Urban Development

Secretary's Representative to the Deputy Secretary. Effective March 8, 2002.

Staff Assistant to the Assistant Secretary for Administration. Effective March 19, 2002.

Staff Assistant to the Director of Executive Scheduling. Effective March 19, 2002.

Special Assistant to the Chief Financial Officer. Effective March 19, 2002.

Staff Assistant to the Director, Center for Faith Based and Community Initiatives. Effective March 20, 2002.

Secretary's Representative to the Deputy Secretary. Effective March 27, 2002.

Principal Director of Executive Secretariat to the Assistant Secretary for Administration. Effective March 27, 2002.

Deputy Director to the Director of Faith Based and Community Initiatives. Effective March 27, 2002.

Department of Justice

Special Assistant to the Director, Violence Against Women Office, Office of Justice Programs. Effective March 1, 2002.

Special Assistant to the Deputy Attorney General. Effective March 1, 2002.

Associate Director and Counsel, Faith Based Task Force to the Principal Deputy Assistant Attorney General, Office of Justice Programs. Effective March 1, 2002.

Special Assistant to the Director, Office of Domestic Preparedness, Office of Justice Programs. Effective March 1, 2002. Secretary (OA) to the United States Attorney, District of Massachusetts. Effective March 1, 2002.

Secretary (Office Automation) to the United States Attorney General's Office, District of Wyoming. Effective March 1, 2002.

Deputy Director to the Director, Office of Public Affairs. Effective March 11, 2002.

Counsel to the Associate Attorney General. Effective March 11, 2002.

Secretary (Office Automation) to the United States Attorney, Eastern District of Pennsylvania. Effective March 12, 2002.

Secretary (OA) to the United States Attorney, District of Delaware. Effective March 12, 2002.

Secretary (OA) to the Assistant United States Attorney, Western District of Oklahoma. Effective March 12, 2002.

Senior Counsel for Voting Reform to the Assistant Attorney General, Civil Rights Division. Effective March 12, 2002.

Special Assistant to the Chairman, Foreign Claims Settlement Commission. Effective March 13, 2002.

Secretary (OA) to the United States Attorney, District of New Hampshire. Effective March 25, 2002.

Public Affairs Specialist to the Director, Office of Public Affairs. Effective March 27, 2002.

Department of Labor

Staff Assistant to the Secretary of Labor. Effective March 4, 2002.

Senior Legislative Officer to the Assistant Secretary for Congressional and Intergovernmental Affairs. Effective March 7, 2002.

Special Assistant to the Assistant Secretary for Public Affairs. Effective March 7, 2002.

Special Assistant to the Director of Scheduling and Advance. Effective March 12, 2002.

Special Assistant to the Assistant Secretary for Administration and Management. Effective March 12, 2002.

Special Assistant to the Assistant Secretary, Pension and Welfare Benefits. Effective March 12, 2002.

Special Assistant to the Director of the Women's Bureau. Effective March 13, 2002.

Special Assistant to the Assistant Secretary for Occupational Safety and Health. Effective March 13, 2002.

Counselor to the Deputy Secretary. Effective March 13, 2002.

Research Assistant to the Assistant Secretary for Congressional and Intergovernmental Affairs. Effective March 15, 2002.

Special Assistant to the Assistant Secretary, Disability Employment Policy. Effective March 20, 2002.

Attorney-Advisor (Labor) to the Solicitor of Labor. Effective March 26, 2002.

Secretary's Representative, San Francisco, CA to the Assistant Secretary for Congressional and Intergovernmental Affairs. Effective March 26, 2002.

Special Assistant to the Director, Women's Bureau. Effective March 27, 2002. Special Assistant to the Chief Financial Officer. Effective March 27, 2002.

Special Assistant to the Assistant Secretary for Occupational Safety and Health. Effective March 27, 2002.

Department of State

Special Assistant to the Assistant Secretary, Bureau of East Asian and Pacific Affairs. Effective March 7, 2002.

Special Assistant to the Deputy Secretary of State. Effective March 7, 2002.

Supervisory Foreign Affairs Officer to the Deputy Office Director, Office to Monitor and Combat Traffic. Effective March 8, 2002.

Staff Assistant to the Assistant Secretary, Bureau of Educational and Cultural Affairs. Effective March 11, 2002.

Foreign Affairs Officer to the Director, Office to Monitor and Combat Trafficking in Persons. Effective March 15, 2002.

Program Officer to the Director, Office of International Visitors, Bureau of Educational and Cultural Affairs. Effective March 22, 2002.

Staff Assistant to the Under Secretary for Arms Control and International Security. Effective March 27, 2002.

Legislative Analyst to the Senior Legislative Analyst. Effective March 27, 2002.

Foreign Affairs Research Analyst to the Assistant Secretary for Intelligence and Research. Effective March 29, 2002.

Public Affairs Specialist to the Assistant Secretary, Bureau of Educational and Cultural Affairs. Effective March 29, 2002.

Public Affairs Specialist to the Deputy Assistant Secretary, Bureau of Public Affairs. Effective March 29, 2002.

Supervisory Management Analyst to the Deputy Assistant Secretary for Logistics Management. Effective March 29, 2002.

Department of Transportation

Special Assistant to the Director, Office of Policy, Federal Highway Administration. Effective March 6, 2002.

Staff Assistant to the Administrator, Federal Highway Administration. Effective March 13, 2002.

Special Assistant to the Under Secretary for Transportation Security. Effective March 25, 2002.

Scheduling/Advance Assistant to the Director for Scheduling and Advance. Effective March 25, 2002.

Department of the Treasury

Special Assistant for Advance to the Director, Scheduling. Effective March 6, 2002.

Environmental Protection Agency

Director, Office of Regional Operations to the Associate Administrator for Congressional and Intergovernmental Relations. Effective March 7, 2002.

Senior Advisor to the Assistant Administrator for International Activities. Effective March 7, 2002.

Special Assistant to the Associate Administrator for the Office of Communications, Education and Media Relations. Effective March 7, 2002.

Associate Regional Administrator to the Regional Administrator, Middle Atlantic Region. Effective March 7, 2002.

Recycling Communications Advisor to the Deputy Director, Office of Solid Waste and Emergency Response. Effective March 11, 2002.

Policy Analyst to the Assistant Administrator, Office of Air and Radiation. Effective March 11, 2002.

Program Assistant to the Assistant Administrator for Air and Radiation. Effective March 28, 2002.

Federal Communications Commission

Deputy Director to the Director, Office of Legislative and Intergovernmental Affairs. Effective March 1, 2002.

Senior Advisor to the Director, Office of Legislative and Intergovernmental Affairs. Effective March 1, 2002.

Federal Emergency Management Agency

Staff Assistant (Scheduling) to the Director. Effective March 12, 2002.

Special Assistant to the Director, Human Resources Division. Effective March 27, 2002.

General Services Administration

Director of External Affairs to the Associate Administrator for Communications. Effective March 5, 2002.

Deputy Associate Administrator for Communications to the Associate Administrator for Communications. Effective March 7, 2002.

Confidential Assistant to the Administrator. Effective March 19, 2002.

International Boundary and Water Commission, United States and Mexico

Confidential Assistant to the Commissioner, International Boundary and Water Commission, United States and Mexico. Effective March 22, 2002.

National Aeronautics and Space Administration

Writer-Editor to the Assistant Administrator for Public Affairs. Effective March 4, 2002.

Special Assistant to the Assistant Administrator for Legislative Affairs. Effective March 5, 2002.

Senior Policy Analyst to the Assistant Administrator for Public Affairs. Effective March 7, 2002.

Industrial Relations Specialist to the Assistant Administrator for External Affairs. Effective March 27, 2002.

Media Relations Specialist to the Assistant Administrator for Public Affairs. Effective March 27, 2002.

National Endowment for the Arts

Special Assistant to the Chairman of the National Endowment for the Arts. Effective March 19, 2002.

National Transportation Safety Board

Director of Government and Industry Affairs to the Chairman. Effective March 12, 2002.

Executive Assistant to the Chairman. Effective March 29, 2002.

Office of Management and Budget

Legislative Assistant to the Associate Director for Legislative Affairs. Effective March 13, 2002.

Office of National Drug Control Policy

Legislative Analyst to the Director, Office of Legislative Affairs. Effective March 18, 2002.

Special Assistant to the Director, Office of National Drug Control Policy. Effective March 27, 2002.

Confidential Counsel to the Director, Office of National Drug Control Policy. Effective March 27, 2002.

Office of Personnel Management

Special Assistant to the Deputy Director. Effective March 13, 2002.

Office of the United States Trade Representative

Special Textile Negotiator to the United States Trade Representative. Effective March 25, 2002.

Overseas Private Investment Corporation

Confidential Assistant to the Chief of Staff. Effective March 29, 2002.

President's Commission on White House Fellowships

Education Director to the Executive Director, President's Commission of White House Fellowships. Effective March 19, 2002.

Selective Service System

Special Assistant to the Director of Selective Service. Effective March 27, 2002.

United States Tax Court

Secretary (Confidential Assistant) to the Judge. Effective March 26, 2002.

Authority: 5 U.S.C. 3301 and 3302; E.O. 10577, 3 CFR 1954–1958 Comp., P.218

Office of Personnel Management.

Kay Coles James,

Director.

[FR Doc. 02–9956 Filed 4–23–02; 8:45 am]

BILLING CODE 6325–01–P

OFFICE OF PERSONNEL MANAGEMENT

Civilian Acquisition Workforce Personnel Demonstration Project; Department of Defense (DoD)

AGENCY: Office of Personnel Management (OPM).

ACTION: Notice of amendment to this demonstration to make employees in the top broadband level of their career path eligible to receive a ''very high'' overall contribution score (OCS) and to reduce the minimum rating period under the Contribution-based Compensation and Appraisal System (CCAS) to 90 calendar days.

SUMMARY: The Department of Defense (DoD), with the approval of OPM, may conduct a personnel demonstration project within DoD's civilian acquisition workforce and among those supporting personnel assigned to work directly with it. (See Section 4308 of the National Defense Authorization Act for Fiscal Year 1996 (Pub. L. 104–106; 10 U.S.C.A. 1701 note), as amended by section 845 of the National Defense Authorization Act for Fiscal Year 1998 (Pub. L. 105–85)). This notice amends the project plan for this demonstration to (1) make employees in the top broadband level of their career path eligible to receive a ''very high'' overall contribution score (OCS) and (2) reduce the minimum rating period under the Contribution-based Compensation and Appraisal System (CCAS) to 90 consecutive calendar days.

DATES: This amendment is effective upon publication of this notice.

FOR FURTHER INFORMATION CONTACT: *DoD:* Anthony D. Echols, Civilian Acquisition Workforce Personnel Demonstration Project, 2001 North Beauregard Street, Suite 750, Alexandria, VA 22311, 703–681–3553. *OPM:* Mary Lamary, U.S. Office of Personnel Management, 1900 E Street NW., Room 7460, Washington, DC 20415, 202–606–2820.

SUPPLEMENTARY INFORMATION:

1. Background

OPM approved and published the project plan for the Civilian Acquisition Workforce Personnel Demonstration Project in the **Federal Register** on January 8, 1999 (Volume 64, Number 5, part VII). An amendment was published in the May 21, 2001, **Federal Register**, Volume 66, Number 98 to (1) correct discrepancies in the list of occupational series included in the project and (2) authorize managers to offer a buy-in to Federal employees entering the project after initial implementation. This demonstration project involves hiring and appointment authorities, broadbanding, simplified classification, a contribution-based compensation and appraisal system, revised reduction-in-force procedures, academic degree and certificate training, and sabbaticals.

2. Overview

To recognize high contributors, the project plan incorporates ''very high'' scores for employees who are capped at the top of their broadband level. Each career path has a different ''very high'' score, as follows: 115 for Business Management and Technical Management Professional, 95 for Technical Management Support, and 70 for Administrative Support.

The project plan reserves ''very high'' scores for employees whose pay rate is at the maximum for their broadband level. Employees with lower pay rates are not eligible to receive the ''very high'' score that could place them in the

inappropriately compensated region below the rails, compensation category B. This produces unintended results. Specifically, employees whose salaries happen to be at the top of their broadband are eligible to receive higher contribution rating increase percentages than other employees in the same broadband. They would receive any payout in the form of a bonus, because their salaries were already at the top of the broadband.

The following explains how this unintended outcome occurs. Figure 2 in the demonstration project plan, titled ''CCAS Compensation Categories,'' shows the rails for the normal pay range and the three resulting compensation categories: A, B, and C. The lower rail of the normal pay range intersects the vertical line representing a 100 score at a base salary equivalent to a GS–15, step 7.

Under the current project plan, employees with salaries equivalent to a GS–15, step 7 are not eligible to receive an overall contribution score (OCS) that would place them in the inappropriately compensated region below the rails, category B, because they are not eligible to receive the ''very high'' score of 115. Therefore, the highest contribution rating increase these employees can receive is 6 percent, the maximum percentage for the appropriately compensated region between the rails, category C. (See Table 6, Compensation Eligibility Chart, in the demonstration project plan which breaks out the contribution rating increase percentages by compensation category.)

Other employees with salaries at the GS–15, step 10 level (the top of broadband level IV of the Business Management and Technical Management Professional career path), however, are eligible to receive the ''very high'' OCS of 115. A 115 score would place them in the inappropriately compensated region below the rails, compensation category B. Therefore, these employees are eligible to receive a contribution rating increase up to 20 percent. In other words, this group of employees can receive a higher percentage increase than the first group, just because their salaries are at the maximum rate of the broadband.

This amendment eliminates the potential for such unintended outcomes by making all employees in the top broadband level of each career path eligible to receive ''very high'' scores and contribution rating increases of up to 20 percent, as shown in Table 6.

According to the project plan, if an employee has served under CCAS for less than six months, the rating official must wait for the subsequent annual cycle to assess the employee. Experience gained during the project's operation reveals that a shorter minimum rating period would be beneficial. By instituting this change, more employees will receive ratings of record and be eligible for contribution rating increases and contribution awards. In addition, managers will not have to wait six months or longer to recognize employees' contributions. This notice changes the minimum rating period to 90 consecutive calendar days. It also requires that the first appraisal be rendered within 15 months of entering the demonstration project.

Office of Personnel Management.

Kay Coles James,

Director.

I. Executive Summary

The project was designed by a Process Action Team (PAT) under the authority of the Under Secretary of Defense for Acquisition and Technology, with the participation of and review by DoD and the Office of Personnel Management (OPM). The purpose of the project is to enhance the quality, professionalism, and management of the DoD acquisition workforce through improvements in the human resources management system.

II. Introduction

This demonstration project provides managers, at the lowest practical level, the authority, control, and flexibility they need to achieve quality acquisition processes and quality products. This project not only provides a system that retains, recognizes, and rewards employees for their contribution, but also supports their personal and professional growth.

A. Purpose

The purpose of this notice is to make all employees in the top broadband level of their career path eligible to receive a ''very high'' overall contribution score (OCS) and to reduce the minimum rating period under the Contribution-based Compensation and Appraisal System (CCAS) to 90 consecutive calendar days. Other provisions of the approved plan are unchanged. Pursuant to 5 CFR 470.315, changes are hereby made to the **Federal Register**, Civilian Acquisition Workforce Personnel Demonstration Project; Department of Defense; Notice, Friday, January 8, 1999, Volume 64, Number 5, Part VII, pages 1473, 1474, 1476, and 1490.

B. Employee Notification and Collective Bargaining Requirements

The demonstration project program office shall notify employees of this amendment by posting it on the demonstration project's web pages *(http://www.acq.osd.mil/acqdemo/new_site).* Participating organizations must fulfill any collective bargaining obligations to unions that represent employees covered by the demonstration.

III. Personnel System Changes

A. Overall Contribution Score (OCS)

Change the third sentence of Section III. D. 2 to read:

The horizontal axis spans from 0 to the maximum contribution score of 100, with a notional ''very high'' score of 115 for those employees in the top broadband level of their career path.

Change last sentence of Section III. D. 2., subparagraph 2 to read:

The same is true for the other two career paths: Technical Management Support with a ''very high'' score of 95 for employees in broadband level IV, and Administrative Support with a ''very high'' score of 70 for employees in broadband level III.

Change Section III. D. 3., paragraph 6 to read:

If on October 1, the employee has served under CCAS for less than ninety (90) consecutive calendar days, the rating official shall wait for the subsequent annual cycle to assess the employee. The first CCAS appraisal must be rendered within 15 months after entering the demonstration project.

Insert a new paragraph 7 as follows:

Employees who have served under CCAS for less than 90 consecutive calendar days shall not receive contribution rating increases or contribution awards for that cycle. However, their salaries shall be increased by the amount and at the time of the next General Schedule pay increase under 5 U.S.C. 5303.

In Section VIII A, delete paragraph 3, which contains an obsolete reference to the January 1999 General Schedule pay increase.

[FR Doc. 02–9957 Filed 4–23–02; 8:45 am]

BILLING CODE 6325–43–P

POSTAL RATE COMMISSION

Briefing on Industry Mailing Practices

AGENCY: Postal Rate Commission.

ACTION: Notice of briefing.

SUMMARY: Representatives from Publishers Clearing House will present a briefing on Thursday, May 2, 2002, beginning at 10 a.m., in the Postal Rate Commission's hearing room. The briefing will address the company's

mailing practices. The briefing is open to the public.

DATES: May 2, 2002.

ADDRESSES: Postal Rate Commission (hearing room), 1333 H Street NW., Washington, DC 20268–0001, suite 300.

FOR FURTHER INFORMATION CONTACT: Stephen L. Sharfman, General Counsel, Postal Rate Commission, 202–789–6820.

Steven W. Williams,

Secretary.

[FR Doc. 02–10032 Filed 4–23–02; 8:45 am]

BILLING CODE 7710–FW–M

POSTAL SERVICE

Sunshine Act Meeting

Times and Dates: 1 p.m., Monday, May 6, 2002; 8:30 a.m., Tuesday, May 7, 2002.

Place: Washington, D.C., at U.S. Postal Service Headquarter, 475 L'Enfant Plaza, S.W., in the Benjamin Franklin Room.

Status: May 6–1 p.m. (Closed); 7–8:30 a.m. (Open)

Matters To be Considered:

Monday, May 6–1 p.m. (Closed)

1. Financial Performance.
2. Capital Investment—Singulate Scan, Induction Units.
3. Strategic Planning.
4. Personnel Matters and Compensation Issues.

Tuesday, May 7–8:30 a.m. (Open)

1. Minutes of the Previous Meeting, April 8–9, 2002.
2. Remarks of the Postmaster General and CEO.
3. Audit and Finance Committee Charter.
4. Advanced Computing Environment.
5. Capital Investment.

a. PostalOne! Phase Two, Business Customer Support Systems (BCSS).

6. Tentative Agenda for the June 3–4, 2002, meeting in Washington, D.C.

Contact Person for More Information: William T. Johnstone, Secretary of the Board, U.S. Postal Service, 475 L'Enfant Plaza, SW., Washington, DC 20260–1000. Telephone (202) 268–4800.

William T. Johnstone,

Secretary.

[FR Doc. 02–10224 Filed 4–22–02; 3:16 pm]

BILLING CODE 7710–12–M

SECURITIES AND EXCHANGE COMMISSION

Sunshine Act Meetings

Notice is hereby given, pursuant to the provisions of the Government in the Sunshine Act, Public Law 94–409, that the Securities and Exchange Commission will hold the following meetings during the week of April 22, 2002:

Closed meetings will be held on Tuesday, April 23, 2002 at 10 a.m. and Wednesday, April 24, 2002 at 10 a.m.

Commissioner Glassman, as duty officer, determined that no earlier notice thereof was possible.

Commissioners, Counsel to the Commissioners, the Secretary to the Commission, and recording secretaries will attend the closed meetings. Certain staff members who have an interest in the matters may also be present.

The General Counsel of the Commission, or his designee, has certified that, in his opinion, one or more of the exemptions set forth in 5 U.S.C. 552b(c)(5), (7), (9)(B), and (10) and 17 CFR 200.402(a)(5), (7), (9)(ii) and (10), permit consideration of the scheduled matters at the closed meetings.

The subject matter of the closed meeting scheduled for Tuesday, April 23, 2002, will be:

Litigation matter; institution and settlement of injunctive actions; and institution and settlement of administrative proceedings of an enforcement nature.

The subject matter of the closed meeting scheduled for Wednesday, April 24, 2002, will be:

Formal orders of private investigation; institution and settlement of injunctive actions; and institution and settlement of administrative proceedings of an enforcement nature.

At times, changes in Commission priorities require alterations in the scheduling of meeting items. For further information and to ascertain what, if any, matters have been added, deleted or postponed, please contact:

The Office of the Secretary at (202) 942–7070.

Dated: April 17, 2002.

Margaret H. McFarland,

Deputy Secretary.

[FR Doc. 02–10141 Filed 4–22–02; 11:45 am]

BILLING CODE 8010–01–U

SECURITIES AND EXCHANGE COMMISSION

Investment Technology, Inc., File No. 500–1; Order of Suspension of Trading

April 22, 2002.

It appears to the Securities and Exchange Commission that there is a lack of current and accurate information concerning the securities of Investment Technology Inc. (''Investment Technology'') because of questions regarding the accuracy of assertions by Investment Technology, and by others, in documents sent to and statements made to market makers of the stock of Investment Technology, other brokers and dealers, and to investors concerning, among other things: (1) the company's purported acquisitions of, and mergers with, various companies and businesses; (2) the status of the company's current financial condition and business operations; (3) the identity and background of the company's control persons; and (4) the company's profit growth and stock price appreciation.

The Commission is of the opinion that the public interest and the protection of investors require a suspension of trading in the securities of the above listed company.

Therefore, it is ordered, pursuant to Section 12(k) of the Securities Exchange Act of 1934, that trading in the above listed company is suspended for the period beginning at 9:30 a.m. EST, April 22, 2002 and terminating at 11:59 p.m. EST, on May 3, 2002.

By the Commission.

Margaret H. McFarland,

Deputy Secretary.

[FR Doc. 02–10140 Filed 4–22–02; 12:08 pm]

BILLING CODE 8010–01–P

SMALL BUSINESS ADMINISTRATION

Data Collection Available for Public Comments and Recommendations

ACTION: Notice and request for comments.

SUMMARY: In accordance with the Paperwork Reduction Act of 1995, this notice announces the Small Business Administration's intentions to request approval on a new, and/or currently approved information collection.

DATES: Submit comments on or before June 24, 2002.

ADDRESSES: Send all comments regarding whether this information collection is necessary for the proper performance of the function of the

agency, whether the burden estimates are accurate, and if there are ways to minimize the estimated burden and enhance the quality of the collection, to John Wade, Financial Analyst, Office of Financial Assistance, Small Business Administration, 409 3rd Street, SW., Suite 8300, Washington DC 20416

FOR FURTHER INFORMATION CONTACT: John Wade, Financial Analyst, (202) 205–3647or Curtis B. Rich, Management Analyst, (202) 205–7030.

SUPPLEMENTARY INFORMATION:

Title: Reports to SBA; Provisions of 13 CFR 120 472.

Form No: N/A.

Description of Respondents: Small Business Lending Companies.

Annual Responses: 14.

Annual Burden: 1,120.

Jacqueline White,

Chief, Administrative Information Branch.

[FR Doc. 02–10065 Filed 4–23–02; 8:45 am]

BILLING CODE 8025–01–P

SMALL BUSINESS ADMINISTRATION

Wisconsin District Advisory Board; Public Meeting

The U.S. Small Business Administration advisory board will hold a public meeting on Wednesday May 15, 2002. The Wisconsin Advisory Council meeting will take place at the Metro Milwaukee Association of Commerce building located at 756 North Milwaukee Street, 4th floor Milwaukee, Wisconsin. The time set forth is 12 noon to 1 pm. The purpose for this meeting will be to discuss such matters as may be presented by members, staff of the U.S. Small Business Administration or others present. For further information, please write or call Yolanda Staples-Lassiter, U.S. Small Business Administration, 310 West Wisconsin Ave., Suite 400 Milwaukee, Wisconsin 53202; telephone: (414) 297–1090. The public is invited.

Steve Tupper,

Committee Management Officer.

[FR Doc. 02–10064 Filed 4–23–02; 8:45 am]

BILLING CODE 8025–01–P

OFFICE OF THE UNITED STATES TRADE REPRESENTATIVE

[Docket No. WTO/DS–204]

WTO Dispute Settlement Regarding Telecommunications Trade Barriers in Mexico

AGENCY: Office of the United States Trade Representative.

ACTION: Notice; request for comments.

SUMMARY: The Office of the United States Trade Representative (''USTR'') is providing notice that, on April 17, 2002, the Dispute Settlement Body (''DSB'') of the World Trade Organization (''WTO'') established a dispute settlement panel to examine U.S. claims regarding certain Mexican Government measures affecting basic telecommunications services and the consistency of such measures with Mexico's commitments under the *General Agreement on Trade in Services* (''GATS''). The United States requested establishment of a panel on February 13, 2002. USTR invites written comments from the public concerning the issues raised in this dispute.

DATES: Although the USTR will accept any comments received during the course of the dispute settlement proceedings, comments should be submitted on or before May 25, 2002 to be assured of timely consideration by USTR.

ADDRESSES: Submit comments to Sandy McKinzy, Monitoring and Enforcement Unit, Room 122, Office of the United States Trade Representative, 600 17th Street, NW, Washington, DC, 20508, Attn: Mexico Telecommunications Dispute. Telephone: (202) 395–3582.

FOR FURTHER INFORMATION CONTACT: Demetrios J. Marantis, Associate General Counsel, Office of the United States Trade Representative, 600 17th Street, NW, Washington, DC, (202) 395–7305.

SUPPLEMENTARY INFORMATION: Pursuant to section 127(b) of the Uruguay Round Agreements Act (URAA) (19 U.S.C. 3537(b)(1)), the USTR is providing notice that, on April 17, 2002, the WTO DSB established a dispute settlement panel at the request of the United States to examine Mexican measures affecting basic telecommunications services. The United States requested establishment of a WTO dispute settlement panel on February 13, 2002. The United States previously invited comments from the public after the United States requested consultations with Mexico regarding telecommunications trade barriers in August 2000.[1] USTR is hereby providing additional opportunity for comment on the issues identified in the February 13, 2002 panel request and described below.

Major Issues Raised by the United States

Mexico maintains measures—largely as a result of its ''International Long Distance Rules''—that the United States considers to be inconsistent with Mexico's commitments under the GATS. For instance the current ''interconnection'' rate that all Mexican carriers must charge their foreign counterparts for connecting their calls to Mexico is 13.5 U.S. cents per minute. This rate exceeds the cost of providing this service by over 200 percent even though Mexico committed under the WTO Reference Paper to ensure that its dominant phone company provides ''interconnection'' at rates that are ''*basadas en costos*,'' or ''based on cost.''

Moreover, Mexican measures grant Mexico's dominant phone company the exclusive authority to negotiate this cross-border ''interconnection'' rate. Such measures empower Mexico's dominant phone company to set monopoly rates even though Mexico has an obligation under the WTO Reference Paper to maintain measures to prevent this company from engaging in anti-competitive practices.

Mexico's measures also discriminate against foreign suppliers by preventing them from sending calls into and out of Mexico over leased lines. However, Mexico has committed under the GATS to permit the supply of basic telecommunications services over leased lines on a national treatment basis and committed under the GATS *Annex on Telecommunications* to ensure that foreign basic telecommunications service suppliers have access to and use of leased lines to provide scheduled services.

Procedural Background

On August 17, 2000, the United States requested consultations with the Government of Mexico pursuant to Article 4 of the WTO *Understanding on Rules and Procedures Governing the Settlement of Disputes* (DSU) and Article XXIII of the GATS regarding a wide range of measures affecting telecommunications services. The United States and Mexico held these consultations on October 10, 2000. The consultations provided helpful clarifications but did not resolve the dispute.

On November 10, 2000, the United States requested the establishment of a panel pursuant to Article 6 of the DSU. The DSB considered this request at its meeting on December 12, 2000, at which time the Government of Mexico objected to the establishment of a panel. On November 10, 2000, the United States also requested additional consultations with the Government of Mexico pursuant to Article 4 of the DSU and Article XXIII of the GATS regarding additional measures affecting telecommunications services. These consultations, held on January 16, 2001,

[1] 65 FR 52469 (August 29, 2000).

provided additional clarifications but did not resolve the dispute.

Since the United States initially requested consultations, the Government of Mexico has taken steps to address several of the issues on which the United States and Mexico consulted. However, Mexico has not yet taken steps to address U.S. concerns regarding measures affecting Mexico's international telecommunications market, notably the International Long Distance Rules.

Public Comment: Requirements for Submissions

Interested persons are invited to submit written comments concerning the issues raised in the dispute. Comments must be in English and provided in fifteen copies to Sandy McKinzy at the address provided above. A person requesting that information contained in a comment submitted by that person be treated as confidential business information must certify that such information is business confidential and would not customarily be released to the public by the submitting person. Confidential business information must be clearly marked ''BUSINESS CONFIDENTIAL'' in a contrasting color ink at the top of each page of each copy.

Information or advice contained in a comment submitted, other than business confidential information, may be determined by USTR to be confidential in accordance with section 135(g)(2) of the Trade Act of 1974 (19 U.S.C. 2155(g)(2)). If the submitter believes that information or advice may qualify as such, the submitter—

(1) Must so designate the information or advice;

(2) Must clearly mark the material as ''SUBMITTED IN CONFIDENCE' in a contrasting color ink at the top of each page of each copy; and

(3) Is encouraged to provide a non-confidential summary of the information or advice.

Pursuant to section 127(e) of the URAA (19 U.S.C. 3537(e)), USTR will maintain a file on this dispute settlement proceeding, accessible to the public, in the USTR Reading Room: USTR Reading Room, which is located at 1724 ''F'' St., NW., Washington, DC 20508. The public file will include a listing of any comments received by USTR from the public with respect to the dispute; if a dispute settlement panel is convened, the U.S. submissions to that panel, the submissions, or non-confidential summaries of submissions, to the panel received from other participants in the dispute, as well as the report of the panel; and, if applicable, the report of the Appellate Body. An appointment to review the public file (Docket WTO/DS–204, Mexico Telecom Dispute) may be made by calling the USTR Reading Room at (202) 395–6186. The USTR Reading Room is open to the public from 9:30 a.m. to 12 noon and 1 p.m. to 4 p.m., Monday through Friday.

Bruce Hirsh,

Acting Assistant United States Trade Representative for Monitoring and Enforcement.

[FR Doc. 02–9959 Filed 4–23–02; 8:45 am]

BILLING CODE 3190–01–P

DEPARTMENT OF TRANSPORTATION

Office of the Secretary

[Docket OST–02–12148]

Electronic Transmission and Storage of Drug Testing Information Federal Advisory Committee; Meeting

AGENCY: Office of the Secretary, Department of Transportation.

ACTION: Notice of Federal Advisory Committee meeting.

SUMMARY: Pursuant to the Federal Advisory Committee Act (Pub. L. 92–463, 86 Stat. 770) notice is hereby given that the Department of Transportation (DOT) Electronic Transmission and Storage of Drug Testing Information Federal Advisory Committee will meet in a public session on June 17–18, 2002, at the J.W. Marriott Hotel, 1331 Pennsylvania Avenue, NW., Washington, DC 20004. The purpose of the Committee is to recommend to the Department the type and level of electronic security that should be used for the transmission and storage of drug testing information, to assess the type of format and methodology that would be appropriate, and to recommend the level and type of electronic signature technology that would support the procedures used in the DOT drug and alcohol program.

DATES AND TIME: The Electronic Transmission and Storage of Drug Testing Information Federal Advisory Committee will meet in open session on June 17, 2002, from 8 a.m. to 5 p.m. and on June 18, 2002, from 8 a.m. to 2 p.m.

ADDRESSES: The meeting will take place at the J.W. Marriott Hotel, 1331 Pennsylvania Avenue, NW., Washington, DC 20004. The hotel is two blocks from the Metro Center stop and can be reached by using the 13th Street exit. Attendees, other than Committee members, who need lodging may obtain a discounted room rate directly from the hotel by referring to the ''DOT Federal Advisory Committee'' meeting. The hotel telephone number is (202) 393–2000. A limited number of rooms will be available at the discounted rate and reservations must be made by May 24, 2002.

FOR FURTHER INFORMATION CONTACT: Don Shatinsky, Office of Drug and Alcohol Policy and Compliance (ODAPC), Office of the Secretary, Department of Transportation, at voice (202) 366–3784, fax (202) 366–3897. A list of the committee members may be obtained from Minnie McDonald, ODAPC, at (202) 366–3784 and a copy will be posted in the docket.

SUPPLEMENTARY INFORMATION: The Department established its Procedures for Transportation Workplace Drug and Alcohol Testing Programs (49 CFR part 40) in 1989 and added alcohol testing to the rule in 1994. Part 40 provides uniformity in how drug and alcohol tests are conducted throughout the transportation industry and protects the integrity and confidentiality of the process. Thorough documentation is necessary to support all test results and any subsequent legal challenges. Since the beginning of drug testing, the DOT has sought ways to reduce the significant amount of paper documentation generated for the forensic accountability of drug test results. We are now in an era of various electronic capabilities which can further reduce the paper work burden. The transportation industry is asking us to move more in that direction. We want to accommodate this request, but we want to make sure that the integrity and confidentiality requirements of the program are maintained.

There are approximately 55 drug testing laboratories currently certified by the Department of Health and Human Services (HHS) to conduct drug testing for the transportation industry and for Federal agencies. Approximately 8.3 million transportation workers are in safety-sensitive designated positions requiring drug testing. All laboratories report DOT-mandated test results directly to physicians, designated as medical review officers (MRO). Under the original Part 40, these results were sent by mail or courier, generating substantial paper work requirements. The Department made modest changes when 49 CFR part 40 was updated and republished on December 19, 2000. We permitted greater use of faxes and scanned computer images for reporting test results. Additionally, for negative test results we permitted laboratories to send electronic reports to MROs, provided the laboratory and MRO

ensured that the information is accurate and can be transmitted in such a manner as to prevent unauthorized access or release while it is transmitted or stored.

On June 15 and August 4, 2000, the Department, together with the Office of Management and Budget and HHS, held two public discussions related to development of ''paperless'' laboratories and implementation of electronic reporting by laboratories of drug testing results. Approximately 130 individuals participated in these meetings and in several informal working groups that were set up to review the current ''state of the art'' for secure transmission and storage of electronic information. The meetings' conclusions were twofold: One, there exist numerous effective and workable methods for the security of electronic transmission and storage of information; two, because of the array of methodologies existing, it is essential for the Department to establish minimum standards for the entire process. Many participants expressed interest in future participation as members of a Federal Advisory Committee to assist the Department and HHS in addressing issues of common interest and the impact of electronic documentation reporting and storage on forensic workplace drug testing.

The Department believes that the increased use of electronic reporting is both inevitable and beneficial. At the same time, we want to make sure that there are good, consistent minimum standards for the use of this technology, in order to protect the important integrity and confidentiality requirements of the program. For these reasons, DOT established the Electronic Transmission and Storage of Drug Testing Information Federal Advisory Committee. The purpose of the Committee is to recommend regulatory modifications it deems necessary if Part 40 is to accommodate newer electronic technology. The Committee will assess the current status of electronic security technology and will make recommendations about consistent minimum standards for its use in the transmission and storage of drug testing results. Additionally, the Committee will examine the formats and methodologies used in transmitting electronic information, as well as the concept, parameters, and procedures used in implementing electronic signature technology within the frame work of the DOT drug and alcohol testing program. The Committee will advise DOT regarding these findings. The Department anticipates that, following the receipt of the Committee's final recommendations, DOT will propose changes to Part 40 through a notice of proposed rulemaking that will result in minimum standards for security in transmission and storage of drug testing information and would result in a more widespread use of electronic technology in the program.

This will be the first meeting of the Committee. Two additional meetings are projected during the next 12 to 18 months. During the last meeting, the Committee will make final recommendations to the Department. Matters for discussion at the first meeting will be a review of the current laboratory procedures and data elements that are required as part of the laboratory reporting process, examination of the current state of the art in electronic transmission and storage security, a review of costs associated with the various options currently available, and implementation issues that will need to be considered to ensure that the transportation industry and the various parties supporting the industry's drug and alcohol testing program can meet the recommended minimum standards. In subsequent meetings, the Committee may also address the uses and limitations of electronic signature technology and issues related to its legal acceptability.

Tentative Agenda

Monday, June 17, 2002: 08:30 a.m.—Welcoming Comments and Introduction of the committee members; 9 a.m.—Summary of DOT Drug Testing and Update on Current Procedures Used by Laboratories; 10:30 a.m.—Discussion of Current Electronic Security Methodologies; 12 p.m.—Lunch; 1:15 p.m.—Current MRO Electronic Reporting; 3:30 p.m.—Public Comments or Presentations; 5:00 p.m.—End of First Day. Tuesday, June 18, 2002: 08:00 a.m.—Discussion of Options for Committee Consideration; 10:30 a.m.—Developing Committee Actions Needed for the Next Meeting; 12:00 p.m.—Closing Comments; 2:00 p.m.—End of Meeting.

The meeting will be open to the public on a first-come first-seated basis. Anyone needing special accommodations for persons with disabilities, please notify Minnie McDonald at (202) 366–3784 at least two weeks prior to the meeting.

Members of the public wishing to file a written statement with the DOT Electronic Transmission and Storage of Drug Testing Information Federal Advisory Committee may do so by submitting comments by mail or by delivering them to the Docket Clerk, Attn: Docket No. OST–02–12148, Department of Transportation, 400 7th Street, SW., Room PL–401, Washington, DC, 20590. Comments may also be faxed to the Docket Clerk at (202) 493–2251. Persons wishing their comments to be acknowledged should enclose a stamped, self-addressed postcard with their comments. The docket clerk will date stamp the postcard and return it to the sender. For the convenience of persons wishing to review the docket, it is requested that paper comments be sent in triplicate in an unbound format, no larger than 8 ½ by 11 inches, suitable for copying and electronic filing. Comments may be reviewed at the above address from 9 a.m. through 5 p.m. Monday through Friday. Commenters may also submit their comments electronically. Instructions for electronic submission may be found at the following Web address: *http://dms.dot.gov/submit/.* The public may also review docket comments electronically. The following web address provides instructions and access to the DOT electronic docket: *http://dms.dot.gov/search/.* Please use only one method for submission of your comments. Please do not send duplicates by submitting a written and an electronic version.

There will be a time allocated for the public to speak on any of the above agenda items. Please make your request for the opportunity to make a public comment in writing to Minnie McDonald, ODAPC, at (202) 366–3784, FAX (202) 366–3897, or e-mail address: *minnie.mcdonald@ost.dot.gov/* two weeks prior to the meeting. Your notification should contain your name and corporate designation, consumer affiliation, or government designation. Please include your address, telephone number and e-mail in case there is reason to contact you regarding your presentation. Those wanting to make a verbal statement should also include a short statement describing the topic to be addressed. Requestors will ordinarily be allowed up to 10 minutes to present a topic, however, the time may be limited depending on the number of requestors. If you have submitted a written statement to the docket, there is no need to subsequently duplicate this information by an oral presentation.

The Department would be interested in hearing from the public about their experiences with use of electronic security systems, their effectiveness, problems with initiating such systems, initial cost and maintenance of the systems, practicality of use for small businesses, and any other factors that the Committee should review as part of its final recommendation to DOT. Please note that the Committee will not specifically address the ''paperless

laboratory'' concept, since that process will require new rule making and will need to address issues such as use of electronic technology to fulfill legal requirements for evidential chain of custody procedures. The Committee will be looking at the broad application of electronic security technology as a general concept and not necessarily assessing specific current products on the market. However, entities wanting to address specific technologies and products may submit a short product description and performance data to the docket for the Committee's review.

The Committee meeting will be recorded and transcribed. Within a short time after the meeting, copies of the transcripts will be available on the DOT electronic docket.

Dated: April 18, 2002.

Kenneth C. Edgell,

Acting Director, Office of Drug and Alcohol Policy and Compliance, Department of Transportation.

[FR Doc. 02–10033 Filed 4–23–02; 8:45 am]

BILLING CODE 4910–62–P

DEPARTMENT OF TRANSPORTATION

Maritime Administration

Marine Transportation System National Advisory Council

ACTION: National Advisory Council Public Meeting; Notice

SUMMARY: The Maritime Administration announces that the Marine Transportation System (MTS) National Advisory Council (MTSNAC) will hold a meeting to discuss SEA–21, MTS Security, and other MTS related issues. A public comment period is scheduled for 1 p.m.–1:30 p.m. on Tuesday, May 14, 2002. To provide time for as many people to speak as possible, speaking time for each individual will be limited to three minutes. Members of the public who would like to speak are asked to contact Raymond Barberesi by May 6, 2002. Commenters will be placed on the agenda in the order in which notifications are received. If time allows, additional comments will be permitted. Copies of oral comments must be submitted in writing at the meeting. Additional written comments are welcome and must be filed by May 21, 2002. Send comments to the attention of Mr. Raymond Barberesi, Director, Office of Ports and Domestic Shipping, U.S. Maritime Administration, 400 7th Street, SW, Room 7201, Washington, DC 20590.

DATES: The meeting will be held on Monday, May 13, 2002, from 1:30 p.m. to 5 p.m. and Tuesday, May 14, 2002, from 8:30 a.m. to 3:30 p.m.

ADDRESSES: The meeting will be held at the Windsor Court Hotel, 300 Gravier Street, New Orleans, Louisiana 70130.

FOR FURTHER INFORMATION CONTACT: Raymond Barberesi, (202) 366–4357; Maritime Administration, MAR–830, Room 7201, 400 Seventh St., SW, Washington, DC 20590; R*aymond.Barberesi@marad.dot.gov.*

(Authority: 5 U.S.C. App 2, Sec. 9(a)(2); 41 CFR Part 102–3; DOT Order 1120.3B)

Dated: April 17, 2002.

Joel C. Richard,

Secretary, Maritime Administration.

[FR Doc. 02–9970 Filed 4–23–02; 8:45 am]

BILLING CODE 4910–81–P

DEPARTMENT OF TRANSPORTATION

Research and Special Programs Administration

Actions on Exemption Applications

AGENCY: Research and Special Programs Administration, DOT.

ACTION: Notice of actions on exemption applications.

SUMMARY: In accordance with the procedures governing the application for, and the processing of, exemptions from the Department of Transportation's Hazardous Materials Regulations (49 CFR Part 107, Subpart B), notice is hereby given of the actions on exemption applications in January–March 2002. The modes of transportation involved are identified by a number in the ''Nature of Applications'' portion of the table below as follows: 1—Motor vehicle, 2—Rail freight, 3—Cargo vessel, 4—Cargo Aircraft only, 5—Passenger-carrying aircraft. Application numbers prefixed by the letters EE represent applications for Emergency Exemptions. It should be noted that some of the sections cited were those in effect at the time certain exemptions were issued.

Issued in Washington, DC, on April 9, 2002.

R. Ryan Posten,

Exemptions Program Officer, Office of Hazardous Materials, Exemptions and Approvals.

MODIFICATION EXEMPTIONS

Application No.	Exemption No.	Applicant	Regulation(s) affected	Nature of exemption thereof
3216–M	DOT–E 3216	Solvay Fluorides, St. Louis, MO.	49 CFR 173.314(c), 179.301	To modify the exemption to authorize the transportation of a Division 2.3 material in non-DOT specification multi-unit tank car tanks.
4354–M	DOT–E 4354	PPG Industries, Inc., Pittsburgh, PA.	49 CFR 173.226(b)	To modify the exemption to authorize an additional loading method for the transportation of a Division 6.1 material in UN standard 1H1 drums and 6HA1 composite packagings.
7657–M	DOT–E 7657	Welker Engineering Company, Sugarland, TX.	49 CFR 173.201, 173.202, 173.203, 173.302(a)(1), 173.304(a)(1), 173.304(b)(1), 175.3.	To modify the exemption to authorize the transportation of an additional Division 2.3 material in non-DOT specification cylinders.
9221–M	DOT–E 9221	Applied Companies, Valencia, CA.	49 CFR 173.302(a)(4), 175.3	To modify the exemption to authorize cargo vessel as an additional mode for transporting Division 2.2 materials in non-DOT specification stainless steel cylinders.
9880–M	DOT–E 9880	GE Reuter-Stokes, Twinsburg, OH.	49 CFR 173.302, 175.3, Part 172 Subpart E and F.	To modify the exemption to authorize the transportation of an additional Division 2.2 materials in non-DOT specification containers described as hermetically sealed electron tube devices.

MODIFICATION EXEMPTIONS—Continued

Application No.	Exemption No.	Applicant	Regulation(s) affected	Nature of exemption thereof
9940–M	DOT–E 9940	GE Reuter-Stokes, Twinsburg, OH.	49 CFR 172.400, 173.306, 175.3.	To modify the exemption to authorize the transportation of an additional Division 2.2 material in non-DOT specification containers described as hermetically sealed electron tube devices.
10695–M	DOT–E 10695	3M Company, St. Paul, MN.	49 CFR 172.101, 172.504, 172.505(a), 173.323, 174.81, 176.84, 177.848.	To authorize return shipments of partial packs from customer locations of aluminum cartridges containing ethylene oxide labeled as flammable gas prepared by trained and tested 3M employees.
10798–M	DOT–E 10798	Chemetall Foote Corporation, Kings Mountain, NC.	49 CFR 174.67(j), (j)	To modify the exemption to authorize the transportation of a Division 4.2 and an additional Class 3 material in DOT Specification tank cars.
10929–M	DOT–E 10929	Bulkmatic Transport Company, Jersey City, NJ.	49 CFR 174.67(1), (j)	To modify the exemption to authorize the transportation of additional Class 3 materials in DOT Specification tank cars.
11316–M	DOT–E 11316	TRW Automotive Occupant Safety Systems, Queen Creek, AZ.	49 CFR 173.116(c), 173.116(e), 173.116(f), 173.62(c), Part 172, Subparts D, E.	To modify the exemption to authorize the transportation of a Division 1.4G and additional 1.4S material for shipment to additional TRW facilities and to increase quantity of power devices or igniters per tray from 16 to 36.
11770–M	DOT–E 11770	Gas Cylinder Technologies, Inc., Tecumseh, Ontarior N8N 2M4 Canada.	49 CFR 173.302, 173.304	To modify the exemption to authorize an additional chemistry composition for the manufacture of non-DOT specification cylinders, comparagble to DOT 3E, for the transportation of Division 2.1, 2.2 and 2.3 materials.
11827–M	DOT–E 11827	NRS America Inc., White Plains, NY.	49 CFR 180.352(b)(3), 180.605(c)(1).	To modify the exemption to authorize the transportation of an additional Division 5.1 material in certain lined DOT Specification IM 101 portable tanks and UN standard UN 31A Intermediate Bulk Containers.
11924–M	DOT–E 11924	Wrangler Corp., A Division of Lapoint Industries, Auburn, ME.	49 CFR 173.12(b)(2)(i)	To modify the exemption to authorize two additional DOT Specification containers for use as outer packaging for lab pack applications transporting various classes of hazardous wastes.
11952–M	DOT–E 11952	Department of Defense (MTMC), Alexandria, VA.	49 CFR 173.306(a)	To modify the exemption to authorize the use of a new laser guided training round configuration with a quantity increase of pressure vessels in the aluminum and wooden outer containers.
12068–M	DOT–E 12068	Sea Launch Company, L.L.C., Long Beach, CA.	49 CFR 173.62, Part 172 Subparts C, D, E and F, Part 173 Subparts E, F and G.	To modify the exemption to authorize the transportation of additional Class 3 and Division 2.2 materials contained in the Sea Launch Integrated Launch Vehicle with and without payload.
12296–M	DOT–E 12296	Clean Earth Systems, Inc. Tampa, FL.	49 CFR 173.12(b)(2)(i)	To modify the exemption to authorize certain DOT Specification UN11HH2 composite Intermediate Bulk Containers as outer packaging for lab packs when transporting various classes of hazardous materials.
12339–M	DOT–E 12339	Air Products and Chemicals, Inc., Allentown, PA.	49 CFR 173.192(a)(3), 173.302(a)(5), 173.302(F), 173.3L04(a)(4), 173.304(d)(3)(i).	To modify the exemption to authorize the transportation of an additional Division 2.3 material in DOT Specification 3AL aluminum cylinders via cargo vessel.
12473–M	DOT–E 12473	Old Bridge Metals & Chemicals, Inc., Old Bridge, NJ.	49 CFR 173.12(c)	To modify the exemption to authorize rail freight as an additional mode of transportation for the transportation of Class 8 materials in DOT Specification UN1H1 and UN1H2 plastic drums.
12772–M	DOT–E 12772	Air Cruisers, Inc., Belmar, NJ.	49 CFR 172.301, 173.219(b)(1), 173.22a, 173.301(e).	To reissue an exemption originally issued on an emergency basis for the transportation of non-DOT specification cylinders, filled in excess of their marked service pressure, containing a Division 2.2 material.

MODIFICATION EXEMPTIONS—Continued

Application No.	Exemption No.	Applicant	Regulation(s) affected	Nature of exemption thereof
12817–M	DOT–E 12817	Phibro-Tech, Inc., Fort Lee, NJ.	49 CFR 172.301(c), 173.219(b)(1), 173.302(a).	To reissue the exemption originally issued on an emergency basis authorizing the reuse of Specification UN 1H1 non-removable head plastic drums for the transportation of certain Class 8 materials to Environmental Protection Agency licensed treatment, storage or disposal facilities.
12885–M	DOT–E 12885	United States Dept. of Agriculture, Missoula, MT.	49 CFR 173.303(c)	To reissue the exemption originally issued on an emergency basis for the transportation of gasoline in a non-Dot specification steel drum with a pump installed mounted in a helitorch frame.
12892–M	DOT–E 12892	Bulk Truck & Transport Service, Inc., Hanover, IN.	49 CFR 172.203(a), 178.337–10(d).	To modify the exemption to reissue the exemption originally issued on an emergency basis for continued use of MC 331 cargo tanks that do not meet the minimum rear bumper requirements specified in the HMR transporting Division 2.1 materials.

NEW EXEMPTIONS

Application No.	Exemption No.	Applicant	Regulation(s) affected	Nature of exemption thereof
12674–N	DOT–E 12674	G&S Aviation, Donnelly, ID.	49 CFR 172.101 (Col. 9A), 175.75(a)(1), 175.75(a)(2).	To authorize the transportation in commerce of propane in 4BA/4BW type cylinders aboard small passenger-carrying aircraft to remote locations. (mode 5)
12695–N	DOT–E 12695	Global Composites International, Inc., San Dimas, CA.	49 CFR 173.302(a)(1), 173.304(a)(1), 173.34(e), 175.3.	To authorize the manufacture, mark, sale and use of non-DOT specification cylinders for use in transporting certain Division 2.1 and 2.2 hazardous materials. (modes 1, 2, 3, 4)
12724–N	DOT–E 12724	E.I. DuPont de Nemours & Co., Inc., Wilmington, DE.	49 CFR 172.203(a), 178.345–10(b)(3), 180.405(h).	To authorize the transportation in commerce of MC 312 cargo tanks equipped with pressure relief systems that do not conform to the requirements of the HMR. (mode 1)
12781–N	DOT–E 12781	International Business Aircraft, Inc., Tulsa, OK.	49 CFR 172.101 Column 9B, 172.204(c)(3), 173.27(b)(2)(3), 175.30(a)(1).	To authorize the transportation in commerce of Class 1 explosives which are forbidden or exceed quantities presently authorized. (mode 4)
12783–N	DOT–E 12783	CryoSurgery, Inc., Nashville, TN.	49 CFR 173.304(a)(1), 173.306(a).	To authorize the transportation in commerce of small units of compressed gas, refrigerant 404A as limited quantities and/or ORM–D intended for medical use. (modes 1, 2, 3, 4, 5)
12784–N	DOT–E 12784	CryoSurgery, Inc., Nashville, TN.	49 CFR 173.304(a)(1), 173.306(a).	To authorize the transportation in commerce of compressed, refrigerant 22, when shipped in relatively small units to be reclassed as ORM–D and transported as consumer commodity for medical purposes. (modes 1, 2, 3, 4, 5)
12841–N	DOT–E 12841	FIBA Technologies, Inc., Westboro, MA.	49 CFR 173.315, 173,318, 176.76(g)(1).	To authorize the manufacture, marking, sale and use of an IMO Type 7/US DOT MC 338 tank permanently fitted within an ISO frame for use in transporting various hazardous materials. (modes 1, 2)
12842–N	DOT–E 12842	Giant Resource Recovery Aerosols, Inc. (GRR), Summerville, SC.	49 CFR 173.156(b)	To authorize the transportation in commerce of aerosols, in specially designed containers for use in transporting Division 2.1 and 2.2 gases to collection site for recycling. (mode 1)
12858–N	DOT–E 12858	Union Carbide Corporation, South Charlestown, WV.	49 CFR 172.203, 173.31(c)(1), 179.13.	To authorize the transportation in commerce of a DOT specification 105J400W tank car having a gross weight on rail of 286,000 pounds, for use in transportation Division 2.1, 2.3, Poison-Inhalation Hazard/Zone D. (mode 2)
12865–N	DOT–E 12865	BOC Gases, Riverton, NJ.	49 CFR 173.301(j)	To authorize the transportation in commerce of non-DOT specification cylinders for export containing various compressed gases without pressure relief devices. (modes 1, 3)

NEW EXEMPTIONS—Continued

Application No.	Exemption No.	Applicant	Regulation(s) affected	Nature of exemption thereof
1868–N	DOT–E 12868	Anderson Development Company, Adrian, MI.	49 CFR 173.301(j)	To authorize the transportation in commerce of non-DOT specification cylinders for export containing various compressed gases without pressure relief devices. (modes 1, 3)
1869–N	DOT–E 12869	Praxair, Inc., Danbury, CT.	49 CFR 173.301(j)	To authorize the transportation in commerce of non-DOT specification cylinders for export containing various compressed gases without pressure relief devices. (modes 1, 3)
12877–N	DOT–E 12877	BAE Systems, Pomona, CA.	49 CFR 172.101 Column 9A, 172.400(a), 172.500(a), 175.3.	To authorize the transportation in commerce of cesium, Division 4.3, without required labeling and placarding in specially designed packaging to be used on military aircraft. (modes 1, 4, 5)
12897–N	DOT–E 12897	ATK Thiokol Propulsion, Brigham City, UT.	49 CFR 173.242, 173.32(a)	To authorize the transportation in commerce of ammonium perchlorate, Division 5.1, in DOT 53 portable tanks not presently authorized (modes 1, 2)
12899–N	DOT–E 12899	Pencor Reservoir Fluid Specialists, Broussard, LA.	49 CFR 173.201(c), 173.202(c), 173.203(c), 173.302(a), 173.304(a) & (b), 173.34(d), 175.3.	To authorize the manufacture, mark, sale and use of non-DOT specification cylinders comparable to DOT Specification 3A cylinders for use in transporting Division 2.1, 2.2 and Class 3 material. (modes 1, 2, 3, 4)
12903–N	DOT–E 12903	Cargill Inc., Minneapolis, MN.	49 CFR 172.203(a), 173.26, 179.13.	To authorize the transportation in commerce of Class 3 material in DOT Specification 111A100W1 tank cars having a maximum gross weight of 286,000 pounds. (mode 2)

EMERGENCY EXEMPTIONS

Application No.	Exemption No.	Applicant	Regulation(s) affected	Nature of exemption thereof
EE 10915–M	DOT–E 10915	Luxfer Gas Cylinders, Riverside, CA.	49 CFR 173.302(a)(1), 173.304(a)(d), 173.34(e), 175.3.	Modified exemption to authorize shipment of compressed gas n.o.s. as additional commodity and corrected UN number. (modes 1, 2, 3, 4, 5).
EE 12447–M	DOT–E 12447	Akzo Nobel, Norcross, GA.	49 CFR 172.301(c), 172.407(c)(1).	Modified description and capacity of cans contained in fiberboard boxes printed with incorrect size hazard warning labels. (mode 1).
EE 12807–M	DOT–E 12807	Clariant Corporation, Charlotte, NC.	49 CFR 172.302(c), 180.352(b)(1).	To reissue exemption issued on emergency basis to authorize the one-way transportation of a UN31A IBC, which was filled with a flammable liquid, beyond its requalification due date. (mode 1).
EE 12892–N	DOT–E 12892	Bulk Truck and Transport Service, Inc., Hanover, IN.	49 CFR 172.203(a), 178.337–10(d).	Emergency request for continued use of MC 331 cargo tanks that do not meet the minimum rear bumper requirements of 49 CFR 178.337–10(d). (mode 1).
EE 12893–N	DOT–E 12893	Department of Justice, Justice Management Division, Washington, DC.	49 CFR 172.101 Column 8C	Request an emergency exemption for the transportation of small solid materials contaminated or suspected of being contaminated with anthrax (mode 1).
EE 12894–N	DOT–E 12894	Department of Justice, Justice Management Division, Washington, DC.	49 CFR 172.101 Column 8C	Request an emergency exemption to transport large solid materials contaminated with or suspected of being contaminated with anthrax (mode 1).
EE 12896–N	DOT–E 12896	Environmental Protection Agency, Washington, DC.	49 CFR 172.101 Column 8C	Request an emergency exemption to transport solid materials contaminated with anthrax bacteria in non-DOT spec. packaging. (mode 1).
EE 12907–N	DOT–E 12907	Allied Universal Corp., Miami, FL.	49 CFR 173.24(b), 179.300–12(b), 179.300–13(a), 179.300–14.	Request for an emergency exemption to transport a leaking ton cylinder that has been fitted with an emergency B kit to prevent leaking during transportation. (mode 1).
EE 12908–N	DOT–E 12908	JCI Jones Chemicals, Inc., Milford, VA.	49 CFR 173.24(b), 179.300–12(b), 179.300–13(a), 179.300–14.	Request one time transportation of a leaking container containing sulfur dioxide, equipped with a Chlorine Institute B-kit, from Ocean City, MD to Milford, VA. (mode 1).
EE 12913–N	DOT–E 12913	Novelty, Inc., Greenfield, IN.	49 CFR 172.301(c), 173.22(a)(4).	Emergency request for relief from packaging requirements for lighters that have already been approved. (mode 1).

EMERGENCY EXEMPTIONS—Continued

Application No.	Exemption No.	Applicant	Regulation(s) affected	Nature of exemption thereof
EE 12914–N	DOT–E 12914	Jones Chemicals, Inc., Milford, VA.	49 CFR 172.301(c), 173.34(d)	Emergency request to transport a DOT 3A cylinder containing chlorine that was found leaking and has had a Chlorine Institute approved A-Kit applied. (mode 1).
EE 12915–N	DOT–E 12915	Airgas-Nor Pac, Inc., Portland, OR.	49 CFR 172.301(c), 173.34(d)	For one-time transportation of leaking cylinder containing chlorine and applied with Chlorine Institute ''A-kit'' from Klamath Falls, Oregon to Tacoma, Washington. (mode 1).
EE 12916–N	DOT–E 12916	Allied Universal Corp., Miami, FL.	49 CFR 173.34(d)	Request for an emergency exemption to transport a leaking 150 lb. cylinder that has been fitted with an A kit to prevent leaking during transportation. (mode 1).
EE 12917–N	DOT–E 12917	Northwest Ohio Towing & Recovery, Inc., Beaverdam, OH.	49 CFR 173.242(b)	Emergency request to transport cargo tanks (aviation refuelers) containing the residue of gasoline. The cargo tanks were built to MC 306 specifications but have not tested and maintained as such. (mode 1).
EE 12918–N	DOT–E 12918	Jones Chemicals, Inc., Charlotte, NC.	49 CFR 172.301(c), 173.34(d)	Emergency request to transport a 3A480 cylinder with a leaking valve that has had a Chlorine Institute approved A Kit applied. (mode 1).
EE 12919–N	DOT–E 12919	Acambis, Inc., Cambridge, MA.	49 CFR 173.196(b), 178.609 ...	Request for an emergency exemption to use packagings for infectious substances that have not been performance-tested. (mode 1).
EE 12934–N	DOT–E 12934	Kuehne Chemical Company, South Kearny, NJ.	49 CFR 173.24, 179.300–12(b), 179.300–13(a), 179.300–14.	Request for an emergency exemption to transport a leaking ton cylinder that has been fitted with a B kit. (mode 1).
EE 12935–N	DOT–E 12935	JCI Jones Chemicals, Inc., Charlotte, NC.	49 CFR 173.34(d)	Request for an emergency exemption to authorize the transportation in commerce of a leaking ton cylinder that has been fitted with an emergency A Kit to prevent leaking during transportation. (mode 1).
EE 12937–N	DOT–E 12937	BASF Corporation, Mount Olive, NJ.	49 CFR 172.301(a), 172.400, 173.213(c).	Emergency request to transport pendimethal described as flammable solid n.o.s., UN 1325, III in a 5M1 multi wall paper bag that is certified to PG II (mode 1, 2, 4).
EE 12938–N	DOT–E 12938	TRW Systems & Information Technology, Redondo Beach, CA.	49 CFR 173.24(b)(1), 173.302(a)(1), 173.304(a)(2), 173.34(d).	Request for an emergency exemption to transport anhydrous ammonia in a non-DOT specification container. (mode 1).
EE 12939–N	DOT–E 12939	Allied Universal Corp., Miami, FL.	49 CFR 173.34(d)	Request to transport a leaking ton cylinder that has been fitted with an emergency A kit to prevent leaking during transportation. (mode 1).
EE 12940–N	DOT–E 12940	T.J. Egan Waste Systems, Bloomfield, NJ.	49 CFR 172.101 Column 8C, 172.302(c).	Request for emergency exemption to transport co-mingled regulated and solid waste in bulk packagings. (mode 1).
EE 12947–N	DOT–E 12947	Safety Kleen (TG), Inc., Columbia, SC.	49 CFR 173.202	Request for an emergency exemption to transport a class 3 material in a bulk, non-DOT specification container. (mode 1).
EE 12948–N	DOT–E 12948	Kuehne Chemical Company, South Kearny, NJ.	49 CFR 173.24, 179.300–12(b), 179.300–13(a), 179.300–14.	Request for an emergency exemption to transport a leaking ton tank car tank containing chlorine, that has been fitted with an emergency B kit to prevent leaking during transportation. (mode 1).
EE 12957–N	DOT–E 12957	Transportation Services Unlimited, Miami, FL.	49 CFR 173.302(c), 179.300–12(b), 179.300–13(a), 179.300–14.	Emergency request to transport two DOT specification 106A500X tank cars one of which has a problem with the fusible plug and one which has a problem with the valve. Each tank has a Chlorine Institute B Kit applied. (mode 1).
EE 12958–N	DOT–E 12958	DPC Enterprises, Houston, TX.	49 CFR 173.34(d)	Request for emergency exemption to transport a leaking ton cylinder that has been fitted with an A kit to prevent leaking. (mode 1).
EE 12962–N	DOT–12962	Allied Universal Corp., Miami, FL.	49 CFR 172.302 (c), 179.300–12(b), 179.300–13(a), 179.300–14.	Emergency request to transport a one ton container (DOT Spec 106A500X) that developed a leak in the valve and has a Emergency B kit applied. (mode 1).

EMERGENCY EXEMPTIONS—Continued

Application No.	Exemption No.	Applicant	Regulation(s) affected	Nature of exemption thereof
EE 12971–N	DOT–E 12971	Allied Universal Corporation, Miami, FL.	49 CFR 172.302(c), 179.300–12(b), 179.300–13(a), 179.300–14.	Emergency request to transport a DOT Specification 106A500X containing sulfur dioxide that developed a leak in one of the valves and has a Chlorine Institute Emergency B Kit applied. (mode 1).

DENIALS

4453–M	Request by Dyno Nobel, Inc. Salt Lake City, UT to modify the exemption to allow for the transportation of an additional Division 1.5D explosive in a non-DOT specification bulk, hopper-type tank denied January 31, 2002.
8554–M	Request by Dyno Nobel, Inc. Salt Lake City, UT to modify the exemption to allow for the transportation of an additional Division 1.5D explosive in DOT Specification MC–306, MC–307 and MC–312 cargo tanks denied January 31, 2002.
8723–M	Request by Dyno Nobel, Inc. Salt Lake City, UT to modify the exemption to allow for the transportation, in bulk, of an additional Division 1.5D explosive in certain authorized motor vehicles and portable tanks denied January 31, 2002.
9401–M	Request by Societe Nationale de Wagon-Reservoirs 79009 Paris, FR to modify the exemption to authorize the transportation of additional Division 2.2 materials in non-Dot specification IMO Type 5 portable tanks denied March 25, 2002.
10705–M	Request by Baker Petrolite Victoria, TX to modify the exemption to authorize the use of contract carriers for the transportation of a Division 6.1 material, without the segregation requirements, by highway motor vehicle denied March 25, 2002.
10833–M	Request by Health Care Waste Services Bronx, NY to modify the exemption to authorize an additional non-DOT specification steel container for use as bulk outer packaging transporting Division 6.2 materials in dual packagings denied January 18, 2002.
11244–M	Request by Aerospace Design & Development, Inc. Longmont, CO to modify the exemption to allow for a design change of the non-DOT specification titanium alloy cylinder for the transportation of Division 2.2 materials denied January 28, 2002.
11993–M	Request by BREED Technologies, Inc. Lakeland, FL to modify the exemption to authorize a new design style of the non-DOT specification cylinders used as components of automobile vehicle safety systems for the transportation of Division 2.1 and 2.2 materials denied March 13, 2002.
12586–N	Request by Wilsonart International Inc. Temple, TX to authorize rail cars to remain attached while standing without the physical presence of an unloader denied January 28, 2002.
12755–N	Request by Air Canada Ottawa, ON to authorize the transportation in commerce of hazardous materials by aircraft that exceed the quantity limitations in the HMR denied January 10, 2002.

[FR Doc. 02–10036 Filed 4–23–02; 8:45 am]
BILLING CODE 4909–60–M

DEPARTMENT OF THE TREASURY

Fiscal Service

Revision of the Treasury Current Value of Funds Rate

AGENCY: Financial Management Service, Fiscal Service, Treasury.

ACTION: Notice of revised rate for use in Federal debt collection and for discount and rebate evaluation.

SUMMARY: Pursuant to section 11 of the Debt Collection Act of 1982, as amended, (31 U.S.C. 3717), the Secretary of the Treasury is responsible for computing and publishing the percentage rate to be used in assessing interest charges for outstanding debts on claims owed the Government. Treasury's Cash Management Regulations (I TFM 6–8000) prescribe use of this rate by agencies as a comparison point in evaluating the cost-effectiveness of a cash discount. In addition, 5 CFR 1315.8 of the Prompt Payment rule on ''Rebates'' requires that this rate be used in determining when agencies should pay purchase card invoices when a rebate is offered by the card issuer. Notice is hereby given that the applicable rate is 3 percent for the period July 1, 2002 through December 31, 2002.

DATES: The rate will be in effect for the period beginning on July 1, 2002, and ending on December 31, 2002.

FOR FURTHER INFORMATION CONTACT: Inquiries should be directed to the Risk Management Division, Financial Management Service, Department of the Treasury, 401 14th Street, SW., Washington, DC 20227 (Telephone: (202) 874–6650).

SUPPLEMENTARY INFORMATION: The rate reflects the current value of funds to the Treasury for use in connection with Federal Cash Management systems and is based on investment rates set for purposes of the Public Moneys Investments Act, Pub. L. 95–147, 91 Stat. 1227. The rate is computed each year by averaging Treasury Tax and Loan (TT&L) account investment rates for the 12-month period ending every September 30, rounded to the nearest whole percentage, for applicability effective January 1. The rate is subject to quarterly revisions if the annual average, on a moving average basis, changes by 2 per centum. The rate in effect for the period July 1, 2002 through December 31, 2002 reflects the average investment rate for the 12-month period that ended March 31, 2001.

Dated: April 18, 2002.

Bettsy H. Lane,

Assistant Commissioner, Federal Finance.

[FR Doc. 02–10085 Filed 4–23–02; 8:45 am]
BILLING CODE 4810–35–M

DEPARTMENT OF VETERANS AFFAIRS

National Commission on VA Nursing; Meeting

The Department of Veterans Affairs (VA) gives notice under Public Law 92–

463 (Federal Advisory Committee Act) that the National Commission on VA Nursing will hold it's first meeting on May 8, 2002, at the Department of Veterans Affairs, 810 Vermont Avenue, NW, Room 930, Washington, DC 20420. The meeting will begin at 8:15 a.m. and end at 5:30 p.m. The meeting will be open to the public.

The Commission, established under the ''Department of Veterans Affairs Programs Enhancement Act of 2001,'' is to consider legislative and organizational policy changes to enhance the recruitment and retention of nurses and other nursing personnel in VA; and to evaluate the future of the nursing profession in VA. The Commission is required, not later than two years from the date of its first meeting, to submit to Congress and the Secretary of Veterans Affairs a report on the Commission's findings and recommendations.

The meeting will begin with a discussion of the Commission's goals and work plans, and will be led by the Commission's Chairperson, Marilyn M. Pattillo, Ph.D., R.M., C.S., N.P. The Commission will be briefed on VA's mission and on the role of VA nursing personnel in meeting that mission. Members will also be provided information on VA human resources polices related to nursing personnel, an assessment of VA's current and anticipated nurse staffing trends, and information concerning VA's current initiatives to enhance the recruitment and retention of nursing personnel.

No time will be allocated for receiving oral presentations from the public. However, members of the public may direct questions or submit prepared statements for review by the Commission in advance of the meeting, in writing only, to Ms. Stephanie Williams, Program Analyst, at Department of Veterans Affairs (10A2N), 810 Vermont Avenue, NW, Washington, DC 20420. Any member of the public wishing to attend the meeting should contact Ms. Williams, at (202) 273–4944.

Dated: April 17, 2002.

By direction of the Secretary.

Nora E. Egan,

Committee Management Officer.

[FR Doc. 02–9985 Filed 4–23–02; 8:45 am]

BILLING CODE 8320–01–M

DEPARTMENT OF VETERANS AFFAIRS

Voluntary Service National Advisory Committee, Notice of Meeting

The Department of Veterans Affairs gives notice under Public Law 92–463 that the annual meeting of the Department of Veterans Affairs Voluntary Service (VAVS) National Advisory Committee (NAC) will be held at the Double Tree Hotel at Jantzen Beach, 909 Hayden Island Dr., Portland Oregon, on May 15–18, 2002.

The committee, comprised of fifty-nine national voluntary organizations, advises the Under Secretary of Health and other members of the Department of Veterans Affairs Central Office staff on how to coordinate and promote volunteer activities within VA facilities. The primary purposes of this meeting are: to provide an opportunity for the committee's review of volunteer policies and procedures; to accommodate full and open communications between the organizations, representatives and the Voluntary Service Office and field staff; to provide educational opportunities geared towards improving volunteer programs with special emphasis on methods to recruit, retain, motivate and recognize volunteers; and, to approve committee recommendations.

The meeting sessions are scheduled for 6 p.m. until 8 p.m. on May 15, 2002; 8:30 a.m. until 4:30 p.m. on May 16, 2002; 8:30 a.m. until 4:30 p.m. on May 17, 2002; and 8:30 a.m. until 11:30 a.m. on May 18, 2002, with a closing ceremony at 6 p.m. that day. The May 15 session will principally involve opening ceremonies, remarks by several officials and a keynote address by the VA Under Secretary for Health. The May 16 session will feature a presentation of the meeting's objectives, consideration of several committee and subcommittee reports, a presentation on the Veterans History Project and four educational workshops on communications, corporate volunteering, career focus, and recruitment. On May 17, educational workshops will continue and keynote speakers will address the business session and the James Parke Memorial Scholarship Luncheon. The May 18 session will focus on several awards recognizing exceptional volunteer service, will feature another keynote speaker, and will be followed by a closing ceremonies event in the evening.

The meeting is open to the public. Individuals interested in attending are encouraged to contact: Ms. Laura Balun, Administrative Officer, Voluntary Service Office (10C2), Department of Veterans Affairs, 810 Vermont Avenue, NW., Washington, DC 20420, (202) 273–8392.

Dated: April 17, 2002.

By Direction of the Secretary.

Nora E. Egan,

Committee Management Officer.

[FR Doc. 02–9984 Filed 4–23–02; 8:45 am]

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Federal Register

Wednesday,
April 24, 2002

Part II

Environmental Protection Agency

40 CFR Part 63

National Emission Standards for Hazardous Air Pollutants: Surface Coating of Metal Furniture; Proposed Rule

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 63

[FRL–7163–6]

RIN 2060–AG55

National Emission Standards for Hazardous Air Pollutants: Surface Coating of Metal Furniture

AGENCY: Environmental Protection Agency (EPA).

ACTION: Proposed rule.

SUMMARY: This action proposes national emission standards for hazardous air pollutants (NESHAP) for metal furniture surface coating operations located at major sources of hazardous air pollutant (HAP) emissions. These proposed standards would implement section 112(d) of the Clean Air Act (CAA) by requiring these operations to meet HAP emission standards reflecting the application of the maximum achievable control technology (MACT). The primary HAP emitted by these operations are xylene, toluene, glycol ethers, 2-butoxy ethanol, ethylbenzene, and methyl ethyl ketone. Each of the HAP can cause toxic effects such as eye, nose, throat, and skin irritation, and blood cell, heart, liver, and kidney damage. Implementation of the proposed standards would reduce nationwide HAP emissions from major sources by about 70 percent.

DATES: *Comments.* Submit comments on or before June 24, 2002. *Public Hearing.* If anyone wishes to contact EPA to request to speak at a public hearing, they should do so by May 14, 2002. If requested, a public hearing will be held within approximately 30 days following publication of this notice in the **Federal Register**.

ADDRESSES: *Comments.* By U.S. Postal Service, send comments (in duplicate if possible) to: Air and Radiation Docket and Information Center (6102), Attention Docket Number A–97–40, U.S. Environmental Protection Agency, 1200 Pennsylvania Avenue, NW., Washington, DC 20460. In person or by courier, deliver comments (in duplicate if possible) to: Air and Radiation Docket and Information Center (6102), Attention Docket Number A–97–40, U.S. Environmental Protection Agency, 401 M Street, SW., Room M–1500, Washington, DC 20460. The EPA requests a separate copy also be sent to the contact person listed in **FOR FURTHER INFORMATION CONTACT.**

Public Hearing. If a public hearing is held, it will be held at our Office of Administration Auditorium in Research Triangle Park, North Carolina. You should contact Ms. Janet Eck, Coatings and Consumer Products Group, Emission Standards Division (C539–03), U.S. Environmental Protection Agency, Research Triangle Park, North Carolina 27711, telephone number (919) 541–7946, to request to speak at a public hearing or to find out if a hearing will be held.

Docket. Docket No. A–97–40 contains supporting information used in developing the proposed standards. The docket is located at the U.S. Environmental Protection Agency, 401 M Street, SW., Washington, DC 20460 in Room M–1500, Waterside Mall (ground floor), and may be inspected from 8:30 a.m. to 5:30 p.m., Monday through Friday, excluding legal holidays.

FOR FURTHER INFORMATION CONTACT: Dr. Mohamed Serageldin, Coatings and Consumer Products Group, Emission Standards Division (C539–03), U.S. Environmental Protection Agency, Research Triangle Park, NC 27711; telephone number (919) 541–2379; facsimile number (919) 541–5689; electronic mail (e-mail) address: *serageldin.mohamed@epa.gov.*

SUPPLEMENTARY INFORMATION:

Comments. Comments and data may be submitted by e-mail to: *a-and-r-docket@epa.gov.* Electronic comments must be submitted as an ASCII file to avoid the use of special characters and encryption problems and will also be accepted on disks in WordPerfect® file format. All comments and data submitted in electronic form must note the docket number: A–97–40. No confidential business information (CBI) should be submitted by e-mail. Electronic comments may be filed online at many Federal Depository Libraries.

Commenters wishing to submit proprietary information for consideration must clearly distinguish such information from other comments and clearly label it as CBI. Send submissions containing such proprietary information directly to the following address, and not to the public docket, to ensure that proprietary information is not inadvertently placed in the docket: Dr. Mohamed Serageldin, c/o OAQPS Document Control Officer (C404–02), U.S. Environmental Protection Agency, Research Triangle Park, NC 27711. The EPA will disclose information identified as CBI only to the extent allowed by the procedures set forth in 40 CFR part 2. If no claim of confidentiality accompanies a submission when it is received by EPA, the information may be made available to the public without further notice to the commenter.

Public Hearing. Persons interested in presenting oral testimony or inquiring as to whether a hearing is to be held should contact Ms. Janet Eck, Coatings and Consumer Products Group, Emission Standards Division (C539–03), U.S. Environmental Protection Agency, Research Triangle Park, North Carolina 27711; telephone number (919) 541–7946 at least 2 days in advance of the public hearing. Persons interested in attending the public hearing should also contact Ms. Eck to verify the time, date, and location of the hearing. The public hearing will provide interested parties the opportunity to present data, views, or arguments concerning these proposed emission standards.

Docket. The docket is an organized and complete file of all the information considered by the EPA in the development of this rulemaking. The docket is a dynamic file because material is added throughout the rulemaking process. The docketing system is intended to allow members of the public and industries involved to readily identify and locate documents so that they can effectively participate in the rulemaking process. Along with the proposed and promulgated standards and their preambles, the contents of the docket will serve as the record in the case of judicial review. (See section 307(d)(7)(A) of the CAA.) The regulatory text and other materials related to this rulemaking are available for review in the docket or copies may be obtained by mail from the Air and Radiation Docket and Information Center by calling (202) 260–7548. A reasonable fee may be charged for copying docket materials.

World Wide Web (WWW). In addition to being available in the docket, an electronic copy of this proposed rule is also available on the WWW through the Technology Transfer Network (TTN). Following signature by the EPA Administrator, a copy of the proposed rule will be posted on the TTN's policy and guidance page for newly proposed or promulgated rules at *http://www.epa.gov/ttn/oarpg.* The TTN provides information and technology exchange in various areas of air pollution control. If more information regarding the TTN is needed, call the TTN HELP line at (919) 541–5384.

Regulated Entities. The proposed source category definition includes facilities that apply coatings to metal furniture or components of metal furniture. Metal furniture means furniture or components of furniture that are constructed either entirely or partially from metal. Metal furniture

includes, but is not limited to, components of the following types of products as well as the products themselves: household, office, institutional, laboratory, hospital, public building, restaurant, barber and beauty shop, and dental furniture; office and store fixtures; partitions; shelving; lockers; lamps and lighting fixtures; and wastebaskets.

In general, facilities that coat metal furniture are covered under the Standard Industrial Classification (SIC) and North American Industrial Classification System (NAICS) codes listed in table 1. However, facilities classified under other SIC or NAICS codes may be subject to the proposed regulation if they meet the applicability criteria. Not all facilities classified under the SIC and NAICS codes in table 1 will be subject to the proposed standard because some of the classifications cover products outside the scope of the proposed NESHAP for metal furniture.

TABLE 1.—METAL FURNITURE PRODUCT DESCRIPTIONS AND CORRESPONDING SIC AND NAICS CODES

Product description	1987 SIC Code	Equivalent 1997 NAICS Code(s)	Equivalent 1997 NAICS Product Description
Metal Household Furniture	2514	337124	Metal Household Furniture Manufacturing.
Office Furniture, Except Wood	2522	337214	Nonwood Office Furniture Manufacturing.
Public Building and Related Furniture	2531	337127	Institutional Furniture Manufacturing.
Office and Store Fixtures, Partitions, Shelving, and Lockers, Except Wood.	2542	337215	Showcase, Partition, Shelving, and Locker Manufacturing.
Furniture and Fixtures, Not Classified Elsewhere	2599	337127	Institutional Furniture Manufacturing.
Hardware, Not Classified Elsewhere	3429	332951	Hardware Manufacturing.
Metal Stampings, Not Classified Elsewhere (Except Kitchen Utensils, Pots and Pans for Cooking, and Coins).	3469	332116	Metal Stamping.
Wire Springs	3495	332612	Wire Spring Manufacturing.
Fabricated Metal Products, Not Classified Elsewhere	3499	337215	Showcase, Partition, Shelving, and Locker Manufacturing.
Residential Electric Lighting Fixtures	3645	335121	Residential Electric Lighting Fixture Manufacturing.
Commercial, Industrial, and Institutional Electric Lighting Fixtures	3646	335122	Commercial, Industrial, and Institutional Electric Lighting Fixture Manufacturing.
Laboratory Apparatus and Furniture	3821	339111	Laboratory Furniture Manufacturing.
Dental Equipment and Supplies	3843	339114	Dental Equipment Manufacturing.
Manufacturing Industries, Not Classified Elsewhere	3999	337127	Institutional Furniture Manufacturing.
Reupholster and Furniture Repair	7641	81142	Reupholstery and Furniture Repair.
State/Federal Governmental Agencies	.....	.....	State correctional institutions and military installations that apply coatings to metal furniture.

This table is not intended to be exhaustive, but rather provides a guide for readers regarding entities likely to be regulated by this action. To determine whether your coating operation would be regulated by this proposed action, you should examine the applicability criteria in § 63.4881 of the proposed rule. If you have any questions regarding the applicability of this action to a particular entity, consult the person listed in the preceding **FOR FURTHER INFORMATION CONTACT** section.

Outline. The information presented in this preamble is organized as follows:

I. Background
A. What is the source of authority for development of NESHAP?
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A. What source categories would be affected by this proposed rule?
B. What is the relationship to other rules?
C. What are the primary sources of emissions and what are the emissions?
D. What is the affected source?
E. What are the proposed emission limits, operating limits, and other standards?
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III. Rationale for Selecting the Proposed Standards
A. How did we select the source category?
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C. How did we select the affected source?
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A. What are the air impacts?
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V. Administrative Requirements
A. Executive Order 12866, Regulatory Planning and Review
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C. Executive Order 13175, Consultation and Coordination with Indian Tribal Governments
D. Executive Order 13045, Protection of Children from Environmental Health Risks and Safety Risks
E. Executive Order 13211, Actions Concerning Regulations that Significantly Affect Energy Supply, Distribution, or Use
F. Unfunded Mandates Reform Act of 1995
G. Regulatory Flexibility Act, as Amended by the Small Business Regulatory Enforcement Fairness Act of 1996 (SBREFA), 5 U.S.C. 601, *et seq.*
H. Paperwork Reduction Act
I. National Technology Transfer and Advancement Act

I. Background

A. What Is the Source of Authority for Development of NESHAP?

Section 112 of the CAA requires us to list categories and subcategories of major sources and certain area sources

of HAP and to establish NESHAP for the listed source categories and subcategories. The Surface Coating of Metal Furniture category of major sources was listed on July 16, 1992 (57 FR 31576) under the Surface Coating Processes industry group. Major sources of HAP are those that, considering controls, emit or have the potential to emit equal to, or greater than, 10 tons per year (tpy) of any one HAP or 25 tpy of any combination of HAP.

B. What Criteria Are Used in the Development of NESHAP?

Section 112 of the CAA requires that we establish NESHAP for the control of HAP from both new and existing major sources. The CAA requires the NESHAP to reflect the maximum degree of reduction in emissions of HAP that is achievable. This level of control is commonly referred to as the MACT.

The MACT floor is the minimum control level allowed for NESHAP and is defined under section 112(d)(3) of the CAA. In essence, the MACT floor ensures that the standard is set at a level that assures that all major sources achieve a level of control at least as stringent as that already achieved by the better-controlled and lower-emitting sources in each source category or subcategory. For new sources, the MACT floor cannot be less stringent than the emission control that is achieved in practice by the best-controlled similar source. The MACT standards for existing sources can be less stringent than standards for new sources, but they cannot be less stringent than the average emission limitation achieved by the best-performing 12 percent of existing sources in the category or subcategory (or the best-performing five sources for categories or subcategories with fewer than 30 sources).

In developing MACT, we also consider control options that are more stringent than the floor. We may establish standards more stringent than the floor based on the consideration of the cost of achieving the emission reductions, any nonair quality health and environmental impacts, and energy requirements.

C. What Are the Health Effects Associated with HAP Emissions From the Surface Coating of Metal Furniture?

The major HAP emitted from the surface coating of metal furniture include xylene, toluene, glycol ethers, 2-butoxy ethanol, ethylbenzene, and methyl ethyl ketone. These compounds account for about 90 percent of the nationwide HAP emissions from this source category. Other HAP identified in emissions include methyl isobutyl ketone, hexane, and methylene chloride. These pollutants can cause reversible or irreversible toxic effects following sufficient exposure. The potential toxic effects include eye, nose, throat, and skin irritation; nausea, vomiting, headache, and dizziness, and liver and kidney damage.

The degree of adverse effects to human health from exposure to HAP can range from mild to severe. The extent and degree to which the human health effects may be experienced are dependent upon (1) the ambient concentration observed in the area (as influenced by emission rates, meteorological conditions, and terrain); (2) the frequency and duration of exposures; (3) characteristics of exposed individuals (genetics, age, preexisting health conditions, and lifestyle), which vary significantly with the population; and (4) pollutant-specific characteristics (toxicity, half-life in the environment, bioaccumulation, and persistence).

II. Summary of the Proposed Rule

A. What Source Categories Would Be Affected by This Proposed Rule?

The proposed rule would apply to you if you own or operate a metal furniture surface coating facility that is a major source, or is located at a major source, or is part of a major source of HAP emissions. We have defined a metal furniture surface coating facility as one that applies coatings to metal furniture or components of metal furniture. Metal furniture means furniture or components that are constructed either entirely or partially from metal.

You would not be subject to the proposed rule if your metal furniture surface coating facility is located at an area source. An area source of HAP is any facility that has the potential to emit HAP but is not a major source. You may establish area source status by limiting the source's potential to emit HAP through appropriate mechanisms available through the permitting authority.

You would not be subject to the proposed rule if you use only coatings, thinners, and cleaning materials that contain no organic HAP.

The source category does not include research or laboratory facilities or janitorial, building, and facility maintenance operations; or coating application using handheld nonrefillable aerosol containers.

B. What Is the Relationship to Other Rules?

Affected sources subject to the proposed rule may also be subject to other rules. The relationship between this proposed rule and other rules is discussed below. We specifically request comments on how monitoring, recordkeeping, and reporting requirements can be consolidated for sources that are subject to more than one rule. We also request comments regarding instances where a facility could be subject to multiple surface coating NESHAP or where the applicability of one NESHAP versus another is unclear. Commenters should provide specific examples of these instances and discuss any associated adverse effects that would result.

New Source Performance Standards—40 CFR Part 60, Subpart EE. The metal furniture new source performance standards (NSPS) apply to facilities that apply organic coatings to metal furniture and that began construction, reconstruction, or modification after November 28, 1980. The pollutants regulated are volatile organic compounds (VOC). Emissions of VOC are limited to 0.09 kilogram (kg) per liter of coating solids applied, and the affected source is each individual coating operation.

The proposed rule differs from the NSPS in three ways. First, the affected source for the proposed rule is defined broadly as the collection of all coating operations and related activities and equipment at the facility, whereas the affected facility for the NSPS is defined narrowly as each individual coating operation. This broader definition of affected source allows a facility's emissions to be combined for compliance purposes. Second, the proposed rule would regulate organic HAP. While most organic HAP emitted from metal furniture surface coating operations are VOC, some VOC are not listed as HAP and, therefore, the NSPS regulates a broader range of pollutants than would the proposed NESHAP. Third, the emission limitations in the proposed rule would be based on the amount of solids used at the affected source. The NSPS limitations are based on the amount of solids actually applied to the metal furniture which necessitates estimates of transfer efficiency in the compliance calculations.

Because of the differences between the two rules, compliance with either rule cannot be deemed compliance with the other. A metal furniture surface coating facility that meets the applicability requirements of both rules must comply with both. Overlapping reporting, recordkeeping, and monitoring requirements may be resolved through the title V permit process.

National Emission Standards for Wood Furniture Manufacturing Operations—40 CFR Part 63, Subpart JJ. There may be situations where a manufacturer of wood furniture also coats metal components of that wood furniture. The coating of these metal components would be subject to subpart JJ, the rule for wood furniture manufacturing. As such, the proposed rule would not apply to these facilities. The applicability section of the proposed rule clarifies this difference in applicability.

Future national emission standards for the surface coating of miscellaneous metal parts. Metal furniture often contains components, such as metal knobs, hinges, and screws, that have a wider use beyond metal furniture. The coating of such parts would not be subject to the proposed rule provided the coating takes place at a facility that does not apply coatings to other metal furniture. Such metal coating operations would be subject to the future NESHAP for the surface coating of miscellaneous metal parts.

Future national emission standards for the surface coating of plastic parts and products. Plastic parts and products may be components (e.g., plastic handles) of metal furniture. The coating of such plastic parts would be subject to the proposed rule if the coating takes place at a metal furniture surface coating facility; otherwise, the coating operation would be subject to the future NESHAP for the surface coating of plastic parts and products.

C. What Are the Primary Sources of Emissions and What Are the Emissions?

HAP Emission Sources. Emissions from coating application account for more than 60 percent of HAP emissions from the metal furniture surface coating process. Remaining emissions are primarily from cleaning. In most cases, HAP emissions from mixing and storage are relatively small. The organic HAP emissions associated with coatings (the term ''coatings'' includes protective and functional coatings, as well as adhesives) occur at several points. A coating is most often applied by using a spray gun in a spray booth or by dipping the substrate in a tank containing the coating. In a spray booth, volatile components evaporate from the coating applied to the part, as well as from the overspray. The coated part then passes through an open (flash-off) area where additional volatiles evaporate from the coating. The coated part then passes through a drying/curing oven, or is allowed to air dry, where the remaining volatiles are evaporated.

Organic HAP emissions also occur from the activities undertaken during cleaning, where solvent is applied to remove coating residue or other unwanted materials. Cleaning in this industry includes cleaning of spray guns and transfer lines (e.g., tubing or piping), tanks, and the interior of spray booths. Cleaning also includes applying solvents to manufactured parts prior to coating application and to equipment (e.g., cleaning rollers, pumps, conveyors, etc.).

Mixing and Storage. Organic HAP emissions can also occur from displacement of organic vapor-laden air in containers used to store HAP solvents or to mix coatings containing HAP solvents. The displacement of organic HAP vapor-laden air can occur due to filling of containers, temperature or barometric pressure changes, or due to agitation during mixing.

Organic HAP. Available emission data collected during the development of the proposed NESHAP show that the primary organic HAP emitted from the surface coating of metal furniture include xylene, toluene, glycol ethers, 2-butoxy ethanol, ethylbenzene, and methyl ethyl ketone. These compounds account for over 90 percent of this category's nationwide organic HAP emissions. Other significant organic HAP identified include methyl isobutyl ketone, hexane, and methylene chloride.

Inorganic HAP. Based on information reported in survey responses during the development of the proposed NESHAP, inorganic HAP, including chromium, lead, and manganese compounds are contained in two kinds of coatings used by this source category. No inorganic HAP were reported in cleaning materials. Nationwide inorganic HAP emissions are estimated to be less than 5 megagrams per year (Mg/yr).

D. What Is the Affected Source?

We define an affected source as a stationary source, group of stationary sources, or part of a stationary source to which a specific emission standard applies. This proposed rule defines the affected source as the collection of all operations associated with the surface coating of metal furniture or components of metal furniture that are performed at a contiguous area under common control. These operations include preparation of a coating for application (e.g., mixing with thinners); surface preparation of the metal furniture or component; coating application and flash-off; drying and/or curing of applied coatings; cleaning of equipment used in surface coating; storage of coatings, thinners, and cleaning materials; and handling and conveyance of waste materials from the surface coating operations. Coatings include such materials as adhesives and protective or decorative coatings.

E. What Are the Proposed Emission Limits, Operating Limits, and Other Standards?

We are proposing standards that, if promulgated, would limit HAP emissions from the surface coating of metal furniture. The proposed standards include emission limits and operating limits.

Emission Limits. We are proposing to limit organic HAP emissions from each new and reconstructed affected source to no more than 0.094 kilogram HAP per liter of coating solids used (kg/liter) (0.78 pound per gallon (lb/gal)) each calendar month. The proposed limit for each existing affected source is 0.12 kg HAP/liter used (1.0 lb/gal). You would choose from several compliance options in the proposed rule to achieve the emission limit(s). You could comply by applying materials (coatings, thinners, and cleaning materials) that meet the emission limit, either individually or collectively, during each monthly compliance period. You could also use a capture system and add-on control device to meet the emission limit, or a combination of both approaches.

Operating Limits. If you reduce emissions by using a capture system and add-on control device (other than a solvent recovery system for which you conduct a monthly liquid-liquid material balance), the proposed operating limits would apply to you. These limits are site-specific parameter limits you determine during the initial performance test of the system. For capture systems, you would establish average volumetric flow rate limits for each capture device (or enclosure) in each capture system. You would also establish limits on average pressure drop across openings in the capture system.

For thermal and catalytic oxidizers, you would monitor temperature. For solvent recovery systems for which you do not conduct a monthly liquid-liquid material balance, you would monitor the carbon bed temperature and the amount of steam or nitrogen used to desorb the bed. For condensers, you would monitor the temperature of the outlet gas temperature from the condenser.

All operating limits must reflect operation of the capture system and control devices during a performance test that demonstrates achievement of the emission limit during representative operating conditions.

General Provisions. The General Provisions (40 CFR part 63, subpart A) also would apply to you as outlined in the proposed rule. The General Provisions codify certain procedures and criteria for all 40 CFR part 63 NESHAP. The General Provisions contain administrative procedures, preconstruction review procedures for new sources, and procedures for conducting compliance-related activities such as notifications, reporting, and recordkeeping, performance testing, and monitoring. The proposed rule refers to individual sections of the General Provisions to emphasize key sections that you should be aware of. However, unless specifically overridden in the proposed rule, all of the applicable General Provisions requirements would apply to you.

F. What Are the Proposed Testing and Initial Compliance Requirements?

Compliance Dates. Existing affected sources would have to be in compliance with the final standards no later than 3 years after the effective date of the subpart. The effective date is the date on which the final rule is published in the **Federal Register**. New and reconstructed sources would have to be in compliance upon startup of the affected source or no later than the effective date, whichever is later.

The proposed initial compliance period is 1 month and begins on the compliance date and ends on the last day of the first full calendar month following the compliance date; except that for new and reconstructed sources required to conduct performance tests, it ends on the last day of the first full calendar month following the performance test. Being ''in compliance'' means that the owner or operator of the affected source meets all the requirements of the rule to achieve the proposed emission limit(s) and operating limits by the end of the initial compliance period. At the end of the initial compliance period, the owner or operator would use the data and records generated to determine whether or not the affected source is in compliance for that period. If it does not meet the applicable limit(s), then it is out of compliance for the entire initial compliance period.

Emission Limit(s). There are several proposed options for complying with the proposed emission limit(s), and the testing and initial compliance requirements vary accordingly.

If you demonstrate compliance based on the materials used in the affected source, you would determine the mass of organic HAP and the volume of solids in all materials used during the initial compliance period.

To determine the mass of organic HAP in coatings, thinners, and cleaning materials and the volume coating solids, you could either rely on manufacturer's data or on results from the test methods listed below. Under § 63.4941 of the proposed rule, you would be required to determine the mass of organic HAP in coatings, thinners, and cleaning materials. To do this, you would count HAP that are present at 1 percent by mass or more if they are not carcinogens identified by the Occupational Safety and Health Administration (OSHA) at 29 CFR 1910.1200(d)(4), and count HAP that are present at 0.1 percent by mass or more if they are OSHA-identified carcinogens. Coating and solvent manufacturers are accustomed to providing a breakdown of material components according to this distinction and routinely report the values on Material Safety Data Sheets for the materials, as required by OSHA. We could have selected some other way to count HAP components of materials but concluded that allowing this long-standing approach to be used for compliance with the proposed NESHAP would provide the information needed for compliance assurance and would not impose any additional burden on the industry. We request comment on the appropriateness of this provision of the proposed rule.

You may use alternative test methods provided you get EPA approval in accordance with the NESHAP General Provisions, § 63.7(f). If there is any inconsistency between the test method results (either EPA's or an approved alternative) and manufacturer's data, the test method results would prevail for compliance and enforcement purposes.

- For organic HAP content, use Method 311 of 40 CFR part 63, appendix A;
- The proposed rule allows you to use nonaqueous volatile matter as a surrogate for organic HAP, which would include all organic HAP plus all other organic compounds. If you choose this option, then use Method 24 of 40 CFR part 60, appendix A; and
- For volume coating solids, use either manufacturer's data or ASTM Method D2697–86 (1998) or ASTM Method D6093–97.

To demonstrate initial compliance based on the materials used, you would be required to either ensure that the organic HAP content of each coating meets the emission limit and that you use no organic HAP-containing thinners or cleaning materials; or ensure that the total mass of organic HAP in all coatings, thinners, and cleaning materials divided by the total volume of coating solids meets the emission limit. For the latter option, you would be required to:

- For the initial compliance period, determine the quantity of each coating, thinner, and cleaning material used in the affected source.
- Determine the mass of organic HAP in each coating, thinner, and cleaning material.
- Determine the volume fraction solids for each coating.
- Calculate the total mass of organic HAP for materials and total volume of coating solids used in the affected source for the compliance period. You may subtract from the total mass of organic HAP the amount contained in waste materials you send to a hazardous waste treatment, storage, and disposal facility (TSDF) regulated under 40 CFR part 262, 264, 265, or 266. The proposed calculation equation (Equation 1 in § 63.4951) adds together all the organic HAP in the coatings, thinners, and cleaning materials and allows you to subtract organic HAP in waste materials as indicated above. The calculated mass of organic HAP is, therefore, not based on actual measurement of emissions to the atmosphere but rather assumes that all organic HAP used (less those in waste materials as appropriate) are emitted. This means of determining organic HAP emissions for compliance is consistent with the means by which we calculated emission rates from industry data on which the proposed emission limits are based. We believe that Equation 1 is a simple mass-balance relationship which adequately quantifies the organic HAP emissions without imposing an excessive burden on respondents. We request comment on our approach for determining emissions and on any alternatives.
- Calculate the ratio of the total mass of organic HAP for the materials used to the total volume of coating solids used.
- Record the calculations and results and include them in your notification of compliance status (see section II.H of this preamble).

If you use a capture system and control device, other than a solvent recovery system for which you conduct a monthly liquid-liquid material balance, you would:

- Conduct an initial performance test to determine the capture and control efficiencies of the equipment (described below) and to establish operating limits to be achieved on a continuous basis (also described below). The performance test would have to be completed no later than the compliance date for existing sources and 180 days after the compliance date for new and

reconstructed sources. You would also need to schedule it in time to obtain the results for use in completing your compliance determination for the initial compliance period.

- Determine the mass of organic HAP in each material and the volume fraction coating solids for each coating used during the initial compliance period.
- Calculate the organic HAP emissions from all the controlled coating operations using the capture and control efficiencies determined during the performance test and the total mass of organic HAP in materials used in controlled coating operations.
- Calculate the total mass of organic HAP emissions from uncontrolled coating operations.
- Calculate the ratio of the total mass of HAP emissions from both controlled and uncontrolled coating operations to the total volume of coating solids used during the initial compliance period.
- Record the calculations and results and include them in your Notification of Compliance Status.

The capture and control efficiency for a capture and control system, other than a solvent recovery system for which you conduct monthly liquid-liquid material balances, would be demonstrated based on emission capture and reduction efficiency. To determine the capture efficiency, you would either verify the presence of a permanent total enclosure using EPA Method 204 of 40 CFR part 51, appendix M (and all materials must be applied and dried within the enclosure), or use one of three protocols in § 63.4965 to measure capture efficiency. If you have a permanent total enclosure and all materials are applied and dried within the enclosure and you route all exhaust gases from the enclosure to a control device, then you would assume 100 percent capture.

To determine the emission reduction efficiency of the control device, you would conduct measurements of the inlet and outlet gas streams. The test would consist of three runs, each run lasting 1 hour, using the following EPA Methods in 40 CFR part 60, appendix A:

- Method 1 or 1A for selection of the sampling sites.
- Method 2, 2A, 2C, 2D, 2F, or 2G to determine the gas volumetric flow rate.
- Method 3, 3A, or 3B for gas analysis to determine dry molecular weight.
- Method 4 to determine stack moisture.
- Method 25 or 25A to determine organic volatile matter concentration. In lieu of Method 25 or 25A, you may use Method 18 if you know the HAP constituents in the inlet and outlet gas streams and you quantify at least 90 percent of the organic compounds in the gas stream. Alternatively, any other test method or data that have been validated according to the applicable procedures in Method 301 of 40 CFR part 63, appendix A, and approved by the Administrator, could be used.

If you use a solvent recovery system, you could determine the overall control efficiency using a liquid-liquid material balance instead of conducting an initial performance test. If you use the material balance alternative, you would be required to measure the amount of all materials used in the affected source during the initial compliance period and determine the total volatile matter contained in these materials. You would also measure the amount of volatile matter recovered by the solvent recovery system during the compliance period. Then you would compare the amount recovered to the amount used to determine the overall control efficiency, and apply this efficiency to the organic HAP to solids ratio for the materials used. You would record the calculations and results and include them in your Notification of Compliance Status.

Operating Limits. In accordance with section 114(a) of the CAA, the proposed operating limits would require the use of continuous parameter monitoring systems (CPMS) to ensure that sources are in compliance. The monitoring must be capable of detecting deviations with sufficient representativeness, accuracy, precision, reliability, frequency, and timeliness to determine if compliance is continuous during a reporting period.

As mentioned above, you would establish operating limits as part of the initial performance test of a capture system and control device, other than a solvent recovery system for which you conduct liquid-liquid material balances. The operating limits are the minimum or maximum (as applicable) values achieved for capture systems and control devices during the most recent performance test that demonstrated compliance with the emission limit. If you operate your capture system and control device at different sets of representative operating conditions, you must establish operating limits for the parameters for each different operating condition.

The proposed rule specifies the parameters to monitor for the types of emission control systems commonly used in the industry. You would be required to install, calibrate, maintain, and continuously operate all monitoring equipment according to manufacturer's specifications and ensure that the CPMS meet the requirements in § 63.4968 of the proposed rule. If you use control devices other than those identified in the proposed rule, you would submit the operating parameters to be monitored to the Administrator for approval. The authority to approve the parameters to be monitored is retained by the EPA and is not delegated to States. We request comment on whether there are alternative means of monitoring performance for add-on controls which would be appropriate. Commenters should address the relative effectiveness and cost of alternatives.

If you use a thermal or catalytic oxidizer, you would continuously monitor temperature and record it at least every 15 minutes. For thermal oxidizers, the temperature monitor is placed in the firebox or in the duct immediately downstream of the firebox before any substantial heat exchange occurs. The operating limit would be the average temperature measured during the performance test, and during each 3-hour period the average temperature would have to be at or above this limit. For catalytic oxidizers, temperature monitors are placed immediately before and after the catalyst bed. The operating limits would be the average combustion temperature just before the catalyst bed and the average temperature difference across the catalyst bed during the performance test, and for each 3-hour period the average combustion temperature and the average temperature difference would have to be at or above these limits.

If you use a solvent recovery system, and do not conduct liquid-liquid material balances to demonstrate compliance, then you would monitor the carbon bed temperature after each regeneration and the total amount of steam or nitrogen used to desorb the bed for each regeneration. The operating limits would be the carbon bed temperature (not to be exceeded) and the amount of steam or nitrogen used for desorption (to be met as a minimum).

If you use a condenser, you would monitor the outlet gas temperature to ensure that the air stream is being cooled to a low enough temperature. The operating limit would be the average condenser outlet gas temperature measured during the performance test, and for each 3-hour period the average temperature would have to be at or below this limit.

For each capture system, you would establish operating limits for gas volumetric flow rate and pressure drop across an opening in each enclosure or capture device. The operating limit would be the average volumetric flow rate and average pressure drop across the opening during the performance test, to be met as a minimum.

We request comment on the proposed testing and initial compliance requirements discussed above.

G. What Are the Proposed Continuous Compliance Provisions?

Emission Limit(s)

If you demonstrate compliance with the proposed emission limit(s) based on the materials used in the affected source, you would ensure, for each monthly compliance period, that the ratio of organic HAP to coating solids meets the emission limit. You would follow the same procedures as you would for the initial compliance period, as described in section II.F of this preamble.

For each coating operation on which you use a capture system and control device, other than solvent recovery for which you conduct a monthly liquid-liquid material balance, you would use the continuous parameter monitoring results for the month in determining the mass of organic HAP emissions. If the monitoring results indicate no deviations from the operating limits and there were no bypasses of the control device, then you would assume the capture system and control device is achieving the same percent emission reduction efficiency as it did during the performance test. You would then apply this percent reduction to the total mass of organic HAP in materials used in controlled coating operations to determine the monthly emission rate from those operations. If there were any deviations from the operating limits during the month or any bypasses of the control device, you would account for them in the calculation of the monthly emission rate by assuming the capture system and control device were achieving zero emission reduction during the periods of deviation.

For each coating operation on which you use a solvent recovery system and conduct a liquid-liquid material balance each month, you would use the liquid-liquid material balance to determine control efficiency. To determine the overall control efficiency, you must measure the amount of all materials applied during each month and determine the volatile matter content of these materials. You must also measure the amount of volatile matter recovered by the solvent recovery system during the month, calculate the overall control efficiency, and apply it to the total mass of organic HAP in the materials used to determine total organic HAP emissions.

The monthly emission rate for your affected source would be the total mass of organic HAP emissions from all controlled and uncontrolled coating operations divided by the total volume of coating solids used during the compliance period.

Operating Limits. If you use a capture system and control device, the proposed rule would require you to achieve on a continuous basis the operating limits you establish during the performance test described in section II.F of this preamble. If the continuous monitoring shows that the capture system and control device is operating outside the range of values established during the performance test, then you have deviated from the established operating limits.

If you operate a capture system and control device that allows emissions to bypass the control device, you would have to demonstrate that HAP emissions from each emission point within the affected source are being routed to the control device by monitoring for potential bypass of the control device. You may choose from the following four monitoring procedures:

(1) Flow control position indicator to provide a record of whether the exhaust stream is directed to the control device;

(2) Car-seal or lock-and-key valve closures to secure the bypass line valve in the closed position when the control device is operating;

(3) Valve closure continuous monitoring to ensure any bypass line valve or damper is closed when the control device is operating; or

(4) Automatic shutdown system to stop the coating operation when flow is diverted from the control device. If the bypass monitoring procedures indicate that emissions are not routed to the control device, then you have deviated from the emission limit.

Operations During Startup, Shutdown, and Malfunction. If you use a capture system and control device for compliance, you would be required to develop and operate according to a startup, shutdown, and malfunction plan during periods of startup, shutdown, and malfunction of the capture system and control device.

Emissions Reductions Plan for Mixing, Storage, and Waste Handling. If you use a capture system and control device for compliance, you would be required to develop and operate according to a plan for reducing emissions from mixing operations, storage tanks or other containers, and waste handling operations. This plan would include a description of all steps taken to minimize emissions from these sources (e.g., using closed storage containers, practices to minimize emissions during filling and transfer of contents from containers, using spill minimization techniques, placing solvent-laden cloth in closed containers immediately after use, etc.). If you do not develop a plan or you do not implement the plan, this would be a deviation from the work practice standard.

We request comment on the proposed continuous compliance requirements discussed above.

H. What Are the Proposed Notification, Recordkeeping, and Reporting Requirements?

You would be required to comply with the applicable requirements in the NESHAP General Provisions, subpart A of 40 CFR part 63, as described in the proposed rule. The General Provisions notification requirements include: (1) Initial notifications, (2) notification of performance test if you are complying using a capture system and control device, (3) notification of compliance status, and (4) additional notifications required for affected sources with continuous monitoring systems. The General Provisions also require certain records and periodic reports.

Initial Notifications. If the proposed standards apply to you, you would be required to send a notification to the EPA Regional Office in the region where your facility is located and to your State agency at least 1 year before the compliance date for existing sources and within 120 days after the date of initial startup for new and reconstructed sources, or 120 days after publication of the final rule, whichever is later. This report notifies us and your State agency that you have an existing facility that is subject to the proposed standard or that you have constructed a new facility. Thus, it allows you and the permitting authority to plan for compliance activities. You would also need to send a notification of planned construction or reconstruction of a source that would be subject to the rule and apply for approval to construct or reconstruct.

Notification of Performance Test. If you demonstrate compliance by using a capture system and control device for which you do not conduct a monthly liquid-liquid material balance, you would be required to conduct a performance test, as described in section II.F of this preamble, no later than the compliance date for your affected source. You would be required to notify your EPA Regional Office (or the delegated State or local agency) at least 60 calendar days before the performance test is scheduled to begin, as indicated in the General Provisions for the NESHAP.

Notification of Compliance Status. Your compliance procedures would depend on which compliance option you choose. For each compliance option, you would send us a

Notification of Compliance Status within 30 days after the end of the initial compliance period described in section II.F of this preamble. In the notification, you would certify whether the affected source has complied with the standards, identify the option you used to demonstrate initial compliance, summarize the data and calculations supporting the compliance demonstration, and describe how you will determine continuous compliance.

If you elect to comply by using a capture system and control device for which you conduct performance tests, you must provide the results of the tests. Your notification would also include the measured range of each monitored parameter and the operating limits established during the performance test, and information showing whether the source has achieved its operating limits during the initial compliance period.

Recordkeeping Requirements. You would be required to keep records of reported information and all other information necessary to document compliance with the proposed rule for 5 years. As required under the General Provisions, records for the 2 most recent years would be required to be kept on-site; the other 3 years' records could be kept off-site. Records pertaining to the design and operation of the control and monitoring equipment would have to be kept for the life of the equipment.

Depending on the compliance option that you choose, you could need to keep records of the following:

- Organic HAP content, volatile matter content, solids content, and quantity of the coatings, thinners, and cleaning materials used during each compliance period;
- All documentation supporting initial notifications and notifications of compliance status.

If you demonstrate compliance by using a capture system and control device, you would also need to keep records of the following:

- The occurrence and duration of each startup, shutdown, or malfunction of the emission capture system and control device;
- All maintenance performed on the capture system and control device;
- Actions taken during startup, shutdown, and malfunction that are different from the procedures specified in the affected source's startup, shutdown, and malfunction plan;
- All information necessary to demonstrate conformance with the affected source's startup, shutdown, and malfunction plan when the plan procedures are followed;
- All information necessary to demonstrate conformance with the affected source's plan for minimizing emissions from mixing, storage, and waste handling operations;
- Each period during which a CPMS is malfunctioning or inoperative (including out-of-control periods);
- All required measurements needed to demonstrate compliance with the standards; and
- All results of performance tests.

The proposed rule would require you to collect and keep records according to certain minimum data requirements for the CPMS. Failure to collect and keep the specified minimum data would be a deviation that is separate from any emission limit, operating limit, or work practice standard.

Deviations, as determined from these records, would need to be recorded and also reported, as described in section II.H of this preamble. A deviation is any instance when any requirement or obligation established by the proposed rule including, but not limited to, the emission limit(s), operating limits, and work practice standards, is not met.

If you use a capture system and control device to reduce HAP emissions, you would have to make your startup, shutdown, and malfunction plan available for inspection if the Administrator requests to see it. It would stay in your records for the life of the affected source or until the source is no longer subject to the standards. If you revise the plan, you would need to keep the previous superceded versions on record for 5 years following the revision.

Periodic Reports. Each reporting year is divided into two semiannual reporting periods. If no deviations occur during a semiannual reporting period, you would submit a semiannual report stating that the affected source has been in continuous compliance. If deviations occur, you would need to document them in the report as follows:

- Report each deviation from the monthly emission limit.
- If you are complying by using a thermal oxidizer, report all times when a 3-hour average temperature is below the operating limit.
- If you are complying by using a catalytic oxidizer, report all times when a 3-hour average temperature difference across the catalyst bed is below the operating limit, and when a 3-hour average combustion temperature before the catalyst bed is below the operating limit.
- If you are complying by using oxidizers, or solvent recovery systems where liquid-liquid material balances are not conducted, report all times when the value of the site-specific operating parameter used to monitor the capture system performance was less than the operating limit established for the capture system.
- If you are complying by using a carbon adsorber for which you do not conduct liquid-liquid material balances, report all times when the steam or nitrogen flow is less than, and/or the carbon bed temperature is more than, the operating limits.
- If you are complying by using a condenser, report all times when a 3-hour average outlet temperature is higher than the operating limit.
- If your capture system contains bypass lines that could divert emissions from the control device to the atmosphere, report all times when emissions were not routed to the control device.
- Report other specific information on the periods of time the deviations occurred.

You would also have to include an explanation in each semiannual report if a change occurs that might affect the compliance status of the affected source or you change to another option for meeting the emission limit.

Other Reports. You would be required to submit reports for periods of startup, shutdown, and malfunction of the capture system and control device. If the procedures you follow during any startup, shutdown, or malfunction are inconsistent with your plan, you would report those procedures with your semiannual reports in addition to the immediate reports required by § 63.10(d)(5)(ii).

We request comment on the proposed notification, recordkeeping, and reporting requirements discussed above.

III. Rationale for Selecting the Proposed Standards

A. How Did We Select the Source Category?

The surface coating of metal furniture is a source category that is on the list of source categories to be regulated because it contains major sources which emit or have the potential to emit, considering controls, at least 10 tons of any one HAP or at least 25 tons of any combination of HAP annually. The proposed rule would control HAP emissions from both new and existing major sources. Area sources are not being regulated under this proposed rule.

The surface coating of metal furniture as described in the listing includes any facility engaged in the surface coating and manufacture or repair of metal furniture parts or products (including, but not limited to, chairs, tables, cabinets, and bookcases). We use the

metal furniture product lists contained in the SIC and NAICS code descriptions to describe the vast array of metal furniture parts and products.

We intend the source category to include facilities for which the surface coating of metal furniture is either their principal activity or is an integral part of a production process which is the principal activity. Most coating operations are located at plant sites that are dedicated to these activities. However, some may be located at sites for which some other activity is principal. Collocated surface coating operations comparable to the types and sizes of the dedicated facilities, in terms of the coating process and applicable emission control techniques, are included in the source category.

The source category does not include research or laboratory facilities or janitorial, building, and facility maintenance operations.

The statute gives us discretion to determine if and how to subcategorize. Once the floor has been determined for new or reconstructed and existing affected sources for a source category or subcategory, we must set MACT standards that are no less stringent than the MACT floor. Such standards must then be met by all sources within the source category or subcategory. A subcategory is a group of similar sources within a given source category. As part of the regulatory development process, we evaluate the similarities and differences between industry segments or groups of facilities comprising a source category. In establishing subcategories, we consider factors such as process operations (type of operation, raw materials, chemistry/formulation data, associated equipment, and final products); emission characteristics (amount and type of HAP); control device applicability; and opportunities for pollution prevention. We may also consider existing regulations or guidance from States and other regulatory agencies in determining subcategories. The data available to us indicate that there are not significant differences across the source category in the substrates coated, the coating technologies used, the range of HAP content in the coatings and materials used, or the applicability of control measures used. Based on this information, we believe that subcategories are not warranted for the metal furniture surface coating source category. We specifically request comment on this view and ask that commenters provide data, information, and rationale to support their position.

B. How Did We Select the Regulated Pollutants?

Organic HAP. Available emission data collected during the development of the proposed NESHAP show that the primary organic HAP emitted from the surface coating of metal furniture include xylene, toluene, glycol ethers, 2-butoxy ethanol, ethylbenzene, and methyl ethyl ketone. These compounds account for about 90 percent of this category's nationwide organic HAP emissions. However, many other organic HAP are used, or can be used, in metal furniture coatings, thinners, and cleaning materials. Therefore, the proposed rule would regulate emissions of all organic HAP.

Inorganic HAP. Based on information reported in response to surveys during the development of the proposed NESHAP, most of the coatings used in this source category do not contain inorganic HAP. Approximately 680 coatings were reported in the survey responses from the metal furniture industry, and only 2 coatings are reported as containing inorganic HAP such as chromium, lead, or manganese compounds. These 2 coatings represent less than 0.5 percent of the total volume of coatings reported in the survey responses. The facilities in this source category using coatings with inorganic HAP employ either a waterwash system or dry particulate filters that reduce inorganic HAP emissions from the spray booth exhaust. At this time, it does not appear that emissions of inorganic HAP from this source category warrant Federal regulation.

C. How Did We Select the Affected Source?

In selecting the affected source(s) for emission standards, our primary goal is to ensure that MACT is applied to HAP-emitting operations or activities within the source category being regulated. The affected source also serves to distinguish where new source MACT applies under a particular standard. Specifically, the General Provisions in subpart A of 40 CFR part 63 define the terms ''construction'' and ''reconstruction'' with reference to the term ''affected source'' (40 CFR 60.2) and provide that new source MACT applies when construction or reconstruction of an affected source occurs (40 CFR 60.5). The collection of equipment and activities evaluated in determining MACT (including the MACT floor) is used in defining the affected source.

When an emission standard is based on a collection of emissions sources, or total facility emissions, we select an affected source based on that same collection of emission sources, or the total facility, as well. This approach for defining the affected source broadly is particularly appropriate for industries where a plantwide emission standard provides the opportunity and incentive for owners and operators to utilize control strategies that are more cost effective than if separate standards were established for each emission point within a facility.

Selection of the Affected Source. The affected source for these proposed standards is broadly defined to include all operations associated with the coating and cleaning of metal furniture and cleaning of equipment. These operations include storage and mixing of coatings and other materials; surface preparation of the metal furniture prior to coating application; coating application and flash-off, drying and curing of applied coatings; cleaning operations; and waste handling operations.

In selecting the affected source, we considered, for each operation, the extent to which HAP-containing materials are used and the level of HAP that are emitted. Cleaning and coating application, flash-off, and curing/drying operations account for the majority of HAP emissions at metal furniture surface coating operations, and most of the industry's emission reduction efforts have been focused on these areas. Thus, we included these operations in the affected source.

We were not able to obtain data to adequately quantify HAP emissions from storage, mixing, and waste handling. However, solvents that are added to coatings as thinners, and other HAP-containing additives to coatings, may be emitted during mixing and storage. The level of emissions would depend on the type of mixing equipment, the type of storage container, and the work practices adopted at the facility. Emissions from waste handling operations depend on the type of system used to collect and transport organic HAP-containing waste coatings, thinners, and cleaning materials in the facility. For example, solvent-laden rags that are used to clean spray booths or tanks could be a source of HAP emissions. The method used to isolate and store such rags would affect the level of emissions to ambient air. Mixing, storage, and waste handling operations are included in the affected source.

A broad definition of the affected source was selected to provide maximum flexibility in complying with the proposed emission limits for organic HAP. In planning its total usage of HAP-

containing materials, each facility can select among available coatings, thinners, and cleaning materials to comply with the proposed limits.

Additional information on the metal furniture surface coating operations selected for regulation, and other operations, are included in the docket for the proposed standards.

D. How Did We Determine the Basis and Level of the Proposed Standards for Existing and New Sources?

The sections below present the rationale for determining the MACT floor, regulatory alternatives beyond the floor, and selection of the proposed standards for existing and new affected sources.

How did we determine the MACT floor technology? After we identify the specific source categories or subcategories of sources to regulate under section 112, we must develop emission standards for each category or subcategory. Section 112 establishes a minimum baseline or ''floor'' for standards. For new sources in a category or subcategory, the standards cannot be less stringent than the emission control that is achieved in practice by the best-controlled similar source (section 112(d)(3)). The standards for existing sources can be less stringent than standards for new sources, but they cannot be less stringent than the average emission limitation achieved by the best-performing 12 percent of existing sources (or the best-performing 5 sources for categories or subcategories with fewer than 30 sources).

Within the metal furniture industry, organic HAP emission control for cleaning and surface coating operations is accomplished primarily through the use of lower-HAP coatings, thinners, and cleaning materials. Add-on capture and control systems for organic HAP are rarely used by the industry. While lower organic HAP materials are broadly used throughout the industry, each particular coating technology is not used at every facility. Rather, facilities use various combinations of low-HAP coatings, thinners, and cleaning materials. Thus, the most reasonable approach to establishing a MACT floor appeared to be evaluation of a facility's organic HAP emissions from all coating-related operations. To account for differences in production levels from one facility to another, we normalized the organic HAP emissions by the volume of coating solids used. We believe coating solids usage is an appropriate indicator of overall production level.

We used information obtained from industry survey responses to estimate the sourcewide organic HAP emissions. We calculated total organic HAP emissions by assuming that 100 percent of the volatile components in all coatings (including adhesives), thinners, and cleaning materials (including surface preparation materials) are emitted.

The survey response information was also used to determine the total volume of coating solids used. We included protective and functional coatings, as well as adhesives, in this total.

Using the sourcewide organic HAP emissions and the total volume of coating solids used. We calculated the normalized organic HAP emission rate in units of kilograms organic HAP per liter of coating solids used. The facilities were then ranked from the lowest emission rate to the highest. We based this analysis on a total of 49 facilities reporting over 9 million liters usage of approximately 680 coatings and adhesives, as well as 730,000 liters of cleaning materials.

A detailed description of the determination of the MACT floor is provided in a memo (the MACT floor memo) in the docket for the proposed rule. The description includes all the assumptions and it documents the methodology that was used. (See **ADDRESSES** section of this preamble for information on the docket). We specifically request comment on the methodology used to determine the MACT floor, as summarized below.

The MACT floor for existing sources was determined by the arithmetic mean of the HAP emission rates of the top 12 percent of 49 facilities, which were the top 6 facilities. This mean value was 0.12 kg organic HAP/liter of coating solids used (1.0 lb/gal) and represents the existing source MACT floor for organic HAP. The survey data showed no appreciable differences between the floor facilities and the remaining facilities in the database in the substrates coated, the coating technologies used, or the applicability of control measures across the various operations.

Using the list of facilities ranked by emission rates, we observed that the best controlled source emitted 0.094 kg organic HAP/liter of coating solids used (0.78 lb/gal). Before establishing this level of emissions as the new source MACT floor, we evaluated the metal furniture surface coating operations at this source to determine if the coating technology (in terms of the coating type and application method) used was transferable throughout the industry. We also determined whether the product type produced at this source affected the emissions such that the source may not be similar to all other sources in the category. For example, a source that coats only interior parts could have significantly different requirements and coating choices than a source that had the visual and quality requirements associated with coating parts for the exterior of the product. We also determined that the emission limit represented by the lowest-emitting source could be achieved through the use of add-on control devices for those facilities electing to use higher organic HAP coatings, thinners, and cleaning materials.

The best-controlled source produces products (metal storage cabinets, lockers, and racks) that are not unusual for the industry. The source spray applies solvent-based coatings, and all cleaning materials used for surface preparation prior to coating are free of organic HAP. Coating application equipment is cleaned with solvents containing organic HAP. Thus, the source is employing technologies that are already in widespread use throughout the metal furniture coating industry. We believe that this source is similar to other sources in the category and represents the best-controlled source in our database.

We recognize that some sources may have limited choices in the coatings available for their particular application. As a result, lower-HAP coatings may not be available to meet the needs of every source. However, if the source is also using cleaning materials that contain organic HAP, then it may be able to meet the emission limit by reformulating these cleaning materials. A source also would have the option of using capture systems and control devices to reduce emissions although we believe choice of this option is not likely for most sources.

How did we consider beyond-the-floor technology? After the floors have been determined for new and existing sources in a source category or subcategory, we must set emission standards that are no less stringent than the floors. Such standards must then be met by all sources within the category or subcategory. We identify and consider any reasonable regulatory alternatives that are ''beyond the floor,'' taking into account emission reduction, cost, nonair quality health and environmental impacts, and energy requirements. These alternatives may be different for new and existing sources because of different MACT floors, and separate standards may be established for new and existing sources.

We identified three regulatory alternatives more stringent than the MACT floor level of control for organic HAP. These alternatives were (1)

conversion to powder coatings; (2) conversion to liquid coatings that have a very low, or no, organic HAP content; and (3) use of add-on capture systems and control devices.

Information indicates that several metal furniture surface coating facilities have converted to using only powder coatings. Such facilities typically produce a single type of product (such as warehouse shelving units), do not require unusual finishes, and use a small number of colors. Many metal furniture surface coating facilities, however, manufacture more than one product and often use a wide array of colors. Many also achieve finish types that cannot be duplicated with powder coatings.

Powder coating may not produce the varied surface finishes and colors available from liquid coatings. Although powder coatings may be somewhat more durable than conventional liquid coatings, specialty finishes such as antique and crackle, as well as the palette of designer colors offered by some manufacturers, may not be adequately duplicated by powder coatings. Consequently, while powder coating is a proven technology that can be used in many situations, we do not believe it is appropriate to require the use of powder coatings for all segments of the metal furniture industry and have not included them in our proposal as a beyond-the-floor option.

Lower organic HAP liquid coatings fall into two primary categories. The most common are coatings formulated with solvents that are not organic HAP (but may be VOC). The second category are those coatings that result from alternate technologies such as Ultraviolet (UV)-curable coatings and autophoretic coatings. The UV-curable coatings may or may not include organic solvents, which may contain HAP or VOC, to keep the pigment and other components of the coating in solution until curing. Autophoretic coatings use no organic HAP and only small amounts of VOC, but they may contain inorganic HAP. These coatings are applied using a dip application method where a chemical reaction deposits the coating on the surface of the part.

These lower organic HAP coatings are currently in production use but their applicability is limited for this industry. The selection of lower organic HAP coatings is limited and is not extensive enough to broadly meet the needs of all segments of the metal furniture industry. Given the limited applicability of UV-curable and autophoretic coating technologies, we do not believe it is feasible to require the use of these coating technologies and have not included them in our proposal as a beyond-the-floor option for organic HAP.

It is technically feasible to achieve organic HAP emission rates lower than the MACT floor levels through the use of emission capture systems and control devices. For example, the use of a permanent total enclosure and an oxidizer could further reduce organic HAP emissions from typical sources by about 4.2 Mg (4.6 tons) to 31 Mg (34 tons) per year. However, the cost of such a system could be approximately $1 million. We believe that the additional emission reduction would not justify the additional cost. Therefore, we have not included the use of emission capture and control systems in our proposal as a beyond-the-floor option.

How did we select the standards? For existing sources, we based the standards on the existing source MACT floor. As described earlier, we believe that beyond-the-floor options are not technically or economically feasible for all existing sources. For the same reasons, we are basing the proposed standards for new sources on the new source MACT floor.

Without having information on the benefits that would be achieved by further reducing emissions beyond the floor, we believe that the additional emission reductions that could be achieved do not warrant the costs that each source could incur. Therefore, we would not require beyond-the-floor levels of emission reductions in this proposed rule. After implementation of a final MACT rule for this category, we will evaluate the health and environmental risks that may be posed as a result of exposure to emissions from the metal furniture surface coating source category, as required by section 112(f) of the CAA. At that time, we will evaluate whether additional controls are warranted in light of the available risk information. We specifically request comment on our proposal not to base the CAA section 112(d) standards on a beyond-the-floor option. A beyond-the-floor option could apply to all segments of the metal furniture surface coating source category or to only certain segments. Comments supporting our proposed decision not to go beyond the floor as well as comments opposing the decision should include data, information, and rationale supporting the position of the commenter.

We note here that our assumption, in the development of the MACT floors, that 100 percent of the organic HAP in the materials used are emitted by the affected source would not apply when the source sends waste organic HAP-containing materials to a facility for treatment or disposal. We made this assumption because the industry survey responses provided little information as to the amount of organic HAP recovered and recycled or treated and disposed. We, therefore, believe that this practice is not common within the metal furniture industry. We recognize, however, that some metal furniture facilities may conduct such activities and should be allowed to account for such activities in determining their emissions. Thus, the proposed regulation would allow you to reduce the affected sourcewide organic HAP emissions by the amount of any organic HAP contained in waste treated or disposed at a hazardous waste treatment, storage, and disposal facility that is regulated under 40 CFR part 262, 264, 265, or 266.

E. How Did We Select the Format of the Standards?

Numerical emission standards are required by section 112 of the CAA unless we determine that it is not feasible to prescribe or enforce an emission standard, in which case a design, equipment, work practice, or operational standard can be set (section 112(h) of the CAA). The formats considered for the proposed standards and the considerations in selection of the format are discussed below.

We selected as the format of the proposed standards for organic HAP, mass of organic HAP per volume of coating solids used. The performance-based nature of this proposed format would allow metal furniture coating operation owners and operators flexibility in choosing any combination of means (including coating reformulation, use of lower-HAP or non-HAP materials, solvent elimination, work practices, and add-on control devices) to comply with the emission limit that is workable for their particular situations.

We selected volume of coating solids as a component of the proposed standards to normalize the rate of organic HAP emissions across all sizes and types of facilities. We could not normalize by surface area due to lack of information. We selected the volume of coating solids used because it is directly related to the surface area coated (i.e., the average dry film thickness of coatings on most metal furniture products is generally consistent) and, therefore, provides an equitable basis for all coatings, regardless of differences in coating densities. A format based on the mass or weight of coating solids (instead of volume) could result in inequitable standards for higher-density pigmented coatings, such as basecoats or enamels,

compared to coatings with lower densities per unit volume.

Other choices for the format of the standards that we considered, but rejected, included a usage limit (mass per unit time) and a never-to-be-exceeded limit on the organic HAP content of coatings and cleaning materials. As it is not our intent to limit a facility's production under these proposed standards, we have not proposed a usage limit. We also chose not to propose a never-to-be-exceeded limit because the availability of all the different kinds of coatings required by the metal furniture industry at or below such a limit does not appear to be sufficient to meet the needs of all segments of the industry.

F. How Did We Select the Testing and Initial Compliance Requirements?

The proposed standards would allow you to choose among several methods to demonstrate compliance with the proposed standards for organic HAP: (1) Coatings with low or no organic HAP; (2) an overall organic HAP emission rate from all coatings, thinners, and cleaning materials that is less than the applicable emission limit; or (3) capture systems and control devices.

Coatings with Low or No Organic HAP. You would be required to document the organic HAP content of all coatings and show that each is less than the applicable emission limit. You would also have to show that each thinner and each cleaning material used contains no organic HAP. Method 311 is the method developed by EPA for determining the mass fraction of organic HAP in coatings and has been used in previous surface coating NESHAP. We have not identified any other methods that provide advantages over Method 311 for use in the proposed standards.

Method 24 is the method developed by EPA for determining the mass fraction of volatile matter for coatings and can be used if you choose to determine the nonaqueous volatile matter content as a surrogate for organic HAP. In past standards, VOC emission control measures have been implemented in the coatings industry, with Method 24 as the compliance method. We have not identified any other methods that provide advantages over Method 24 for use in the proposed standards.

The proposed requirements for determining volume coating solids would allow you to choose between using manufacturer's data or measuring the volume with either ASTM Method D2697–86 (1998) or ASTM Method D6093–97.

Overall Organic HAP Emission Rate. To demonstrate compliance using this option, you would calculate the organic HAP emission rate for your affected source, based on the mass of organic HAP in all coatings, thinners, and cleaners and the volume of coating solids used during the compliance period, and demonstrate that it does not exceed the applicable emission limit. You would document these values using the methods discussed previously.

Capture Systems and Control Devices. If you use a capture system and control device, other than a solvent recovery device for which you conduct a monthly liquid-liquid material balance, you would be required to conduct an initial performance test of the system to determine its overall control efficiency. For a solvent recovery system for which you conduct a liquid-liquid material balance, you would determine the quantity of volatile matter applied in the affected source and the quantity recovered during the initial compliance period to determine its overall control efficiency. For both cases, the overall control efficiency would be combined with the monthly mass of organic HAP in the coatings and other materials used in the affected source to derive the monthly HAP emission rate in kg HAP/liter of coating solids used. If you conduct a performance test, you would also determine parameter operating limits during the test. The test methods that the proposed standards would require for the performance test (described in section II.F of this preamble) have been required under many standards of performance for industrial surface coating sources under 40 CFR part 60 and NESHAP under 40 CFR part 63. We have not identified any other methods that provide advantages over these methods.

G. How Did We Select the Continuous Compliance Requirements?

To ensure continuous compliance with the proposed organic HAP emission limit(s) and/or operating limits, the proposed standards would require continuous parameter monitoring of capture systems and control devices and recordkeeping. We selected the following requirements based on reasonable cost, ease of execution, and usefulness of the resulting data to both the owners or operators and EPA for ensuring continuous compliance with the emission limit(s) and/or operating limits.

We are proposing that certain parameters be continuously monitored for the types of capture systems and control devices commonly used in the industry. These monitoring parameters have been used in other standards for similar industries. The values of these parameters that correspond to compliance with the proposed emission limit(s) are established during the initial or most recent performance test that demonstrates compliance. These values are your operating limits for the capture system and control device.

You would be required to determine consecutive 3-hour average values for most monitored parameters for the affected source. We selected this averaging period to ensure the control system is continuously operating at conditions that are the same or better than those recorded during a performance test demonstrating compliance with the emission limit(s).

To demonstrate continuous compliance with the monthly emission limit(s), you would also need records of the quantity of coatings and other materials used and the data and calculations supporting your determination of their HAP content. If you conduct monthly liquid-liquid material balances, you would need records of the quantity of volatile matter used in the affected source and the quantity recovered by the solvent recovery system each month.

H. How Did We Select the Notification, Recordkeeping, and Reporting Requirements?

You would be required to comply with the applicable requirements in the NESHAP General Provisions, subpart A of 40 CFR part 63, as described in Table 2 of the proposed subpart RRRR. We evaluated the General Provisions requirements and included those we determined to be the minimum notification, recordkeeping, and reporting necessary to ensure compliance with, and effective enforcement of, the proposed standards.

I. How Did We Select the Compliance Date?

You would be allowed 3 years to comply with the final standards for existing affected sources. This is the maximum period allowed by the CAA. We believe that 3 years for compliance is necessary to allow adequate time to accommodate the variety of compliance methods that existing sources may use. Most sources in this category would need this 3-year maximum amount of time to develop and test reformulated coatings, particularly those who may opt to comply using a different lower-emitting coating technology. We want to encourage the use of these pollution prevention technologies. In addition, time would be needed to establish

records management systems required for enforcement purposes. Sources that choose to use emission capture and control systems may need this time to purchase and install them and to obtain a permit for the use of add-on controls.

The CAA requires that new or reconstructed affected sources comply with standards immediately upon startup or the effective date of the final rule, whichever is later.

IV. Summary of Environmental, Energy, and Economic Impacts

Model plants were developed to aid in the estimation of the impacts the MACT floor level of control would have on the metal furniture industry. Three model plants distinguished by size, as measured by the total volume of coating solids used, were developed. Impacts were then developed for each model plant, and these individual impacts were scaled to nationwide levels based on the number of facilities corresponding to each model plant size. We used the model plant approach because we did not have adequate data to determine impacts for each actual facility.

A variety of compliance methods are available to the industry to meet the proposed emission limit(s). We analyzed the information obtained from the industry survey responses, industry site visits, trade groups, and industry representatives to determine which compliance methods would most likely be used by existing and new sources. We expect that the most widely-used method would be low-HAP content liquid coatings (coatings with HAP contents at or below the emission limits) and lower-HAP cleaning materials. Powder coatings and add-on capture and control systems would likely be used to a lesser extent. Various combinations of these methods may be used. For the purpose of assessing impacts, we assumed that all existing sources would convert to lower-HAP content liquid coatings, thinners, and cleaning materials. We assumed that new sources would also use lower-HAP materials.

We first estimated the impacts of the proposed emission limits on the three model plants. To scale up the model plant impacts to nationwide levels, we multiplied the individual model plant impacts by the estimated number of major sources in the United States corresponding to each model plant size. We used United States Census Bureau data as the basis for this estimate, which was a total of 655 facilities. For more information on how impacts were estimated, see Chapters 7 and 8 of the background information document, EPA–453/R–01–010.

A. What Are the Air Impacts?

For existing major sources, we estimated that compliance with the proposed emission limits would result in a reduction of nationwide organic HAP emissions of 13,900 Mg/yr (15,274 tpy). This represents a reduction of approximately 70 percent from the baseline organic HAP emissions of 20,300 Mg/yr (22,308 tpy).

The estimated baseline organic HAP emissions for new sources (20 over the first 5 years after promulgation of the final rule) would be approximately 635 Mg (698 tons) in the fifth year. Emissions from new sources would be reduced by approximately 465 Mg (511 tons) in the fifth year as a result of the proposed standards (73 percent reduction).

B. What Are the Cost Impacts?

An affected source may incur three types of costs to comply with the proposed standards: capital, direct, and indirect. Capital costs represent the one-time purchase of equipment. We have included coatings, thinners, and cleaning materials as direct costs incurred on a continuing basis for materials consumed in the manufacturing process. The cost of utilities, where applicable, is also included in the direct costs. Indirect costs typically include overhead, taxes, insurance, and administrative costs, as well as capital recovery costs.

Existing sources. To comply with the proposed emission limits, we estimated that existing facilities would likely use reformulated coatings, thinners, and cleaning materials. No capital costs have been attributed to these compliance methods. We estimated full costs for 517 facilities. Approximately 60 facilities would have only recordkeeping and reporting costs because these facilities would already be in compliance with the proposed standards (based on survey responses). Facilities that would achieve area source status before the compliance date of the final standards will only incur costs of reading the rule. In addition to the direct costs, all affected sources would incur some recordkeeping and reporting costs.

We estimated no incremental costs associated with the use of lower-HAP coatings and thinners. Only the incremental cost of organic HAP-free cleaning materials over organic HAP cleaning materials was counted. The average annual cost for each facility incurring full costs is approximately $26,574. This value includes monitoring, recordkeeping, and reporting costs.

We estimated total nationwide annual costs in the fifth year to comply with the proposed emission limits to be $14.8 million for existing sources. These costs include $4.66 million direct costs associated with material usage and $10.1 million for recordkeeping and reporting.

New Sources. We estimated the number of new major sources based on information from industry trade groups. Starting with the anticipated annual sales growth for the industry, excluding price increases and inflation, we determined the amount of coating capacity that would be needed to meet the predicted increase in demand. Based on information provided by industry representatives, we assumed that 75 percent of this coating capacity could be absorbed by excess capacity at existing facilities. The remaining 25 percent increase in capacity was estimated to be met by the construction of four new facilities per year for the first 5 years after promulgation of the final standards.

Based on available information, we determined which compliance methods will most likely be used by new sources and, therefore, which compliance methods to use to estimate the cost impacts. We determined that new sources would choose reformulated lower organic HAP content materials to meet the new source emission limit.

For the 20 new facilities anticipated over the 5-year period after promulgation of the final standards, annual costs in the fifth year are estimated to be $0.6 million. We estimated no incremental costs associated with use of lower-HAP coatings and thinners. Only the incremental cost of organic HAP-free cleaning materials over organic HAP cleaning materials was counted. There are no anticipated capital costs.

C. What Are the Economic Impacts?

We performed an economic impact analysis (EIA) to provide an estimate of the facility and market impacts of the proposed standards as well as its social costs. In general, we expect the economic impacts of the proposed standards to be minimal, with price increases and production decreases of less than 0.1 percent. Given the negligible market impacts of this proposed rule, the social costs are expected to be roughly the same as the estimated engineering compliance costs of $14.8 million for existing sources.

For affected facilities, the distribution of costs is slanted toward the lower impact levels with many facilities

incurring only those related to recordkeeping and reporting. The EIA indicates that these regulatory costs are expected to represent only 0.1 percent of the value of product shipments, which should not cause producers to cease or alter their current operations. Hence, no firms or facilities are expected to become at risk of closure because of the proposed standards. International trade impacts would only occur for the metal household furniture segment of the industry, but the small price increase (i.e., 0.04 percent) on this segment indicates negligible impacts, if any. Based on the projected characteristics and costs for new sources, EPA does not expect any differential impacts on these sources. For more information, refer to the ''Economic Impact Analysis of the Proposed NESHAP: Surface Coating of Metal Furniture'' (Docket No. A–97–40).

D. What are the Nonair Health, Environmental, and Energy Impacts?

Based on information from the industry survey responses, there was no indication that the use of low organic HAP content coatings, thinners, and cleaning materials would result in any increase or decrease in nonair health, environmental, and energy impacts. There would be no change in the utility requirements associated with the use of these materials, so there would be no change in the amount of energy consumed as a result of the material conversion. Also, we estimate that there would be no significant change in the amount of materials used or the amount of waste produced and there would be no additional energy requirements for affected sources.

V. Administrative Requirements

A. Executive Order 12866, Regulatory Planning and Review

Under Executive Order 12866 (58 FR 51735, October 4, 1993), the EPA must determine whether the regulatory action is ''significant'' and therefore subject to review by the Office of Management and Budget (OMB) and the requirements of the Executive Order. The Executive Order defines ''significant regulatory action'' as one that is likely to result in a rule that may:

(1) Have an annual effect on the economy of $100 million or more or adversely affect in a material way the economy, a sector of the economy, productivity, competition, jobs, the environment, public health or safety, or State, local, or tribal governments or communities;

(2) Create a serious inconsistency or otherwise interfere with an action taken or planned by another agency;

(3) Materially alter the budgetary impact of entitlements, grants, user fees, or loan programs, or the rights and obligation of recipients thereof; or

(4) Raise novel legal or policy issues arising out of legal mandates, the President's priorities, or the principles set forth in the Executive Order.

Pursuant to the terms of Executive Order 12866, OMB has notified EPA that it considers this a ''significant regulatory action'' within the meaning of the Executive Order. The EPA has submitted the action to OMB for review. Changes made in response to OMB suggestions or recommendations will be documented in the docket (see **ADDRESSES** section of this preamble).

B. Executive Order 13132, Federalism

Executive Order 13132, entitled ''Federalism'' (64 FR 43255, August 10, 1999), requires EPA to develop an accountable process to ensure ''meaningful and timely input by State and local officials in the development of regulatory policies that have federalism implications.'' ''Policies that have federalism implications'' is defined in the Executive Order to include regulations that have ''substantial direct effects on the States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government.''

Under Section 6 of Executive Order 13132, EPA may not issue a regulation that has federalism implications, that imposes substantial direct compliance costs, and that is not required by statute, unless the Federal government provides the funds necessary to pay the direct compliance costs incurred by State and local governments, or EPA consults with State and local officials early in the process of developing the proposed regulation. The EPA also may not issue a regulation that has federalism implications and that preempts State law, unless the Agency consults with State and local officials early in the process of developing the proposed regulation.

This proposed rule does not have federalism implications. It will not have substantial direct effects on the States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government, as specified in Executive Order 13132. Pursuant to the terms of Executive Order 13132, it has been determined that this rule does not have ''federalism implications,'' because it does not meet the necessary criteria. Thus, the requirements of section 6 of the Executive Order do not apply to this proposed rule.

C. Executive Order 13175, Consultation and Coordination With Indian Tribal Governments

Executive Order 13175, entitled ''Consultation and Coordination with Indian Tribal Governments'' (65 FR 67249, November 6, 2000), requires EPA to develop an accountable process to ensure ''meaningful and timely input by tribal officials in the development of regulatory policies that have tribal implications.'' ''Policies that have tribal implications'' is defined in the Executive Order to include regulations that have ''substantial direct effects on one or more Indian tribes, on the relationship between the Federal government and the Indian tribes, or on the distribution of power and responsibilities between the Federal government and Indian tribes.''

This proposed rule does not have tribal implications. It will not have substantial direct effects on tribal governments, on the relationship between the Federal government and Indian tribes, or on the distribution of power and responsibilities between the Federal government and Indian tribes, as specified in Executive Order 13175. No tribal governments own or operate metal furniture surface coating facilities. Thus, Executive Order 13175 does not apply to this rule.

D. Executive Order 13045, Protection of Children from Environmental Health Risks and Safety Risks

Executive Order 13045 (62 FR 19885, April 23, 1997) applies to any rule that: (1) is determined to be ''economically significant'' as defined under Executive Order 12866, and (2) concerns an environmental health or safety risk that EPA has reason to believe may have a disproportionate effect on children. If the regulatory action meets both criteria, the EPA must evaluate the environmental health or safety effects of the planned rule on children, and explain why the planned regulation is preferable to other potentially effective and reasonably feasible alternatives considered by the Agency.

The EPA interprets Executive Order 13045 as applying only to those regulatory actions that are based on health or safety risks, such that the analysis required under section 5–501 of the Executive Order has the potential to influence the regulation. This proposed rule is not subject to Executive Order 13045 because it is based on technology performance and not on health or safety

risks. No children's risk analysis was performed because no alternative technologies exist that would provide greater stringency at a reasonable cost. Furthermore, this rule has been determined not to be ''economically significant'' as defined under Executive Order 12866.

E. Executive Order 13211, Actions Concerning Regulations that Significantly Affect Energy Supply, Distribution, or Use

This rule is not a ''significant energy action'' as defined in Executive Order 13211, ''Actions Concerning Regulations that Significantly Affect Energy Supply, Distribution, or Use'' (66 FR 28355, May 22, 2001) because it is not likely to have a significant adverse effect on the supply, distribution, or use of energy. Further, we have concluded that this proposed rule is not likely to have any adverse energy effects. Affected sources are expected to comply with the proposed rule through pollution prevention rather than end-of-pipe controls, and therefore, there would be no increase in energy usage.

F. Unfunded Mandates Reform Act of 1995

Title II of the Unfunded Mandates Reform Act of 1995 (UMRA), Public Law 104–4, establishes requirements for Federal agencies to assess the effects of their regulatory actions on State, local, and tribal governments and the private sector. Under section 202 of the UMRA, the EPA generally must prepare a written statement, including a cost-benefit analysis, for proposed and final rules with ''Federal mandates'' that may result in expenditures by State, local, and tribal governments, in the aggregate, or by the private sector, of $100 million or more in any 1 year. Before promulgating an EPA rule for which a written statement is needed, section 205 of the UMRA generally requires the EPA to identify and consider a reasonable number of regulatory alternatives and adopt the least-costly, most cost-effective, or least-burdensome alternative that achieves the objectives of the rule. The provisions of section 205 do not apply when they are inconsistent with applicable law. Moreover, section 205 allows the EPA to adopt an alternative other than the least-costly, most cost-effective, or least-burdensome alternative if the Administrator publishes with the final rule an explanation why that alternative was not adopted. Before the EPA establishes any regulatory requirements that may significantly or uniquely affect small governments, including tribal governments, it must have developed under section 203 of the UMRA a small government agency plan. The plan must provide for notifying potentially affected small governments, enabling officials of affected small governments to have meaningful and timely input in the development of EPA regulatory proposals with significant Federal intergovernmental mandates, and informing, educating, and advising small governments on compliance with the regulatory requirements.

The EPA has determined that this proposed rule does not contain a Federal mandate that may result in expenditures of $100 million or more for State, local, and tribal governments, in the aggregate, or the private sector in any 1 year. The maximum total annual cost of this rule for any year has been estimated to be less than $15.4 million. Thus, today's proposed rule is not subject to the requirements of sections 202 and 205 of the UMRA. In addition, the EPA has determined that this proposed rule contains no regulatory requirements that might significantly or uniquely affect small governments. This rule contains requirements that may apply to State governments' correctional institutions that manufacture or repair metal furniture. However, these requirements do not uniquely or significantly affect those institutions. Therefore, today's proposed rule is not subject to the requirements of section 203 of the UMRA.

G. Regulatory Flexibility Act (RFA), as Amended by the Small Business Regulatory Enforcement Fairness Act of 1996 (SBREFA), 5 U.S.C. 601, et seq.

The RFA generally requires an agency to prepare a regulatory flexibility analysis of any rule subject to notice and comment rulemaking requirements under the Administrative Procedures Act or any other statute unless the agency certifies that the rule will not have a significant economic impact on a substantial number of small entities. Small entities include small businesses, small organizations, and small governmental jurisdictions.

For the purposes of assessing the impacts of today's proposed standards on small entities, small entity is defined as: (1) A small business ranging from 100–1,000 employees or less than $5 million in annual sales (see Table 2); (2) a small governmental jurisdiction that is a government of a city, county, town, school district, or special district with a population of less than 50,000; and (3) a small organization that is any not-for-profit enterprise which is independently owned and operated and is not dominant in its field.

TABLE 2.—SMALL BUSINESS ADMINISTRATION (SBA) SMALL BUSINESS SIZE STANDARDS FOR COMPANIES OWNING FACILITIES IN THE METAL FURNITURE SOURCE CATEGORY BY NAICS CODES [a, b]

1997 NAICS code	Product description	SBA size standard (employees)
421610	Electrical Apparatus and Equipment, Wiring Supplies, and Construction Material Wholesalers.	100
337124	Metal Household Furniture Manufacturing	500
337214	Nonwood Office Furniture Manufacturing	500
336360	Motor Vehicle Fabric Accessories and Seat Manufacturing	500
337127	Institutional Furniture Manufacturing	500
337215	Showcase, Partition, Shelving, and Locker Manufacturing	500
332951	Hardware Manufacturing	500
332116	Metal Stamping	500
332612	Wire Spring Manufacturing	500
337215	Showcase, Partition, Shelving, and Locker Manufacturing	500
335121	Residential Electric Lighting Fixture Manufacturing	500
335122	Commercial, Industrial, and Institutional Electric Lighting Fixture Manufacturing	500
339111	Laboratory Apparatus and Furniture Manufacturing	500
339114	Dental Equipment and Supplies Manufacturing	500
337211	Wood Office Furniture Manufacturing	500
337212	Custom Architectural Woodwork and Millwork Manufacturing	500
332312	Fabricated Structural Metal Manufacturing (pt)	500

TABLE 2.—SMALL BUSINESS ADMINISTRATION (SBA) SMALL BUSINESS SIZE STANDARDS FOR COMPANIES OWNING FACILITIES IN THE METAL FURNITURE SOURCE CATEGORY BY NAICS CODES [a, b]—Continued

1997 NAICS code	Product description	SBA size standard (employees)
336391	Motor Vehicle Air-Conditioning Manufacturing	750
811420	Reupholstery and Furniture Repair	$5 million (sales)

[a] The Agency assumed a small business size definition of 1,000 employees for those companies included in the SBREFA analysis without available information on SIC or NAICS code.
[b] Code of Federal Regulations (CFR). Small Business Size Standards-Part 121. 13-CFR–121. January 2001. As obtained from <http://www.sba.gov/regulations/part121.pdf>.

After considering the economic impacts of today's proposed rule on small entities, I certify that this action will not have a significant economic impact on a substantial number of small entities.

In accordance with the RFA and SBREFA, the EPA conducted an assessment of the proposed standards on small businesses within the metal furniture coating industry. Based on Small Business Administration size definitions and reported sales and employment data, EPA's survey identified 10 of the 24 companies owning metal furniture facilities as small businesses. Although small businesses represent almost 42 percent of the companies within the source category, they are expected to incur 12 percent of the total industry compliance costs. Under the proposed standards, the average annual compliance cost share of sales for small businesses is 0.18 percent, with two of the ten small businesses not expected to incur any additional costs because they are permitted as synthetic minor HAP emission sources. In addition, small businesses in this industry typically have 5 percent profit margins. For more information, consult the docket for this project.

Although this proposed rule will not have a significant economic impact on a substantial number of small entities, EPA has nonetheless worked aggressively to minimize the impact of this proposed rule on small entities, consistent with our obligations under the CAA. We solicited input from small entities during the data-gathering phase of the proposed rulemaking.

We are proposing compliance options which give small entities flexibility in choosing the most cost effective and least burdensome alternative for their operation. For example, a facility could purchase and use low-HAP coatings (i.e., pollution prevention) that meet the proposed standards instead of using add-on capture and control systems. This method of compliance can be demonstrated with minimum burden by using purchase and usage records. No testing of materials would be required, as the facility owner could show that their coatings meet the emission limits by providing formulation data supplied by the manufacturer.

We continue to be interested in the potential impacts of the proposed rule on small entities and welcome comments on issues related to such impacts.

H. Paperwork Reduction Act

The information collection requirements in the proposed standards have been submitted for approval to the OMB under the Paperwork Reduction Act, 44 U.S.C. 3501, *et seq.* An Information Collection Request (ICR) document has been prepared by EPA (ICR No. 1952.01) and a copy may be obtained from Sandy Farmer by mail at the Collection Strategies Division (2822), U.S. Environmental Protection Agency, 1200 Pennsylvania Avenue, NW, Washington, DC 20460, by email at farmer.sandy@epa.gov, or by calling (202) 260–2740. A copy may also be downloaded off the internet at *http://www.epa.gov/icr.* The information requirements are not effective until OMB approves them.

The information requirements are based on notification, recordkeeping, and reporting requirements in the NESHAP General Provisions (40 CFR part 63, subpart A), which are mandatory for all owners and operators subject to national emission standards. These recordkeeping and reporting requirements are specifically authorized by section 114 of the CAA (42 U.S.C. 7414). All information submitted to the EPA pursuant to the recordkeeping and reporting requirements for which a claim of confidentiality is made is safeguarded according to Agency policies set forth in 40 CFR part 2, subpart B.

The proposed standards would require maintaining records of all coatings, thinners, and cleaning materials data and calculations used to determine compliance. This information includes the volume used during each monthly compliance period, mass fraction organic HAP, density, and, for coatings only, volume fraction solids.

If an add-on control device is used, records must be kept of the capture efficiency of the capture system, destruction or removal efficiency of the add-on control device, and the monitored operating parameters. In addition, records must be kept of each calculation of the affected sourcewide emissions for each monthly compliance period and all data, calculations, test results, and other supporting information used to determine this value.

The monitoring, recordkeeping, and reporting burden in the fifth year after the effective date of the promulgated rule is estimated to be approximately 165,000 labor hours at a cost of approximately $11 million for new and existing sources.

Burden means the total time, effort, or financial resources expended by persons to generate, maintain, retain, or disclose or provide information to or for a Federal agency. This includes the time needed to review instructions; develop, acquire, install, and utilize technology and systems for the purposes of collecting, validating, and verifying information, processing and maintaining information, and disclosing and providing information; adjust the existing ways to comply with any previously applicable instructions and requirements; train personnel to be able to respond to a collection of information; search data sources; complete and review the collection of information; and transmit or otherwise disclose the information.

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 and 48 CFR chapter 15.

Under the Paperwork Reduction Act, 44 U.S.C. 3501, *et seq.*, the EPA must consider the paperwork burden imposed by any information collection request in a proposed or final rule.

Comments are requested on the Agency's need for this information, the accuracy of the provided burden estimates, and any suggested methods for minimizing respondent burden, including through the use of automated collection techniques. By U.S. Postal Service, send comments on the ICR to the Director, Collection Strategies Division; U.S. Environmental Protection Agency (2822); 1200 Pennsylvania Ave., NW., Washington, DC 20460; or by courier, send comments on the ICR to the Director, Collection Strategies Division; U.S. Environmental Protection Agency (2822); 401 M Street, SW., Room 925H, West Tower; Washington, DC; and to the Office of Information and Regulatory Affairs, Office of Management and Budget, 725 17th Street, NW., Washington, DC 20503, marked ''Attention: Desk Officer for EPA.'' Include the ICR number in any correspondence. Since OMB is required to make a decision concerning the ICR between 30 and 60 days after April 24, 2002, a comment to OMB is best assured of having its full effect if OMB receives it by May 24, 2002. The final rule will respond to any OMB or public comments on the information collection requirements contained in this proposal.

I. National Technology Transfer and Advancement Act

Section 12(d) of the National Technology Transfer and Advancement Act of 1995 (NTTAA), Public Law 104–113, section 12(d) (15 U.S.C. 272 note), directs all Federal agencies to use voluntary consensus standards (VCS) in their regulatory and procurement activities unless to do so would be inconsistent with applicable law or otherwise impractical. The VCS are technical standards (e.g., material specifications, test methods, sampling procedures, business practices, etc.) that are developed or adopted by one or more VCS bodies. The NTTAA directs EPA to provide Congress, through annual reports to OMB, with explanations when EPA does not use available and applicable VCS.

Consistent with the NTTAA, EPA conducted searches to identify VCS for use in emissions monitoring. The search for emissions monitoring procedures identified 20 VCS that appeared to have possible use in lieu of EPA standard reference methods. However, after reviewing the available standards, EPA determined that ten of the candidate consensus standards (ASTM D3154–00, ASTM D3271–87, ASTM D3464–96, ASTM D3796–90, ASTM D3960–98, ASTM D6053–96, ASTM E337–84, ISO 9096: 1992, PTC 19–10–1981, and EN 1093–4:1996) identified for measuring emissions of the HAP or surrogates subject to the proposed emission standards would not be practical due to lack of equivalency, documentation, and validation data (Docket A–97–47). Seven of the remaining candidate consensus standards (BSR/ASME MFC 13m, ASTM Z6871Z, ISO/DIS 14164, ISO PWI 17895, ISO/DIS 11890–1, ISO/DIS 11890–2, and PREN 12619) are under development. The EPA plans to follow, review, and consider adopting these standards after their development is completed.

The ASTM 2369–98 is practical for EPA use as an acceptable alternative in measuring the volatile matter content of surface coatings. This VCS uses the same techniques, equipment, and procedures as Method 24. The EPA will incorporate by reference ASTM D2369–98 into 40 CFR 63.14 in the near future.

The ASTM D2697–86 (1998) and ASTM D6093–97 are acceptable procedures for use in determining the volume fraction of solids for a variety of coatings. The EPA will incorporate by reference ASTM D2697–86 (1998) and ASTM D6093–97 into 40 CFR 63.14 in the near future.

Six consensus standards: ASTM D1475–98, ASTM D2369–98, ASTM D3792–99, ASTM D4017–96a, ASTM D4457–85(Reapproved 91), and ASTM D5403–93 are already incorporated by reference in EPA Method 24; and five consensus standards: ASTM D1979–97, ASTM D3432–89, ASTM D4747–87, ASTM D4827–93, and ASTM PS 9–94 are incorporated by reference in EPA Method 311.

The EPA takes comment on proposed compliance demonstration requirements in the proposed standards and specifically invites the public to identify potentially-applicable VCS. Commentors should also explain why the proposed standards should adopt these VCS in lieu of EPA's methods. Emission test methods and performance specifications submitted for evaluation should be accompanied with a basis for the recommendation, including method validation data and the procedure used to validate the candidate method (if method other than Method 301, 40 CFR part 63, appendix A, was used).

Sections 63.4964 through 63.4966 of the proposed standards list EPA testing methods and performance standards included. Most of the standards have been used by States and industry for more than 10 years. Nevertheless, any State or source may apply to EPA for permission to use alternative methods in place of any of the EPA testing methods or performance standards listed.

List of Subjects in 40 CFR Part 63

Environmental protection, Administrative practice and procedure, Air pollution control, Hazardous substances, Intergovernmental relations, Reporting and recordkeeping requirements.

Dated: March 19, 2002.

Christine Todd Whitman,

Administrator.

For the reasons stated in the preamble, title 40, chapter I, part 63 of the Code of Federal Regulations is proposed to be amended as follows:

PART 63—[AMENDED]

1. The authority citation for part 63 continues to read as follows:

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

2. Part 63 is amended by adding subpart RRRR to read as follows:

Subpart RRRR—National Emission Standards for Hazardous Air Pollutants: Surface Coating of Metal Furniture

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What This Subpart Covers

§ 63.4880 What is the purpose of this subpart?

This subpart establishes national emission standards for hazardous air pollutants (NESHAP) for metal furniture surface coating facilities. This subpart also establishes requirements to demonstrate initial and continuous compliance with the emission limitations.

§ 63.4881 Am I subject to this subpart?

(a) Except as provided in paragraph (c) of this section, the source category to which this subpart applies is surface coating of metal furniture.

(1) Surface coating is the application of coatings to a substrate using, for example, spray guns or dip tanks.

(2) Metal furniture means furniture or components of furniture constructed either entirely or partially from metal. Metal furniture includes, but is not limited to, components of the following types of products as well as the products themselves: household, office, institutional, laboratory, hospital, public building, restaurant, barber and beauty shop, and dental furniture; office and store fixtures; partitions; shelving; lockers; lamps and lighting fixtures; and wastebaskets.

(b) You are subject to this subpart if you own or operate a new, reconstructed, or existing affected source, as defined in § 63.4882, in the source category defined in paragraph (a) of this section and that is a major source, is located at a major source, or is part of a major source of emissions of hazardous air pollutants (HAP). A major source of HAP emissions is any stationary source or group of stationary sources located within a contiguous area and under common control that emits or has the potential to emit any single HAP at a rate of 9.07 megagrams (Mg) (10 tons) or more per year or any combination of HAP at a rate of 22.68 Mg (25 tons) or more per year.

(c) This subpart does not apply to surface coating that meets any of the criteria of paragraphs (c)(1) through (5) of this section.

(1) Surface coating conducted at a source that uses only coatings, thinners, and cleaning materials that contain no organic HAP.

(2) Surface coating of metal components of wood furniture conducted in an operation that is subject to the wood furniture manufacturing NESHAP in subpart JJ of this part.

(3) Surface coating that occurs at research or laboratory facilities or that is part of janitorial, building, and facility maintenance operations.

(4) Surface coating of only small items such as knobs, hinges, or screws that have a wider use beyond metal furniture are not subject to this subpart unless the surface coating occurs at a metal furniture source.

(5) Surface coating of metal furniture conducted for the purpose of repairing or maintaining metal furniture used by a facility and not for commerce is not subject to this subpart, unless organic HAP emissions from the surface coating itself are as high as the rates specified in paragraph (b) of this section.

§ 63.4882 What parts of my plant does this subpart cover?

(a) This subpart applies to each new, reconstructed, and existing affected source.

(b) The affected source is the collection of all of the items listed in paragraphs (b)(1) through (4) of this section that are used for surface coating of metal furniture:

(1) All coating operations as defined in § 63.4981;

(2) All storage containers and mixing vessels in which coatings, thinners, and cleaning materials are stored or mixed;

(3) All manual and automated equipment and containers used for conveying coatings, thinners, and cleaning materials; and

(4) All storage containers and all manual and automated equipment and containers used for conveying waste materials generated by a coating operation.

(c) An affected source is a new affected source if you commenced its construction after April 24, 2002, and the construction is of a completely new metal furniture surface coating facility where previously no metal furniture surface coating facility had existed.

(d) An affected source is reconstructed if you meet the criteria as defined in § 63.2.

(e) An affected source is existing if it is not new or reconstructed.

§ 63.4883 When do I have to comply with this subpart?

The date by which you must comply with this subpart is called the compliance date. The compliance date for each type of affected source is specified in paragraphs (a) through (c) of this section. The compliance date begins the initial compliance period during which you conduct the initial compliance demonstration described in §§ 63.4940, 63.4950, and 63.4960.

(a) For a new or reconstructed affected source, the compliance date is the applicable date in paragraph (a)(1) or (2) of this section:

(1) If the initial startup of your new or reconstructed affected source is before [DATE OF PUBLICATION OF FINAL RULE IN THE FEDERAL REGISTER], the compliance date is [DATE OF PUBLICATION OF FINAL RULE IN THE FEDERAL REGISTER].

(2) If the initial startup of your new or reconstructed affected source occurs after [DATE OF PUBLICATION OF FINAL RULE IN THE FEDERAL REGISTER], the compliance date is the date of initial startup of your affected source.

(b) For an existing affected source, the compliance date is the date 3 years after [DATE OF PUBLICATION OF FINAL RULE IN THE FEDERAL REGISTER].

(c) For an area source that increases its emissions or its potential to emit such that it becomes a major source of HAP emissions, the compliance date is specified in paragraphs (c)(1) and (2) of this section.

(1) For any portion of the source that becomes a new or reconstructed affected source subject to this subpart, the compliance date is the date of initial startup or [DATE OF PUBLICATION OF FINAL RULE IN THE FEDERAL REGISTER], whichever is later.

(2) For any portion of the source that becomes an existing affected source subject to this subpart, the compliance date is the date 1 year after the area source becomes a major source or 3 years after [DATE OF PUBLICATION OF FINAL RULE IN THE FEDERAL REGISTER], whichever is later.

(d) You must meet the notification requirements in § 63.4910 according to the dates specified in that section and in subpart A of this part. Some of the notifications must be submitted before the compliance dates described in paragraphs (a) through (c) of this section.

Emission Limitations

§ 63.4890 What emission limits must I meet?

(a) For a new or reconstructed affected source, you must limit organic HAP emissions to the atmosphere to no more than 0.094 kilogram (kg) organic HAP per liter (0.78 pound per gallon (lb/gal)) of coating solids used during each compliance period, determined according to the procedures in § 63.4941, § 63.4951, or § 63.4961.

(b) For an existing affected source, you must limit organic HAP emissions to the atmosphere to no more than 0.12 kg organic HAP per liter (1.0 lb/gal) of coating solids used during each compliance period, determined according to the procedures in § 63.4941, § 63.4951, or § 63.4961.

§ 63.4891 What are my options for meeting the emission limits?

You must include all coatings, thinners, and cleaning materials used in the affected source when determining whether the organic HAP emission rate is equal to or less than the applicable emission limit in § 63.4890. To make this determination, you must use at least one of the three compliance options listed in paragraphs (a) through (c) of this section. You may apply any of the compliance options to an individual coating operation or to multiple coating operations as a group or to the entire affected source. You may use different compliance options for different coating operations or at different times on the same coating operation. However, you may not use different compliance options at the same time on the same coating operation. If you switch between compliance options for any coating operation or group of coating operations, you must document this switch as required by § 63.4930(c), and you must report it in the next semiannual compliance report required in § 63.4920.

(a) *Compliant material option.* Demonstrate that the organic HAP content of each coating used in the coating operation(s) is less than or equal to the applicable emission limit in § 63.4890 and that each thinner and each cleaning material used contains no organic HAP. You must meet all the requirements of §§ 63.4940, 63.4941, and 63.4942 to demonstrate compliance with the emission limit using this option.

(b) *Emission rate without add-on controls option.* Demonstrate that, based on the coatings, thinners, and cleaning materials used in the coating operation(s), the organic HAP emission rate for the coating operation(s) is less than or equal to the applicable emission limit in § 63.4890, calculated as a monthly emission rate. You must meet all the requirements of §§ 63.4950, 63.4951, and 63.4952 to demonstrate compliance with the emission limit using this option.

(c) *Emission rate with add-on controls option.* Demonstrate that, based on the coatings, thinners, and cleaning materials used in the coating operation(s), and the emission capture and add-on control efficiencies achieved, the organic HAP emission rate for the coating operation(s) is less than or equal to the applicable emission limit in § 63.4890, calculated as a monthly emission rate. If you use this compliance option, you must also demonstrate that all capture systems and add-on control devices for the coating operation(s) meet the operating limits required in § 63.4892, except for solvent recovery systems for which you conduct liquid-liquid material balances according to § 63.4961(j); and that you meet the work practice standards required in § 63.4893. You must meet all the requirements of §§ 63.4960 through 63.4968 to demonstrate compliance with the emission limits, operating limits, and work practice standards using this option.

§ 63.4892 What operating limits must I meet?

(a) For any coating operation(s) on which you use the compliant material option or the emission rate without add-on controls option, you are not required to meet any operating limits.

(b) For any controlled coating operation(s) on which you use the emission rate with add-on controls option, except those for which you use a solvent recovery system and conduct a liquid-liquid material balance according to § 63.4961(j), you must meet the operating limits specified in Table 1 of this subpart. These operating limits apply to the emission capture and control systems on the coating operation(s) for which you use this option, and you must establish the operating limits during the performance test according to the procedures in § 63.4967. You must meet the operating limits at all times after you establish them.

(c) If you use an add-on control device other than those listed in Table 1 of this subpart, or wish to monitor an alternative parameter and comply with a different operating limit, you must apply to the Administrator for approval of alternative monitoring under § 63.8(f).

§ 63.4893 What work practice standards must I meet?

(a) For any coating operation(s) on which you use the compliant material option or the emission rate without add-on controls option, you are not required to meet any work practice standards.

(b) If you use the emission rate with add-on controls option, you must develop and implement a work practice plan to minimize organic HAP emissions from the storage, mixing, and conveying of coatings, thinners, and cleaning materials used in, and waste materials generated by, the controlled coating operation(s) for which you use this option; or you must meet an alternative standard as provided in paragraph (c) of this section. The plan must specify practices and procedures to ensure that, at a minimum, the elements specified in paragraphs (b)(1) through (5) of this section are implemented.

(1) All organic-HAP-containing coatings, thinners, cleaning materials, and waste materials must be stored in closed containers.

(2) Spills of organic-HAP-containing coatings, thinners, cleaning materials, and waste materials must be minimized.

(3) Organic-HAP-containing coatings, thinners, cleaning materials, and waste materials must be conveyed from one location to another in closed containers or pipes.

(4) Mixing vessels which contain organic-HAP-containing coatings and other materials must be closed except when adding to, removing, or mixing the contents.

(5) Emissions of organic HAP must be minimized during cleaning of storage, mixing, and conveying equipment.

(c) As provided in § 63.6(g), we, the U.S. Environmental Protection Agency (EPA), may choose to grant you permission to use an alternative to the work practice standards in this section.

General Compliance Requirements

§ 63.4900 What are my general requirements for complying with this subpart?

(a) You must be in compliance with the emission limitations in this subpart as specified in paragraphs (a)(1) and (2) of this section.

(1) Any coating operation(s) for which you use the compliant material option or the emission rate without add-on controls option, as specified in § 63.4891(a) and (b), must be in compliance with the applicable emission limit in § 63.4890 at all times.

(2) Any coating operation(s) for which you use the emission rate with add-on controls option, as specified in § 63.4891(c), must be in compliance with the applicable emission limit in § 63.4890 at all times except during periods of startup, shutdown, and malfunction. Each controlled coating operation must be in compliance with the operating limits for emission capture systems and add-on control devices required by § 63.4892 at all times, except during periods of startup, shutdown, and malfunction, and except for solvent recovery systems for which you conduct liquid-liquid material balances according to § 63.4961(j). Each controlled coating operation must be in compliance with the work practice standards in § 63.4893 at all times.

(b) You must always operate and maintain your affected source, including all air pollution control and monitoring equipment you use for purposes of complying with this subpart, according to the provisions in § 63.6(e)(1)(i).

(c) If your affected source uses an emission capture system and add-on control device, you must maintain a log detailing the operation and maintenance of the emission capture system, add-on control device, and continuous parameter monitors during the period between the compliance date specified for your affected source in § 63.4883 and the date when the initial emission capture system and add-on control device performance tests have been completed, as specified in § 63.4960. This requirement does not apply to a solvent recovery system for which you conduct a liquid-liquid material balance according to § 63.4961(j).

(d) If your affected source uses an emission capture system and add-on control device, you must develop and implement a written startup, shutdown, and malfunction plan according to the provisions in § 63.6(e)(3). The plan must address startup, shutdown, and corrective actions in the event of a malfunction of the emission capture system or the add-on control device. The plan must also address any coating operation equipment that may cause increased emissions or that would affect capture efficiency if the process equipment malfunctions, such as conveyors that move parts among enclosures.

§ 63.4901 What parts of the General Provisions apply to me?

Table 2 of this subpart shows which parts of the General Provisions in §§ 63.1 through 63.15 apply to you.

Notifications, Reports, and Records

§ 63.4910 What notifications must I submit?

(a) *General.* You must submit the notifications in §§ 63.7(b) and (c), 63.8(f)(4), and 63.9(b) through (e) and (h) that apply to you by the dates specified in those sections, except as provided in paragraphs (b) and (c) of this section.

(b) *Initial Notification.* You must submit the Initial Notification required by § 63.9(b) for a new or reconstructed affected source no later than 120 days after initial startup or 120 days after [DATE OF PUBLICATION OF FINAL RULE IN THE FEDERAL REGISTER], whichever is later. For an existing affected source, you must submit the Initial Notification no later than 1 year after [DATE OF PUBLICATION OF FINAL RULE IN THE FEDERAL REGISTER].

(c) *Notification of Compliance Status.* You must submit the Notification of Compliance Status required by § 63.9(h) no later than 30 calendar days following the end of the initial compliance period described in §§ 63.4940, 63.4950, or 63.4960 that applies to your affected source. The Notification of Compliance Status must contain the information specified in paragraphs (c)(1) through (9) of this section and in § 63.9(h).

(1) Company name and address.

(2) Statement by a responsible official with that official's name, title, and signature, certifying the truth, accuracy, and completeness of the content of the report.

(3) Date of the report and beginning and ending dates of the reporting period. The reporting period is the initial compliance period described in §§ 63.4940, 63.4950, or 63.4960 that applies to your affected source.

(4) Identification of the compliance option or options specified in § 63.4891 that you used on each coating operation in the affected source during the initial compliance period.

(5) Statement of whether or not the affected source achieved the emission limitations for the initial compliance period.

(6) If you had a deviation, include the information in paragraphs (c)(6)(i) and (ii) of this section.

(i) A description of and statement of the cause of the deviation.

(ii) If you failed to meet the applicable emission limit in § 63.4890, include all the calculations you used to determine the kg organic HAP emitted per liter of coating solids used. You do not need to submit information provided by the materials suppliers or manufacturers or test reports.

(7) For each of the data items listed in paragraphs (c)(7)(i) through (iv) of this section that is required by the compliance option(s) you used to demonstrate compliance with the emission limit, include an example of how you determined the value, including calculations and supporting data. Supporting data can include a copy of the information provided by the supplier or manufacturer of the example coating or material or a summary of the results of testing conducted according to § 63.4941(a), (b), or (c). You do not need to submit copies of any test reports.

(i) Mass fraction of organic HAP for one coating, for one thinner, and for one cleaning material.

(ii) Volume fraction of coating solids for one coating.

(iii) Density for one coating, one thinner, and one cleaning material, except that if you use the compliant material option, only the example coating density is required.

(iv) The amount of waste materials and the mass of organic HAP contained in the waste materials for which you are claiming an allowance in Equation 1 of § 63.4951.

(8) The calculation of kg organic HAP emitted per liter coating solids used for the compliance option(s) you used, as specified in paragraphs (c)(8)(i) through (iii) of this section.

(i) For the compliant material option, provide an example calculation of the organic HAP content (H_c) for one coating, using Equation 1 of § 63.4941.

(ii) For the emission rate without add-on controls option, provide the calculation of the total mass of organic HAP emissions during the initial

compliance period (H_e); the calculation of the total volume of coating solids used during the initial compliance period (V_{st}); and the calculation of the organic HAP emission rate for the initial compliance period (H_{avg}), using Equations 1, 2, and 3, respectively, of § 63.4951.

(iii) For the emission rate with add-on controls option, provide the calculation of the total mass of organic HAP emissions for the coatings, thinners, and cleaning materials used during the initial compliance period (H_e), using Equations 1 and 1A through 1C of § 63.4951; the calculation of the total volume of coating solids used during the initial compliance period (V_{st}), using Equation 2 of § 63.4951; the calculation of the mass of organic HAP emission reduction during the initial compliance period by emission capture systems and add-on control devices, using Equations 1 and 1A through 1D of § 63.4961 for H_C, and Equations 2 and 3 of § 63.4961 for H_{CSR}, as applicable; and the calculation of the organic HAP emission rate (H_{HAP}) for the initial compliance period, using either Equation 4 of § 63.4961 or Equation 1 of § 63.4962, as applicable.

(9) For the emission rate with add-on controls option, you must include the information specified in paragraphs (c)(9)(i) through (iv) of this section. The requirements in paragraphs (c)(9)(i) through (iii) of this section do not apply to solvent recovery systems for which you conduct liquid-liquid material balances according to § 63.4961(j).

(i) For each emission capture system, a summary of the data and copies of the calculations supporting the determination that the emission capture system is a permanent total enclosure (PTE) or a measurement of the emission capture system efficiency. Include a description of the protocol followed for measuring capture efficiency, summaries of any capture efficiency tests conducted, and any calculations supporting the capture efficiency determination. If you use the data quality objective (DQO) or lower confidence limit (LCL) approach, you must also include the statistical calculations to show you meet the DQO or LCL criteria in appendix A to subpart KK of this part. You do not need to submit complete test reports.

(ii) A summary of the results of each add-on control device performance test. You do not need to submit complete test reports.

(iii) A list of each emission capture system's and add-on control device's operating limits and a summary of the data used to calculate those limits.

(iv) A statement of whether or not you developed and implemented the work practice plan required by § 63.4893.

§ 63.4920 What reports must I submit?

(a) *Semiannual compliance reports.* You must submit semiannual compliance reports for each affected source according to the requirements of paragraphs (a)(1) through (7) of this section. The semiannual compliance reporting requirements may be satisfied by reports required under other parts of the Clean Air Act (CAA), as specified in paragraph (a)(2) of this section.

(1) *Dates.* Unless the Administrator has approved a different schedule for submission of reports under § 63.10(a), you must prepare and submit each semiannual compliance report according to the dates specified in paragraphs (a)(1)(i) through (iv) of this section.

(i) The first semiannual compliance report must cover the first semiannual reporting period which begins the day after the end of the initial compliance period described in §§ 63.4940, 63.4950, or 63.4960 that applies to your affected source and ends on June 30 or December 31, whichever occurs first following the end of the initial compliance period.

(ii) Each subsequent semiannual compliance report must cover the subsequent semiannual reporting period from January 1 through June 30 or the semiannual reporting period from July 1 through December 31.

(iii) Each semiannual compliance report must be postmarked or delivered no later than July 31 or January 31, whichever date is the first date following the end of the semiannual reporting period.

(iv) For each affected source that is subject to permitting regulations pursuant to 40 CFR part 70 or 71, and if the permitting authority has established dates for submitting semiannual reports pursuant to 40 CFR 70.6(a)(3)(iii)(A) or 40 CFR 71.6(a)(3)(iii)(A), you may submit the first and subsequent compliance reports according to the dates the permitting authority has established instead of according to the date specified in paragraph (a)(1)(iii) of this section.

(2) *Inclusion with Title V report.* Each affected source that has obtained a title V operating permit pursuant to 40 CFR part 70 or 71 must report all deviations as defined in this subpart in the semiannual monitoring report required by 40 CFR 70.6(a)(3)(iii)(A) or 40 CFR 71.6(a)(3)(iii)(A). If an affected source submits a semiannual compliance report pursuant to this section along with, or as part of, the semiannual monitoring report required by 40 CFR 70.6(a)(3)(iii)(A) or 40 CFR 71.6(a)(3)(iii)(A), and the semiannual compliance report includes all required information concerning deviations from any emission limitation in this subpart, its submission shall be deemed to satisfy any obligation to report the same deviations in the semiannual monitoring report. However, submission of a semiannual compliance report shall not otherwise affect any obligation the affected source may have to report deviations from permit requirements to the permitting authority.

(3) *General requirements.* The semiannual compliance report must contain the information specified in paragraphs (a)(3)(i) through (v) of this section, and the information specified in paragraphs (a)(4) through (7) and (c)(1) of this section that is applicable to your affected source.

(i) Company name and address.

(ii) Statement by a responsible official with that official's name, title, and signature, certifying the truth, accuracy, and completeness of the content of the report.

(iii) Date of report and beginning and ending dates of the reporting period. The reporting period is the 6-month period ending on June 30 or December 31.

(iv) Identification of the compliance option or options specified in § 63.4891 that you used on each coating operation during the reporting period. If you switched between compliance options during the reporting period, you must report the beginning and ending dates you used each option.

(v) If you used the emission rate without add-on controls or the emission rate with add-on controls compliance option (§ 63.4891(b) or (c)), the calculation results for each monthly organic HAP emission rate during the 6-month reporting period.

(4) *No deviations.* If there were no deviations from the emission limitations in §§ 63.4890, 63.4892, and 63.4893 that apply to you, the semiannual compliance report must include a statement that there were no deviations from the emission limitations during the reporting period. If you used the emission rate with add-on controls option and there were no periods during which the continuous parameter monitoring systems (CPMS) were out-of-control as specified in § 63.8(c)(7), the semiannual compliance report must include a statement that there were no periods during which the CPMS were out-of-control during the reporting period.

(5) *Deviations: compliant material option.* If you used the compliant material option, and there was a

deviation from the applicable emission limit in § 63.4890, the semiannual compliance report must contain the information in paragraphs (a)(5)(i) through (iv) of this section.

(i) Identification of each coating used that deviated from the emission limit, and of each thinner and cleaning material used that contained organic HAP, and the dates and time periods each was used.

(ii) The calculation of the organic HAP content (H_C, using Equation 1 of § 63.4941) for each coating identified in paragraph (a)(5)(i) of this section. You do not need to submit background data supporting this calculation, for example, information provided by coating suppliers or manufacturers, or test reports.

(iii) The determination of mass fraction of organic HAP for each coating, thinner, and cleaning material identified in paragraph (a)(5)(i) of this section. You do not need to submit background data supporting this calculation, for example, information provided by material suppliers or manufacturers, or test reports.

(iv) A statement of the cause of each deviation.

(6) *Deviations: emission rate without add-on controls option.* If you used the emission rate without add-on controls option, and there was a deviation from the applicable emission limit in § 63.4890, the semiannual compliance report must contain the information in paragraphs (a)(6)(i) through (iii) of this section.

(i) The beginning and ending dates of each compliance period during which the organic HAP emission rate exceeded the applicable emission limit in § 63.4890.

(ii) The calculations used to determine the organic HAP emission rate for the compliance period in which the deviation occurred. You must submit the calculations for Equations 1, 1A through 1C, 2, and 3 in § 63.4951; and if applicable, the calculation used to determine R_w according to § 63.4951(e)(4). You do not need to submit background data supporting these calculations, for example, information provided by materials suppliers or manufacturers, or test reports.

(iii) A statement of the cause of each deviation.

(7) *Deviations: emission rate with add-on controls option.* If you used the emission rate with add-on controls option, and there was a deviation from an emission limitation (including any periods when emissions bypassed the add-on control device and were diverted to the atmosphere), the semiannual compliance report must contain the information in paragraphs (a)(7)(i) through (xiv) of this section. This includes periods of startup, shutdown, and malfunction during which deviations occurred.

(i) The beginning and ending dates of each compliance period during which the organic HAP emission rate exceeded the applicable emission limit in § 63.4890.

(ii) The calculations used to determine the organic HAP emission rate for each compliance period in which a deviation occurred. You must provide the calculation of the total mass of organic HAP emissions for the coatings, thinners, and cleaning materials used during the compliance period (H_e), using Equations 1 and 1A through 1C of § 63.4951 and, if applicable, the calculation used to determine R_w according to § 63.4951(e)(4); the calculation of the total volume of coating solids used during the compliance period (V_{st}), using Equation 2 of § 63.4951; the calculation of the mass of organic HAP emission reduction during the compliance period by emission capture systems and add-on control devices, using Equations 1 and 1A through 1D of § 63.4961 for H_C, and Equations 2 and 3 of § 63.4961 for H_{CSR}, as applicable; and the calculation of the organic HAP emission rate for the compliance period (H_{HAP}), using either Equation 4 of § 63.4961 or Equation 1 of § 63.4962, as applicable. You do not need to submit the background data supporting these calculations, for example information provided by materials suppliers or manufacturers, or test reports.

(iii) The date and time that each malfunction started and stopped.

(iv) A brief description of the CPMS.

(v) The date of the latest CPMS certification or audit.

(vi) The date and time that each CPMS was inoperative, except for zero (low-level) and high-level checks.

(vii) The date, time, and duration that each CPMS was out-of-control, including the information in § 63.8(c)(8).

(viii) The date and time period of each deviation from an operating limit in Table 1 of this subpart; date and time period of any bypass of the add-on control device; and whether each deviation occurred during a period of startup, shutdown, or malfunction or during another period.

(ix) A summary of the total duration of each deviation from an operating limit in Table 1 of this subpart and each bypass of the add-on control device during the semiannual reporting period and the total duration as a percent of the total source operating time during that semiannual reporting period.

(x) A breakdown of the total duration of the deviations from the operating limits in Table 1 of this subpart and bypasses of the add-on control device during the semiannual reporting period into those that were due to startup, shutdown, control equipment problems, process problems, other known causes, and other unknown causes.

(xi) A summary of the total duration of CPMS downtime during the semiannual reporting period and the total duration of CPMS downtime as a percent of the total source operating time during that semiannual reporting period.

(xii) A description of any changes in the CPMS, coating operation, emission capture system, or add-on control device since the last semiannual reporting period.

(xiii) For each deviation from the work practice standards, a description of the deviation; the date and time period of the deviation; and the actions you took to correct the deviation.

(xiv) A statement of the cause of each deviation.

(b) *Performance test reports.* If you use the emission rate with add-on controls option, you must submit reports of performance test results for emission capture systems and add-on control devices no later than 60 days after completing the tests as specified in § 63.10(d)(2).

(c) *Startup, shutdown, malfunction reports.* If you used the emission rate with add-on controls option and you had a startup, shutdown, or malfunction during the semiannual reporting period, you must submit the reports specified in paragraphs (c)(1) and (2) of this section.

(1) If your actions were consistent with your startup, shutdown, and malfunction plan, you must include the information specified in § 63.10(d) in the semiannual compliance report required by paragraph (a) of this section.

(2) If your actions were not consistent with your startup, shutdown, and malfunction plan, you must submit an immediate startup, shutdown, and malfunction report as described in paragraph (c)(2)(i) and (ii) of this section.

(i) You must describe the actions taken during the event in a report delivered by facsimile, telephone, or other means to the Administrator within 2 working days after starting actions that are inconsistent with the plan.

(ii) You must submit a letter to the Administrator within 7 working days after the end of the event, unless you have made alternative arrangements with the Administrator as specified in

§ 63.10(d)(5)(ii). The letter must contain the information specified in § 63.10(d)(5)(ii).

§ 63.4930 What records must I keep?

You must collect and keep records of the data and information specified in this section. Failure to collect and keep these records is a deviation from the applicable standard.

(a) A copy of each notification and report that you submitted to comply with this subpart, and the documentation supporting each notification and report.

(b) A current copy of information provided by materials suppliers or manufacturers, such as manufacturer's formulation data, or test data used to determine the mass fraction of organic HAP and density for each coating, thinner, and cleaning material and the volume fraction of coating solids for each coating. If you conducted testing to determine mass fraction of organic HAP, density, or volume fraction of coating solids, you must keep a copy of the complete test report. If you use information provided to you by the manufacturer or supplier of the material that was based on testing, you must keep the summary sheet of results provided to you by the manufacturer or supplier. You are not required to obtain the test report or other supporting documentation from the manufacturer or supplier.

(c) For each compliance period, the records specified in paragraphs (c)(1) through (4) of this section.

(1) A record of the coating operations at which you used each compliance option and the time periods (beginning and ending dates and times) you used each option.

(2) For the compliant material option, a record of the calculation of the organic HAP content for each coating (H_c), using Equation 1 of § 63.4941.

(3) For the emission rate without add-on controls option, a record of the calculation of the total mass of organic HAP emissions for the coatings, thinners, and cleaning materials used during each compliance period (H_e), using Equations 1, 1A through 1C, and 2 of § 63.4951 and, if applicable, the calculation used to determine R_w according to § 63.4951(e)(4); the calculation of the total volume of coating solids used during each compliance period (V_{st}), using Equation 2 of § 63.4951; and the calculation of the organic HAP emission rate for each compliance period (H_{avg}), using Equation 3 of § 63.4951.

(4) For the emission rate with add-on controls option, records of the calculations specified in paragraphs (c)(4)(i) through (v) of this section.

(i) The calculation of the total mass of organic HAP emissions for the coatings, thinners, and cleaning materials used during each compliance period (H_e), using Equations 1 and 1A through 1C of § 63.4951 and, if applicable, the calculation used to determine R_w according to § 63.4951(e)(4);

(ii) The calculation of the total volume of coating solids used during each compliance period (V_{st}), using Equation 2 of § 63.4951;

(iii) The calculation of the mass of organic HAP emission reduction by emission capture systems and add-on control devices, using Equations 1 and 1A through 1D of § 63.4961 for H_C, and Equations 2 and 3 of § 63.4961 for H_{CSR}, as applicable;

(iv) The calculation of the organic HAP emission rate for each compliance period (H_{HAP}), using either Equation 4 of § 63.4961 or Equation 1 of § 63.4962, as applicable.

(d) A record of the name and volume of each coating, thinner, and cleaning material used during each compliance period.

(e) A record of the mass fraction of organic HAP for each coating, thinner, and cleaning material used during each compliance period.

(f) A record of the volume fraction of coating solids for each coating used during each compliance period.

(g) A record of the density for each coating used during each compliance period; and, if you use either the emission rate without add-on controls or the emission rate with add-on controls compliance option, the density for each thinner and cleaning material used during each compliance period.

(h) If you use an allowance in Equation 1 of § 63.4951 for organic HAP contained in waste materials sent to or designated for shipment to a treatment, storage, and disposal facility (TSDF) according to § 63.4951(e)(4), you must keep records of the information specified in paragraphs (h)(1) through (3) of this section.

(1) The name and address of each TSDF to which you sent waste materials for which you use an allowance in Equation 1 of § 63.4951, a statement of which subparts under 40 CFR parts 262, 264, 265, and 266 apply to the facility, and the date of each shipment.

(2) Identification of the coating operations producing waste materials included in each shipment and the month or months in which you used the allowance for these materials in Equation 1 of § 63.4951.

(3) The methodology used in accordance with § 63.4951(e)(4) to determine the total amount of waste materials sent to or the amount collected, stored, and designated for transport to a TSDF each month; and the methodology to determine the mass of organic HAP contained in these waste materials. This must include the sources for all data used in the determination, methods used to generate the data, frequency of testing or monitoring, and supporting calculations and documentation, including the waste manifest for each shipment.

(i) [Reserved]

(j) You must keep records of the date, time, and duration of each deviation.

(k) If you use the emission rate with add-on controls option, you must keep the records specified in paragraphs (k)(1) through (9) of this section.

(1) For each deviation, a record of whether the deviation occurred during a period of startup, shutdown, or malfunction.

(2) The records in § 63.6(e)(3)(iii) through (v) related to startup, shutdown, and malfunction.

(3) The records required to show continuous compliance with each operating limit specified in Table 1 of this subpart that applies to you.

(4) If you operate under multiple operating conditions that affect emission capture system efficiency or add-on control device organic HAP destruction or removal efficiency, and you are using different emission capture system efficiency or add-on control device organic HAP destruction or removal efficiency factors for each condition, then you must keep records of the data you used to calculate the organic HAP emission rate for each compliance period, as described by Equation 1 in § 63.4962.

(5) For each capture system that is a PTE, the data and documentation you used to support a determination that the capture system meets the criteria in Method 204 of appendix M to 40 CFR part 51 for a PTE and has a capture efficiency of 100 percent, as specified in § 63.4965(a).

(6) For each capture system that is not a PTE, the data and documentation you used to determine capture efficiency according to the requirements specified in §§ 63.4964 and 63.4965(b) through (e), including the records specified in paragraphs (k)(6)(i) through (iii) of this section that apply to you.

(i) *Records for a liquid-to-uncaptured-gas protocol using a temporary total enclosure or building enclosure.* Records of the mass of total volatile hydrocarbon (TVH) as measured by Method 204A or F of appendix M to 40 CFR part 51 for each material used in the coating operation, and the total TVH for all

materials used, during each capture efficiency test run, including a copy of the test report. Records of the mass of TVH emissions not captured by the capture system that exited the temporary total enclosure or building enclosure during each capture efficiency test run, as measured by Method 204D or E of appendix M to 40 CFR part 51, including a copy of the test report. Records documenting that the enclosure used for the capture efficiency test met the criteria in Method 204 of appendix M to 40 CFR part 51 for either a temporary total enclosure or a building enclosure.

(ii) *Records for a gas-to-gas protocol using a temporary total enclosure or a building enclosure.* Records of the mass of TVH emissions captured by the emission capture system as measured by Method 204B or C of appendix M to 40 CFR part 51 at the inlet to the add-on control device, including a copy of the test report. Records of the mass of TVH emissions not captured by the capture system that exited the temporary total enclosure or building enclosure during each capture efficiency test run, as measured by Method 204D or E of appendix M to 40 CFR part 51, including a copy of the test report. Records documenting that the enclosure used for the capture efficiency test met the criteria in Method 204 of appendix M to 40 CFR part 51 for either a temporary total enclosure or a building enclosure.

(iii) *Records for an alternative protocol.* Records needed to document a capture efficiency determination using an alternative method or protocol as specified in § 63.4965(e), if applicable.

(7) The records specified in paragraphs (k)(7)(i) and (ii) of this section for each add-on control device organic HAP destruction or removal efficiency determination as specified in § 63.4966.

(i) Records of each add-on control device performance test conducted according to §§ 63.4964 and 63.4966.

(ii) Records of the coating operation conditions during the add-on control device performance test showing that the performance test was conducted under representative operating conditions.

(8) Records of the data and calculations you used to establish the emission capture and add-on control device operating limits as specified in § 63.4967 and to document compliance with the operating limits as specified in Table 1 of this subpart.

(9) A record of the work practice plan required by § 63.4893 and documentation that you are implementing the plan on a continuous basis.

§ 63.4931 In what form and for how long must I keep my records?

(a) Your records must be in a form suitable and readily available for expeditious review, according to § 63.10(b)(1). Where appropriate, the records may be maintained as electronic spreadsheets or as a database.

(b) As specified in § 63.10(b)(1), you must keep each record for 5 years following the date of each occurrence, measurement, maintenance, corrective action, report, or record.

(c) You must keep each record on site for at least 2 years after the date of each occurrence, measurement, maintenance, corrective action, report, or record, according to § 63.10(b)(1). You may keep the records off site for the remaining 3 years.

Compliance Requirements for the Compliant Material Option

§ 63.4940 By what date must I conduct the initial compliance demonstration?

You must complete the initial compliance demonstration for the initial compliance period according to the requirements in § 63.4941. The initial compliance period begins on the applicable compliance date specified in § 63.4883 and ends on the last day of the first full month following the compliance date. The initial compliance demonstration includes the calculations according to § 63.4941 and supporting documentation showing that, during the initial compliance period, you used no coating with an organic HAP content that exceeded the applicable emission limit in § 63.4890 and you used no thinners or cleaning materials that contained organic HAP.

§ 63.4941 How do I demonstrate initial compliance with the emission limitations?

You may use the compliant material option for any individual coating operation, for any group of coating operations in the affected source, or for all the coating operations in the affected source. You must use either the emission rate without add-on controls option or the emission rate with add-on controls option for any coating operation in the affected source for which you do not use this option. To demonstrate initial compliance using the compliant material option, the coating operation or group of coating operations must use no coating with an organic HAP content that exceeds the applicable emission limit in § 63.4890 and must use no thinner or cleaning material that contains organic HAP as determined according to this section. Any coating operation for which you use the compliant material option is not required to meet the operating limits or work practice standards required in §§ 63.4892 and 63.4893, respectively. To demonstrate initial compliance with the emission limitations using the compliant material option, you must meet all the requirements of this section for the coating operation or group of coating operations using this option. Use the procedures in this section on each coating, thinner, and cleaning material in the condition it is in when it is received from its manufacturer or supplier and prior to any alteration. You do not need to redetermine the HAP content of cleaning materials that are reclaimed and reused onsite provided these materials in their condition as received were demonstrated to comply with the compliant material option.

(a) *Determine the mass fraction of organic HAP for each material used.* You must determine the mass fraction of organic HAP for each coating, thinner, and cleaning material used during the compliance period by using one of the options in paragraphs (a)(1) through (5) of this section.

(1) *Method 311 (appendix A to 40 CFR part 63).* You may use Method 311 for determining the mass fraction of organic HAP. Use the procedures specified in paragraphs (a)(1)(i) and (ii) of this section when performing a Method 311 test.

(i) Count each organic HAP that is measured to be present at 0.1 percent by mass or more for Occupational Safety and Health Administration (OSHA)-defined carcinogens as specified in 29 CFR 1910.1200(d)(4) and at 1.0 percent by mass or more for other compounds. For example, if toluene (not an OSHA carcinogen) is measured to be 0.5 percent of the material by mass, you do not have to count it. Express the mass fraction of each organic HAP you count as a value truncated to four places after the decimal point (for example, 0.3791).

(ii) Calculate the total mass fraction of organic HAP in the test material by adding up the individual organic HAP mass fractions and truncating the result to three places after the decimal point (for example, 0.763).

(2) *Method 24 (appendix A to 40 CFR part 60).* For coatings, you may use Method 24 to determine the mass fraction of non-aqueous volatile matter and use that value as a substitute for mass fraction of organic HAP.

(3) *Alternative method.* You may use an alternative test method for determining the mass fraction of organic HAP once the Administrator has approved it. You must follow the

procedure in § 63.7(f) to submit an alternative test method for approval.

(4) *Information from the supplier or manufacturer of the material.* You may rely on information other than that generated by the test methods specified in paragraphs (a)(1) through (3) of this section, such as manufacturer's formulation data, if it represents each organic HAP that is present at 0.1 percent by mass or more for OSHA-defined carcinogens as specified in 29 CFR 1910.1200(d)(4) and at 1.0 percent by mass or more for other compounds. For example, if toluene (not an OSHA carcinogen) is 0.5 percent of the material by mass, you do not have to count it. If there is a disagreement between such information and results of a test conducted according to paragraphs (a)(1) through (3) of this section, then the test method results will take precedence.

(5) *Solvent blends.* Solvent blends may be listed as single components for some materials in data provided by manufacturers or suppliers. Solvent blends may contain organic HAP which must be counted toward the total organic HAP mass fraction of the materials. When test data and manufacturer's data for solvent blends are not available, you may use the default values for the mass fraction of organic HAP in these solvent blends listed in Table 3 or 4 of this subpart. If you use the tables, you must use the values in Table 3 for all solvent blends that match Table 3 entries, and you may only use Table 4 if the solvent blends in the materials you use do not match any of the solvent blends in Table 3 and you only know whether the blend is aliphatic or aromatic. However, if the results of a Method 311 test indicate higher values than those listed on Table 3 or 4 of this subpart, the Method 311 results will take precedence.

(b) *Determine the volume fraction of coating solids for each coating.* You must determine the volume fraction of coating solids (liters of coating solids per liter of coating) for each coating used during the compliance period by a test or by information provided by the supplier or the manufacturer of the material, as specified in paragraphs (b)(1) and (2) of this section. If test results obtained according to paragraph (b)(1) of this section do not agree with the information obtained under paragraph (b)(2) of this section, the test results will take precedence.

(1) *ASTM Method D2697–86(1998) or D6093–97.* You may use ASTM Method D2697–86(1998) or D6093–97 to determine the volume fraction of coating solids for each coating. Divide the nonvolatile volume percent obtained with the methods by 100 to calculate volume fraction of coating solids.

(2) *Information from the supplier or manufacturer of the material.* You may obtain the volume fraction of coating solids for each coating from the supplier or manufacturer.

(c) *Determine the density of each coating.* Determine the density of each coating used during the compliance period from test results using ASTM Method D1475–98 or information from the supplier or manufacturer of the material. If there is disagreement between ASTM Method D1475–98 test results and the supplier's or manufacturer's information, the test results will take precedence.

(d) *Calculate the organic HAP content of each coating.* Calculate H_C, the organic HAP content, kg organic HAP per liter coating solids, of each coating used during the compliance period, using Equation 1 of this section:

$$H_c = \frac{(D_c)(W_c)}{V_s} \qquad \text{(Eq. 1)}$$

Where:

H_C = organic HAP content of the coating, kg organic HAP per liter coating solids.

D_C = density of coating, kg coating per liter coating, determined according to paragraph (c) of this section.

W_C = mass fraction of organic HAP in the coating, kg organic HAP per kg coating, determined according to paragraph (a) of this section.

V_S = volume fraction of coating solids, liter coating solids per liter coating, determined according to paragraph (b) of this section.

(e) *Compliance demonstration.* The calculated organic HAP content, H_C, for each coating used during the initial compliance period must be less than or equal to the applicable emission limit in § 63.4890; and each thinner and cleaning material used during the initial compliance period must contain no organic HAP, determined according to paragraph (a) of this section. You must keep all records required by §§ 63.4930 and 63.4931. As part of the Notification of Compliance Status required in § 63.4910, you must identify the coating operation(s) for which you used the compliant material option and submit a statement that the coating operation(s) was (were) in compliance with the emission limitations during the initial compliance period because you used no coatings for which the organic HAP content exceeded the applicable emission limit in § 63.4890, and you used no thinners or cleaning materials that contained organic HAP.

§ 63.4942 How do I demonstrate continuous compliance with the emission limitations?

(a) For each compliance period, to demonstrate continuous compliance, you must use no coating for which the organic HAP content, H_C, determined using Equation 1 of § 63.4941, exceeds the applicable emission limit in § 63.4890, and use no thinner or cleaning material that contains organic HAP, determined according to § 63.4941(a). Each month following the initial compliance period described in § 63.4940 is a compliance period.

(b) If you choose to comply with the emission limitations by using the compliant material option, the use of any coating, thinner, or cleaning material that does not meet the criteria specified in paragraph (a) of this section is a deviation from the emission limitations that must be reported as specified in §§ 63.4910(c)(6) and 63.4920(a)(5).

(c) As part of each semiannual compliance report required by § 63.4920, you must identify the coating operation(s) for which you used the compliant material option. If there were no deviations from the emission limitations in § 63.4890, submit a statement that the coating operation(s) was (were) in compliance with the emission limitations during the reporting period because you used no coating for which the organic HAP content exceeded the applicable emission limit in § 63.4890 and you used no thinner or cleaning material that contained organic HAP.

(d) You must maintain records as specified in §§ 63.4930 and 63.4931.

Compliance Requirements for the Emission Rate Without Add-On Controls Option

§ 63.4950 By what date must I conduct the initial compliance demonstration?

You must complete the initial compliance demonstration for the initial compliance period according to the requirements of § 63.4951. The initial compliance period begins on the applicable compliance date specified in § 63.4883 and ends on the last day of the first full month following the compliance date. The initial compliance demonstration includes the calculations showing that the organic HAP emission rate for the initial compliance period was equal to or less than the applicable emission limit in § 63.4890.

§ 63.4951 How do I demonstrate initial compliance with the emission limitations?

You may use the emission rate without add-on controls option for any individual coating operation, for any

group of coating operations in the affected source, or for all the coating operations in the affected source. You must use either the compliant material option or the emission rate with add-on controls option for any coating operation in the affected source for which you do not use this option. To demonstrate initial compliance using the emission rate without add-on controls option, the coating operation or group of coating operations must meet the applicable emission limit in § 63.4890, but is not required to meet the operating limits or work practice standards in §§ 63.4892 and 63.4893, respectively. You must meet all the requirements of this section to demonstrate initial compliance with the applicable emission limit in § 63.4890 for the coating operation(s). When calculating the organic HAP emission rate according to this section, do not include any coatings, thinners, or cleaning materials used on coating operations for which you use the compliant material option or the emission rate with add-on controls option. You do not need to include organic HAP in coatings, thinners, or cleaning materials that are reclaimed and reused in the coating operation for which you use the emission rate without add-on controls option.

(a) *Determine the mass fraction of organic HAP for each material.* Determine the mass fraction of organic HAP for each coating, thinner, and cleaning material used during the compliance period according to the requirements in § 63.4941(a).

(b) *Determine the volume fraction of coating solids for each coating.* Determine the volume fraction of coating solids for each coating used during the compliance period according to the requirements in § 63.4941(b).

(c) *Determine the density of each material.* Determine the density of each coating, thinner, and cleaning material used during the compliance period according to the requirements in § 63.4941(c) from test results using ASTM Method D1475–98, information from the supplier or manufacturer of the material, or reference sources providing density or specific gravity data for pure materials. If there is disagreement between ASTM Method D1475–98 test results and such other information sources, the test results will take precedence.

(d) *Determine the volume of each material used.* Determine the volume (liters) of each coating, thinner, and cleaning material used during the compliance period by measurement or usage records.

(e) *Calculate the mass of organic HAP emissions.* The mass of organic HAP emissions, H_e, is the combined mass of organic HAP contained in all coatings, thinners, and cleaning materials used during the compliance period minus the organic HAP in certain waste materials. Calculate H_e using Equation 1 of this section:

$$H_e = A + B + C - R_w \qquad \text{(Eq. 1)}$$

Where:

H_e = total mass of organic HAP emissions during the compliance period, kg.

A = total mass of organic HAP in the coatings used during the compliance period, kg, as calculated in Equation 1A of this section.

B = total mass of organic HAP in the thinners used during the compliance period, kg, as calculated in Equation 1B of this section.

C = total mass of organic HAP in the cleaning materials used during the compliance period, kg, as calculated in Equation 1C of this section.

R_w = total mass of organic HAP in waste materials sent or designated for shipment to a hazardous waste TSDF for treatment or disposal during the compliance period, kg, determined according to paragraph (e)(4) of this section. (You may assign a value of zero to R_w if you do not wish to use this allowance.)

(1) Calculate A, the kg organic HAP in the coatings used during the compliance period using Equation 1A of this section:

$$A = \sum_{i=1}^{m} \left(Vol_{c,i}\right)\left(D_{c,i}\right)\left(W_{c,i}\right) \qquad \text{(Eq. 1A)}$$

Where:

A = total mass of organic HAP in the coatings used during the compliance period, kg.

$Vol_{c,i}$ = total volume of coating, i, used during the compliance period, liters.

$D_{c,i}$ = density of coating, i, kg coating per liter coating.

$W_{c,i}$ = mass fraction of organic HAP in coating, i, kg organic HAP per kg coating.

m = number of different coatings used during the compliance period.

(2) Calculate B, the kg of organic HAP in the thinners used during the compliance period using Equation 1B of this section:

$$B = \sum_{j=1}^{m} \left(Vol_{t,j}\right)\left(D_{t,j}\right)\left(W_{t,j}\right) \qquad \text{(Eq. 1B)}$$

Where:

B = total mass of organic HAP in the thinners used during the compliance period, kg.

$Vol_{t,j}$ = total volume of thinner, j, used during the compliance period, liters.

$D_{t,j}$ = density of thinner, j, kg per liter.

$W_{t,j}$ = mass fraction of organic HAP in thinner, j, kg organic HAP per kg thinner.

n = number of different thinners used during the compliance period.

(3) Calculate C, the kg organic HAP in the cleaning materials used during the compliance period using Equation 1C of this section:

$$C = \sum_{k=1}^{p} \left(Vol_{s,k}\right)\left(D_{s,k}\right)\left(W_{s,k}\right) \qquad \text{(Eq. 1C)}$$

Where:

C = total mass of organic HAP in the cleaning materials used during the compliance period, kg.

$Vol_{s,k}$ = total volume of cleaning material, k, used during the compliance period, liters.

$D_{s,k}$ = density of cleaning material, k, kg per liter.

$W_{s,k}$ = mass fraction of organic HAP in cleaning material, k, kg organic HAP per kg material.

p = number of different cleaning materials used during the compliance period.

(4) If you choose to account for the mass of organic HAP contained in waste materials sent or designated for shipment to a hazardous waste TSDF (R_w) in the calculation of H_e (Equation 1 of this section), then you must determine R_w according to paragraphs (e)(4)(i) through (iv) of this section.

(i) You may include in the determination of R_w only waste materials that are generated by coating operations for which you use Equation 1 of this section and that will be treated or disposed of by a facility regulated as a TSDF under 40 CFR part 262, 264, 265, or 266. The TSDF may be either off-site or on-site. You may not include in R_w the organic HAP contained in wastewater.

(ii) You must determine either the amount of the waste materials sent to a TSDF during the compliance period or the amount collected and stored during the compliance period and designated for future transport to a TSDF. Do not include in your determination of R_w any waste materials sent to a TSDF during a compliance period if you have already

included them in the amount collected and stored during that or a previous compliance period.

(iii) Determine the total mass of organic HAP contained in the waste materials specified in paragraph (e)(4)(ii) of this section.

(iv) You may use any reasonable methodology to determine the amount of waste materials and the total mass of organic HAP they contain, and you must document your methodology as required in § 63.4930(h). To the extent that waste manifests include this information, they may be used as part of the documentation of the amount of waste materials and mass of organic HAP contained in them.

(f) *Calculate the total volume of coating solids used.* Determine V_{st}, the total volume of coating solids used, liters, which is the combined volume of coating solids for all the coatings used during the compliance period, using Equation 2 of this section:

$$V_{st} = \sum_{i=1}^{m} \left(Vol_{c,i}\right)\left(V_{s,i}\right) \qquad \text{(Eq. 2)}$$

Where:

V_{st} = total volume of coating solids used during the compliance period, liters.

$Vol_{c,i}$ = total volume of coating, i, used during the compliance period, liters.

$V_{s,i}$ = volume fraction of coating solids for coating, i, liter solids per liter coating, determined according to § 63.4941(b).

m = number of coatings used during the compliance period.

(g) *Calculate the organic HAP emission rate.* Calculate H_{avg}, the organic HAP emission rate for the compliance period, kg organic HAP per liter coating solids used, using Equation 3 of this section:

$$H_{avg} = \frac{H_e}{V_{st}} \qquad \text{(Eq. 3)}$$

Where:

H_{avg} = organic HAP emission rate for the compliance period, kg organic HAP per liter coating solids.

H_e = total mass of organic HAP emissions from all materials used during the compliance period, kg, as calculated by Equation 1 of this section.

V_{st} = total volume of coating solids used during the compliance period, liters, as calculated by Equation 2 of this section.

(h) *Compliance demonstration.* The organic HAP emission rate for the initial compliance period, H_{avg}, must be less than or equal to the applicable emission limit in § 63.4890. You must keep all records as required by §§ 63.4930 and 63.4931. As part of the Notification of Compliance Status required by § 63.4910, you must identify the coating operation(s) for which you used the emission rate without add-on controls option and submit a statement that the coating operation(s) was (were) in compliance with the emission limitations during the initial compliance period because the organic HAP emission rate was less than or equal to the applicable emission limit in § 63.4890, determined according to this section.

§ 63.4952 How do I demonstrate continuous compliance with the emission limitations?

(a) To demonstrate continuous compliance, the organic HAP emission rate for each compliance period, determined according to § 63.4951(a) through (g), must be less than or equal to the applicable emission limit in § 63.4890. Each month following the initial compliance period described in § 63.4950 is a compliance period.

(b) If the organic HAP emission rate for any compliance period exceeded the applicable emission limit in § 63.4890, this is a deviation from the emission limitations for that compliance period and must be reported as specified in §§ 63.4910(c)(6) and 63.4920(a)(6).

(c) As part of each semiannual compliance report required by § 63.4920, you must identify the coating operation(s) for which you used the emission rate without add-on controls option. If there were no deviations from the emission limitations, you must submit a statement that the coating operation(s) was (were) in compliance with the emission limitations during the reporting period because the organic HAP emission rate for each compliance period was less than or equal to the applicable emission limit in § 63.4890.

(d) You must maintain records as specified in §§ 63.4930 and 63.4931.

Compliance Requirements for the Emission Rate With Add-On Controls Option

§ 63.4960 By what date must I conduct performance tests and other initial compliance demonstrations?

(a) *New and reconstructed affected sources.* For a new or reconstructed affected source, you must meet the requirements of paragraphs (a)(1) through (4) of this section.

(1) All emission capture systems, add-on control devices, and CPMS must be installed and operating no later than the applicable compliance date specified in § 63.4883. Except for solvent recovery systems for which you conduct liquid-liquid material balances according to § 63.4961(j), you must conduct a performance test of each capture system and add-on control device according to §§ 63.4964, 63.4965, and 63.4966, and establish the operating limits required by § 63.4892, no later than 180 days after the applicable compliance date specified in § 63.4883. For a solvent recovery system for which you conduct liquid-liquid material balances according to § 63.4961(j), you must initiate the first material balance no later than 180 days after the applicable compliance date specified in § 63.4883.

(2) You must develop and begin implementing the work practice plan required by § 63.4893 no later than the compliance date specified in § 63.4883.

(3) You must complete the initial compliance demonstration for the initial compliance period according to the requirements of § 63.4961. The initial compliance period begins on the applicable compliance date specified in § 63.4883 and ends on the last day of the first full month following the compliance date. The initial compliance demonstration includes the results of emission capture system and add-on control device performance tests conducted according to §§ 63.4964, 63.4965, and 63.4966; results of liquid-liquid material balances conducted according to § 63.4961(j); calculations showing whether the organic HAP emission rate for the initial compliance period was equal to or less than the emission limit in § 63.4890(a); the operating limits established during the performance tests and the results of the continuous parameter monitoring required by § 63.4968; and documentation of whether you developed and implemented the work practice plan required by § 63.4893.

(4) You do not need to comply with the operating limits for the emission capture system and add-on control device required by § 63.4892 until after you have completed the performance tests specified in paragraph (a)(1) of this section. Instead, you must maintain a log detailing the operation and maintenance of the emission capture system, add-on control device, and continuous parameter monitors during the period between the compliance date and the performance test. You must begin complying with the operating limits for your affected source on the date you complete the performance tests specified in paragraph (a)(1) of this section. The requirements in this paragraph do not apply to solvent recovery systems for which you conduct liquid-liquid material balances.

(b) *Existing affected sources.* For an existing affected source, you must meet the requirements of paragraphs (b)(1) through (3) of this section.

(1) All emission capture systems, add-on control devices, and CPMS must be installed and operating no later than the applicable compliance date specified in

§ 63.4883. Except for solvent recovery systems for which you conduct liquid-liquid material balances according to § 63.4961(j), you must conduct a performance test of each capture system and add-on control device according to the procedures in §§ 63.4964, 63.4965, and 63.4966, and establish the operating limits required by § 63.4892, no later than the compliance date specified in § 63.4883. For a solvent recovery system for which you conduct liquid-liquid material balances according to § 63.4961(j), you must initiate the first material balance no later than the compliance date specified in § 63.4883.

(2) You must develop and begin implementing the work practice plan required by § 63.4893 no later than the compliance date specified in § 63.4883.

(3) You must complete the initial compliance demonstration for the initial compliance period according to the requirements of § 63.4961. The initial compliance period begins on the applicable compliance date specified in § 63.4883 and ends on the last day of the first full month following the compliance date. The initial compliance demonstration includes the results of emission capture system and add-on control device performance tests conducted according to §§ 63.4964, 63.4965, and 63.4966; results of liquid-liquid material balances conducted according to § 63.4961(j); calculations showing whether the organic HAP emission rate for the initial compliance period was equal to or less than the emission limit in § 63.4890(b); the operating limits established during the performance tests and the results of the continuous parameter monitoring required by § 63.4968; and documentation of whether you developed and implemented the work practice plan required by § 63.4893.

§ 63.4961 How do I demonstrate initial compliance?

(a) *When add-on controls are used.* You may use the emission rate with add-on controls option for any coating operation, for any group of coating operations in the affected source, or for all of the coating operations in the affected source. You may include both controlled and uncontrolled coating operations in a group for which you use this option. You must use either the compliant material option or the emission rate without add-on controls option for any coating operation in the affected source for which you do not use the emission rate with add-on controls option. To demonstrate initial compliance, the coating operation(s) for which you use the emission rate with add-on controls option must meet the applicable emission limit in § 63.4890, and each controlled coating operation must meet the operating limits and work practice standards required in §§ 63.4892 and 63.4893, respectively. You must meet all the requirements of this section to demonstrate initial compliance with the emission limitations. When calculating the organic HAP emission rate according to this section, do not include any coatings, thinners, or cleaning materials used on coating operations for which you use the compliant material option or the emission rate without add-on controls option.

(b) *Compliance with operating limits.* Except as provided in § 63.4960(a)(4), you must establish and demonstrate continuous compliance during the initial compliance period with the operating limits required by § 63.4892, using the procedures specified in §§ 63.4967 and 63.4968.

(c) *Compliance with work practice requirements.* You must develop, implement, and document your implementation of the work practice plan required by § 63.4893 during the initial compliance period, as specified in § 63.4930.

(d) *Compliance with emission limits.* You must follow the procedures in paragraphs (e) through (n) of this section to demonstrate compliance with the applicable emission limit in § 63.4890.

(e) *Determine the mass fraction of organic HAP, density, volume used, and volume fraction of coating solids.* Follow the procedures specified in § 63.4951(a) through (d) to determine the mass fraction of organic HAP, density, and volume of each coating, thinner, and cleaning material used during the compliance period; and the volume fraction of coating solids for each coating used during the compliance period.

(f) *Calculate the total mass of organic HAP emissions before add-on controls.* Using Equation 1 of § 63.4951, calculate the total mass of organic HAP emissions before add-on controls from all coatings, thinners, and cleaning materials used during the compliance period, H_e.

(g) *Calculate the organic HAP emission reduction for each controlled coating operation.* Determine the mass of organic HAP emissions reduced for each controlled coating operation during the compliance period. The emission reduction determination quantifies the total organic HAP emissions that pass through the emission capture system and are destroyed or removed by the add-on control device. Use the procedures in paragraph (h) of this section to calculate the mass of organic HAP emission reduction for each controlled coating operation using an emission capture system and add-on control device other than a solvent recovery system for which you conduct liquid-liquid material balances. For each controlled coating operation using a solvent recovery system for which you conduct a liquid-liquid material balance, use the procedures in paragraph (j) of this section to calculate the organic HAP emission reduction.

(h) *Calculate the organic HAP emission reduction for controlled coating operations not using liquid-liquid material balance, H_C.* For each controlled coating operation using an emission capture system and add-on control device other than a solvent recovery system for which you conduct liquid-liquid material balances, calculate H_C, using Equation 1 of this section. The calculation of H_C applies the emission capture system efficiency and add-on control device efficiency to the mass of organic HAP contained in the coatings, thinners, and cleaning materials that are used in the coating operation served by the emission capture system and add-on control device during the compliance period. For any period of time a deviation specified in § 63.4963(c) or (d) occurs in the controlled coating operation, including a deviation during a period of startup, shutdown, or malfunction, you must assume zero efficiency for the emission capture system and add-on control device. Equation 1 of this section treats the materials used during such a deviation as if they were used on an uncontrolled coating operation for the time period of the deviation:

$$H_c = \left(A_I + B_I + C_I\right)\left(\frac{CE}{100} \times \frac{DRE}{100}\right) + H_{unc} \qquad \text{(Eq. 1)}$$

Where:

H_C = mass of organic HAP emission reduction for the controlled coating operation during the compliance period, kg.

A_I = total mass of organic HAP in the coatings used in the controlled coating operation during the compliance period, excluding coatings used during deviations, kg, as calculated in Equation 1A of this section.

B_I = total mass of organic HAP in the thinners used in the controlled coating operation during the compliance period, excluding thinners used during deviations, kg, as calculated in Equation 1B of this section.

C_I = total mass of organic HAP in the cleaning materials used in the controlled coating operation during the compliance period, excluding cleaning materials used during deviations, kg, as calculated in Equation 1C of this section.

CE = capture efficiency of the emission capture system vented to the add-on control device, percent. Use the test methods and procedures specified in §§ 63.4964 and 63.4965 to measure and record capture efficiency.

DRE = organic HAP destruction or removal efficiency of the add-on control device, percent. Use the test methods and procedures in §§ 63.4964 and 63.4966 to measure and record the organic HAP destruction or removal efficiency.

H_{unc} = total mass of organic HAP in the coatings, thinners, and cleaning materials used during all deviations specified in § 63.4963(c) and (d) that occurred during the compliance period in the controlled coating operation, kg, as calculated in Equation 1D of this section.

(1) Calculate A_I, the mass of organic HAP in the coatings used in the controlled coating operation, kg, using Equation 1A of this section. Do not include in the calculation of A_I the coatings used during any deviation specified in § 63.4963(c) or (d) that occurred during the month. Include such coatings in the calculation of H_{unc} in Equation 1D of this section.

$$A_I = \sum_{i=1}^{m} (Vol_{c,i})(D_{c,i})(W_{c,i}) \qquad \text{(Eq. 1A)}$$

Where:

A_I = total mass of organic HAP in the coatings used in the controlled coating operation during the compliance period, excluding coatings used during deviations, kg.

$Vol_{c,i}$ = total volume of coating, i, used during the compliance period except during deviations, liters.

$D_{c,i}$ = density of coating, i, kg per liter.

$W_{c,i}$ = mass fraction of organic HAP in coating, i, kg per kg.

m = number of different coatings used.

(2) Calculate B_I, the mass of organic HAP in the thinners used in the controlled coating operation, kg, using Equation 1B of this section. Do not include in the calculation of B_I the thinners used during any deviation specified in § 63.4963(c) or (d) that occurred during the month. Include such coatings in the calculation of H_{unc} in Equation 1D of this section.

$$B_I = \sum_{j=1}^{n} (Vol_{t,j})(D_{t,j})(W_{t,j}) \qquad \text{(Eq. 1B)}$$

Where:

B_I = total mass of organic HAP in the thinners used in the controlled coating operation during the compliance period, excluding thinners used during deviations, kg.

$Vol_{t,j}$ = total volume of thinner, j, used during the compliance period except during deviations, liters.

$D_{t,j}$ = density of thinner, j, kg per liter.

$W_{t,j}$ = mass fraction of organic HAP in thinner, j, kg per kg.

n = number of different thinners used.

(3) Calculate C_I, the mass of organic HAP in the cleaning materials used in the controlled coating operation, kg, using Equation 1C of this section. Do not include in the calculation of C_I the cleaning materials used during any deviation specified in § 63.4963(c) or (d) that occurred during the compliance period. Include such cleaning materials in the calculation of H_{unc} in Equation 1D of this section.

$$C_I = \sum_{k=1}^{p} (Vol_{s,k})(D_{s,k})(W_{s,k}) \qquad \text{(Eq. 1C)}$$

Where:

C_I = total mass of organic HAP in the cleaning materials used in the controlled coating operation during the compliance period, excluding cleaning materials used during deviations, kg.

$Vol_{s,k}$ = total volume of cleaning material, k, used during the compliance period except during deviations, liters.

$D_{s,k}$ = density of cleaning material, k, kg per liter.

$W_{s,k}$ = mass fraction of organic HAP in cleaning material, k, kg per kg.

p = number of different cleaning materials used.

(4) Calculate H_{unc}, the mass of organic HAP in the coatings, thinners, and cleaning materials used in the controlled coating operation during deviations specified in § 63.4963(c) and (d), using Equation 1D of this section:

$$H_{unc} = \sum_{h=1}^{q} (Vol_h)(D_h)(W_h) \qquad \text{(Eq. 1D)}$$

Where:

H_{unc} = total mass of organic HAP in the coatings, thinners, and cleaning materials used during all deviations specified in § 63.4963(c) and (d) that occurred during the compliance period in the controlled coating operation, kg.

Vol_h = total volume of coating, thinner, or cleaning material, h, used in the controlled coating operation during deviations, liters.

D_h = density of coating, thinner, or cleaning material, h, kg per liter.

W_h = mass fraction of organic HAP in coating, thinner, or cleaning material, h, kg organic HAP per kg coating.

q = number of different coatings, thinning solvents, or cleaning materials.

(i) [Reserved]

(j) *Calculate the organic HAP emission reduction for controlled coating operations using liquid-liquid material balance, H_{CSR}.* For each controlled coating operation using a solvent recovery system for which you conduct liquid-liquid material balances,

calculate H_{CSR} by applying the volatile organic matter collection and recovery efficiency to the mass of organic HAP contained in the coatings, thinners, and cleaning materials that are used in the coating operation controlled by the solvent recovery system during the compliance period. Perform a liquid-liquid material balance for each compliance period as specified in paragraphs (j)(1) through (6) of this section. Calculate the mass of organic HAP emission reduction by the solvent recovery system as specified in paragraph (j)(7) of this section.

(1) For each solvent recovery system, install, calibrate, maintain, and operate according to the manufacturer's specifications, a device that indicates the cumulative amount of volatile organic matter recovered by the solvent recovery system each compliance period. The device must be initially certified by the manufacturer to be accurate to within ±2.0 percent of the mass of volatile organic matter recovered.

(2) For each solvent recovery system, determine the mass, M_{VR}, of volatile organic matter recovered for the compliance period, kg, based on measurement with the device required in paragraph (j)(1) of this section.

(3) Determine the mass fraction, C_V, of volatile organic matter for each coating, thinner, and cleaning material used in the coating operation controlled by the solvent recovery system during the compliance period, kg volatile organic matter per kg coating. You may determine the volatile organic matter mass fraction using Method 24 of 40 CFR part 60, appendix A, or an EPA approved alternative method, or you may use information provided by the manufacturer or supplier of the coating. In the event of any inconsistency between information provided by the manufacturer or supplier and the results of Method 24 of 40 CFR part 60, appendix A, or an approved alternative method, the test method results will govern.

(4) Determine the density of each coating, thinner, and cleaning material used in the coating operation controlled by the solvent recovery system during the compliance period, kg per liter, according to § 63.4951(c).

(5) Measure the volume of each coating, thinner, and cleaning material used in the coating operation controlled by the solvent recovery system during the compliance period, liters.

(6) Calculate the solvent recovery system's volatile organic matter collection and recovery efficiency, R_V, using Equation 2 of this section:

$$R_v = 100 \frac{M_{VR}}{\sum_{i=1}^{m} Vol_i D_i WV_{c,i} + \sum_{j=1}^{n} Vol_j D_j WV_{t,j} + \sum_{k=1}^{p} Vol_k D_k WV_{s,k}} \qquad \text{(Eq. 2)}$$

Where:

R_V = volatile organic matter collection and recovery efficiency of the solvent recovery system during the compliance period, percent.

M_{VR} = mass of volatile organic matter recovered by the solvent recovery system during the compliance period, kg.

Vol_i = volume of coating, i, used in the coating operation controlled by the solvent recovery system during the compliance period, liters.

D_i = density of coating, i, kg per liter.

$WV_{c,i}$ = mass fraction of volatile organic matter for coating, i, kg volatile organic matter per kg coating.

Vol_j = volume of thinner, j, used in the coating operation controlled by the solvent recovery system during the compliance period, liters.

D_j = density of thinner, j, kg per liter.

$WV_{t,j}$ = mass fraction of volatile organic matter for thinner, j, kg volatile organic matter per kg thinner.

Vol_k = volume of cleaning material, k, used in the coating operation controlled by the solvent recovery system during the compliance period, liters.

D_k = density of cleaning material, k, kg per liter.

$WV_{s,k}$ = mass fraction of volatile organic matter for cleaning material, k, kg volatile organic matter per kg cleaning material.

m = number of different coatings used in the coating operation controlled by the solvent recovery system during the compliance period.

n = number of different thinners used in the coating operation controlled by the solvent recovery system during the compliance period.

p = number of different cleaning materials used in the coating operation controlled by the solvent recovery system during the compliance period.

(7) Calculate the mass of organic HAP emission reduction for the coating operation controlled by the solvent recovery system during the compliance period, H_{CSR}, using Equation 3 of this section:

$$H_{CSR} = \left(A_I + B_I + C_I\right)\left(\frac{R_V}{100}\right) \qquad \text{(Eq. 3)}$$

Where:

H_{CSR} = mass of organic HAP emission reduction for the coating operation controlled by the solvent recovery system during the compliance period, kg.

A_I = total mass of organic HAP in the coatings used in the coating operation controlled by the solvent recovery system, kg, calculated using Equation 1A of this section.

B_I = total mass of organic HAP in the thinners used in the coating operation controlled by the solvent recovery system, kg, calculated using Equation 1B of this section.

C_I = total mass of organic HAP in the cleaning materials used in the coating operation controlled by the solvent recovery system, kg, calculated using Equation 1C of this section.

R_V = volatile organic matter collection and recovery efficiency of the solvent recovery system, percent, from Equation 2 of this section.

(k) *Calculate the total volume of coating solids used.* Determine V_{st}, the total volume of coating solids used, liters, which is the combined volume of coating solids for all the coatings used during the compliance period, using Equation 2 of § 63.4951.

(l) *Calculate the organic HAP emissions rate.* Determine H_{HAP}, the organic HAP emission rate to the atmosphere, kg organic HAP per liter coating solids used during the compliance period, using either Equation 4 of this section or Equation 1 of § 63.4962.

$$H_{HAP} = \frac{H_e - \sum_{i=1}^{q}\left(H_{C,i}\right) - \sum_{j=1}^{r}\left(H_{CSR,j}\right)}{V_{st}} \qquad \text{(Eq. 4)}$$

Where:

H_{HAP} = organic HAP emission rate for the compliance period, kg.

H_e = total mass of organic HAP emissions before add-on controls from all the coatings, thinners, and cleaning materials used during the compliance period, kg, determined according to paragraph (f) of this section.

$H_{C,i}$ = total mass of organic HAP emission reduction for controlled coating operation, i, not using liquid-liquid material balances, during the compliance period, kg, from Equation 1 of this section.

$H_{CSR,j}$ = total mass of organic HAP emission reduction for controlled coating operation, j, using a liquid-liquid material balance, during the compliance period, kg, from Equation 3 of this section.

V_{st} = total volume of coating solids used during the compliance period, liters, from Equation 2 of § 63.4951.

q = number of controlled coating operations except those controlled with a solvent recovery system.

r = number of coating operations controlled with a solvent recovery system.

(m) *Compliance demonstration.* To demonstrate initial compliance with the emission limit, H_{HAP}, calculated using either Equation 4 of this section or Equation 1 of § 63.4962, must be less than or equal to the applicable emission limit in § 63.4890. You must keep all records as required by §§ 63.4930 and 63.4931. As part of the Notification of Compliance Status required by § 63.4910, you must identify the coating operation(s) for which you used the emission rate with add-on controls option and submit a statement that the coating operation(s) was (were) in compliance with the emission limitations during the initial compliance period because the organic HAP emission rate was less than or equal to the applicable emission limit in § 63.4890, and you achieved the operating limits required by § 63.4892 and the work practice standards required by § 63.4893.

§ 63.4962 How do I determine the organic HAP emission rate for a controlled coating operation not using a liquid-liquid material balance if I operate it under different sets of representative operating conditions?

(a) This section applies only to controlled coating operations for which you do not conduct liquid-liquid material balances to demonstrate compliance. If you operate such a controlled coating operation, its emission capture system, or its add-on control device at multiple sets of representative operating conditions that result in different capture system or add-on control device efficiencies during a compliance period, you must determine the organic HAP emission rate according to either paragraph (b) or (c) of this section. The cases described in paragraphs (a)(1) and (2) of this section are examples of such operating conditions.

(1) You use a single add-on control device to reduce emissions from two or more coating operations and the number of coating operations vented to the add-on control device is variable during the compliance period. This case also includes situations where you have more than one capture device on the same coating operation and the number of capture devices vented to the add-on control device is changed during the compliance period.

(2) The coatings or cleaning materials you apply or the products to which you apply them differ during the compliance period, and the differences in resulting emissions are such that the emission capture efficiency or add-on control device efficiency changes. This case includes a change in the shape or size of the product coated such that there is a change in capture efficiency of the capture system. This case also includes a change in the materials that results in an inlet concentration to the add-on control device that is sufficiently lower such that the percent reduction the add-on control device can achieve changes, or a change in the volatility of the organic HAP in the materials used such that a lower proportion of the HAP is captured by the capture system and a higher amount is not captured by the capture system.

(b) If you conduct performance tests under the representative operating conditions that are expected to result in the lowest emission capture system and add-on control device efficiencies, as allowed under § 63.4964(b)(2), then determine the organic HAP emission rate according to the procedures and equations in § 63.4961. You do not need to follow paragraph (c) of this section.

(c) If you conduct performance tests under multiple sets of representative operating conditions to establish different emission capture system and add-on control device efficiencies for each set of operating conditions, as allowed under § 63.4964(b)(1), then determine the organic HAP emission rate according to paragraphs (c)(1) and (2) of this section.

(1) You must use Equation 1 of this section for determining HHAP, the organic HAP emission rate, kg organic HAP emitted per liter coating solids used:

$$H_{HAP} = \frac{H_e - \sum_{i=1}^{q}\left(H_{c,i_1} + H_{c,i_2} + \ldots H_{C,i_n}\right) - \sum_{j=1}^{r}\left(H_{CSR_j}\right)}{V_{st}} \qquad \text{(Eq. 1)}$$

Where:

H_{HAP} = organic HAP emission rate for the compliance period, kg organic HAP per liter coating solids.

H_e = total mass of organic HAP emissions before add-on controls from all coatings, thinners, and cleaning materials used during the compliance period, kg, determined according to § 63.4961(f).

$H_{C,i1}$, $H_{C,i2}$, $H_{C,in}$ = total mass of organic HAP emission reduction, kg, for controlled coating operation, i, while operating under each operating condition, n, during the compliance period, from Equation 1 of § 63.4961.

$H_{CSR,j}$ = total mass of organic HAP emission reduction, kg, for controlled coating operation, j, using a liquid-liquid material balance during the compliance period, from Equation 3 of § 63.4961.

V_{st} = total volume of coating solids used during the compliance period, liters, from Equation 2 of § 63.4951.

n = number of different operating conditions that affect emission capture system efficiency or add-on control device organic HAP destruction or removal efficiency under which the coating operation operated during the compliance period.

q = number of controlled coating operations not controlled by a solvent recovery system.
r = number of coating operations controlled by a solvent recovery system.

(2) To determine the $H_{C,in}$ in Equation 1 of this section, follow the steps in paragraphs (c)(2)(i) through (iii) of this section.

(i) Use Equation 1 of § 63.4961 to calculate the HC for each operating condition, n, of each controlled coating operation, i.

(ii) For the factors A_I, B_I, and C_I in Equation 1 of § 63.4961, use the mass of organic HAP contained in the coatings, thinners, and cleaning materials used in each controlled coating operation, i, while operating under each operating condition, n.

(iii) In Equation 1 of § 63.4961, use the emission capture system efficiency and add-on control device organic HAP destruction or removal efficiency that apply under each operating condition, n. These efficiencies for each operating condition are determined from the performance test required by § 63.4960 and as specified in § 63.4964(b).

§ 63.4963 How do I demonstrate continuous compliance with the emission limitations?

(a) To demonstrate continuous compliance with the applicable emission limit in § 63.4890, the organic HAP emission rate for each compliance period, determined according to the procedures in § 63.4961 (and in § 63.4962, if applicable), must be equal to or less than the applicable emission limit in § 63.4890. Each month following the initial compliance period described in § 63.4960 is a compliance period.

(b) If the organic HAP emission rate for any compliance period exceeded the applicable emission limit in § 63.4890, this is a deviation from the emission limitation for that compliance period and must be reported as specified in §§ 63.4910(c)(6) and 63.4920(a)(7).

(c) You must demonstrate continuous compliance with each operating limit required by § 63.4892 that applies to you, as specified in Table 1 of this subpart.

(1) If an operating parameter is out of the allowed range specified in Table 1 of this subpart, this is a deviation from the operating limit that must be reported as specified in §§ 63.4910(b)(6) and 63.4920(a)(7).

(2) If an operating parameter deviates from the operating limit specified in Table 1 of this subpart, then you must assume that the emission capture system and add-on control device were achieving zero efficiency during the time period of the deviation. For the purposes of completing the compliance calculations specified in §§ 63.4961 and 63.4962, you must treat the materials used during a deviation on a controlled coating operation as if they were used on an uncontrolled coating operation for the time period of the deviation, as indicated in Equation 1 of § 63.4961.

(d) You must meet the requirements for bypass lines in § 63.4968(b) for controlled coating operations for which you do not conduct liquid-liquid material balances. If any bypass line is opened and emissions are diverted to the atmosphere when the coating operation is running, this is a deviation that must be reported as specified in §§ 63.4910(c)(6) and 63.4920(a)(7). For the purposes of completing the compliance calculations in §§ 63.4961 and 63.4962, you must treat the materials used during a deviation on a controlled coating operation as if they were used on an uncontrolled coating operation for the time period of the deviation, as indicated in Equation 1 of § 63.4961.

(e) You must demonstrate continuous compliance with the work practice standards in § 63.4893. If you did not develop a work practice plan, or you did not implement the plan, or you did not keep the records required by § 63.4930(k)(9), this is a deviation from the work practice standards that must be reported as specified in §§ 63.4910(c)(6) and 63.4920(a)(7).

(f) As part of each semiannual compliance report required in § 63.4920, you must identify the coating operation(s) for which you used the emission rate with add-on controls option. If there were no deviations from the emission limitations, submit a statement that you were in compliance with the emission limitations during the reporting period because the organic HAP emission rate for each compliance period was less than or equal to the applicable emission limit in § 63.4890, and you achieved the operating limits required by § 63.4892 and the work practice standards required by § 63.4893 during each compliance period.

(g) During periods of startup, shutdown, or malfunction of the emission capture system, add-on control device, or coating operation that may affect emission capture or control device efficiency, you must operate in accordance with the startup, shutdown, and malfunction plan required by § 63.4900(d).

(h) Consistent with §§ 63.6(e) and 63.7(e)(1), deviations that occur during a period of startup, shutdown, or malfunction of the emission capture system, add-on control device, or coating operation that may affect emission capture or control device efficiency are not violations if you demonstrate to the Administrator's satisfaction that you were operating in accordance with the startup, shutdown, and malfunction plan. The Administrator will determine whether deviations that occur during a period you identify as a startup, shutdown, or malfunction are violations, according to the provisions in § 63.6(e).

(i) [Reserved]

(j) You must maintain records as specified in §§ 63.4930 and 63.4931.

§ 63.4964 What are the general requirements for performance tests?

(a) You must conduct each performance test required by § 63.4960 according to the requirements in § 63.7(e)(1) and under the conditions in this section unless you obtain a waiver of the performance test according to the provisions in § 63.7(h).

(1) *Representative coating operation operating conditions.* You must conduct the performance test under representative operating conditions for the coating operation. Operations during periods of startup, shutdown, or malfunction, and periods of nonoperation do not constitute representative conditions. You must record the process information that is necessary to document operating conditions during the test and explain why the conditions represent normal operation.

(2) *Representative emission capture system and add-on control device operating conditions.* You must conduct the performance test when the emission capture system and add-on control device are operating at a representative flow rate, and the add-on control device is operating at a representative inlet concentration. You must record information that is necessary to document emission capture system and add-on control device operating conditions during the test and explain why the conditions represent normal operation.

(b) If the coating operation, emission capture system, or add-on control device will be operated at different sets of representative operating conditions, you must conduct the performance test according to either paragraph (b)(1) or (2) of this section:

(1) Test at each of the representative operating conditions and establish emission capture system and add-on control device efficiencies and operating limits for each operating condition. To demonstrate continuous compliance following the performance test, record the conditions under which the process, emission capture system, and add-on control device are operating during each time period of operation, and calculate the organic HAP emission rate as described in § 63.4962.

(2) Test at the representative operating conditions that are expected to result in the lowest emission capture system and add-on control device efficiencies and establish efficiencies and operating limits based on this test. Use these efficiencies in the emission calculations in § 63.4961.

(c) You must conduct each performance test of an emission capture system according to the requirements in § 63.4965. You must conduct each performance test of an add-on control device according to the requirements in § 63.4966.

(d) The performance test to determine add-on control device organic HAP destruction or removal efficiency must consist of three runs as specified in § 63.7(e)(3) and each run must last at least 1 hour.

§ 63.4965 How do I determine the emission capture system efficiency?

You must use the procedures and test methods in this section to determine capture efficiency as part of the performance test required by § 63.4960.

(a) *Assuming 100 percent capture efficiency.* You may assume the capture system efficiency is 100 percent if both of the conditions in paragraphs (a)(1) and (2) of this section are met:

(1) The capture system meets the criteria in Method 204 of appendix M to 40 CFR part 51 for a PTE and directs all the exhaust gases from the enclosure to an add-on control device.

(2) All coatings, thinners, and cleaning materials used in the coating operation are applied within the capture system; coating solvent flash-off and coating, curing, and drying occurs within the capture system; and the removal of or evaporation of cleaning materials from the surfaces they are applied to occurs within the capture system. For example, this criterion is not met if parts enter the open shop environment when being moved between a spray booth and a curing oven.

(b) *Measuring capture efficiency.* If the capture system does not meet both of the criteria in paragraphs (a)(1) and (2) of this section, then you must use one of the three protocols described in paragraphs (c), (d), and (e) of this section to measure capture efficiency. The capture efficiency measurements use TVH capture efficiency as a surrogate for organic HAP capture efficiency. For the protocols in paragraphs (c) and (d) of this section, the capture efficiency measurement must consist of three test runs. Each test run must be at least 3 hours duration or the length of a production run, whichever is longer, up to 8 hours. For the purposes of this test, a production run means the time required for a single part to go from the beginning to the end of production, which includes surface preparation activities and drying or curing time.

(c) *Liquid-to-uncaptured-gas protocol using a temporary total enclosure or building enclosure.* The liquid-to-uncaptured-gas protocol compares the mass of liquid TVH in materials used in the coating operation, referred to as TVH_{used}, to the mass of TVH emissions not captured by the emission capture system, referred to as $TVH_{uncaptured}$. Use a temporary total enclosure or a building enclosure and the procedures in paragraphs (c)(1) through (6) of this section to measure emission capture system efficiency using the liquid-to-uncaptured-gas protocol.

(1) Either use a building enclosure or construct an enclosure around the coating operation where coatings, thinners, and cleaning materials are applied, and all areas where emissions from these applied coatings and materials subsequently occur, such as flash-off, curing, and drying areas. The areas of the coating operation where capture devices collect emissions for routing to an add-on control device, such as the entrance and exit areas of an oven or spray booth, must also be inside the enclosure. The enclosure must meet the applicable definition of a temporary total enclosure or building enclosure in Method 204 of appendix M to 40 CFR part 51.

(2) Use Method 204A or 204F of appendix M to 40 CFR part 51 to determine the mass fraction, kg TVH per kg material, of TVH liquid input from each coating, thinner, and cleaning material used in the coating operation during each capture efficiency test run. To make the determination, substitute TVH for each occurrence of the term volatile organic compounds (VOC) in the methods.

(3) Use Equation 1 of this section to calculate TVH_{used}, the total mass of TVH liquid input from all the coatings, thinners, and cleaning materials used in the coating operation during each capture efficiency test run:

$$TVH_{used} = \sum_{i=1}^{n} (TVH_i)(Vol_i)(D_i) \qquad \text{(Eq. 1)}$$

Where:

TVH_i = mass fraction of TVH in coating, thinner, or cleaning material, i, that is used in the coating operation during the capture efficiency test run, kg TVH per kg material.

Vol_i = total volume of coating, thinner, or cleaning material, i, used in the coating operation during the capture efficiency test run, liters.

D_i = density of coating, thinner, or cleaning material, i, kg material per liter material.

n = number of different coatings, thinners, and cleaning materials used in the coating operation during the capture efficiency test run.

(4) Use Method 204D or E of appendix M to 40 CFR part 51 to measure $TVH_{uncaptured}$, the total mass, kg, of TVH emissions that are not captured by the emission capture system; they are measured as they exit the temporary total enclosure or building enclosure during each capture efficiency test run. To make the measurement, substitute TVH for each occurrence of the term VOC in the methods.

(i) Use Method 204D if the enclosure is a temporary total enclosure.

(ii) Use Method 204E if the enclosure is a building enclosure. During the capture efficiency measurement, all organic compound emitting operations inside the building enclosure, other than the coating operation for which capture efficiency is being determined, must be shut down, but all fans and blowers must be operating normally.

(5) For each capture efficiency test run, determine the percent capture efficiency, CE, of the emission capture system using Equation 2 of this section:

$$CE = \frac{(TVH_{used} - TVH_{uncaptured})}{TVH_{used}} \times 100 \qquad \text{(Eq. 2)}$$

Where:

CE = capture efficiency of the emission capture system vented to the add-on control device, percent.

TVH_{used} = total mass of TVH liquid input used in the coating operation during the capture efficiency test run, kg.

$TVH_{uncaptured}$ = total mass of TVH that is not captured by the emission capture system and that exits from the temporary total enclosure or building enclosure during the capture efficiency test run, kg.

(6) Determine the capture efficiency of the emission capture system as the average of the capture efficiencies measured in the three test runs.

(d) *Gas-to-gas protocol using a temporary total enclosure or a building enclosure.* The gas-to-gas protocol compares the mass of TVH emissions captured by the emission capture system, referred to as $TVH_{captured}$, to the mass of TVH emissions not captured, referred to as $TVH_{uncaptured}$. Use a temporary total enclosure or a building enclosure and the procedures in paragraphs (d)(1) through (5) of this section to measure emission capture system efficiency using the gas-to-gas protocol.

(1) Either use a building enclosure or construct an enclosure around the coating operation where coatings, thinners, and cleaning materials are applied, and all areas where emissions from these applied coatings and materials subsequently occur, such as flash-off, curing, and drying areas. The areas of the coating operation where capture devices collect emissions generated by the coating operation for routing to an add-on control device, such as the entrance and exit areas of an oven or a spray booth, must also be inside the enclosure. The enclosure must meet the applicable definition of a temporary total enclosure or building enclosure in Method 204 of appendix M to 40 CFR part 51.

(2) Use Method 204B or 204C of appendix M to 40 CFR part 51 to measure $TVH_{captured}$, the total mass, kg, of TVH emissions captured by the emission capture system during each capture efficiency test run as measured at the inlet to the add-on control device. To make the measurement, substitute TVH for each occurrence of the term VOC in the methods.

(i) The sampling points for the Method 204B or 204C measurement must be upstream from the add-on control device and must represent total emissions routed from the capture system and entering the add-on control device.

(ii) If multiple emission streams from the capture system enter the add-on control device without a single common duct, then the emissions entering the add-on control device must be simultaneously measured in each duct and the total emissions entering the add-on control device must be determined.

(3) Use Method 204D or 204E of appendix M to 40 CFR part 51 to measure $TVH_{uncaptured}$, the total mass, kg, of TVH emissions that are not captured by the emission capture system; they are measured as they exit the temporary total enclosure or building enclosure during each capture efficiency test run. To make the measurement, substitute TVH for each occurrence of the term VOC in the methods.

(i) Use Method 204D if the enclosure is a temporary total enclosure.

(ii) Use Method 204E if the enclosure is a building enclosure. During the capture efficiency measurement, all organic compound emitting operations inside the building enclosure, other than the coating operation for which capture efficiency is being determined, must be shut down, but all fans and blowers must be operating normally.

(4) For each capture efficiency test run, determine the percent capture efficiency, CE, of the emission capture system using Equation 3 of this section:

$$CE = \frac{TVH_{captured}}{\left(TVH_{captured} + TVH_{uncaptured}\right)} \times 100 \qquad \text{(Eq. 3)}$$

Where:

CE = capture efficiency of the emission capture system vented to the add-on control device, percent.

$TVH_{captured}$ = total mass of TVH captured by the emission capture system as measured at the inlet to the add-on control device during the emission capture efficiency test run, kg.

$TVH_{uncaptured}$ = total mass of TVH that is not captured by the emission capture system and that exits from the temporary total enclosure or building enclosure during the capture efficiency test run, kg.

(5) Determine the capture efficiency of the emission capture system as the average of the capture efficiencies measured in the three test runs.

(e) *Alternative capture efficiency protocol.* As an alternative to the procedures specified in paragraphs (c) and (d) of this section, you may determine capture efficiency using any other capture efficiency protocol and test methods that satisfy the criteria of either the DQO or LCL approach as described in appendix A to subpart KK of this part.

§ 63.4966 How do I determine the add-on control device emission destruction or removal efficiency?

You must use the procedures and test methods in this section to determine the add-on control device emission destruction or removal efficiency as part of the performance test required by § 63.4960. You must conduct three test runs as specified in § 63.7(e)(3), and each test run must last at least 1 hour.

(a) For all types of add-on control devices, use the test methods specified in paragraphs (a)(1) through (5) of this section.

(1) Use Method 1 or 1A of appendix A to 40 CFR part 60, as appropriate, to select sampling sites and velocity traverse points.

(2) Use Method 2, 2A, 2C, 2D, 2F, or 2G of appendix A to 40 CFR part 60, as appropriate, to measure gas volumetric flow rate.

(3) Use Method 3, 3A, or 3B of appendix A to 40 CFR part 60, as appropriate, for gas analysis to determine dry molecular weight.

(4) Use Method 4 of appendix A to 40 CFR part 60, to determine stack gas moisture.

(5) Methods for determining gas volumetric flow rate, dry molecular weight, and stack gas moisture must be performed, as applicable, during each test run.

(b) Measure total gaseous organic mass emissions as carbon at the inlet and outlet of the add-on control device simultaneously, using either Method 25 or 25A of appendix A to 40 CFR part 60, as specified in paragraphs (b)(1) through (3) of this section. You must use the same method for both the inlet and outlet measurements.

(1) Use Method 25 if the add-on control device is an oxidizer and you expect the total gaseous organic concentration as carbon to be more than 50 parts per million (ppm) at the control device outlet.

(2) Use Method 25A if the add-on control device is an oxidizer and you expect the total gaseous organic concentration as carbon to be 50 ppm or less at the control device outlet.

(3) Use Method 25A if the add-control device is not an oxidizer.

(c) If two or more add-on control devices are used for the same emission stream, then you must measure emissions at the outlet of each device. For example, if one add-on control device is a concentrator with an outlet for the high-volume, dilute stream that has been treated by the concentrator, and a second add-on control device is an oxidizer with an outlet for the low-volume, concentrated stream that is treated with the oxidizer, you must measure emissions at the outlet of the oxidizer and the high volume dilute stream outlet of the concentrator.

(d) For each test run, determine the total gaseous organic emissions mass flow rates for the inlet and the outlet of the add-on control device, using Equation 1 of this section. If there is more than one inlet or outlet to the add-on control device, you must calculate the total gaseous organic mass flow rate using Equation 1 of this section for each inlet and each outlet and then total all of the inlet emissions and total all of the outlet emissions.

$$M_f = Q_{sd} C_c (12)(0.0416)\left(10^{-6}\right) \qquad \text{(Eq. 1)}$$

Where:

M_f = total gaseous organic emissions mass flow rate, kg/per hour (h).

C_c = concentration of organic compounds as carbon in the vent gas, as determined by Method 25 or Method 25A, parts per million by volume (ppmv), dry basis.

Q_{sd} = volumetric flow rate of gases entering or exiting the add-on control device, as determined by Method 2, 2A, 2C, 2D, 2F, or 2G, dry standard cubic meters/hour (dscm/h).

0.0416 = conversion factor for molar volume, kg-moles per cubic meter (mol/m^3) (@ 293 Kelvin (K) and 760 millimeters of mercury (mmHg)).

(e) For each test run, determine the add-on control device organic emissions destruction or removal efficiency, DRE, using Equation 2 of this section:

$$DRE = \frac{M_{fi} - M_{fo}}{M_{fi}} \qquad \text{(Eq. 2)}$$

Where:

DRE = organic emissions destruction or removal efficiency of the add-on control device, percent.

M_{fi} = total gaseous organic emissions mass flow rate at the inlet(s) to the add-on control device, using Equation 1 of this section, kg/h.

M_{fo} = total gaseous organic emissions mass flow rate at the outlet(s) of the add-on control device, using Equation 1 of this section, kg/h.

(f) Determine the emission destruction or removal efficiency of the add-on control device as the average of the efficiencies determined in the three test runs and calculated in Equation 2 of this section.

§ 63.4967 How do I establish the emission capture system and add-on control device operating limits during the performance test?

During the performance test required by § 63.4960 and described in §§ 63.4964, 63.4965, and 63.4966, you must establish the operating limits required by § 63.4892 according to this section, unless you have received approval for alternative monitoring and operating limits under § 63.8(f) as specified in § 63.4892.

(a) *Thermal oxidizers.* If your add-on control device is a thermal oxidizer, establish the operating limits according to paragraphs (a)(1) and (2) of this section.

(1) During the performance test, you must monitor and record the combustion temperature at least once every 15 minutes during each of the three test runs. You must monitor the temperature in the firebox of the thermal oxidizer or immediately downstream of the firebox before any substantial heat exchange occurs.

(2) Use the data collected during the performance test to calculate and record the average combustion temperature maintained during the performance test. This average combustion temperature is the minimum operating limit for your thermal oxidizer, unless you are determining operating limits for multiple operating conditions as specified in § 63.4964(b)(1) and paragraph (f) of this section.

(b) *Catalytic oxidizers.* If your add-on control device is a catalytic oxidizer, establish the operating limits according to either paragraphs (b)(1) and (2) or paragraphs (b)(3) and (4) of this section.

(1) During the performance test, you must monitor and record the temperature just before the catalyst bed and the temperature difference across the catalyst bed at least once every 15 minutes during each of the three test runs.

(2) Use the data collected during the performance test to calculate and record the average temperature just before the catalyst bed and the average temperature difference across the catalyst bed maintained during the performance test. These are the minimum operating limits for your catalytic oxidizer, unless you are determining operating limits for multiple operating conditions as specified in § 63.4964(b)(1) and paragraph (f) of this section.

(3) As an alternative to monitoring the temperature difference across the catalyst bed, you may monitor the temperature at the inlet to the catalyst bed and implement a site-specific inspection and maintenance plan for your catalytic oxidizer as specified in paragraph (b)(4) of this section. During the performance test, you must monitor and record the temperature just before the catalyst bed at least once every 15 minutes during each of the three test runs. Use the data collected during the performance test to calculate and record the average temperature just before the catalyst bed during the performance test. This is the minimum operating limit for your catalytic oxidizer, unless you are determining operating limits for multiple operating conditions as specified in § 63.4964(b)(1) and paragraph (f) of this section.

(4) You must develop and implement an inspection and maintenance plan for your catalytic oxidizer(s) for which you elect to monitor according to paragraph (b)(3) of this section. The plan must address, at a minimum, the elements specified in paragraphs (b)(4)(i) through (iii) of this section.

(i) Annual sampling and analysis of the catalyst activity (i.e., conversion efficiency) following the manufacturer's or catalyst supplier's recommended procedures.

(ii) Monthly inspection of the oxidizer system, including the burner assembly and fuel supply lines for problems and, as necessary, adjust the equipment to assure proper air-to-fuel mixtures.

(iii) Annual internal and monthly external visual inspection of the catalyst bed to check for channeling, abrasion, and settling. If problems are found, you must replace the catalyst bed and conduct a new performance test to determine destruction efficiency according to § 63.4966.

(c) *Carbon adsorbers.* If your add-on control device is a carbon adsorber, establish the operating limits according to paragraphs (c)(1) and (2) of this section.

(1) You must monitor and record the total regeneration desorbing gas (e.g., steam or nitrogen) mass flow for each regeneration cycle, and the carbon bed temperature after each carbon bed regeneration and cooling cycle, for the regeneration cycle either immediately preceding or immediately following the performance test.

(2) The operating limits for your carbon adsorber are the minimum total desorbing gas mass flow recorded during the regeneration cycle, and the maximum carbon bed temperature recorded after the cooling cycle, unless you are determining operating limits for multiple operating conditions as specified in § 63.4964(b)(1) and paragraph (f) of this section.

(d) *Condensers.* If your add-on control device is a condenser, establish the operating limits according to paragraphs (d)(1) and (2) of this section.

(1) During the performance test, you must monitor and record the condenser outlet (product side) gas temperature at least once every 15 minutes during each of the three test runs.

(2) Use the data collected during the performance test to calculate and record the average condenser outlet (product side) gas temperature maintained during the performance test. This average condenser outlet gas temperature is the maximum operating limit for your condenser, unless you are determining operating limits for multiple operating conditions as specified in § 63.4964(b)(1) and paragraph (f) of this section.

(e) *Emission capture system.* For each capture device that is not part of a PTE that meets the criteria of § 63.4965(a), establish an operating limit for either the gas volumetric flow rate or duct static pressure, as specified in paragraphs (e)(1) and (2) of this section. The operating limit for a PTE is specified in Table 1 of this subpart.

(1) During the capture efficiency determination required by § 63.4960 and described in §§ 63.4964 and 63.4965, you must monitor and record either the gas volumetric flow rate or the duct static pressure for each separate capture device in your emission capture system at least once every 15 minutes during each of the three test runs at a point in the duct between the capture device and the add-on control device inlet.

(2) Calculate and record the average gas volumetric flow rate or duct static pressure for the three test runs for each capture device. This average gas volumetric flow rate or duct static pressure is the minimum operating limit for that specific capture device, unless you are determining operating limits for multiple operating conditions as specified in § 63.4964(b)(1) and paragraph (f) of this section.

(f) *Multiple operating conditions.* If you are determining operating limits for multiple operating conditions for the emission capture system or add-on control device as specified in § 63.4964(b)(1), you must conduct a performance test under each operating condition and establish the operating limits for the parameters under each operating condition according to paragraphs (f)(1) and (2) of this section.

(1) You must monitor and record the value of the parameter that corresponds to the applicable operating limit during the performance test under each operating condition.

(2) The average parameter value recorded during the performance test under each condition is the operating limit for that parameter when the coating operation is operating under that condition.

(g) *Concentrators.* If your add-on control device includes a concentrator, you must establish operating limits for the concentrator according to paragraphs (g)(1) and (2) of this section.

(1) During the performance test, you must monitor and record the desorption concentrate stream gas temperature at least once every 15 minutes during each of the three runs of the performance test.

(2) Use the data collected during the performance test to calculate and record the average temperature. This is the minimum operating limit for the desorption concentrate gas stream temperature.

(3) During the performance test, you must monitor and record the pressure drop of the dilute stream across the concentrator at least once every 15 minutes during each of the three runs of the performance test.

(4) Use the data collected during the performance test to calculate and record the average pressure drop. This is the maximum operating limit for the dilute stream across the concentrator.

§ 63.4968 What are the requirements for continuous parameter monitoring system (CPMS) installation, operation, and maintenance?

(a) *General.* You must install, operate, and maintain each CPMS specified in paragraphs (c), (e), and (f) of this section according to paragraphs (a)(1) through (6) of this section. You must install, operate, and maintain each CPMS specified in paragraphs (b) and (d) of this section according to paragraphs (a)(3) through (5) of this section.

(1) The CPMS must complete a minimum of one cycle of operation for each successive 15-minute period. You must have a minimum of four equally spaced successive cycles of CPMS operation in 1 hour.

(2) You must determine the average of all recorded readings for each successive 3-hour period of the emission capture system and add-on control device operation.

(3) You must record the results of each inspection, calibration, and validation check of the CPMS.

(4) You must maintain the CPMS at all times and have available necessary parts for routine repairs of the monitoring equipment.

(5) You must operate the CPMS and collect emission capture system and add-on control device parameter data at all times that a controlled coating operation is operating, except during monitoring malfunctions, associated repairs, and required quality assurance or control activities (including, if applicable, calibration checks and required zero and span adjustments).

(6) You must not use emission capture system or add-on control device parameter data recorded during monitoring malfunctions, associated repairs, out-of-control periods, or required quality assurance or control activities when calculating data averages. You must use all the data collected during all other periods in calculating the data averages for determining compliance with the emission capture system and add-on control device operating limits.

(7) A monitoring malfunction is any sudden, infrequent, not reasonably preventable failure of the CPMS to provide valid data. Monitoring failures that are caused in part by poor maintenance or careless operation are not malfunctions. Any period for which the monitoring system is out-of-control and data are not available for required calculations is a deviation from the monitoring requirements.

(b) *Capture system bypass line.* You must meet the requirements of paragraphs (b)(1) and (2) of this section for each emission capture system that contains bypass lines that could divert emissions away from the add-on control device to the atmosphere.

(1) You must monitor or secure the valve or closure mechanism controlling the bypass line in a nondiverting position in such a way that the valve or closure mechanism cannot be opened without creating a record that the valve was opened. The method used to monitor or secure the valve or closure mechanism must meet one of the requirements specified in paragraphs (b)(1)(i) through (iv) of this section.

(i) *Flow control position indicator.* Install, calibrate, maintain, and operate according to the manufacturer's

specifications a flow control position indicator that takes a reading at least once every 15 minutes and provides a record indicating whether the emissions are directed to the add-on control device or diverted from the add-on control device. The time of occurrence and flow control position must be recorded, as well as every time the flow direction is changed. The flow control position indicator must be installed at the entrance to any bypass line that could divert the emissions away from the add-on control device to the atmosphere.

(ii) *Car-seal or lock-and-key valve closures.* Secure any bypass line valve in the closed position with a car-seal or a lock-and-key type configuration. You must visually inspect the seal or closure mechanism at least once every month to ensure that the valve is maintained in the closed position, and the emissions are not diverted away from the add-on control device to the atmosphere.

(iii) *Valve closure monitoring.* Ensure that any bypass line valve is in the closed (non-diverting) position through monitoring of valve position at least once every 15 minutes. You must inspect the monitoring system at least once every month to verify that the monitor will indicate valve position.

(iv) *Automatic shutdown system.* Use an automatic shutdown system in which the coating operation is stopped when flow is diverted by the bypass line away from the add-on control device to the atmosphere when the coating operation is running. You must inspect the automatic shutdown system at least once every month to verify that it will detect diversions of flow and shut down the coating operation.

(2) If any bypass line is opened, you must include a description of why the bypass line was opened and the length of time it remained open in the semiannual compliance reports required in § 63.4920.

(c) *Thermal oxidizers and catalytic oxidizers.* If you are using a thermal oxidizer or catalytic oxidizer as an add-on control device (including those used with concentrators or with carbon adsorbers to treat desorbed concentrate streams), you must comply with the requirements in paragraphs (c)(1) through (3) of this section:

(1) For a thermal oxidizer, install a gas temperature monitor in the firebox of the thermal oxidizer or in the duct immediately downstream of the firebox before any substantial heat exchange occurs.

(2) For a catalytic oxidizer, install gas temperature monitors both upstream and downstream of the catalyst bed. The temperature monitors must be in the gas stream immediately before and after the catalyst bed to measure the temperature difference across the bed.

(3) For all thermal oxidizers and catalytic oxidizers, you must meet the requirements in paragraphs (a) and (c)(3)(i) through (vii) of this section for each gas temperature monitoring device.

(i) Locate the temperature sensor in a position that provides a representative temperature.

(ii) Use a temperature sensor with a measurement sensitivity of 4 degrees Fahrenheit or 0.75 percent of the temperature value, whichever is larger.

(iii) Shield the temperature sensor system from electromagnetic interference and chemical contaminants.

(iv) If a gas temperature chart recorder is used, it must have a measurement sensitivity in the minor division of at least 20 degrees Fahrenheit.

(v) Perform an electronic calibration at least semiannually according to the procedures in the manufacturer's owners manual. Following the electronic calibration, you must conduct a temperature sensor validation check in which a second or redundant temperature sensor placed nearby the process temperature sensor must yield a reading within 30 degrees Fahrenheit of the process temperature sensor's reading.

(vi) Conduct calibration and validation checks any time the sensor exceeds the manufacturer's specified maximum operating temperature range or install a new temperature sensor.

(vii) At least monthly, inspect components for integrity and electrical connections for continuity, oxidation, and galvanic corrosion.

(d) *Carbon adsorbers.* If you are using a carbon adsorber as an add-on control device, you must monitor the total regeneration desorbing gas (e.g., steam or nitrogen) mass flow for each regeneration cycle, the carbon bed temperature after each regeneration and cooling cycle, and comply with paragraphs (a)(3) through (5) and (d)(1) and (2) of this section.

(1) The regeneration desorbing gas mass flow monitor must be an integrating device having a measurement sensitivity of plus or minus 10 percent, capable of recording the total regeneration desorbing gas mass flow for each regeneration cycle.

(2) The carbon bed temperature monitor must have a measurement sensitivity of 1 percent of the temperature recorded or 1 degree Fahrenheit, whichever is greater, and must be capable of recording the temperature within 15 minutes of completing any carbon bed cooling cycle.

(e) *Condensers.* If you are using a condenser, you must monitor the condenser outlet (product side) gas temperature and comply with paragraphs (a) and (e)(1) and (2) of this section.

(1) The gas temperature monitor must have a measurement sensitivity of 1 percent of the temperature recorded or 1 degree Fahrenheit, whichever is greater.

(2) The temperature monitor must provide a gas temperature record at least once every 15 minutes.

(f) *Emission capture systems.* The capture system monitoring system must comply with the applicable requirements in paragraphs (f)(1) and (2) of this section.

(1) For each flow measurement device, you must meet the requirements in paragraphs (a) and (f)(1)(i) through (iv) of this section.

(i) Locate a flow sensor in a position that provides a representative flow measurement in the duct from each capture device in the emission capture system to the add-on control device.

(ii) Reduce swirling flow or abnormal velocity distributions due to upstream and downstream disturbances.

(iii) Conduct a flow sensor calibration check at least semiannually.

(iv) At least monthly, inspect all components for integrity, all electrical connections for continuity, and all mechanical connections for leakage.

(2) For each pressure drop measurement device, you must comply with the requirements in paragraphs (a) and (f)(2)(i) through (vi) of this section.

(i) Locate the pressure sensor(s) in or as close to a position that provides a representative measurement of the pressure drop across each opening you are monitoring.

(ii) Minimize or eliminate pulsating pressure, vibration, and internal and external corrosion.

(iii) Check pressure tap pluggage daily.

(iv) Using an inclined manometer with a measurement sensitivity of 0.0002 inch water, check gauge calibration quarterly and transducer calibration monthly.

(v) Conduct calibration checks any time the sensor exceeds the manufacturer's specified maximum operating pressure range or install a new pressure sensor.

(vi) At least monthly, inspect all components for integrity, all electrical connections for continuity, and all mechanical connections for leakage.

(g) *Concentrators.* If you are using a concentrator, such as a zeolite wheel or rotary carbon bed concentrator, you must comply with the requirements in paragraphs (g)(1) and (2) of this section.

(1) You must install a temperature monitor in the desorption gas stream. The temperature monitor must meet the requirements in paragraphs (a) and (c)(3) of this section.

(2) You must install a device to monitor pressure drop across the zeolite wheel or rotary carbon bed. The pressure monitoring device must meet the requirements in paragraphs (a) and (g)(2)(i) through (vii) of this section.

(i) Locate the pressure sensor(s) in or as close to a position that provides a representative measurement of the pressure.

(ii) Minimize or eliminate pulsating pressure, vibration, and internal and external corrosion.

(iii) Use a gauge with a minimum tolerance of 0.5 inch of water or a transducer with a minimum tolerance of 1 percent of the pressure range.

(iv) Check the pressure tap daily.

(v) Using a manometer, check gauge calibration quarterly and transducer calibration monthly.

(vi) Conduct calibration checks any time the sensor exceeds the manufacturer's specified maximum operating pressure range or install a new pressure sensor.

(vii) At least monthly, inspect all components for integrity, all electrical connections for continuity, and all mechanical connections for leakage.

Other Requirements and Information

§ 63.4980 Who implements and enforces this subpart?

(a) This subpart can be implemented and enforced by us, the EPA, or a delegated authority such as your State, local, or tribal agency. If the EPA Administrator has delegated authority to your State, local, or tribal agency, then that agency (as well as EPA) has the authority to implement and enforce this subpart. You should contact your EPA Regional Office to find out if implementation and enforcement of this subpart is delegated to your State, local, or tribal agency.

(b) In delegating implementation and enforcement authority of this subpart to a State, local, or tribal agency under subpart E of this part, the authorities contained in paragraph (c) of this section are retained by the Administrator and are not transferred to the State, local, or tribal agency.

(c) The authorities that will not be delegated to State, local, or tribal agencies are as follows:

(1) Approval of alternatives to the work practice standards in § 63.4893 under § 63.6(g).

(2) Approval of major alternatives to test methods under § 63.7(e)(2)(ii) and (f), and as defined in § 63.90.

(3) Approval of major alternatives to monitoring under § 63.8(f) and as defined in § 63.90.

(4) Approval of major alternatives to recordkeeping and reporting under § 63.10(f) and as defined in § 63.90.

§ 63.4981 What definitions apply to this subpart?

Terms used in this subpart are defined in the CAA, in 40 CFR 63.2, the General Provisions of this part, and in this section as follows:

Add-on control means an air pollution control device, such as a thermal oxidizer or carbon adsorber, that reduces pollution in an air stream by destruction or removal before discharge to the atmosphere.

Adhesive means any chemical substance that is applied for the purpose of bonding two surfaces together.

Capture device means a hood, enclosure, room, floor sweep, or other means of containing or collecting emissions and directing those emissions into an add-on air pollution control device.

Capture efficiency or *capture system efficiency* means the portion (expressed as a percentage) of the pollutants from an emission source that is delivered to an add-on control device.

Capture system means one or more capture devices intended to collect emissions generated by a coating operation in the use of coatings or cleaning materials, both at the point of application and at subsequent points where emissions from the coatings or cleaning materials occur, such as flashoff, drying, or curing. As used in this subpart, multiple capture devices that collect emissions generated by a coating operation are considered a single capture system.

Cleaning material means a solvent used to remove contaminants and other materials, such as dirt, grease, oil, and dried or wet coating (e.g., depainting), from a substrate before or after coating application or from equipment associated with a coating operation, such as spray booths, spray guns, racks, tanks, and hangers. Thus, it includes any cleaning material used on substrates or equipment or both.

Coating means a material applied to a substrate for decorative, protective, or functional purposes. Such materials include, but are not limited to, paints, sealants, caulks, inks, adhesives, and maskants. Decorative, protective, or functional materials that consist only of protective oils for metal, acids, bases, or any combination of these substances are not considered coatings for the purposes of this subpart.

Coating operation means equipment used to apply cleaning materials to a substrate to prepare it for coating application or to remove dried coating (surface preparation); to apply coating to a substrate (coating application) and to dry or cure the coating after application; or to clean coating operation equipment (equipment cleaning). A single coating operation may include any combination of these types of equipment, but always includes at least the point at which a coating or cleaning material is applied and all subsequent points in the affected source where organic HAP emissions from that coating or cleaning material occur. There may be multiple coating operations in an affected source. Coating application with hand-held nonrefillable aerosol containers, touchup markers, or marking pens is not a coating operation for the purposes of this subpart.

Coating solids means the nonvolatile portion of the coating that makes up the dry film.

Continuous parameter monitoring system (CPMS) means the total equipment that may be required to meet the data acquisition and availability requirements of this subpart, used to sample, condition (if applicable), analyze, and provide a record of coating operation, or capture system, or add-on control device parameters.

Controlled coating operation means a coating operation from which some or all of the organic HAP emissions are routed through an emission capture system and add-on control device.

Deviation means any instance in which an affected source subject to this subpart, or an owner or operator of such a source:

(1) Fails to meet any requirement or obligation established by this subpart, including but not limited to any emission limit, or operating limit, or work practice standard;

(2) Fails to meet any term or condition that is adopted to implement an applicable requirement in this subpart and that is included in the operating permit for any affected source required to obtain such a permit; or

(3) Fails to meet any emission limit, or operating limit, or work practice standard in this subpart during startup, shutdown, or malfunction, regardless of whether or not such failure is permitted by this subpart.

Emission limitation means an emission limit, operating limit, or work practice standard.

Enclosure means a structure that surrounds a source of emissions and captures and directs the emissions to an add-on control device.

Exempt compound means a specific compound that is not considered a VOC due to negligible photochemical reactivity. The exempt compounds are listed in 40 CFR 51.100(s).

Manufacturer's formulation data means data on a material (such as a coating) that are supplied by the material manufacturer based on knowledge of the ingredients used to manufacture that material, rather than based on testing of the material with the test methods specified in § 63.4941(a)(1) through (3). Manufacturer's formulation data may include, but are not limited to, information on density, organic HAP content, volatile organic matter content, and coating solids content.

Mass fraction of organic HAP means the ratio of the mass of organic HAP to the mass of a material in which it is contained; kg of organic HAP per kg of material.

Month means a calendar month or a pre-specified period of 28 days to 35 days to allow for flexibility in recordkeeping when data are based on a business accounting period.

Organic HAP content means the mass of organic HAP per volume of coating solids for a coating, calculated using Equation 1 of § 63.4941. The organic HAP content is determined for the coating in the condition it is in when received from its manufacturer or supplier and does not account for any alteration after receipt.

Permanent total enclosure (PTE) means a permanently installed enclosure that meets the criteria of Method 204 of appendix M, 40 CFR part 51, for a PTE and that directs all the exhaust gases from the enclosure to an add-on control device.

Protective oil means an organic material that is applied to metal for the purpose of providing lubrication or protection from corrosion without forming a solid film. This definition of protective oil includes, but is not limited to, lubricating oils, evaporative oils (including those that evaporate completely), and extrusion oils.

Research or laboratory facility means a facility whose primary purpose is for research and development of new processes and products, that is conducted under the close supervision of technically trained personnel, and is not engaged in the manufacture of final or intermediate products for commercial purposes, except in a de minimis manner.

Responsible official means responsible official as defined in 40 CFR 70.2.

Startup, initial means the first time equipment is brought online in a facility.

Surface preparation means use of a cleaning material on a portion of or all of a substrate. This includes use of a cleaning material to remove dried coating, which is sometimes called ''depainting.''

Temporary total enclosure means an enclosure constructed for the purpose of measuring the capture efficiency of pollutants emitted from a given source as defined in Method 204 of appendix M, 40 CFR part 51.

Thinner means an organic solvent that is added to a coating after the coating is received from the supplier.

Total volatile hydrocarbon (TVH) means the total amount of nonaqueous volatile organic matter determined according to Methods 204 and 204A through 204F of appendix M to 40 CFR part 51 and substituting the term TVH each place in the methods where the term VOC is used. The TVH includes both VOC and non-VOC.

Uncontrolled coating operation means a coating operation from which none of the organic HAP emissions are routed through an emission capture system and add-on control device.

Volatile organic compound (VOC) means any compound defined as VOC in 40 CFR 51.100(s).

Volume fraction of coating solids means the ratio of the volume of coating solids (also known as volume of nonvolatiles) to the volume of coating; liters of coating solids per liter of coating.

Wastewater means water that is generated in a coating operation and is collected, stored, or treated prior to being discarded or discharged.

Tables to Subpart RRRR of Part 63

If you are required to comply with operating limits by § 63.4892, you must comply with the applicable operating limits in the following table:

TABLE 1 TO SUBPART RRRR OF PART 63.—OPERATING LIMITS IF USING THE EMISSION RATE WITH ADD-ON CONTROLS OPTION

For the following device * * *	You must meet the following operating limit * * *	And you must demonstrate continuous compliance with the operating limit by * * *
1. thermal oxidizer	the average combustion temperature in any 3-hour period must not fall below the combustion temperature limit established according to § 63.4967(a).	i. collecting the combustion temperature data according to § 63.4968(c); ii. reducing the data to 3-hour block averages; and iii. maintaining the 3-hour average combustion at or above the temperature limit.
2. catalytic oxidizer	a. the average temperature measured just before the catalyst bed in any 3-hour period must not fall below the limit established according to § 63.4967(b).	i. collecting the temperature data according to § 63.4968(c); ii. reducing the data to 3-hour block averages; and iii. maintaining the 3-hour average temperature before the catalyst bed at or above the temperature limit.
	b. either ensure that the average temperature difference catalyst bed in any 3-hour period does not fall below the temperature difference limit established according to § 63.4967(b) or develop and implement an inspection and maintenance plan according to § 63.4967(b)(3) and (4).	i. either collecting the temperature data according to across the § 63.4968(c), reducing the data to 3-hour block averages, and maintaining the 3-hour average temperature difference at or above the temperature difference limit; or ii. complying with the inspection and maintenance plan developed according to § 63.4967(b)(3) and (4).
3. carbon adsorber	a. the total regeneration desorbing gas (e.g., steam or nitrogen) mass flow for each carbon bed regeneration cycle must not fall below the total regeneration desorbing gas mass flow limit established according to § 63.4967(c).	i. measuring the total regeneration desorbing gas (e.g., steam or nitrogen) mass flow for each regeneration cycle according to § 63.4968(d); and ii. maintaining the total regeneration desorbing gas mass flow at or above the mass flow limit.

TABLE 1 TO SUBPART RRRR OF PART 63.—OPERATING LIMITS IF USING THE EMISSION RATE WITH ADD-ON CONTROLS OPTION—Continued

For the following device * * *	You must meet the following operating limit * * *	And you must demonstrate continuous compliance with the operating limit by * * *
	b. the temperature of the carbon bed, after completing each regeneration and any cooling cycle, must not exceed the carbon bed temperature limit established according to § 63.4967(c).	i. measuring the temperature of the carbon bed, after completing each regeneration and any cooling cycle, according to § 63.4968(d); and ii. operating the carbon beds such that each carbon bed is not returned to service until completing each regeneration and any cooling cycle until the recorded temperature of the carbon bed is at or below the temperature limit.
4. condenser	the average condenser outlet (product side) gas temperature in any 3-hour period must not exceed the temperature limit established according to § 63.4967(d).	i. collecting the condenser outlet (product side) gas temperature according to § 63.4968(e); ii. reducing the data to 3-hour block averages; and iii. maintaining the 3-hour average gas temperature at the outlet at or below the temperature limit.
5. emission capture system that is a PTE according to § 63.4965(a).	the direction of the air flow at all times must be into the enclosure; and either the average facial velocity of air through all natural draft openings in the enclosure must be at least 200 feet per minute; or the pressure drop across the enclosure must be at least 0.007 inch H2O, as established in Method 204 of appendix M to 40 CFR part 51.	i. collecting the direction of air flow, and either the facial velocity of air through all natural draft openings according to § 63.4968(f)(1) or the pressure drop across the enclosure according to § 63.4968(f)(2); and ii. maintaining the facial velocity of air flow through all natural draft openings or the pressure drop at or above the facial velocity limit or pressure drop limit, and maintaining the direction of air flow into the enclosure at all times.
6. emission capture system that is a PTE according to § 63.4965(a).	the average gas volumetric flow rate or duct static pressure in each duct between a capture device and add-on control device inlet in any 3-hour period must not fall below the average volumetric flow rate or duct static pressure limit established for that capture device according to § 63.4967(e).	i. collecting the gas volumetric flow rate or duct static pressure for each not capture device according to § 63.4968(f); ii. reducing the data to 3-hour block averages; and iii. maintaining the 3-hour average gas volumetric flow rate or duct static pressure for each capture device at or above the gas volumetric flow rate or duct static pressure limit.
7. concentrators, including zeolite wheels and rotary carbon adsorbers.	a. the average gas temperature of the desorption concentrate stream in any 3-hour period must not fall below the limit established according to § 63.4967(g).	i. collecting the temperature data according to 63.4968(g); ii. reducing the data to 3-hour block averages; and iii. maintaining the 3-hour average temperature at or above the temperature limit.
	b. the average pressure drop of the dilute stream across the concentrator in any 3-hour period must not fall below the limit established according to § 63.4967(g).	i. collecting the pressure drop data according to § 63.4968(g); ii. reducing the pressure drop data to 3-hour block averages; and iii. maintaining the 3-hour average pressure drop at or above the pressure drop limit.

You must comply with the applicable General Provisions requirements according to the following table:

TABLE 2 TO SUBPART RRRR OF PART 63.—APPLICABILITY OF GENERAL PROVISIONS TO SUBPART RRRR

Citation	Subject	Applicable to subpart RRRR	Explanation
§ 63.1(a)(1)–(14)	General Applicability	Yes.	
§ 63.1(b)(1)–(3)	Initial Applicability Determination	Yes	Applicability to subpart RRRR is also specified in § 63.4881.
§ 63.1(c)(1)	Applicability After Standard Established	Yes.	
§ 63.1(c)(2)–(3)	Applicability of Permit Program for Area Sources.	No	Area sources are not subject to subpart RRRR.
§ 63.1(c)(4)–(5)	Extensions and Notifications	Yes.	
§ 63.1(e)	Applicability of Permit Program Before Relevant Standard is Set.	Yes.	
§ 63.2	Definitions	Yes	Additional definitions are specified in § 63.4981.
§ 63.3(a)–(c)	Units and Abbreviations	Yes.	

TABLE 2 TO SUBPART RRRR OF PART 63.—APPLICABILITY OF GENERAL PROVISIONS TO SUBPART RRRR—Continued

Citation	Subject	Applicable to subpart RRRR	Explanation
§ 63.4(a)(1)–(5)	Prohibited Activities	Yes.	
§ 63.4(b)–(c)	Circumvention/Severability	Yes.	
§ 63.5(a)	Construction/Reconstruction	Yes.	
§ 63.5(b)(1)–(6)	Requirements for Existing, Newly Constructed, and Reconstructed Sources.	Yes.	
§ 63.5(d)	Application for Approval of Construction/Reconstruction.	Yes.	
§ 63.5(e)	Approval of Construction/Reconstruction	Yes.	
§ 63.5(f)	Approval of Construction/Reconstruction Based on Prior State Review.	Yes.	
§ 63.6(a)	Compliance With Standards and Maintenance Requirements—Applicability.	Yes.	
§ 63.6(b)(1)–(7)	Compliance Dates for New and Reconstructed Sources.	Yes	Section 63.4883 specifies the compliance dates.
§ 63.6(c)(1)–(5)	Compliance Dates for Existing Sources	Yes	Section 63.4883 specifies the compliance dates.
§ 63.6(e)(1)–(2)	Operation and Maintenance	Yes.	
§ 63.6(e)(3)	Startup, Shutdown, and Malfunction Plan	Yes	Only sources using an add-on control device to comply with the standard must complete startup, shutdown, and malfunction plans.
§ 63.6(f)(1)	Compliance Except During Startup, Shutdown, Malfunction.	Yes	Applies only to sources using an add-on and control device to comply with the standard.
§ 63.6(f)(2)–(3)	Methods for Determining Compliance	Yes.	
§ 63.6(g)(1)–(3)	Use of an Alternative Standard	Yes.	
§ 63.6(h)	Compliance With Opacity/Visible Emission Standards.	No	Subpart RRRR does not establish opacity standards and does not require continuous opacity monitoring systems (COMS).
§ 63.6(i)(1)–(16)	Extension of Compliance	Yes.	
§ 63.6(j)	Presidential Compliance Exemption	Yes.	
§ 63.7(a)(1)	Performance Test Requirements—Applicability.	Yes	Applies to all affected sources. Additional requirements for performance testing are specified in §§ 63.4964, 63.4965, and 63.4966.
§ 63.7(a)(2)	Performance Test Requirements—Dates	Yes	Applies only to performance tests for capture system and control device efficiency at sources using these to comply with the standard. Section 63.4960 specifies the schedule for performance test requirements that are earlier than those specified in 63.7(a)(2).
§ 63.7(a)(3)	Performance Tests Required by the Administrator.	Yes.	
§ 63.7(b)–(e)	Performance Test Requirements—Notification, Quality Assurance, Facilities Necessary for Safe Testing, Conditions During Test.	Yes	Applies only to performance tests for capture system and add-on control device efficiency at sources using these to comply with the standard.
§ 63.7(f)	Performance Test Requirements—Use of Alternative Test Method.	Yes	Applies to all test methods except those used to determine capture system efficiency.
§ 63.7(g)–(h)	Performance TestRequirements—Data Analysis, Recordkeeping, Reporting, Waiver of Test.	Yes	Applies only to performance tests for capture system and add-on control device efficiency at sources using these to comply with the standard.
§ 63.8(a)(1)–(3)	Monitoring Requirements—Applicability	Yes	Applies only to monitoring of capture system and add-on control device efficiency at sources using these to comply with the standard. Additional requirements for monitoring are specified in § 63.4968.
§ 63.8(a)(4)	Additional Monitoring Requirements	No	Subpart RRRR does not have monitoring requirements for flares.
§ 63.8(b)	Conduct of Monitoring	Yes.	
§ 63.8(c)(1)–(3)	Continuous Monitoring System (CMS) Operation and Maintenance.	Yes	Applies only to monitoring of capture system and add-on control device efficiency at sources using these to comply with the standard. Additional requirements for CMS operations and maintenance are specified in § 63.4968.
§ 63.8(c)(4)	CMSs	No	Section 63.4968 specifies the requirements for the operation of CMS for capture systems and add-on control devices at sources using these to comply.

TABLE 2 TO SUBPART RRRR OF PART 63.—APPLICABILITY OF GENERAL PROVISIONS TO SUBPART RRRR—Continued

Citation	Subject	Applicable to subpart RRRR	Explanation
§ 63.8(c)(5)	COMS	No	Subpart RRRR does not have opacity or visible emission standards.
§ 63.8(c)(6)	CMS Requirements	No	Section 63.4968 specifies the requirements for monitoring systems for capture systems and add-on control devices at sources using these to comply.
§ 63.8(c)(7)	CMS Out-of-Control Periods	Yes.	
§ 63.8(c)(8)	CMS Out-of-Control Periods reporting	No	Section 63.4920 requires reporting of CMS out-of-control periods.
§ 63.8(d)–(e)	Quality Control Program and CMS Performance Evaluation.	No	Subpart RRRR does not require the use of continuous emissions monitoring systems.
§ 63.8(f)(1)–(5)	Use of an Alternative Monitoring Method	Yes.	
§ 63.8(f)(6)	Alternative to Relative Accuracy Test	No	Subpart RRRR does not require the use of continuous emissions monitoring systems.
§ 63.8(g)(1)–(5)	Data Reduction	No	Sections 63.4967 and 63.4968 specify monitoring data reduction.
§ 63.9(a)–(d)	Notification Requirements	Yes.	
§ 63.9(e)	Notification of Performance Test	Yes	Applies only to capture system and add-on control device performance tests at sources using these to comply with the standard.
§ 63.9(f)	Notification of Visible Emissions/Opacity Test	No	Subpart RRRR does not have opacity or visible emission standards.
§ 63.9(g)(1)–(3)	Additional Notifications When Using CMS	No	Subpart RRRR does not require the use of continuous emissions monitoring systems.
§ 63.9(h)	Notification of Compliance Status	Yes	Section 63.4910 specifies the dates for submitting the notification of compliance status.
§ 63.9(i)	Adjustment of Submittal Deadlines	Yes.	
§ 63.9(j)	Change in Previous Information	Yes.	
§ 63.10(a)	Recordkeeping/Reporting—Applicability and General Information.	Yes.	
§ 63.10(b)(1)	General Recordkeeping Requirements	Yes	Additional requirements are specified in §§ 63.4930 and 63.4931.
§ 63.10(b)(2)(i)–(v)	Recordkeeping Relevant Startup, to Shutdown, and Malfunction Periods and CMS.	Yes	Requirements for Startup, Startup, Shutdown, and Malfunction records only apply to add-on control devices used to comply with the standard.
§ 63.10(b)(2)(vi)–(xi)		Yes.	
§ 63.10(b)(2)(xii)	Records	Yes.	
§ 63.10(b)(2)(xiii)		No	Subpart RRRR does not require the use of continuous emissions monitoring systems.
§ 63.10(b)(2)(xiv)		Yes.	
§ 63.10(b)(3)	Recordkeeping Requirements for Applicability Determinations.	Yes.	
§ 63.10(c)(1)–(6)	Additional Recordkeeping Requirements for Sources with CMS.	Yes.	
§ 63.10(c)(7)–(8)		No	The same records are required in § 63.4920(a)(7)
§ 63.10(c)(9)–(15)		Yes.	
§ 63.10(d)(1)	General Reporting Requirements	Yes	Additional requirements are specified in § 63.4920.
§ 63.10(d)(2)	Report of Performance Test Results	Yes	Additional requirements are specified in § 63.4920(b).
§ 63.10(d)(3)	Reporting Opacity or Visible Emissions Observations.	No	Subpart RRRR does not require opacity or visible emissions observations.
§ 63.10(d)(4)	Progress Reports for Sources With Compliance Extensions.	Yes.	
§ 63.10(d)(5)	Startup, Shutdown, and Malfunction Reports	Yes	Applies only to add-on control devices at sources using these to comply with the standard.
§ 63.10(e)(1)–(2)	Additional CMS Reports	No	Subpart RRRR does not require the use of continuous emissions monitoring systems.
§ 63.10(e)(3)	Excess Emissions/CMS Performance Reports	No	Section 63.4920(b) specifies the contents of periodic compliance reports.
§ 63.10(e)(4)	COMS Data Reports	No	Subpart RRRR does not specify requirements for opacity or COMS.
§ 63.10(f)	Recordkeeping/Reporting Waiver	Yes.	
§ 63.11	Control Device Requirements/Flares	No	Subpart RRRR does not specify use of flares for compliance.
§ 63.12	State Authority and Delegations	Yes.	

TABLE 2 TO SUBPART RRRR OF PART 63.—APPLICABILITY OF GENERAL PROVISIONS TO SUBPART RRRR—Continued

Citation	Subject	Applicable to subpart RRRR	Explanation
§ 63.13	Addresses	Yes.	
§ 63.14	Incorporation by Reference	Yes.	
§ 63.15	Availability of Information/Confidentiality	Yes.	

You may use the mass fraction values in the following table for solvent blends for which you do not have test data or manufacturer's formulation data:

TABLE 3 TO SUBPART RRRR OF PART 63.—DEFAULT ORGANIC HAP MASS FRACTION FOR SOLVENTS AND SOLVENT BLENDS

Solvent/Solvent blend	CAS. No.	Average organic HAP mass fraction	Typical organic HAP, percent by mass
1. Toluene	108–88–3	1.0	Toluene.
2. Xylene(s)	1330–20–7	1.0	Xylenes, ethylbenzene.
3. Hexane	110–54–3	0.5	n-hexane.
4. n-Hexane	110–54–3	1.0	n-hexane.
5. Ethylbenzene	100–41–4	1.0	Ethylbenzene.
6. Aliphatic 140		0	None.
7. Aromatic 100		0.02	1% xylene, 1% cumene.
8. Aromatic 150		0.09	Naphthalene.
9. Aromatic naphtha	64742–95–6	0.02	1% xylene, 1% cumene.
10. Aromatic solvent	64742–94–5	0.1	Naphthalene.
11. Exempt mineral spirits	8032–32–4	0	None.
12. Ligroines (VM & P)	8032–32–4	0	None.
13. Lactol spirits	64742–89–6	0.15	Toluene.
14. Low aromatic white spirit	64742–82–1	0	None.
15. Mineral spirits	64742–88–7	0.01	Xylenes.
16. Hydrotreated naphtha	64742–48–9	0	None.
17. Hydrotreated light distillate	64742–47–8	0.001	Toluene.
18. Stoddard solvent	8052–41–3	0.01	Xylenes.
19. Super high-flash naphtha	64742–95–6	0.05	Xylenes.
20. Varsol® solvent	8052–49–3	0.01	0.5% xylenes, 0.5% ethyl benzene.
21. VM & P naphtha	64742–89–8	0.06	3% toluene, 3% xylene.
22. Petroleum distillate mixture	68477–31–6	0.08	4% naphthalene, 4% biphenyl.

You may use the mass fraction values in the following table for solvent blends for which you do not have test data or manufacturer's formulation data:

TABLE 4 TO SUBPART RRRR OF PART 63.—DEFAULT ORGANIC HAP MASS FRACTION FOR PETROLEUM SOLVENT GROUPS [a]

Solvent type	Average organic HAP mass fraction	Typical organic HAP, percent by mass
Aliphatic [b]	0.03	1% Xylene, 1% Toluene, and 1% Ethylbenzene.
Aromatic [c]	0.06	4% Xylene, 1% Toluene, and 1% Ethylbenzene.

[a] Use this table only if the solvent blend does not match any of the solvent blends in Table 3 to this subpart and you only know whether the blend is aliphatic or aromatic.

[b] e.g., Mineral Spirits 135, Mineral Spirits 150 EC, Naphtha, Mixed Hydrocarbon, Aliphatic Hydrocarbon, Aliphatic Naphtha, Naphthol Spirits, Petroleum Spirits, Petroleum Oil, Petroleum Naphtha, Solvent Naphtha, Solvent Blend.

[c] e.g., Medium-flash Naphtha, High-flash Naphtha, Aromatic Naphtha, Light Aromatic Naphtha, Light Aromatic Hydrocarbons, Aromatic Hydrocarbons, Light Aromatic Solvent.

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Part III

Nuclear Regulatory Commission

10 CFR Parts 20, 32, and 35

Medical Use of Byproduct Material; Final Rule

NUCLEAR REGULATORY COMMISSION

10 CFR Parts 20, 32, and 35

RIN 3150–AF74

Medical Use of Byproduct Material

AGENCY: Nuclear Regulatory Commission.

ACTION: Final rule.

SUMMARY: The Nuclear Regulatory Commission (NRC) is amending its regulations regarding the medical use of byproduct material. This final rule is one component of the Commission's overall program for revising its regulatory framework for medical use. The overall goals of this program are to focus NRC's regulations on those medical procedures that pose the highest risk to workers, patients, and the public, and to structure its regulations to be more risk-informed and more performance-based, consistent with the NRC's ''Strategic Plan for Fiscal Year 1997–Fiscal Year 2002.''

EFFECTIVE DATE: This regulation becomes effective on October 24, 2002.

ADDRESSES: Documents related to this rulemaking may be examined at the NRC Public Document Room, One White Flint North, 11555 Rockville Pike, Room O–1 F23, Rockville, MD 20852. Available documents include the final environmental assessment, regulatory analysis, regulatory flexibility analysis, and NUREG–1556, Vol. 9(draft), ''Consolidated Guidance About Materials Licenses: Program Specific Guidance About Medical Use Licenses.'' Documents created or received at the NRC after November 1, 1999, are also available electronically at the NRC's Public Electronic Reading Room on the Internet at *http://www.nrc.gov/reading-rm.html.* From this site, the public can gain entry into the NRC's Agencywide Document Access and Management System (ADAMS), which provides text and image files of NRC's public documents. For more information, contact the NRC Public Document Room (PDR) Reference staff at 1–800–397–4209, 301–415–4737 or by E-mail to *pdr@nrc.gov.*

FOR FURTHER INFORMATION CONTACT: Roger W. Broseus, Office of Nuclear Material Safety and Safeguards, Nuclear Regulatory Commission, Washington, DC 20555–0001, (301) 415–7608, E-mail RWB@nrc.gov.

SUPPLEMENTARY INFORMATION:

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I. Background

Use of Byproduct Material in Medicine

Since 1946, growth in the medical applications of radioisotopes has been very rapid as their usefulness has become more apparent in diagnosis, therapy, and medical research. Today, approximately eleven million patients undergo medical procedures involving byproduct material annually.

Current medical procedures employ a number of radionuclides in a wide variety of chemical and physical forms. Nuclear medicine procedures for diagnostic and therapeutic applications involve the internal administration of radiolabeled tracers. Administration of the radiolabeled tracers, known as radiopharmaceuticals, may be performed by intravenous injection, inhalation, or oral ingestion. In most cases, diagnostic nuclear medicine involves imaging agents used for the delineation and localization of organ tissues by scintigraphy (e.g., technetium-99m hydroxymethylene diphosphonate used as a bone seeking radiopharmaceutical). Organ function may be determined by quantifying the accumulation of radiopharmaceuticals in organs of interest (e.g., iodine-131 uptake studies used to assess thyroid function). Therapeutic nuclear medicine may use various radiopharmaceuticals for the treatment of disease by selective absorption or concentration (e.g., iodine-131 used to treat thyroid cancer). Other therapeutic applications may involve the use of radiopharmaceuticals in colloidal suspensions for the treatment of malignant tumors (e.g., phosphate-32 infusion for treatment of peritoneal or pleural effusions associated with malignant tumors).

Since the early 1900s, radiation therapy has become one of the major modalities of treatment in the management of neoplastic disease, generally referred to as cancer. Radiation therapy may also be used as a palliative agent in the medical treatment process. The objective of conventional radiation therapy using a teletherapy sealed source is to deliver a precisely measured dose of radiation to a defined tumor volume. This is usually accomplished by delivering a dose in daily increments over several weeks. External beam radiation therapy has evolved using innovative technology that has led to the development of the gamma stereotactic radiosurgery device used for treatment of precisely defined intracranial targets (e.g., brain tumors and arteriovenous malformations).

Brachytherapy uses a variety of smaller sealed sources for localized treatment of cancer. Typically, the sealed sources are either inserted in a cavity (e.g., cesium-137 sources used for intracavitary treatment of cervical cancer) or implanted in tissue (e.g., iodine-125 seeds used for interstitial treatment of prostate cancer). Various remote afterloading devices have been developed for low, medium, and high dose-rate brachytherapy treatments.

State and Federal Regulations

Byproduct material and radiation from byproduct material are regulated by either State or Federal laws and regulations. The principal statutory authority for NRC's regulation of the medical use of byproduct material rests in the Atomic Energy Act (AEA) of 1954, as amended, and the Energy Reorganization Act of 1974, as amended. NRC's medical use program includes regulation of the uses of byproduct material in medical diagnosis, therapy, and research. The NRC regulates the administration of byproduct material or radiation from byproduct material in 18 States, the District of Columbia, the Commonwealth of Puerto Rico, and various territories of the United States. There are approximately 1700 NRC licensees authorized for medical use of byproduct material under 10 CFR Part 35, ''Medical Uses of Byproduct Material.''

Thirty-two States have each entered into an agreement with the NRC to regulate the use of byproduct material (as authorized by section 274 of the Atomic Energy Act) within that State. These States issue licenses for certain diagnostic and therapeutic uses of radioactive materials, and currently regulate approximately 4200 institutions, e.g., hospitals, clinics, or physicians in private practice. For additional information on the

Agreement States' regulatory program refer to NRC's Management Directive (M.D.) 5.6, ''Integrated Materials Performance Evaluation Program (IMPEP),'' and M.D. 5.9, ''Adequacy and Compatibility of Agreement States Programs.''

Revision of NRC's Regulatory Program

The Commission examined the issues surrounding its medical use program in detail during a 1993 internal senior management review, a 1996 independent external review by the National Academy of Sciences, Institute of Medicine, and the Commission's Strategic Assessment and Rebaselining Project (SA). In particular, medical oversight was addressed in the SA Direction-Setting Issue Paper Number 7 (DSI 7) (released September 16, 1996). In September 1997, the Commission issued its ''Strategic Plan'' (NUREG–1614, Vol. 1) which stated that its goal in regulating nuclear materials safety is to ''prevent radiation-related deaths or illnesses due to civilian use of source, byproduct, and special nuclear materials.''

In its Staff Requirements Memorandum (SRM)—COMSECY–96–057, ''Materials/Medical Oversight (DSI 7),'' dated March 20, 1997, the Commission stated that it supported continuation of the ongoing medical use regulatory program with improvements, decreased oversight of low-risk activities, and continued emphasis on high-risk activities. This SRM also directed the NRC staff to revise Part 35, associated guidance documents, and, if necessary, the Commission's 1979 Medical Use Policy Statement (MPS) (44 FR 8242; February 9, 1979). The Commission's SRM specifically directed the restructuring of Part 35 into a risk-informed, more performance-based regulation. In addition, the Commission expressed its support for the use of the NRC's Advisory Committee on the Medical Uses of Isotopes (ACMUI) and professional medical organizations and societies in the revision of Part 35 and the MPS.

Based on the Commission's direction in this SRM, the process used by the NRC staff to develop the proposed rule and policy statement provided more opportunity for input from potentially affected parties than the normal notice and comment rulemaking process. The process included a number of public meetings and workshops with stakeholders and other affected parties, the ACMUI, Agreement States, and professional medical societies and organizations. See the proposed rule and policy statement published in the **Federal Register** (63 FR 43516; 63 FR 43580; August 13, 1998).

The Commission, in its SRM of June 30, 1997, SECY–97–115—''Program for Revision of 10 CFR Part 35, 'Medical Uses of Byproduct Material' and Associated **Federal Register** Notice,'' approved the NRC staff's proposed plan for the revision of Part 35. In a document published in the **Federal Register**, ''Medical Use of Byproduct Material: Issues and Request for Public Input'' (62 FR 42219–42220; August 6,1997), the Commission solicited early public input on the proposed rulemaking.

The proposed revisions of Part 35 and the MPS that were developed in response to the Commission's SRMs were published for a 90-day public comment period on August 13, 1998 (63 FR 43516 and 63 FR 43580). The comment period was later extended by 30 days (63 FR 64829; November 23, 1998) at the request of stakeholders. The document presenting the contemplated revision of Part 35 solicited public comment on the proposed rule; discussed the issues that were considered during the development of the proposed rule and associated guidance; and summarized the input that was received from the public, potentially affected parties, the ACMUI, and professional medical organizations. These issues included patient notification, precursor events, Radiation Safety Committee, quality management program, and training and experience for authorized users.

In addition to publishing the proposed rule and MPS in the **Federal Register** for comment, the Commission also held facilitated public meetings during the comment period to discuss the Commission's resolution of the major issues. Publicly noticed workshops were held in San Francisco, CA, on August 19–20, 1998, in Kansas City, MO, on September 16–17, 1998, and in Rockville, MD, on October 21–22, 1998. The Commission also held a public workshop in February 1999 to solicit additional comments on implementation issues associated with the proposed revisions to the training and experience requirements. The Commission was specifically interested in information on the process and criteria for approving medical and other specialty boards and examining organizations and entities. The four public workshops are summarized in ''Summary of Public Meeting on Proposed Revisions to Part 35 and the NRC's Medical Policy Statement,'' San Francisco, CA, August 19–20, 1998 (September 11, 1998); ''Summary of Public Meeting on Proposed Revisions to 10 CFR Part 35, ''Medical Use of Byproduct Material'' and the NRC's Medical Policy Statement,'' Kansas City, MO, September 16–17, 1998 (October 12, 1998); ''Summary of Public Meeting on Proposed Revisions to 10 CFR Part 35, ''Medical Use of Byproduct Material'' and the NRC's Medical Policy Statement,'' Rockville, MD, October 21–22, 1998 (November 18, 1998); and ''Summary of Discussion; Facilitated Part 35 Public Meeting with Representatives of the Medical Boards Held in Rockville, Maryland, February 17–18, 1999'' (April 7, 1999). The summary documents are available for inspection at the NRC Public Document Room, One White Flint North, 11555 Rockville Pike, Room O–1 F23, Rockville, MD 20852. Single copies of the summary documents are available from the persons indicated in the For Further Information Contact section of this document.

The comments received at the workshops and the comments received in response to the proposed rule were all carefully considered by the Part 35 Working and Steering Groups in developing the final rule. Section III, Summary of Public Comments and Responses to Comments, in the **SUPPLEMENTARY INFORMATION** in this document, includes a summary of the comments and the NRC staff's responses to them.

In February 1999, the ACMUI diagnostic and therapeutic subcommittees held public meetings to review the public comments and the NRC staff's first draft of the final rule that addressed the comments. The full ACMUI held a public meeting in March 1999 to discuss specific issues that the Part 35 Working Group wanted the ACMUI to review and comment on before a draft final rule was forwarded for Commission consideration. The ACMUI presented its position on these and other issues at their annual briefing of the Commission in March 1999. In October 1999 and February 2002, the ACMUI briefed the Commission on specific issues that it wanted to bring to the Commission's attention. For additional information on the ACMUI's position on the rulemaking and associated issues refer to Section VI, Coordination with the Advisory Committee on the Medical Uses of Isotopes, in the **SUPPLEMENTARY INFORMATION** in this document.

The Agreement States were involved throughout the rulemaking process. Both the Working Group and Steering Group that developed the revision of Part 35 included representatives of the Agreement States. A draft compatibility chart for Agreement States' regulations

was published for comment with the proposed rule (63 FR 43516; August 13, 1998). The NRC staff discussed the States' rulemaking issues with representatives of the Agreement States at the 1999 annual meeting of the Organization of Agreement States. For additional information refers to Section IV, Summary of Comments on Agreement State Compatibility and Responses to Comments; Section VI, Coordination with NRC Agreement States; and Section X, Issues of Compatibility for Agreement States, in the **SUPPLEMENTARY INFORMATION** in this document.

As the Commission readied the final rule for publication in the **Federal Register**, Congress directed NRC not to implement or enforce certain parts of revised Part 35 relating to diagnostic nuclear medicine until after the NRC submitted a report to Congress explaining why the regulatory burden associated with the rule could not be reduced further without adversely affecting the public health and safety. ''Energy and Water Development Appropriations Act, 2002,'' (Pub. L. 107–66). The NRC transmitted the report to Congress on February 11, 2002. That report concludes that further reduction of regulatory burden beyond that currently proposed in the revised rule has the potential to increase the risk to public health and safety. Although the Act permitted NRC to implement some aspects of the revised rule before submitting the report, NRC chose not to implement any portion of the revised rule until after its report was submitted.

Nevertheless, the NRC acknowledges that stakeholders have identified substantial concerns related to the perceived burden of the implementing guidance and inspection programs. Therefore, the NRC is committed to a program, with public and stakeholder participation, to improve the licensing and inspection guidance to enhance the burden reduction offered by revised Part 35. The NRC noticed the availability of revised draft NUREG–1556, Volume 9, for public comment (67 FR 16467; April 5, 2002); the comment period ends on June 4, 2002. In addition, consideration of future rule changes will remain possible through the NRC's established rulemaking procedures as experience with the new rule is gained by both the NRC and our licensees.

In addition to the revision of Part 35, the Commission published the revision of its policy statement on the Medical Use of Byproduct Material (MPS) (65 FR 47654; August 3, 2000). The revision of the MPS is another component of the Commission's overall program for revising its regulatory framework for medical use. The revision of Part 35 is consistent with the revision of the MPS. Section VIII, Consistency with the Medical Policy Statement, in the **SUPPLEMENTARY INFORMATION** in this document, addresses the consistency of the final rule with each statement in the revised MPS.

The Commission is also concurrently publishing, in a separate document in this **Federal Register**, a modification of ''General Statement of Policy and Procedure for NRC Enforcement Actions,'' NUREG–1600, to revise the examples of severity levels for Part 35 violations to reflect the revised medical use requirements in the final rule. These examples are used in the enforcement process to provide guidance for determining the significance of a particular violation.

Voluntary Consensus Standards

The National Technology Transfer and Advancement Act (NTTAA) of 1995, Public Law 104–113, requires that Federal agencies use technical standards that are developed or adopted by voluntary consensus standards bodies unless the use of such a standard is inconsistent with applicable laws or otherwise impractical. In COMSECY–96–057, ''Materials/Medical Oversight (DSI 7),'' the Commission specifically directed the NRC staff to examine the viability of using or referencing available industry guidance and standards, within Part 35 and related guidance, to the extent that they meet NRC's needs. In addition, Statement 4 in the revised medical use policy statement provides that the NRC regulatory approach consider industry and professional standards that define acceptable approaches of achieving radiation safety.

In developing this final rule, the NRC staff reviewed the technical literature to identify consensus standards and/or protocols that could be used or referenced either in the regulation or associated guidance document. This process included reviewing documents of the official standards consensus bodies that are identified on the National Institutes of Standards and Technology website, e.g., the American National Standards Institute (ANSI). In addition, the NRC staff reviewed protocols developed by technical professional societies that use a consensus process within their own organization, e.g., the American Association of Physicists in Medicine (AAPM). The NRC staff determined that voluntary consensus standards exist that met certain objectives in the final rule. Therefore, the NRC staff did not develop government-unique standards. The requirements in the final rule are, for the most part, performance-based and state the objectives to be achieved. This approach allows the licensee to select among various performance standards to meet the objectives of the regulation. This approach is consistent with the Commission's goal to develop more performance-based regulations. The Commission believes that this approach will provide medical use licensees with significant flexibility in designing their radiation protection programs.

For additional information on how consensus standards were used in the development of the final rule refer to Section III, Summary of Public Comments and Responses to Comments in the **SUPPLEMENTARY INFORMATION** in this document.

II. Petitions for Rulemaking (PRM)

PRM–20–24

The final rule completes action on a Petition for Rulemaking (PRM) filed by the University of Cincinnati, dated April 7,1996 (PRM 20–24), because of its pertinence to Part 35. The petitioner basically requested that the NRC amend 10 CFR 20.1301, ''Dose limits for individual members of the public'' to:

(1) Provide medical use licensees the discretion to permit those visitors determined by the physician to be necessary for the emotional or physical support of the patient to receive up to 5 mSv (0.5 rem) (e.g., parents of very young radiation therapy patients, close family members of elderly patients, or other persons who could provide emotional support to the patient);

(2) Exclude pregnant women and individuals younger than 18 years of age from receiving a dose in excess of 1 mSv (0.1 rem);

(3) Document compliance by issuing a radiation dose monitoring device (i.e., pocket dosimeter, film badge, TLD, or electronic dosimeter) to each specified visitor; and

(4) Require licensees to instruct visitors about radiation safety.

On June 21, 1996 (61 FR 31874), the NRC published a notice of receipt and a request for comment on this petition for rulemaking. The comments received in response to that document were discussed in the August 13, 1998, proposed rule (63 FR 43516). Additional comments on the petition were received in response to the request for comments on the proposed rule and are discussed in Section III, Part III of the **SUPPLEMENTARY INFORMATION** of this document.

The NRC reviewed the petitioner's request and comments received on the

petition and believes there is merit in granting the petition in part. The final rule responds to the petition by amending § 20.1301 to allow a licensee the discretion to permit visitors to receive up to 5 mSv (0.5 rem) in a year from exposure to hospitalized radiation patients, i.e., individuals who cannot be released under § 35.75. We believe the emotional benefit to the patient or the visitor outweighs any increase in radiation risk to the visitor. In addition, we believe that the authorized user (AU) is the appropriate individual to evaluate, on a case-by-case basis, the merits of allowing a visitor to potentially receive this additional dose and would do so only when it is warranted by the situation. AUs have the primary responsibility for the health and safety of their patients. They are also responsible for determining, depending on the patient's condition, whether individuals can visit patients and with what limitations. Therefore, we believe the AU should determine whether a visitor is allowed to receive a dose up to 5 mSv (0.5 rem).

The NRC did not grant request (2) of the petition that NRC exclude pregnant women and individuals younger than 18 years of age from receiving a dose in excess of 1 mSv (0.1 rem). Pregnant visitors are not excluded automatically from visiting individuals who cannot be released under § 35.75. The pregnant visitor is subject to the same exposure limits that are applied to any other adult member of the public. The reasons for not excluding pregnant visitors are two-fold. First, as noted in National Council on Radiation Protection and Measurements (NCRP) Commentary No. 11 (Dose Limits for Individuals Who Receive Exposure from Radionuclide Therapy Patients, 1995), members of a radionuclide therapy patient's family are likely to perceive that visitors will benefit from providing emotional and physical support to the patient during their treatment, and these visitors are likely to be willing to bear greater risk in order to achieve that benefit. Second, declaration of pregnancy by a prospective visitor is strictly voluntary. If a prospective visitor does not voluntarily declare her pregnant status, the AU is not expected to demand confirmation of the visitor's nonpregnant status.

The NRC also did not grant request (3) of the petition that compliance be documented by use of a radiation dose monitoring device (i.e., pocket dosimeter, film badge, TLD, or electronic dosimeter) by each specified visitor. The Commission does not intend to require monitoring and recording of individual doses to visitors of hospitalized radiation patients. The NRC evaluated the costs associated with monitoring doses to visitors versus the benefits derived and determined that, at these low doses, monitoring is not justified. However, this does not preclude the licensee from monitoring and recording doses to visitors.

The NRC also did not grant request (4) of the petition that licensees be required to instruct visitors about radiation safety. We believe that licensees should have flexibility in determining how they will effectively limit radiation exposure of the visitors to levels that are as low as is reasonably achievable.

This completes action on PRM–20–24.

PRM–35–16

On January 11, 2001, the NRC docketed a January 3, 2001, letter from Donald A. Podoloff, MD, of the American College of Nuclear Physicians, and Jonathan M. Links, PhD, of the Society of Nuclear Medicine, to the Office of the Secretary, as a petition for rulemaking under 10 CFR 2.802 (PRM–35–16). The petitioners requested that the Commission: rescind its approval of the NRC staff's proposed revision to 10 CFR Part 35, ''Medical Use of Byproduct Material''; revoke all of 10 CFR Part 35, except for specifically identified requirements; and institute a new rulemaking proceeding to adopt a regulatory scheme for the use of byproduct material in diagnostic nuclear medicine that reflects the discipline's ''unparalleled and undisputed safety record.''

The petitioners believe that the requested changes would benefit the public in two ways. First, substantial requirements for physicians' education, training, and experience, as well as appropriate evidence of mastery by testing would improve the knowledge and abilities of physicians offering diagnostic nuclear medicine. Second, costs to the health care system would decrease without any decrease in safety.

The NRC denied the petition because:

(1) The Commission approved the final rule addressing the issues raised in the petition after an extensive rulemaking process that provided an unprecedented level of enhanced stakeholder and public participation;

(2) The Commission believed that the ACNP/SNM had many opportunities to present their concerns and suggestions as part of that process and did so; and

(3) The petition did not appear to present any significant new information or recommendations that the Commission has not already considered.

This completes action on PRM–35–16.

III. Summary of Public Comments and Responses to Comments

This section summarizes the written and oral comments that we received on the proposed rule and provides responses to these comments. Part I contain a list of the acronyms used in this section. Part II discusses general issues that were considered during the rulemaking. Part III discusses specific comments on the proposed rule.

Part I—Acronyms

The following acronyms are used in the discussion of both the general and specific comments.

AAPM American Association of Physicists in Medicine
ABHP American Board of Health Physics
ABR American Board of Radiology
ABMS American Board of Medical Specialities
ABNM American Board of Nuclear Medicine
ACGME Accreditation Council for Graduate Medical Education
ACMP American College of Medical Physics
ACMUI Advisory Committee on the Medical Uses of Isotopes
ACR American College of Radiology
ALARA As low as is reasonably achievable
AMP Authorized medical physicist
ANP Authorized nuclear pharmacist
ANSI American National Standards Institute, Inc.
AO Abnormal Occurrence
AU Authorized user
FDA Food and Drug Administration
Gy/h Gray per hour
GBq Gigabecquerel
HDR High dose-rate remote afterloader
IDE Investigational Device Exemption
IMPEP Integrated Materials Performance Evaluation Program
IND Investigational New Drug Exemption
INPO Institute for Nuclear Power Operations
IRB Institutional Review Board
JCAHO Joint Commission on the Accreditation of Hospitals Organization
LDR Low dose-rate remote afterloader
MBq Megabecquerel
mCi Millicuries
μCi Microcuries
MDR Medium dose-rate remote afterloader
mSv Millisievert
NAS–IOM National Academy of Sciences-Institute of Medicine
NCRP National Council on Radiation Protection and Measurements
NIST National Institute of Standards and Technology

PDR Pulsed dose-rate remote afterloader
QMP Quality Management Program
SSDR Sealed Source and Device Registry
Sv Sievert
RDRC Radioactive Drug Research Committee
RSC Radiation Safety Committee
RSO Radiation Safety Officer

Part II—General Issues

A. Risk

Issue 1: What Is the Difference Between a Risk-Informed and a Risk-Based Approach to Rulemaking?

Comment. Commenters asked us to explain the difference between a ''risk-based'' rule and a ''risk-informed'' rule.

Response. A ''risk-based'' approach to regulatory decisionmaking is one in which a safety decision is solely based on the numerical results of a risk assessment. This places a heavier reliance on risk assessment results than currently may be practicable. A ''risk-informed'' approach to regulatory decisionmaking represents a philosophy that considers risk insights together with other factors to establish requirements that better focus licensee and regulatory attention on design and operational issues commensurate with their importance to health and safety.

The Commission does not endorse risk-based regulation. In revising Part 35, the Commission used risk insights from available risk information. The Commission considered the completeness and reliability of the available risk information and balanced the insights drawn from this information against other factors, such as decades of licensing and inspection experience, the States' perspectives, statutory requirements, and public and stakeholder interests, in formulating policy.

Issue 2: How Was Risk Used in Revising Part 35?

Comments. Commenters indicated that the NRC's approach to the Part 35 rulemaking was flawed because a formal risk analysis had not been performed before initiating the rulemaking. Some commenters did not believe that the NRC has the expertise to perform or manage a rigorous risk analysis that is needed before publishing the final rule. Other commenters believed the proposed rule did not explain NRC's perception of the regulatory problem and how the rulemaking would solve that problem. Commenters asked that the NRC start the Part 35 rulemaking over by—

(1) Identifying the problem (perform a formal risk-based analysis);

(2) Revising the Medical Policy Statement;

(3) Completing the rulemaking; and

(4) Developing licensing, inspection, and enforcement policies and procedures to support the rule.

Many of these commenters offered possible ways of evaluating risk and asked that stakeholders be allowed to participate in assessing risk. Some commenters indicated that the NRC should establish a risk-benefit ''filter'' to evaluate this and future rulemakings. They believed that this approach would be useful in dealing with emerging technologies. They also believed that, if the NRC had a structured framework for risk analysis, appropriate regulations could be developed to deal with the real risk to the patient, public, and workers.

Other commenters asked that we consider all types of risk before publishing the final rule, e.g., absolute, relative, comparable, perceived, cost, and ''pseudo risks.'' Commenters discussed these types of risks in the following terms and offered the following comments on each type of risk as they are viewed in the regulation of medicine. While most comments were directed at diagnostic nuclear medicine, many of the statements would also apply to therapeutic uses of byproduct material.

Absolute risks are the risks of real health effects (deterministic, stochastic) that include harm to the patient, public, or worker. Commenters indicated that diagnostic nuclear medicine procedures do not present measurable health effects to the patient, public, or workers.

Relative risks are the risks of diagnostic nuclear medicine relative to other diagnostic medical procedures that are currently unregulated for the end-user. The side-effects from many non-radiological medical procedures involve higher risks of harm to the patients than microcurie and millicurie amounts of byproduct material that are used for tracer and localization and imaging studies, where there is no observable radiological or pharmaceutical effect.

Comparable risks are the risks of diagnostic nuclear medicine as compared to other industrial risks (radiological and non-radiological) and other human activities that are acceptable to the general public.

Perceived risks involve the public perception of safe and unsafe uses of radiation that eventually influence the licensee to comply with unnecessary NRC requirements in order to compete in the market place. One commenter noted that most cancer patients are willing to accept higher risks for the benefit of cure. This commenter believed that the large number and prescriptiveness of the current regulations add to the misconception that the public has of radiation. By reducing needless requirements on low risk nuclear medicine, the public perception will adjust accordingly, so that NRC regulatory oversight is less burdensome to licensees.

Cost risks result in overspending on low risk activities. This economic imbalance creates a higher risk for other areas that do not receive the resources that would otherwise be available.

Pseudo risks are unreal risks in which there is no harm associated with the activity or event, e.g., landfill alarms as a result of disposal of short-lived, low-activity radioactive waste from diagnostic nuclear medicine.

Response. In March 1997, the Commission directed the revision and restructuring of Part 35 into a more risk-informed and, where appropriate, more performance-based regulation. This direction was part of the Commission's overall decision to decrease oversight of low-risk activities, such as diagnostic nuclear medicine, while retaining oversight of high-risk activities.

Before initiating the rulemaking, the Commission thoroughly reviewed several extensive assessments, including the external review conducted by the National Academy of Sciences, Institute of Medicine (NAS–IOM), and the related report ''Radiation in Medicine, A Need for Regulatory Reform,'' a 1993 NRC internal senior management review and report, and the Commission's Strategic Assessment and Rebaselining initiative. During the development of the overall revision of Part 35, we considered information on risk provided by members of the public and professional societies, professional medical standards of practice, and event databases maintained by NRC to determine where oversight of lower-risk activities could be decreased and where continuation, or even broadening, of the regulations governing higher-risk activities was needed. In addition, throughout the development of the proposed rule and associated proposed guidance, public workshops were held and early opportunities for comment from the public and other potentially affected parties were provided. These interactions included significant discussions on the risk associated with medical uses of byproduct material. In addition, NRC sought and received comments on the draft guidance document published in August 1998.

In further developing the licensing and inspection guidance, the NRC plans

to seek public comment and hold facilitated public workshops. The NRC expects that the development of the guidance will be completed before the effective date of the rule.

While the NRC did not perform a formal risk assessment, we believe that we have adequately evaluated and considered the risks associated with use of byproduct material in medicine. We have eliminated requirements in the current Part 35 that are contained elsewhere in the Commission's regulations, such as the radiation protection requirements in Part 20. Part 35 licensees will continue to be required to comply with these requirements, such as the ALARA provisions in Part 20, but we do not believe that there is a need to duplicate the requirements in Part 35 unless there are specific, additional radiation protection requirements that are applicable to medical use licensees. We have maintained some prescriptive requirements in the rule that we believe are necessary to ensure adequate protection of the workers, patients, and public. The statements of considerations for the proposed rule and for this final rule and the accompanying Regulatory Analysis explain why we believe changes needed to be made in the regulations.

Issue 3: Is the Risk of Byproduct Material in Diagnostic Nuclear Medicine Low?

Comment. Many commenters provided information indicating that risks associated with the use of byproduct material in diagnostic nuclear medicine is low. The commenters provided reasons for the deregulation of low risk nuclear medicine uses altogether. The commenters indicated that the average patient dose from administration of a single unit dose is comparable to the average annual radiation dose from natural background radiation in the United States. They believed that a zero risk tolerance is extremely impractical and the NRC should not attempt to regulate diagnostic nuclear medicine to account for errors that are harmless. Commenters indicated that the NRC should not substitute theoretical risk values for lack of measurable risk values, that ''real risk'' is based on real harms that are measurable, and that there are no measurable risks involved with diagnostic nuclear medicine.

Commenters went on to state that diagnostic nuclear medicine has an outstanding performance history and that there have been zero consequences to the patients, workers, and public. Another commenter stated that in over 300 million applications of radiation for diagnostic purposes, there has been only one death, which occurred over 30 years ago. Commenters believed that, by requiring compliance with regulations where there is no clear hazard or detrimental radiation dose, the NRC is diverting resources away from higher risk activities, e.g., non-radiological risks related to medical practice. This brand of economics for safety programs creates an unjustifiable imbalance of resource allocation for the licensee. They went on to say that an additional risk burden is placed on the higher, non-radiological risk activities because there is competition for finite resources that support NRC requirements for low risk nuclear medicine. In this sense, NRC requirements are overly burdensome for most licensees.

Response. The NRC agrees that the risk associated with the use of byproduct material in diagnostic nuclear medicine is low. For this reason, the final rule is much different from the current rule. In consideration of the low radiation risks in the diagnostic area, we have reduced the unnecessary regulatory burden for diagnostic nuclear medicine licensees by either eliminating or decreasing the prescriptiveness of the regulations that apply to them. Instead, we are relying on a performance-based approach that emphasizes the training and experience of the authorized user (AU), authorized nuclear pharmacist (ANP), and Radiation Safety Officer (RSO).

Issue 4: Can Regulation of Diagnostic Nuclear Medicine Be Limited to Part 20 and Training and Experience Requirements?

Comment. Commenters stated that the appropriate regulation of diagnostic nuclear medicine should involve only the radiation protection requirements in Part 20 and board certification requirements as an indication of medical competence. Another commenter identified the sections of the proposed rule asserted to perform no useful purpose and to have no risk-based justification. The identified provisions were: §§ 35.6, 35.11(c), 35.13(d), 35.24, 35.27, 35.60, 35.61, 35.62, 35.63, 35.69, 35.204, 35.2024, 35.2060, 35.2061, 35.2063, and 35.2204.

Response. The final rule includes requirements that are needed to protect occupationally exposed individuals, patients, and the public. Certain radiation protection-related requirements unique to medical use are needed in Part 35 because of their contribution to risk reduction. For example, the final rule retains requirements to calibrate instrumentation used to measure the radioactivity of patient dosages before they are administered (§ 35.60). For this reason and because the NRC believes that these requirements are essential to the safe handling of byproduct material, we believe the sections cited by the commenter should not be deleted from the rule. (Note, §§ 35.60 and 35.62 were combined in the final rule.)

B. Licensing

Issue 1: Should Diagnostic Nuclear Medicine Programs Be Given a General License Rather Than a Specific License?

Comments. Many commenters recommended that the NRC issue a general rather than a specific license for diagnostic nuclear medicine programs. The NRC's role would be to establish training and experience requirements for physicians, pharmacists, and RSOs. They indicated that the applicant would provide the NRC with their name, location, and contact information and pay a licensing fee to NRC. Commenters emphasized that, after satisfying the minimum training and experience criteria for low risk nuclear medicine programs, the physician should be authorized to receive and use byproduct material with minimal or no regulatory oversight.

Commenters compared the use of byproduct material in diagnostic nuclear medicine to medical uses of naturally-occurring or accelerator-produced radioactive material (NARM), e.g., thallium-201, gallium-67, and indium-111. Commenters indicated that several states currently have no regulatory authority for NARM. In those states, any physician could receive and use NARM for nuclear medicine procedures without either a registration or a license. There were no training and experience criteria or other radiation safety regulations for medical use of NARM—the medical use of NARM was controlled by current standards for medical care. Commenters believed that the unregulated medical use of NARM products justifies a similar lack of regulations for medical use of byproduct materials that are currently regulated by NRC.

Some commenters suggested that one of the state radiation control agencies should be allowed to establish a pilot program for general licensing of their nuclear medicine licensees. After a period of several years, the NRC could evaluate the pilot program. If the program were found to be successful, the NRC could revise its regulations to issue general licenses for diagnostic nuclear medicine facilities.

Some commenters indicated that it should not be necessary to identify a physician for the medical use program because the focus of the revised Part 35 will be on radiation safety rather than on the physician's (AU's) clinical competence. These commenters recommended that the licensing process be simplified to identify the name and contact information for the management representative responsible for radiation safety and to describe any byproduct material that is normally used and that could become hazardous to public health and safety during a catastrophic event, e.g., an earthquake or a serious fire/explosion. This commenter believed that the NRC should authorize the applicant for broad scope use of byproduct material and should not review the licensee's standard operating procedures before the authorization.

Some Agreement State commenters stated that they were opposed to the use of a general license in the medical use area. Commenters believed that, in the past, regulatory difficulties were created by general licenses for other non-medical uses, e.g., fixed gauges containing sealed sources. The Agreement State representatives believed that if this concept could not be supported for non-medical uses, then it was doubtful that it should be endorsed for medical uses. Many also believed a Radiation Safety Committee (RSC) should be retained to review all aspects of the radiation safety program before submitting an application to the regulatory agency and that the regulatory agency should continue to review procedures before the license or amendment was issued.

Response. The NRC believes that diagnostic nuclear medicine programs should continue to be specifically licensed rather than generally licensed. A specific license is needed because the potential exists for individuals in the diagnostic nuclear medicine setting to be exposed to radiation levels in excess of the Part 20 dose limits, because of the possession of significant quantities of unsealed material, and because the training and experience of the ANP, AU, and RSO are necessary for the safe handling of byproduct material. However, we have reduced the amount of documentation that must be submitted by an individual or organization that is applying for a specific license to use byproduct material in diagnostic nuclear medicine. When applying for this type of license, the applicant only needs to provide us with information on its facility and the training and experience of the authorized medical physicist (AMP), AMP, ANP, AU, and/or RSO, as appropriate. The applicant no longer needs to provide us with detailed operating and emergency procedures, e.g., dose calibrator calibration procedures, survey meter calibration procedures, or safe handling procedures. In many cases, the final rule gives licensees the flexibility to use either the procedures that have been developed by nationally recognized organizations or the manufacturer's instructions. The final rule also reduces the unnecessary regulatory burden on diagnostic nuclear medicine licensees by eliminating or reducing the prescriptiveness of the regulations concerning diagnostic nuclear medicine.

C. Inspection

Issue 1: Could NRC Use an Outside Accrediting Organization for Inspections in Diagnostic Nuclear Medicine?

Comment. Some commenters expressed a belief that the inspection program in diagnostic nuclear medicine was not necessary. They believed that the NRC could allow professional accreditation boards and organizations to conduct inspections on behalf of NRC. They state that these organizations are already involved with nationwide monitoring of the quality of nuclear medicine services in a peer review manner that encourages comprehensive improvement of quality and the safe use of radioactive materials. They compared this approach to NRC's recognition of the Institute of Nuclear Power Operations (INPO) for the reactor industry. These commenters went on to state that the low risks to patients, workers, and the public from the use of byproduct material for diagnostic nuclear medicine practices do not warrant the current level of NRC regulatory oversight.

These commenters also provided two examples in which a similar approach has been used in the medical community. One example is where the medical community and the Food and Drug Administration (FDA) worked closely in implementing the ''Mammography Quality Standards Reauthorization Act of 1998'' (Pub. L. 105–248). The FDA partnered with the American College of Radiology (ACR) to establish the ACR accreditation standards as Federally mandated practice standards for personnel, equipment, quality assurance, and other activities involved in mammography. These national standards have led to broad improvements in mammography nationwide. A second example is where the State bureaus for hospital standards recognize the Joint Commission on the Accreditation of Hospitals Organization (JCAHO) accreditation as evidence that State laws have been met by the certified institutions. This approach allows State governments to focus their resources on those facilities that are not certifiable by the JCAHO. This reduces duplication of inspection effort and provides cost savings to the medical institutions.

The commenters thought that the NRC should delegate the inspection program to an accrediting organization by rulemaking or by administrative action after the NRC has reviewed the accreditation organizations. They also indicated that this rulemaking or administrative action should result in a reduction in NRC fees assessed to licensees that voluntarily submit to the accreditation process.

Commenters indicated that the NRC should review the accrediting program to assure that the content of the current monitoring (accrediting) program was adequate and equivalent to the NRC inspection program. Commenters indicated that the site review teams would identify deficiencies, recommend corrective actions, allow time for implementation of improvements, and offer an appeal process to the licensees. They believed that the NRC should then recognize the accreditation organization monitoring programs as adequate to evaluate radiation safety practices of nuclear medicine licensees.

Along with the final rule, commenters recommended that the NRC post a list of approved accreditation boards and organizations. Licensees could voluntarily select the appropriate organization to evaluate their radiation safety programs. Accredited licensees would not be subject to direct inspection by NRC. Licensees that did not voluntarily select an NRC-approved accreditation organization would be subject to direct inspection by the NRC or an Agreement State. Commenters indicated that the NRC could audit the site review teams and randomly accompany them to observe the appropriateness of the evaluation process.

Commenters cautioned that the accreditation organizations should not become the enforcement arm of the NRC and should not be required to report detailed, confidential findings to NRC. Commenters believed a pass/fail list of licensees that voluntarily submitted to the site review team could be made available to NRC. Alternatively, the NRC could condition the nuclear medicine licenses to require the licensees to notify NRC upon certification, re-certification, or change in certification

status (e.g., probation, suspension, termination).

Some commenters did not agree with this approach to inspection. Commenters did not believe there would be a cost savings associated with this approach. They cited increased costs to utilities because of the INPO standards and to medical facilities because the cost of mammography operations were increased by the Mammography Quality Standards Act. These commenters believed that any cost savings associated with JCAHO certification were offset by increased fees from other organizations.

Commenters that did not favor this approach indicated that site review team members would not have the authority of the Federal Government behind them as NRC inspectors do now. Some indicated that the proposed alternative was self-serving and did not account for independent clinics and institutions. These commenters indicated that NRC's endorsement of the accreditation process will set up an unfair advantage and will be used only to increase membership in accrediting organizations.

Representatives from some Agreement States did not think it was likely that Agreement States would relinquish their inspection programs to accrediting organizations.

Response. The NRC's inspection program is separate from this rulemaking and may be changed without changing the regulations. The NRC agrees that diagnostic nuclear medicine licensees, as a whole, have operated safely in the past and that the radiation risk to public, patients, and workers is low. The inspection and enforcement history indicates cooperation and successful implementation of radiation protection programs by most licensees.

NRC licensees are encouraged to audit their own activities and discover and correct their own violations. A voluntary program of inspection by an accrediting organization is one method to accomplish this goal. For example, if accrediting organizations were noted to be successful in discovering violations and assuring that those violations are corrected, the frequency of inspections at accredited facilities could be decreased. Under this scenario, some NRC inspections could still be performed to verify the effectiveness of the voluntary program undertaken by the accrediting organization, but the overall number of inspections performed by the NRC would be reduced.

In summary, we believe the proposal for involvement of professional accreditation boards and organizations in the inspection program should be further explored in an ongoing dialogue. In the interim, the NRC will continue to inspect nuclear medicine licensees but will also continue to make improvements to the inspection program, e.g., focusing the inspection program on risk and decreasing the inspection frequency for good performance.

Issue 2: What Changes Should Be Made in the Inspection Process as a Result of the Revised Part 35?

Comment. Commenters expressed a concern that NRC inspections were too detailed and focused on records and use of checklists. Some commenters asked that NRC inspectors focus on radiation safety program management. They indicated that, if the program was managed properly, there would be no need to evaluate program records or the written procedures. Commenters believed that inspectors should be satisfied if the big picture does not indicate a violation because the final rule will be less prescriptive, more risk-informed, and performance-based. Other commenters asked that inspectors rely on conversations with licensee staff, and independent measurements to form a basis for inspection findings.

Commenters asked that the NRC provide training on the new rule to inspectors before the final rule is published. They also asked that the period between inspections be increased. Commenters believe that the inspector should be able to recognize the differences between the current and final rule. Agreement State representatives also believe that there will be a critical need to provide training on the final rule to their inspectors. Some commenters also asked that inspectors be encouraged to describe the good practices. They believed this would foster a more positive relationship among NRC, workers, management, and the public.

Response. In recent years, the NRC changed the focus of its medical inspections from a detail oriented inspection (check-list) to a more performance-oriented inspection. Under this approach, inspectors are directed to focus more on observations, interviews, and measurements than on record reviews to assess program adequacy. We have also revised our process for documenting inspection results. Before 1998, routine inspections were documented using a checklist format. In 1998 and 1999, we revised our procedures to allow findings to be documented in narrative form. This revision was designed to give the inspectors more flexibility and to promote a more performance-based inspection process.

In recent years, we have also revised our inspection policy to focus on risk. The inspection policy now requires inspectors to extend the time between inspections for good performers, those licensees that have relatively few violations for several inspections in succession and no escalated enforcement actions. The time between inspections is also based on the radiation risks associated with the use of the byproduct material. For example, a licensee using byproduct material for imaging and localization studies in a hospital setting is scheduled to be inspected every 3 years. If this licensee is inspected and demonstrates good performance, the next inspection will be scheduled to be conducted after 5 years, rather than 3 years. A licensee using a high dose-rate remote afterloader (HDR) will be inspected every year. If this licensee is inspected and demonstrates good performance, the next inspection will be scheduled to be conducted after 2 years, rather than 1 year.

The NRC is in the process of implementing the Medical Pilot Inspection Program that was approved by the Commission in SRM–SECY–00–0001 (February 14, 2000), ''Pilot Program for NMSS Initiative on Streamlining Inspection and Enforcement.'' We are conducting inspections under the pilot program for licensees authorized to use unsealed byproduct material under §§ 35.100, 35.200, and 35.300. This 1-year program is intended to streamline the inspection process and to focus inspections on radiation safety performance and more risk-informed outcomes. The intent of the pilot program is to demonstrate that the streamlined approach can—

(1) Maintain, and potentially enhance, safety;

(2) Reduce unnecessary burdens on the licensee;

(3) Increase NRC efficiency and effectiveness; and

(4) Increase public confidence by explicitly addressing more risk-informed outcomes. If successful, the program will be extended to other NRC material licensee inspection programs.

Under this pilot program, inspectors are shifting primary focus away from detailed examination of the licensee's processes, policies, and procedures to an evaluation of the adequacy of outcomes for six radiation safety based and outcome oriented focus elements (FEs). These FEs are:

(1) Adequate program surveillance and corrective actions;

(2) Knowledgeable staff and management;

(3) Occupational and public doses within regulatory limits;

(4) Adequate security and control of licensed material;

(5) Use of licensed material only as authorized; and

(6) Radiopharmaceutical administrations conforming to the physicians written directives.

The extent and depth of the inspection will be guided by the outcomes for the FEs and the potential risk associated with licensed activities. If the desired outcomes are not achieved by the licensee, then a detailed evaluation will follow. It will identify root causes and contributing factors for the licensee's apparent failure to conduct a satisfactory radiation protection program. The detailed evaluation will be similar to the approach that has been used during routine NRC inspections in the past, e.g., review of processes, policies, and procedures, additional observations, and interviews of licensee staff members.

The experience gained from this program will be used to revise all medical inspection procedures. This will help to ensure that the medical inspection procedures incorporate the more risk-informed, more performance-based approach used in the rulemaking.

We will continue to qualify inspectors using NRC Inspection Manual Chapter 1246, ''Formal Qualification Programs in the Nuclear Material Safety and Safeguards Program Area.'' During the inspector qualification program, the candidate completes self-study exams for the various parts of 10 CFR Chapter I and obtains classroom and practical laboratory experience for each type of medical use. The candidate accompanies other qualified inspectors and the inspection supervisor during inspections of various types of licenses for medical use programs to develop inspection skills necessary to evaluate radiation safety programs independently and to relate inspection findings to the NRC enforcement policy. Finally, individuals must pass an oral qualification board before they become certified to conduct inspections without direct supervision.

The Agreement States also have formal training programs for their inspectors. Agreement State inspector qualification are reviewed during NRC's periodic review of the Agreement State program.

NRC inspectors also participate in ongoing refresher training. This training includes new innovations in the health physics field as well as training in new initiatives underway at the NRC. Individuals performing medical inspections will receive training in the final Part 35 as well as in any guidance documents associated with the rulemaking. Training will focus on the concepts associated with a more risk-informed, more performance-based rule. In addition, inspectors received training on the pilot program for streamlining inspections before the pilot program was introduced.

Issue 3: Will the Agreement State Inspection Program Change as a Result of Changes in the NRC Inspection Program?

Comment. Several commenters stated that Agreement States may experience problems with their inspection programs if they follow NRC's lead in moving from a prescriptive to a more performance-based approach to inspecting. Other commenters stated that, if the NRC adopted an approach in which inspections would be deferred or eliminated, States may not be able to, or choose not to, follow NRC's example.

Response. Moving from prescriptive to more performance-based inspections will require a period of adjustment for both the NRC and Agreement States, as well as for the licensees. NRC and the Agreement States will address any needed adjustments via their internal training programs. In addition, Agreement States will be provided with copies of guidance documents currently under development by the NRC. Finally, Agreement States are afforded the flexibility to inspect more frequently based on local concerns.

Issue 4: What Changes Will Be Made in the Enforcement Program as a Result of the Revised Part 35?

Comment. A commenter agreed with the principal of a performance-based regulation, but questioned whether there would be any changes in the enforcement program.

Response. The NRC's enforcement program is separate from this rulemaking and may be changed without changing the regulations. However, as a result of some changes in the rule, the Commission is also publishing, in a separate document in this **Federal Register**, a modification of ''General Statement of Policy and Procedure for NRC Enforcement Actions,'' NUREG–1600 (Enforcement Policy), to revise the examples of severity levels for violations associated with the requirements to: (1) Use written directives for certain medical uses of byproduct material; and (2) develop, implement, and maintain certain procedures for medical uses that require a written directive (10 CFR 35.40 and 35.41). The revised examples reflect the revised requirements in Part 35.

In a broader effort, the NRC is revising its enforcement policy to make that program more risk-informed and performance-based. For example, a number of lesser violations are no longer considered in the aggregate at a higher severity level. This change was introduced in the version of the Enforcement Policy published in the **Federal Register** on November 9, 1999 (64 FR 61142).

Additionally, during the time that this rulemaking was being developed, guidance to the NRC staff was issued on non-escalated enforcement actions (EGM 98–007) in the materials enforcement area to assure that:

(1) Non-cited violations are used for non-repetitive, non-willful Severity Level IV violations;

(2) The use of enforcement discretion not to issue a citation is considered where warranted for Severity Level IV violations in accordance with Sections VII.B.2 through VII.B.6 of the Enforcement Policy;

(3) Responses are not required for cited Severity Level IV violations if the licensee's corrective actions are already available in a docketed report or other correspondence;

(4) RSC meeting minutes and other licensee program audit records are not used to identify violations that the licensee is already aware of unless the corrective action for the violation is not prompt or comprehensive; and

(5) Multiple examples of the same violation are grouped into a single citation when appropriate.

D. Industry Standards

Issue 1: Can Standards of Practice Be Used as an Alternative to Regulation?

Comment. Some commenters asked whether the NRC would consider replacement of regulations with standards of practice or industry standards that are well understood by medical professionals. For instance, one commenter points out that the American Association of Physicists in Medicine (AAPM) has recently published several excellent reports that relate to radiation safety, including the reports of Task Groups 59, 56, and 40.

Some commenters believed that we could allow a licensee to commit to follow an established standard of practice and thereby limit our regulatory oversight. Commenters also pointed out that many current regulations have become the standard of care and, in instrumentation cases, the

manufacturer's guidance. Conversely, some commenters believed that we, as regulators, had the role of defining the minimum level of practice necessary to directly enhance safety. The commenters indicated that there are some limited cases where those practicing are not following ''voluntary'' standards of practice; therefore regulations were needed. Finally, some commenters questioned our role in regulating an activity that is also regulated by another government agency or by the state.

Response. The National Technology Transfer and Advancement Act (NTTAA) of 1995, Public Law 104–113, requires that Federal agencies use technical standards that are developed or adopted by voluntary consensus standards bodies unless the use of such a standard is inconsistent with applicable laws or is otherwise impractical. The Commission specifically directed the NRC staff to examine the viability of using or referencing available industry guidance and standards within Part 35 and related guidance to the extent that they meet NRC's needs.

In developing the final regulations for therapeutic uses of sealed sources, the NRC consulted several American Association of Physicists in Medicine (AAPM) reports, including AAPM Radiation Therapy Task Group No. 40—Comprehensive QA for Radiation Oncology, 1994 (AAPM TG–40); AAPM Radiation Therapy Committee Task Group No. 56—Code of Practice for Brachytherapy Physics, 1997 (AAPM TG–56); AAPM Radiation Therapy Committee Task Group No. 59—High Dose Rate Brachytherapy Treatment Delivery, 1998 (AAPM TG–59); and AAPM Report No. 54—Stereotactic Radiosurgery, 1995. In developing several other sections of the rule, we also consulted other nationally recognized bodies' reports, including the American National Standards Institute, Inc. (ANSI), ACR, and the American College of Medical Physics (ACMP). We understand that these and other standards of practice are often voluntary and, as such, medical professionals are not required to follow them. The final rule and guidance include statements of the objectives to be achieved and allow the licensee to select among the various performance standards to meet the objectives of the regulation. For example, in § 35.60 we allow a licensee to calibrate instrumentation in accordance with nationally recognized standards or the manufacturer's instructions rather than to submit their specific calibration procedures for our review and approval. We believe that this provides the licensee significant flexibility in designing its radiation protection program.

We agree that, in some cases, the licensed community must comply with several different Federal and state regulations for a single type of use. For instance, in the case of sealed radioactive sources for therapeutic medical uses, the licensed community must comply with FDA regulations for devices and must also comply with NRC regulations on the use of the radioactivity in or on humans. Whenever possible, we reviewed the various state and Federal regulations, including other NRC regulations, to limit duplication of requirements.

For additional information on how consensus standards were used in the development of the final rule refer to Section I, Background in the **SUPPLEMENTARY INFORMATION** in this document.

E. Training and Experience

1. Training and Experience—General

Issue 1: Why Are There Two Sets of Training and Experience Requirements in the Final Part 35?

Comment: One commenter noted that much of Subpart J is redundant with, but not identical to the training and experience requirements listed in the individual sections of the other subparts. The training and experience requirements should be identical if they are included in two subparts within the same part, or they should only be listed once in the part.

Response. The NRC believes that Subpart J should be retained for a 2-year transition period as stated in the proposed rule (63 FR 43516; August 13, 1998). The issue of recognition of medical and other specialty boards was discussed during an ACMUI briefing of the Commission on February 19, 2002. In that meeting, two committee members expressed concern that some boards did not qualify for recognition and may not be ready to apply for recognition within 6 months after publication of the final rule. Therefore, implementation of the new Part 35, without Subpart J, could disrupt the current license authorization process for new medical personnel because many license authorizations are granted based on recognition of board certification. The Commission has considered this matter and decided to retain the current training requirements in Subpart J for a 2-year period after the effective date of the final rule. As stated in Section IX, Implementation, during that 2-year period, licensees will have the option of complying with either the requirements of Subpart J or the requirements in Subparts B and D-H. During this transition period, the NRC will continue working with the ACMUI and the medical community to resolve any concerns with the training and experience requirements. The Commission will consider changes to the training and experience requirements, as appropriate.

The training and experience requirements in Subparts B and D through H of the final rule provide alternative pathways for individuals who are not board certified, i.e., the rule specifies the total number of hours of training and experience needed to become an AMP, ANP, AU, or RSO. This was done because we do not believe that we should require that individuals be board certified, but we believe that we should require that they have adequate training to safely handle byproduct material. The primary difference between the ''board certification route'' and the ''alternative pathways'' concerns the regulatory process used for being approved as an AMP, ANP, or AU. For example, if an individual is certified by a board recognized by NRC, a licensee does not need to amend its license before it allows that individual to work as an AU, ANP, or AMP (reference § 35.14(a) and § 35.24(a)). However, if the individual is not board certified, the licensee must apply for and receive an amendment from NRC before it allows that individual to begin work (§ 35.13(b)). In the case of an RSO, a licensee must always amend its license before it allows an individual to work as an RSO unless the individual would be considered a temporary RSO under § 35.24(c).

Issue 2: Would It Be Best for Regulations To Be Developed, Administered, and Monitored by Medical Speciality Organizations?

Comment. A commenter believed that the training and experience requirements would be best developed, administered, and monitored by medical speciality organizations with expertise in clinical applications of radiation-related technologies. The commenter cited the Mammography Quality Standards Reauthorization Act as an example of a cooperative public/private partnership that uses the strengths of both established accreditation/certification programs and Federal Government enforcement authority.

Response. The NRC acknowledges and values the expertise of medical and other speciality boards involved in

radiation-related technologies. We have met with many of these boards and received valuable information that was used to develop the final rule. However, we believe that the administration of this rule is best performed by the NRC.

Issue 3: Should Speciality Boards Be Listed by Name in the Regulations?

Comment. Some commenters recommended that the regulations list the boards, by name, because the boards rarely change. Another set of commenters stated that the cardiology board should be listed by name in the rule. Other commenters expressed concern that NRC would recognize boards that were not recognized by the American Board of Medical Specialities (ABMS).

Response. The NRC believes that any reference, by name, to boards should be deleted from the regulation because a rulemaking is needed to add new boards, to change the name of boards, or to delete existing boards. This has been a problem with the current Part 35 on several occasions when individuals requesting AU status have been certified by a board that is not listed in the regulations. In these cases, the NRC evaluated the training of these individuals, in consultation with the Advisory Committee on the Medical Uses of Isotopes (ACMUI), on a case-by-case basis. In the future, without need for a rulemaking, NRC could recognize boards in a more timely manner. (**Note:** We have provisions in §§ 35.50, 35.51, 35.55, 35.190, 35.290, 35.390, 35.392, 35.394, 35.490, 35.491, 35.590, and 35.690 that allow individuals, who are certified by NRC-recognized boards, to function as an ANP, ANP, AU, or RSO.) Under the final rule, the boards must be recognized by the NRC or an Agreement State. The NRC will recognize a board if its certification process requires or will require an individual to meet all of the applicable requirements listed in the alternative pathway of the training and experience requirements in Subparts B and D through H. For example, the individual must complete the required number of hours of training and experience that covers specific topics; obtain a signed preceptor certification; and complete specifically identified patient casework, if required.

We do not believe that the NRC's recognition of boards should be limited to those boards that are recognized by the ABMS. Our recognition is contingent on whether the certification process includes all the requirements listed in the alternative pathway. Before we recognize a board, we will review the board's submittal with ACMUI. We will maintain a list of recognized boards on our website.

Boards that are listed in current Part 35, as well as any other boards that are not listed in the current rule, such as the cardiology boards, will need to apply for recognition under the revised Part 35. We believe it is necessary to obtain a commitment from all of the boards that their certifications meet the criteria in the alternative pathways in the final rule because it has been several years since NRC reviewed many of them.

Issue 4: Should the Board Certification Process Be ''Approved'' or ''Recognized'' by the NRC?

Comment. Commenters questioned the phrase ''whose certification process has been approved by the Commission'' because the board will continue to exist regardless of whether the Commission approves the board for Commission purposes.

Response. Based on this comment, the NRC changed all training and experience requirements to state that the medical and other specialty board's certification process must be ''recognized'' by the Commission.

Issue 5: What Is the Preceptor's Role?

Comment. A commenter stated the proposed regulations place an inappropriate burden on the preceptor to provide written certification that the applicant has satisfactorily completed the didactic instruction in a structured educational program, obtained the required hours of supervised practical experience, and achieved a level of competency to function independently as an AU. The commenter recommended that all didactic training be certified or approved by an independent organization not associated with any society, board, or medical speciality. The commenter stated that the preceptor should not make any judgment regarding competency and should simply attest that an individual completed the training program.

Response. The regulations in the final rule do place a high degree of responsibility on the preceptor. Because the preceptor must be an AMP, ANP, AU, or RSO, the NRC believes that the preceptor is in the best position to certify that the individual has achieved a level of competency sufficient to function independently as an AMP, ANP, AU, or RSO. We do not believe this places an undue burden on a preceptor, but rather it demonstrates a high degree of confidence in the preceptor. Further, we believe that these types of judgments of competency in training and experience are consistent with the duties of individuals who direct training programs or provide training.

Issue 6: What Are the Training and Experience Requirements for Physicians Who Perform Research on Human Subjects?

Comment. A commenter asked what the training and experience requirements are for physicians who perform research on human subjects.

Response. There is no difference between the training and experience requirements for the administration of byproduct material or radiation from byproduct material to a human research subject and the training and experience requirements for an administration to a patient. For example, if the research involves using unsealed byproduct material for imaging and localization studies for which a written directive is required, the physician performing the research must meet the requirements in § 35.390. If the research involves use of sealed byproduct material in a remote afterloader, the physician must meet the requirements in § 35.690.

Issue 7: Should the Training and Experience Requirements Include an Examination?

Comment. The NRC received comments both opposed to and in support of a requirement for individual who would like to become an AMP, ANP, AU, or RSO to pass an examination that would assess whether they had sufficient radiation safety knowledge.

Some commenters supported the exam concept. One thought that it would provide an alternative to a requirement for a long training program. Those commenters who supported the examination believe that an examination is an important tool that should be used to assure that individuals have the necessary skill to handle byproduct material safely. Other commenters believed that the examination would be warranted if an individual had not taken an examination as part of a board certification.

Several commenters stressed the practical problems of implementing the requirements for an examination. They noted that establishing an examination program was extremely time-intensive and expensive. According to several commenters, maintaining the confidentiality of questions was a concern. Some commenters said that the examination requirement was unnecessary and should be deleted unless the NRC had information that significant numbers of AMPs, ANPs,

AUs, and RSOs were being inadequately trained.

Other commenters indicated that many training organizations already use testing as part of their educational programs. Therefore, the testing requirement would only increase training costs without adding benefit or value.

Some commenters argued that neither should the NRC give the exam itself, nor should it determine the passing score. Other commenters suggested that examining organizations submit questions to the NRC and that the NRC should develop the exam. Some commenters recommended that the NRC collaborate with one or more boards to develop the radiation safety exam. Others suggested that several boards collaborate to develop a radiation safety examination independent of the NRC. Commenters also recommended that the NRC contract either directly or indirectly with a testing service to administer the exam.

Several commenters stated that the proposed requirement in Appendix A for examining organizations to ensure that examinations are not given to individuals who have also been instructed by the examining organization was too prescriptive. One commenter explained that professional organizations must be trusted to both offer instruction and testing. Another commenter encouraged the NRC to keep the two functions separate.

Response. The NRC believes that the training and experience requirements in the final rule for AMPs, ANPs, AUs, and RSOs are sufficient to assure that the radiation safety of the public, patients, human research subjects, and workers is maintained. Therefore, we deleted the requirement for an examination from all the training and experience sections. Instead of an examination, we will rely on the preceptor's certification that an individual has completed the required training and experience and has achieved a level of competency sufficient to function independently as an AMP, ANP, AU, or RSO.

Issue 8: Should Part 35 Contain Training and Experience Requirements for Technologists?

Comment. Many commenters suggested that minimum training and experience requirements be established for nuclear medicine technologists. In addition, they suggested that technologists be required to pass an exam. Commenters stated that there is a need for training and experience requirements for those individuals who actually handle radioactive materials.

One commenter felt that health care agencies, rather than the NRC, should mandate licensure requirements for technologists. Commenters opposed NRC requiring specific training and experience for nuclear medicine technologists, but supported mandated licensure requirements by health care agencies.

Response. The NRC recognizes that technologists have an important and substantial role in the medical use of byproduct material. However, the licensee is responsible for ensuring that the training and experience of individuals working under the supervision of an AU or ANP are adequate. We will continue to rely on the regulations in § 35.27, Supervision, to assure that individuals working under the supervision of an AU or ANP are provided adequate training. Therefore, we have not established training and experience requirements for technologists or other individuals using byproduct material under the supervision of an AU or ANP.

Issue 9: Will the Training and Experience Requirements for Physicians Affect Training Requirements for Technologists?

Comment. Commenters were concerned that the reduction in the duration of some of the physicians' training programs would negatively affect the amount of training that licensees expect technologists to have completed. They were concerned that if NRC reduced the training requirements for AUs that licensees might reduce their training requirements for technologists. The commenters believed that as the technology becomes more sophisticated, a reduction in training could lead to poor quality studies and result in unnecessary radiation exposure to patients.

Response. The NRC believes that under the final rule AUs will have sufficient training and experience to assure that byproduct material is handled safely. In addition, an AU is required to be a physician, dentist, or podiatrist. It is the licensee's responsibility to determine the level of training and experience, in addition to the instruction required in § 35.27, needed for individuals working under the supervision of an AU.

2. Training and Experience—Unsealed Byproduct Material.

For the most part, comments received on the following sections related to more than one section. Therefore, the NRC is summarizing comments received on these sections in this portion of the statement of considerations. Comments that pertain only to specific sections are discussed under that particular section heading.

As discussed earlier, the training and experience requirements in proposed § 35.290 were moved to final § 35.190 and the training and experience requirements in proposed § 35.292 were moved to final § 35.290. For purpose of the following discussion, the summary of the comments refers to the sections in the proposed rule and the response refers to the sections in the final rule.

Section 35.190, Training for uptake, dilution, and excretion studies.

Section 35.290, Training for imaging and localization studies.

Section 35.390, Training for use of unsealed byproduct material for which a written directive is required.

Section 35.392, Training for the oral administration of sodium iodide iodine-131 (I–131) requiring a written directive in quantities less than or equal to 1.22 Gigabecquerels (33 millicuries).

Section 35.394, Training for the oral administration of sodium iodide I–131 requiring a written directive in quantities greater than 1.22 Gigabecquerels (33 millicuries).

Issue 1: Should NRC's Training and Experience Requirements Focus on Radiation Safety Rather Than Clinical Competency?

Comment. Commenters generally supported the NRC focusing training and experience requirements on radiation safety rather than on clinical competency. Some commenters believed that the training and experience requirements for physicians who wish to use unsealed byproduct material should be based on demonstrated competence in nuclear science and radiation safety. These commenters did not believe that the NRC should define the criteria for clinical competence, but rather should allow clinical training to be defined by relevant medical specialty organizations such as the Accreditation Council for Graduate Medical Education (ACGME)-approved training programs or the ABMS-sanctioned certifying boards. However, commenters noted that ''AU status'' was frequently equated with clinical competency. As a result, these commenters encouraged the NRC to clearly state that a license granted under Part 35 only reflects the qualifications of a physician to safely handle radioactive material for medical use and not to practice nuclear medicine.

Response. The current training and experience requirements for AUs under §§ 35.100, 35.200, and 35.300 have been revised to focus on radiation safety. The NRC believes that the focus of these

training requirements should not be clinical competency. Clinical competency is best addressed by State Medical Boards, certifying organizations, and hospital credentialing committees. An individual's status as an AU means that the individual has met the requirements to handle byproduct material safely. It does not reflect an assessment of the individual's clinical or professional competency.

Issue 2: Should Training and Experience Be Limited to FDA-Approved Uses of Byproduct Material?

Comment. A commenter recommended that training and experience be obtained in those activities that are related to FDA-approved uses of byproduct material, and that all research, drug testing, and related non-FDA approved procedures be excluded from training and experience activities.

Response. The training and experience requirements in the final rule focus on radiation safety, not on clinical competency. Therefore, the NRC believes that individuals should have training and experience in the safe handling of all types of byproduct material. Thus, training and experience should not be limited to FDA-approved uses of byproduct material.

Issue 3: Where Should Training Be Obtained?

Comment. A commenter recommended that the NRC not recognize training and experience that has been obtained at a facility that is supported by either commercial manufacturers or suppliers. Other commenters recommended that practical training should be in an ACGME-accredited program in nuclear medicine or a graduate level course at an accredited university. Another commenter recommended that only those physicians completing an accredited residency program in an ABMS-approved speciality be allowed to become AUs under § 35.390.

Response. The NRC does not believe that the rule should specify where the training should be obtained because this level of prescriptiveness is not warranted by the types and levels of byproduct material that are handled under §§ 35.100, 35.200, and 35.300. We will investigate any allegations regarding inadequate training programs on a case-by-case basis. In addition, we do not believe that the rule should prohibit an individual from obtaining training at locations whose activities are supported by commercial manufacturers, suppliers, or the owners/investors. We will rely on the preceptor's written certification for final assurance that an individual has completed the required training and experience and is competent to function independently as an AU.

Issue 4: Should NRC Provide ''Deemed'' Status to Individuals?

Comment: Commenters questioned whether NRC would provide ''deemed'' status to diplomates of the American Board of Nuclear Medicine (ABNM) and whether diplomates of the American Board of Radiology (ABR) or the ABNM should be licensed to use diagnostic radionuclides without additional education or examination requirements.

Response. Any individual who is an AMP, teletherapy physicist, ANP, AU, or RSO on a license issued by the Commission or Agreement State, a permit issued by a Commission master material licensee, a permit issued by a Commission or Agreement State broad scope licensee, or a permit issued by a Commission master material license broad scope permittee before the effective date of the final rule will continue to be considered such by NRC. After the rule becomes effective, these individuals will have ''deemed'' status as an AMP, ANP, AU, or RSO on licenses that authorize similar type(s) of use(s) of byproduct material, i.e., there will be no change in what an individual is ''authorized'' to do. For example, an individual currently recognized as a ''teletherapy physicist'' would be recognized as an AMP for teletherapy units under the final Part 35. However, the individual could not be listed as an AMP on a license only authorizing use of gamma stereotactic radiosurgery, unless he or she also satisfied the requirements in the new § 35.51(b)(1) for experience with the tasks that are applicable to those units (§§ 35.635, 35.645 and 35.652). The teletherapy physicist could not be listed as an AMP on a license that only included gamma stereotactic radiosurgery units and remote afterloaders, unless the individual obtained written certification, signed by a preceptor AMP, that he or she had satisfactorily completed the applicable requirements and had achieved a level of competency to function independently as an AMP for those types of uses.

The same criteria would apply in determining if AUs have ''deemed status'' under the final rule. They would only continue to be recognized as AUs for the type(s) of use(s) of byproduct material for which they already have AU status. An AU under the current § 35.932, Training for treatment of hyperthyroidism, would continue to be recognized as an AU for the use of I–131 for diagnosis of thyroid function under the new § 35.390, Training for use of unsealed byproduct material for which a written directive is required. However, if the individual would also like AU status for parenteral administration of any beta emitter or a photon-emitting radionuclide with a photon energy less than 150 keV, the individual would have to satisfy the applicable training and experience requirements for this use in § 35.390.

Once the final rule becomes effective, diplomates of boards, such as the ABNM and ABR, will be considered to have met the training and experience requirements if the boards have been recognized by NRC. Recognition of a board will be contingent on whether the board's certification process includes all the requirements listed in the alternative pathways for satisfying the training and experience requirements. However, as stated previously, the Commission is retaining the current training requirements in Subpart J for a 2-year period after the effective date of the final rule. During that 2-year period, licensees will have the option of meeting either the requirements of Subpart J or the requirements in Subparts B and D–H.

Issue 5: Why Are There Different Requirements for Training of AUs Under §§ 35.100, 35.200, and 35.300?

Comment. Commenters questioned why the training and experience requirements for using byproduct material under §§ 35.100, 35.200, and 35.300 are different. They indicated that the basic radiation safety practices and knowledge of radiation science should be the same regardless of the quantity of byproduct material and how it is used.

Response. The NRC recognizes that there is a certain degree of basic radiation safety knowledge that is common among all the types of use, e.g., use of the decay formula and decontamination techniques. However, we also believe that there are some basic differences between the uses of byproduct material under §§ 35.100, 35.200, and 35.300 that warrant additional training and experience, e.g., increased potential for exposures in excess of Part 20 limits and the potential for adverse biological effects. For example, AUs handling byproduct material for imaging and localization studies, as compared to uptake, dilution, and excretion studies, are generally handling larger quantities and many different radionuclides. Also, AUs meeting the training and experience requirements in § 35.190 are not authorized to prepare radioactive drugs

using generators and reagent kits, but AUs under § 35.290 are authorized to prepare drugs using generators and reagent kits. Finally, AUs under § 35.390 are handling material in quantities that can cause deterministic effects.

Issue 6: How Long Should the Training Programs Be for Individuals Who Would Like To Become AUs Under §§ 35.190, 35.290, and 35.390?

Comment. Numerous comments both supported and opposed the duration of the proposed training and experience requirements for individuals who would like to become an AU for unsealed byproduct material.

Some commenters strongly supported the proposed reduction of the training and experience requirements for use of unsealed byproduct material in diagnostic nuclear cardiology because of the minimal risk to patients and public safety.

Some commenters believed that NRC should not establish an ''arbitrary'' number of training and experience hours. They indicated that it may take some individuals more time to master needed information. They believe that classroom training should focus on radiation safety and that there should be a requirement to show evidence of mastery in comprehensive nuclear and radiation science through an exam. In addition, they believe that the rule should clearly identify what knowledge and skills an individual should have.

A commenter suggested that the proposed requirements for an individual who would like to use material under § 35.100 be changed from 20 hours of classroom and laboratory experience to 40 hours of supervised practical experience.

A commenter recommended that the proposed requirement for an individual who would like to use material under § 35.200 should be a minimum of 240 hours of supervised practical experience. For the same type of use, another commenter suggested that an individual complete a 6-month/1200 hour training program in an ACGME-accredited or equivalent training program. Finally, a commenter recommended that individuals certified by the ABR or ABNM should automatically qualify as AUs. These commenters also indicated that as an alternative pathway to board certification, an individual who would like to use material under § 35.200 should be required to complete a dedicated 4-month nuclear medicine/radiology training program that integrates radiation safety training with clinical training and experience. This integrated experience should be obtained in an ACGME-approved residency program in diagnostic radiology or nuclear medicine.

A commenter stated that the current training and experience requirements for physicians authorized for nuclear medicine therapy (§ 35.390) are minimal to a fault. The commenter cited the 1996 NAS–IOM analysis of NRC's medical program that recommended increasing the requirements for a nuclear medicine therapy AU. Another commenter found it inconsistent that the use of unsealed byproduct material for therapy requires far less training than the use of sealed byproduct material. Another position is that therapeutic nuclear medicine represents a higher risk for patients. Therefore, the training and experience requirements to become an AU for therapy should be greater than those for diagnostic nuclear medicine.

A commenter recommended that the current requirements for an individual who would like to use unsealed byproduct material under § 35.300 should be revised to be at least equal to or greater than the requirements to use material under § 35.200. Another commenter suggested that an individual have 100 hours, rather than 40 hours, of supervised practical experience under the supervision of an AU. The commenter went on to state that this additional time would be used to cover the requirements that pertain to dosages requiring a written directive.

Another commenter stressed the importance of remembering that, under § 35.300, byproduct material is used for therapeutic treatments and that the possibility of injury to the patient and others is very real. This commenter stated that he had personally seen both significant bone marrow suppression after using strontium for bone pain and life-threatening pulmonary edema after treatment of a patient with iodine-131 (I–131) for metastatic thyroid cancer of the lungs.

Response. The NRC believes that the regulatory text should contain a list of the subject areas to be addressed in a training program. In the final rule, we have not included a requirement for an examination to demonstrate that an individual has sufficient knowledge in radiation safety. Instead, we will rely on the duration of the training program and the preceptor's written certification that a physician has completed the required training and experience and is competent to function independently as an AU.

The following discussion summarizes the training and experience requirements for use of unsealed byproduct material under §§ 35.100, 35.200, and 35.300. We believe the specified training periods will provide individuals with sufficient knowledge to handle byproduct material safely. We also believe that it is sufficient to specify the overall period for training. We do not believe that any further breakdown is needed in terms of the hours devoted to classroom/laboratory training and work experience. Note, this same approach is used in the current rule for the training and experience requirements for an ANP. In addition, this approach will provide needed flexibility in designing and implementing training programs.

In § 35.190, Training for uptake dilution and excretion studies, the total number of hours (i.e., 60 hours) in the final rule is the same as the total number of hours in the current rule and in the proposed rule. AUs, qualified under § 35.290, § 35.390, or equivalent Agreement State requirements, may use byproduct material under § 35.100. AUs qualified under § 35.190 are not authorized to prepare unsealed byproduct material using generators and reagent kits.

In § 35.290, Training for imaging and localization studies, we agree with the public comments that the proposed 120 hours is not sufficient. AUs in this category are authorized to prepare unsealed byproduct material for medical use using generators and reagent kits. Therefore, we have increased the period of training in § 35.290 from 120 hours in the proposed rule to 700 hours (essentially 4 months) in the final rule. This change was necessary to assure that physicians spend an adequate amount of time in an environment in which radioactive drugs are routinely being prepared and/or administered for medical use. Note that the 700 hours in the final rule is a reduction from the current 1200 hours of training required for imaging and localization studies.

As stated earlier, we have not specified a breakdown between the number of hours of didactic (i.e., classroom and laboratory) and work experience to allow flexibility in designing and implementing training programs. Therefore, the number of hours of classroom and laboratory training needed to address the required subject areas in § 35.290(c)(1)(i) may vary with individual training programs. The remainder of the required 700 hours would be devoted to supervised work experience to include, but not be limited to, the subject areas in § 35.290(c)(1)(ii).

We recognize that physicians in training will not dedicate all of their time specifically to the subject areas in § 35.290(c)(1)(ii) and will be attending

to other clinical matters involving the diagnostic use of the material under the supervision of an AU (e.g., reviewing case histories or interpreting scans). Even though these clinical matters are not specifically required by the NRC, this type of supervised work experience may be counted toward the supervised work experience to obtain the required 700 hours.

We agree that the training and experience requirements should be increased for individuals who would like to use byproduct material for which a written directive is required. The hours have been increased from 80 hours in the current rule to 700 hours in the revised § 35.390, Training for use of unsealed byproduct material that requires a written directive. We believe this increase is needed because these physicians would be authorized to elute generators and prepare radioactive drugs, as well as to administer a wide variety of radionuclides requiring written directives. Thus, the associated radiation risks of the use could be greater. In addition, the work experience in the administration of such dosages to patients must specifically include at least three cases in each of the following categories for which the individual is requesting AU status:

1. Oral administration of less than or equal to 1.22 Gigabecquerels (33 millicuries) of sodium iodide I–131;
2. Oral administration of greater than 1.22 Gigabecquerels (33 millicuries) of sodium iodide I–131;
3. Parenteral administration of any beta-emitter or a photon-emitting radionuclide with a photon energy less than 150 keV; and/or
4. Parenteral administration of any other radionuclide.

Physicians who are authorized under § 35.390 for all of these types of administrations also meet the requirements in §§ 35.190, 35.290, 35.392, and 35.394.

Issue 7: What Are the Appropriate Training Requirements for an Individual Who Would Like To Use I–131 for Treatment of Hyperthyroidism and Thyroid Cancer?

Comment. Commenters were strongly opposed to the proposed changes to the requirements for the administration of I–131 for treatment of hyperthyroidism and thyroid cancer. Commenters felt that there was no justification for revising the current § 35.932, Training for treatment of hyperthyroidism, and to do so would conflict with NRC's guidelines of ''minimizing intrusion into medical judgments affecting patients and into other areas considered to be a part of the practice of medicine.'' These commenters indicated that the increased training was not warranted in light of endocrinologists' impeccable safety record with the use of I–131 and the fact that there have been no records of therapeutic misadministrations of any byproduct material by endocrinologists. In addition, commenters stated that, in reality, most of the practical aspects of handling I–131 that would be covered in the proposed 40 hours of additional training is already covered in the 80 hours of didactic training and in the supervised clinical training that is currently required by § 35.932, Training for treatment of hyperthyroidism, and § 35.934, Training for treatment of thyroid carcinoma.

Commenters stated that the clinical endocrinologist is the physician best qualified to take care of patients with thyroid disease and part of their responsibility is to protect their patients from unnecessary burdens. Commenters stated that the practical effect of increasing the basic radiation physics and safety training from 80 hours to 120 hours would be to exclude endocrinologists from administering I–131 to patients with hyperthyroidism and thyroid cancer. Some commenters went on to state that increasing the requirement for licensure would actually result in fewer endocrinologists being able to take care of their own patients and would ultimately place increased and undue strain on the patients such as:

1. Increased costs to the patient. The cost to patients receiving treatment in a hospital setting are double or triple the cost of an endocrinologist administering I–131 in his/her own office.
2. Increased potential safety hazards for the patient. There is much more personal and focused attention given to the patient in the endocrinologist's office. In other settings, the patient is one of dozens of people waiting to be treated with a variety of doses for a variety of diseases. Thus, the possibility of error in communications and for the misadministration of I–131 is greatly increased.
3. Increased emotional trauma during treatment. Patient anxiety and fear will be increased as a result of patients being required to go to nuclear medicine departments where other patients are being treated for all manner of disease, including cancer. This is an unnecessary exposure of the patient to psychological trauma and can be a deterrent to a patient seeking appropriate care.
4. Increased need to visit additional specialists. With fewer endocrinologists administering I–131, patients will have to endure another layer of specialty consultation, resulting in delays in treatment, inconvenience and loss of time from work, significant increase in the cost of treatment, and exposure to unfamiliar settings and personnel.

Commenters were also concerned that the proposed rule required that the 40 hours of supervised practical experience be obtained at a medical institution. They thought this is a prescriptive requirement which is not warranted because acceptable training could be provided in other clinical settings. Other commenters noted that this requirement would make it more difficult for endocrinologists to receive supervised practical experience from mentors or preceptors who practice and administer radioiodine in their offices, rather than in medical institutions.

A commenter thought it paradoxical that the proposed rule would actually decrease the amount of clinical experience needed for licensure. The commenter indicated that currently, under § 35.932, physicians are required to have supervised clinical experience with 10 patients with hyperthyroidism and, under § 35.934, they are required to have supervised clinical experience with 3 patients with thyroid cancer. The commenter indicated that, in the proposed rule, an individual must have experience with 5 cases. This commenter believed that this was a step backward from the current regulations because the clinical experience and practical aspects of the use of radioiodine are obtained during clinical experience, rather than obtained in a classroom setting. According to another commenter, the blanket requirement for 5 cases for each procedure may not always be appropriate. This commenter thought that it might be better to list the procedures and the number of required cases in the regulations.

Response. In the final rule, §§ 35.392 and 35.394 have been added to specifically address oral administrations of sodium iodide I–131. These sections do not increase the duration of training for an endocrinologist over the current requirements in §§ 35.932 and 35.934.

In the final rule, § 35.392 was added to provide the training and experience requirements for physicians who only seek authorization for the oral administration of sodium iodide I–131 in dosages less than or equal to 1.22 gigabecquerels (GBq) (33 millicuries (mCi)) and do not seek authorization to prepare radioactive drugs using generators and reagent kits. To qualify as an AU under this limited authorization, an individual must have 80 hours of classroom and laboratory training and supervised work experience that includes 3 cases

involving the oral administration of sodium iodide I–131 in dosages less than or equal to 1.22 GBq (33 mCi). The NRC has not specified a breakdown between the number of hours of didactic (i.e., classroom and laboratory) and supervised work experience to allow licensees flexibility in designing and implementing training programs. Therefore, the number of hours of classroom and laboratory training and supervised work experience needed to adequately address the required subject areas can vary with individual training programs. These individuals may not prepare unsealed byproduct materials using generators and reagent kits.

Also, § 35.394 was added in the final rule to provide training and experience requirements for physicians who only seek authorization for the oral administration of sodium iodide I–131 in dosages greater than 1.22 GBq (33 mCi) and do not seek authorization to prepare radioactive drugs using generators and reagent kits. To qualify as an AU under this limited authorization, an individual must have 80 hours of classroom and laboratory training and work experience that includes 3 cases involving the oral administration of sodium iodide I–131 in quantities greater than 1.22 GBq (33 mCi). Physicians authorized under § 35.394 would also meet the training and experience criteria in § 35.392. These individuals may not prepare unsealed byproduct materials using generators and reagent kits.

We agree that it is not necessary for the supervised work experience required by §§ 35.392 and 35.394 to be obtained at a medical institution. The essential element of this requirement is who is supervising the individual rather than where the experience is obtained. The final rule allows an individual to obtain work experience at any type of medical facility (e.g., medical institution, clinic, or private practice office), if the experience is under the supervision of an AU who meets the applicable requirements.

Issue 8: Should There Be a Difference Between the Training and Experience Requirements for Use of Sodium Iodide I–131 Liquid and Capsules?

Comment. A commenter indicated that an individual who only planned on using iodine in a capsule should not be required to have as much training as someone who planned on using liquid iodine. The commenter recommended that only 40 hours of training was needed to learn how to handle I–131 capsules.

Response. The final training and experience requirements do not differentiate between the different forms of I–131. The NRC believes that AUs should have the flexibility to prescribe whatever form of I–131 they believe appropriate. Although there are differences between handling iodine in capsule form and liquid form (e.g., decontamination procedures), we do not believe that the differences are significant enough to warrant a separate category for training.

Issue 9: Should Diagnostic Use of I–131 Be Authorized Under § 35.200 or § 35.300?

Comment. A commenter noted that the proposed rule would move requirements for whole body imaging using sodium iodide I–131 from § 35.200 to § 35.300. The commenter argued that this would prevent physicians who are imaging specialists from performing the procedure and allow therapy specialists to do the procedure. This commenter suggested that the procedure not be included in either, but instead be listed as a line item authorization and that specified training and experience requirements be adopted for it.

Response. The NRC does not believe that training and experience criteria for the use of sodium iodide I–131 for whole body imaging should be excluded from the regulations. The radiation safety considerations associated with the diagnostic use of millicurie quantities of sodium iodide I–131 more closely resemble the therapeutic use of sodium iodide I–131 than most diagnostic imaging and localization studies using technetium-99m. Therefore, the training and experience requirements for the use of sodium iodide I–131 in quantities greater than 1.11 Megabecquerels (MBq) (30 microcuries (μCi)), regardless of how it will be used, requires additional experience in the administration of these types of dosages.

The final rule reduces the required number of cases, as stated in the proposed rule, from 5 to 3 for each type of use for which authorization is requested. We believe that a physician's involvement in 3 cases will provide him or her with adequate training and experience. In addition, we do not believe that requiring physicians to obtain administration experience or demonstrate they have such experience for three cases of sodium iodide I–131 represents an unwarranted burden, nor would it discourage such physicians from becoming authorized to use I–131.

Issue 10: Should Both §§ 35.190 and 35.290 in the Final Rule Refer to Reagent Kits?

Comment. A commenter stated that the proposed § 35.292 (final § 35.290) does not refer to ''reagent kits,'' although proposed § 35.290 (final § 35.190) does, and questioned whether this was an error.

Response. The training and experience requirements to become an AU for imaging and localization require a physician to have experience with generators and reagent kits because physicians authorized under the final § 35.290 (proposed § 35.292) may prepare unsealed byproduct material using generator systems and reagent kits. Under the final § 35.190 (proposed § 35.290), physicians are not authorized to prepare byproduct material using generator systems and reagent kits. Therefore, it is appropriate that final § 35.290, and not final § 35.190, requires experience with eluting generator systems appropriate for preparing unsealed byproduct material for imaging and localization studies, measuring and testing the eluate for radiochemical purity, and processing the eluate with reagent kits.

Issue 11: Is It Necessary To Require Training in Calibrating Dose Calibrators and in Calculating and Measuring Dosages?

Comment. A commenter stated that there was an inconsistency between the training and experience requirements in the proposed §§ 35.292 and 35.390 and the requirement to calibrate dose calibrators in § 35.60 and the requirement to measure unit dosages in § 35.63. The commenter recommended that we replace the phrase ''Calculating, measuring, and safely preparing patient or human research subject dosages,'' with the phrase ''Determining and safely preparing patient or human research subject dosages.''

Response. The NRC believes that physicians who plan to use unsealed byproduct material must have training in calibrating instruments used to measure the activity of unsealed byproduct materials, in calculating and measuring dosages, and in eluting generators even though, in practice, an AU may choose to only use unit dosages. We believe that this training is important because AUs who meet the qualifications in the final §§ 35.290 and 35.390 are not restricted to using unit dosages. The training requirements do not interfere with the practice of medicine or pharmacy because the rule provides sufficient flexibility for

procuring and preparing unsealed byproduct material.

We have not replaced the words ''calculating and measuring'' with the word ''determining.'' Use of the words ''calculating and measuring'' clearly states our intent that an individual receive training in calculating (perform radioactive decay calculations) and measuring (use instrumentation to determine the activity) the activity of unsealed byproduct material.

Issue 12: Were There Any Other Changes Made to These Sections Between the Proposed and Final Rule?

Response. Yes. The NRC revised the requirement for individuals to have experience administering dosages to patients or human research subjects to state: ''Administering dosages of radioactive drugs to patients or human research subjects.'' This was done to state clearly that experience administering radioactive drugs need not be limited to radioactive drugs containing byproduct material because there is no difference between the safety precautions that must be exercised when administering byproduct or nonbyproduct material.

We revised the requirement for individuals to have experience using procedures to contain spilled byproduct material safely and using proper decontamination procedures to state: ''Using procedures to contain spilled radioactive material safely and using proper decontamination procedures.'' This was done to state clearly that experience with containing spilled radioactive material and decontaminating areas need not be limited to byproduct material because there is no difference between the safety precautions that must be exercised when handling byproduct or nonbyproduct material.

We revised §§ 35.290(c)(ii)(G) and 35.390(b)(ii)(F) to state: ''* * * measuring and testing the eluate for radionuclidic purity* * *'' rather than ''* * * measuring and testing the eluate for radiochemical purity.'' This change has been made because it more accurately reflects the testing that licensees actually perform for quality control testing on generator eluates, e.g., determining the molybdenum-99 concentration in the eluate from a molybdenum-99/technetium-99m generator.

We added a reference to § 35.390 in paragraph (b) of §§ 35.100, 35.200, and 35.300. This was done to recognize that an individual who meets the requirements in § 35.390 has sufficient training and experience to handle material safely under §§ 35.100, 35.200, and 35.300.

3. Training and Experience—Sealed Byproduct Material.

For the most part, comments received on the following two sections related to more than one section. Therefore, the NRC is summarizing the comments received on these two sections in this discussion. Comments that pertain only to specific sections are discussed under that particular section heading.

Section 35.490, Training for use of manual brachytherapy sources.

Section 35.690, Training for use of remote afterloader units, teletherapy units, and gamma stereotactic radiosurgery units.

Issue 1: What Is the Appropriate Level of Training To Require?

Comment. Some commenters felt that the current training requirements should be retained and that lessening of the current training requirements could have a tremendous detrimental effect on patient care. Many of these same commenters believed that the training for coronary artery therapy should be of the same level as for all other sealed source therapy. Conversely, some commenters supported lessening the training requirements to a level that considers only radiation safety and not clinical competence.

Response. The NRC did not change the training levels required by these sections. We believe that individuals should complete a structured educational program that includes both classroom and laboratory training and work experience. We recognize that radiation safety training and clinical competency may be intertwined, especially for therapeutic uses of sealed sources. Therefore, we agree that significant changes should not be made in the current training requirements for AUs in this area.

Issue 2: Can This Section Be Revised To Refer to the Appropriate Review Committee and the Appropriate Time Division Reviewed by the Committee?

Comment. A commenter suggested that §§ 35.490(b)(2) and 35.690(b)(2) should refer to the Residency Review Committee for Radiation Oncology (since 1993). The commenter also stated that the phrase ''that includes one year in a formal training program'' should be replaced with ''in radiation oncology as part of a formal training program.''

Response. The NRC agrees with the suggested changes because the changes reflect the changes in the certification process since 1993. We have incorporated the requested changes in the rule.

Issue 3: Is Concurrent Training Allowed for Clinical and Work Experience?

Comment. A commenter pointed out that, as written in the proposed rule, 6 years of training is required unless concurrent training is allowed. The commenter felt that the proposed rule would require 500 hours of supervised practical experience plus 3 years of supervised clinical experience. The commenter also felt that the proposed rule would require 3 years of training with, for instance, iridium-192 sources, and an additional 3 years of training in order to use gamma stereotactic radiosurgery sources.

Response. The NRC agrees that concurrent training should be allowed for the clinical and work (practical) experience requirements in §§ 35.490 and 35.690. Therefore, we revised the regulatory text in §§ 35.490(b)(2) and 35.690(b)(2) to allow for concurrent work and clinical experience.

Issue 4: Were There Any Other Changes Made in These Sections Between the Proposed and Final Rule?

Response. Yes. The NRC deleted the phrase ''or equivalent program approved by the NRC'' from §§ 35.490(b)(2) and 35.690(b)(2) because a program equivalent to the ACGME program does not exist.

F. Global Changes in the Rule.

Issue 1: What Is the Sealed Source and Device Registry and How Do I Access the Registry?

Comment. A commenter noted that the proposed revision would be strengthened if there were an indication as to the nature of the Sealed Source and Device Registry and how to obtain a copy.

Response. The Sealed Source and Device Registry (SSDR), as defined in § 35.2, is the national registry containing all the registration certificates, generated by both NRC and the Agreement States, that summarize the radiation safety information for sealed sources and devices and describe the licensing and use conditions approved for these products. The information contained in the registry is summarized from information provided during registration of the source or device in accordance with § 32.210, Registration of product information. The Commission or Agreement State evaluates the information submitted to register a source (or device) and, if acceptable, issues a ''Safety Evaluation of Sealed Source (or Device).'' A

compilation of these evaluations can be found electronically at the following address: *http://www.hsrd.ornl.gov/nrc/ssdr/ssdrindx.htm*.

Issue 2: Should the Requirements in the Current Rule Related to Possession of Survey Instruments Be Deleted?

Comment. A commenter stated that the requirements in the current Part 35 concerning possession of survey instruments are very useful and should not be deleted from the rule (§§ 35.120, 35.220, 35.320, 35.420, 35.520, and 35.620 in the current Part 35). This commenter believed that the Part 20 requirements are not specific enough on this point.

Response. The NRC does not believe specific requirements relating to possession of survey instruments are needed in Part 35. Section 20.1501 requires that the licensee make, or cause to be made, surveys to demonstrate compliance with 10 CFR Part 20. This provision requires, in part, the licensee to ensure that instruments and equipment used to show compliance with Part 20 are periodically calibrated. In addition, § 30.33(a)(2) of this chapter requires licensees to have adequate instrumentation. Information on the types of instruments is available in NUREG–1556, Vol. 9 (draft), ''Consolidated Guidance About Materials Licenses: Program-Specific Guidance about Medical Use Licenses.''

Issue 3: Should the Term ''Dose Calibrator'' Be Replaced With the Term ''Radionuclide Calibrator'' in the Training and Experience Requirements for Unsealed Byproduct Material?

Comment. Commenters suggested that we replace the term ''dose calibrator'' with the term ''radionuclide calibrator'' in proposed §§ 35.50, 35.55, 35.290, 35.292, 35.390, 35.920 and 35.930.

Response. The reference to ''dose calibrators'' in §§ 35.50, 35.55, 35.190, 35.290, and 35.390 has been deleted in the final rule and replaced with ''instruments used to determine the activity of dosages.'' (§§ 35.920 and 35.930 will be retained 2 years after the effective date of the final rule.) As stated in the discussion of § 35.60, this change recognizes that there are various types of instruments that can be used to measure the activity of unsealed byproduct material. Therefore, the NRC believes that individuals should have experience with the different types of instruments and not be limited only to experience with dose calibrators.

Issue 4: Were There Any Other Changes Made to the Rule Between the Proposed and Final Rule?

Response. Yes. References in the proposed rule to § 35.290 have been changed to § 35.190 and references to § 35.292 have been changed to § 35.290. This was done because the training and experience requirements in proposed §§ 35.290 and 35.292 were moved to §§ 35.190 and 35.290, respectively. This change groups the sections that specify the requirements for an individual who would like to become an AU for a specific type of use with the section that provides information on that specific type of use. For example, § 35.100 provides authorization for use of unsealed byproduct material for uptake, dilution, and excretion studies for which a written directive is not required and § 35.190 contains the training and experience requirements for someone who would like to use material under § 35.100.

Throughout the final rule, the NRC has replaced the word ''promptly'' with the phrase ''as-soon-as-possible.'' In the proposed rule, we used both ''promptly'' and ''as-soon-as-possible.'' For the purpose of this rule, both could be used interchangeably. Therefore, we have chosen to use the phrase ''as-soon-as-possible'' to maintain consistency within the rule. The phrase ''as-soon-as-possible'' is used to indicate that the required action should be taken immediately considering the circumstances. The term ''as soon as possible'' adds a degree of reasonableness to ''immediate.'' For example, a notification might be made the next morning rather than in the middle of the night.

G. Costs of the Revision

Issue 1: How Will Less Prescriptive Requirements in the Proposed Rule Affect Regulatory Compliance and Implementation Costs?

Comment. Some commenters suggested that a shift from a more prescriptive to a less prescriptive and more performance-based regulatory system could lead to overall cost increases for regulatory compliance. For example, they said that if licensees are not required to submit procedures as part of their licensing application, and if NRC does not review their procedures at the time of licensing, the burden of reviewing the procedures may shift to inspections in the field. Therefore, these commenters believed that inspections might be more time-consuming and costly for both licensees and NRC. In addition, the frequency of review might increase because inspection cycles are shorter than licensing review cycles. Furthermore, the qualifications of inspectors might need to be increased, thus increasing the costs of implementing the rule. However, other commenters thought that less prescriptive regulatory requirements were desirable because, among other advantages, they would lower regulatory compliance costs.

Response. The NRC estimates that licensees will incur lower compliance costs under less prescriptive regulatory requirements. Certain requirements have been eliminated and other requirements have been revised to allow licensees greater flexibility in compliance. For example, licensees will have greater flexibility in setting up Radiation Safety Committees and some licensees will not be required to form such committees. We plan to revise our licensing and inspection procedures and criteria to reflect the less prescriptive regulatory approach. Under the new performance-based approach, as long as licensees do not experience safety-related problems or medical events, they will be able to select the most efficient method of achieving regulatory compliance. It should not be necessary for NRC to incur implementation costs for inspections to review the approach licensees have selected, unless performance-related information suggests that a review is needed. For example, the NRC does not expect to review licensees' procedures unless a problem occurs that indicates the procedures may be inadequate and should be reviewed.

Issue 2: How Will the Cost and Availability of Health Care Involving Radionuclides Be Impacted by the Revised Regulations?

Comment. Commenters argued that the costs of regulatory compliance could have the effect of reducing the availability of certain medical procedures by making them more expensive to the patient or by creating an incentive for physicians to substitute other procedures that have lower regulatory costs for diagnostic or therapeutic procedures involving radionuclides. Others stated that in their opinion the proposed rule was a positive step toward reducing compliance costs and creating concise and pertinent radiation safety standards.

Response. The NRC believes that physicians act in the best interest of their patients. Therefore, the NRC expects that physicians will continue to select procedures that will result in the best diagnostic or therapeutic outcome for their patients.

Issue 3: How Will the Revised Regulations Affect Fees to Medical Licensees?

Comment. Commenters suggested that if the revised Part 35 regulations result in lower implementation costs to NRC and the Agreement States, there should be a reduction of licensing fees for medical use licensees.

Response. Lower implementation costs that might result from this revision of Part 35 may not necessarily result in lower fees assessed to Part 35 licensees. Although budgeted costs are a major factor affecting the annual fees that individual NRC materials licensees are assessed, there are many other contributing factors. For example, a decrease in total costs to be assessed to materials licensees may not result in a decrease in the annual fee each licensee pays if there is also a significant decrease in the number of licensees available to pay the budgeted costs. Similarly, a decrease in costs associated with the implementation of Part 35 might be offset by increased costs for other activities.

Most NRC materials licensees are subject to Part 171 annual fees only. The annual fees are established to recover NRC's budgeted costs allocated to this class of licensees, including the costs for inspections, license amendments, license renewals, and generic activities such as rulemaking and development of regulatory guides. The new license and inspection costs, which are indicative of the complexity of the various types of materials licenses, are used as a proxy for allocating the budgeted costs for the license fee categories within the materials license class.

In FY 1999, the Commission determined that it would continue its policy to streamline and stabilize fees by adjusting the annual fees based on the percent change in the NRC's total budget each year, with additional adjustments for the number of licensees paying fees, changes in Part 170 collections, and other adjustments that may be required, unless there is a substantial change in the total NRC budget or the magnitude of the budget allocated to a specific class of licensees, in which case the annual fee base would be reestablished. The Commission established new baseline annual fees in FY 1999, and determined at that time that future annual fees should be rebaselined every three years, or earlier if warranted. After carefully considering all factors, including the changes to the amount of the budget allocated to classes of licensees, and weighing the complex issues related to both fairness and stability of fees, the Commission determined that it was appropriate to rebaseline the annual fees in FY 2001. A final rule revising the fee schedules was published on June 14, 2001 (66 FR 32452).

Issue 4: Will Part 35 Create a Net Hazard by Imposing Costs for Regulatory Compliance That Could Be Better Spent Addressing Some Other Societal Risk?

Comment. Commenters argued that for every approximately $9 to $12 million spent on regulatory compliance and, therefore, not available for spending on some other aspect of safety, a life will be lost. They suggested that NRC has not demonstrated that the impact of the Part 35 regulations in terms of patients saved from harm outweighs the costs imposed.

Response. The NRC agrees that Part 35 should not impose costs that do not correspond to the risks being addressed. We have developed a rule that is intended to be more risk-informed, in which risk insights are considered together with other factors to establish requirements that better focus licensee and regulatory attention on design and operational issues commensurate with their importance to public health and safety. We have also made the final rule less prescriptive and more performance-based to help ensure that it does not create unnecessary compliance or implementation costs. Therefore, we believe that the final rule properly balances the risks and costs involved.

Issue 5: What Is the Total Cost of Regulating the Medical Uses of Radionuclides?

Comment. Several commenters stated that it would be useful to know the total cost of regulating the medical uses of radionuclides. Knowledge of the full costs, in the view of some commenters, would allow the selection of the least costly and least restrictive regulations and would allow a more rational allocation of resources than the current system. Some commenters reported that their estimates indicated that the annual cost of regulatory compliance exceeded $100 million; others reported that their estimate indicated the annual cost exceeded $130 million just for paperwork; still others reported that their estimate indicated the annual cost exceeded $500 million to $1 billion the first year and hundreds of millions per year thereafter. In contrast, other commenters stated that developing an estimate of the total cost of compliance was probably very difficult or impossible.

Response. In evaluating the costs of regulatory compliance and implementation, the NRC has used detailed information whenever it is available. We have sought data from a number of sources, including medical speciality groups, manufacturers, members of the ACMUI, the National Institutes of Health, and various published sources. However, certain necessary data are treated as proprietary. Other data are not collected or are available only in a disaggregated form. Many of the compliance costs will vary substantially from licensee to licensee, depending on the number and type of modalities and procedures that they use and perform. Other compliance costs will be dependent on numerous interrelated variables. We believe that an effort to collect the necessary data and/or develop necessary models to provide substitutes for missing or unavailable data would require very considerable time and expense. We are concerned that at the conclusion of such an effort, because of many remaining gaps and uncertainties in the underlying data, an estimate of the total cost of the regulations would still fall within such broad confidence bounds that it would be fundamentally flawed. In this regard, we note that commenters' estimates of the total costs of the regulations vary by at least one order of magnitude and provide little or no underlying basis for their conclusions. Therefore, we prepared an estimate of the regulatory costs for a typical single practitioner licensee in order to satisfy the requirements of the Regulatory Flexibility Act. We have not prepared an estimate of the kind called for by the commenters because of the reasons discussed above.

Issue 6: Is NRC Aware That Certain Costs Are Not Reimbursable by the Health Care Financing Agency (HCFA)?

Comment. Several commenters noted that HCFA does not reimburse certain regulatory costs. Therefore, they asserted that either unnecessary regulations should be eliminated, or that NRC should intercede with HCFA to change the reimbursement policy. Estimates of the impact of HCFA's policy varied. A commenter suggested that at least 35 percent of medicine is practiced in the public sector (Medicare, Medicaid, and State health care programs); that in nuclear medicine a larger percentage of costs are being paid by Federal agencies; and that absence of reimbursement can reduce a physician's revenues by 15 to 30 percent. Another commenter estimated that regulatory compliance costs an estimated $30 to $40 per patient for a diagnostic procedure involving radionuclide materials. However, another commenter noted that for a procedure for which

reimbursement was $750 to $1,500, an estimated unpaid cost of compliance of $35 to $40 was not particularly significant.

Response. The NRC believes that involvement by NRC in HCFA's development of policy on reimbursement is outside the scope of this rulemaking and NRC's jurisdiction.

Issue 7: Will Testing Requirements for New Authorized Users, Authorized Nuclear Pharmacists, etc., Cause an Unnecessary Increase in Cost Without Commensurate Benefit?

Comment. Commenters argued that the testing requirements in the proposed rule were not necessary. Providers of didactic training already make use of testing as a validation system. In addition, testing would substantially increase the costs of implementing the rule. Development, administration, and maintenance of a separate testing system would not be cost effective. Unless testing were offered frequently, the requirement could create an obstacle to adequate staffing of medical institutions or nuclear pharmacies and actually negatively impact compliance and safety.

Response. The NRC agrees with the commenters and have removed the testing requirement that was in the proposed rule.

Issue 8: Does the OMB Estimate Accurately Summarize the Paperwork Burden of the Proposed Rule?

Comment. Commenters suggested that the OMB estimate of the Part 35 recordkeeping and reporting requirements is too low, listing several items that in their opinion were not properly included. Some commenters argued that NRC's suggested procedures are ''useless'' and, therefore, licensees will need to write numerous procedures. In addition, increased legal costs, amendment costs, and costs from discarded doses needed to be included. Commenters also suggested that hundreds of millions of dollars in paperwork costs were missing from the estimate, or that such costs are ''staggering,'' without providing a more specific description of the sources of the missing costs.

Response. The estimates for the information collection burden of many of the reporting and recordkeeping requirements in the proposed rule were based on previous estimates that were made available for public comment and submitted to the Office of Management and Budget (OMB). In a number of cases, the reporting and recordkeeping requirements in the final rule have been reduced from the requirements in the current rule. Therefore, the total information collection burden is lower than previously submitted to OMB for the current Part 35. In addition to information from previous burden estimates, we also obtained updated data from other sources such as NRC licensees, NRC regional licensing and inspection staff, NRC data bases, Agreement States, and stakeholders.

We agree that the estimates for the information collection burden associated with the testing requirements in the proposed rule were uncertain and may have been too low. However, the testing requirements are not included in the final rule.

Issue 9: Do the Potential Health and Safety Benefits of Requiring All Licensees to Possess Dose Calibrators Outweigh the Cost of the Calibrators?

Comment. Commenters suggested that the NRC should not require all licensees to possess a dose calibrator. They noted that certain categories of licensees only use unit dosages, and, therefore, obtaining a dose calibrator would create an unnecessary expense for them.

Response. The NRC has revised § 35.63 to require a licensee to determine and record the activity of each dosage before medical use. For a unit dosage, this determination could be made by a decay correction, based on the activity or activity concentration determined by (1) a manufacturer or preparer licensed under § 32.72 of this chapter or equivalent Agreement State requirements, or (2) an NRC or Agreement State licensee in accordance with a Radioactive Drug Research Committee-approved protocol or an Investigational New Drug (IND) protocol accepted by FDA for use in research. Therefore, a licensee who uses only unit dosages would not be required to incur the cost of a dose calibrator. However, the requirements also allow a licensee to use a dose calibrator to determine the activity of the unit dosage by direct measurement of radioactivity if he or she chooses to do so.

Issue 10: Do the Potential Health and Safety Benefits of Requiring Licensees To Conduct an Annual Retrospective Review of a Sample of Records of Administrations That Require a Written Directive Outweigh the Costs of the Reviews?

Comment. Commenters on a ''strawman'' version of the rule stated that the review that would be required by § 35.24(c) of the proposed rule, under which licensees would have been required to review a representative sample of records of administrations that require a written directive, would be an expensive requirement that would not reduce the rate of medical events. Furthermore, they said that a licensee would be forced to review 100 percent of the records to ensure that an inspection does not uncover a problem that was not reported.

Response. The NRC agrees that the proposed requirement was too prescriptive and, therefore, we deleted it from the final rule.

Issue 11: Do the Potential Health and Safety Benefits of Requiring Licensees To Establish Procedures To Provide Reasonable Assurance That a Radiopharmaceutical Will Not Be Unintentionally Administered to a Pregnant or Breast-Feeding Woman Outweigh the Costs of Compliance?

Comment. Commenters argued that a requirement to provide reasonable assurance that a radiopharmaceutical will not be unintentionally administered to a pregnant or breast-feeding woman could result in the administration of pregnancy tests for nearly all patients of child-bearing age, and this will increase costs.

Response. The NRC recognizes that the standard of practice for authorized users is to assess the pregnancy or nursing status of their female patients (see ACR ''Standard for the Performance of Therapy with Unsealed Radionuclide Sources,'' 1996, and ''Society of Nuclear Medicine General Procedure Guidelines for Imaging with Radionuclides,'' 1997). As a result, we do not believe that it is necessary for the NRC to require a licensee to assess the pregnancy or nursing status of patients before a medical treatment involving byproduct material.

Issue 12: Should Costs of Regulatory Implementation and Compliance by Licensees of Agreement States Be Included in the Regulatory Analysis?

Comment. A commenter argued that the regulatory analysis should reflect the possibility that Agreement States may not adopt all of the regulatory provisions included in the proposed rule.

Response. The NRC agrees with the commenter that, depending on the compatibility level assigned to particular regulatory requirements, Agreement States may not adopt all of the provisions in the proposed rule. However, in order to estimate the full impact of the regulatory changes in Part 35, we have assumed in developing the Regulatory Analysis that the Agreement States will adopt and implement all the provisions. However, we have provided sufficient details concerning estimated numbers of Agreement State licensees. Therefore, anyone who wishes to do so can estimate the effects of different

assumptions concerning Agreement State adoption and implementation of the requirements in the final rule.

Issue 13: Does the Regulatory Analysis Properly Estimate the Costs of Compliance With Particular Sections of the Proposed Rule?

Comment. Commenters criticized the estimates in the Regulatory Analysis for particular sections of the proposed rule. In particular, they suggested that the time necessary to prepare a license amendment could be greater than estimated for § 35.6, that the number of license amendments likely to be submitted under § 35.13 could be estimated more precisely, and that the time required for a meeting of a Radiation Safety Committee could be greater than estimated. Commenters also suggested that the interaction of §§ 35.400, 35.500, and 35.590 with § 35.12 was unclear, and additional license amendments might need to be costed under § 35.12. Commenters questioned whether the intent of the rule was to require calibration of every brachytherapy source under § 35.432, and, if so, said that additional costs should be estimated. Commenters also asked for substantiation for the $1000 estimate for calibrating brachytherapy sources and asked for clarification regarding the number of affected licensees. When no incremental cost was indicated for a particular section of the proposed rule (e.g., §§ 35.610, 35.3045, and 35.3067), a commenter requested that a cost estimate be provided.

Response. The NRC reviewed the Regulatory Analysis and provided additional clarification when possible for the points raised by the commenters. We concluded that the estimated time for preparation of an application for a license amendment under § 35.6 would not differ significantly from the time necessary to prepare any other license amendment application.

We also concluded that because the changes to the requirements concerning when a license amendment is required reflect changes to other sections of the rule (e.g., revisions to the requirements concerning changes to the areas of use under §§ 35.100 and 35.200) a count of former license amendment applications would not provide useful data. We agree that the time required for Radiation Safety Committee meetings can vary, but concluded that the elimination of prescriptive requirements for the Radiation Safety Committee, including the number of required attendees and procedural requirements concerning the meetings, would result in an average reduction in the duration of meetings. We concluded that the commenter had not correctly interpreted the interaction of §§ 35.400, 35.500 and 35.590 with § 35.12, particularly because the commenter appeared to be referring to the strawman proposed rule. Therefore, we did not provide the estimate called for. The estimate of $1000 per licensee for calibration of brachytherapy sources was based on information from NRC staff and members of the ACMUI concerning the number of calibrations that would be performed by an average licensee and the time necessary to perform each calibration. With respect to the commenter's request for a total cost estimate, see the response to Issue 5.

Part III—Specific Comments on the Proposed Rule

Part 20—Standards for Protection Against Radiation

Section 20.1002, Scope

Issue 1: Were Any Changes Made to This Section Between the Proposed and Final Rule?

Response. Yes. The NRC amended this section to replace the phrase ''to exposure from individuals administered radioactive material and released in accordance with § 35.75'' with the phrase ''to exposure from individuals administered radioactive material and released under § 35.75.'' This change clarifies that the dose to individual members of the public from a licensed operation does not include doses received by individuals exposed to patients who were released by the licensee under the provisions of § 35.75.

In 1997, we amended the regulations for the release of patients administered radioactive material to base the criteria for patient release on the potential dose to other individuals exposed to the patient (62 FR 4120; January 29, 1997). As part of that rulemaking, we also amended the regulatory text in §§ 20.1002, 20.1003 and 21.1301 to reflect the Commission's policy that patient release is governed by § 35.75, not § 20.1301 (62 FR 4120; January 29, 1997, see page 4122).

Current §§ 20.1002, 20.1003, and 20.1301(a)(1) indicate that the dose limits for individual members of the public or for an occupationally exposed individual from a licensed operation do not include doses received by individuals exposed to patients who were released in accordance with § 35.75. Upon further review, we believe that changes needed to be made to the current regulatory text in §§ 20.1002, 20.1003, and 20.1301, to further clarify that the dose limits do not apply to the maximally exposed individual from a patient or human research subject who has been administered unsealed byproduct material or implant containing byproduct material (reference § 35.75) and has been released from the licensee's control.

Under § 35.75, a licensee may release an individual from its control if the total effective dose equivalent to any other individual from exposure to the released individual is not likely to exceed 5 millisievert (mSv)(0.5 rem). The licensee is required to comply with all the requirements in § 35.75. Failure to comply with any of the provisions in § 35.75 may result in enforcement action. This change in § 20.1002 makes it clear that any violations will be cited against § 35.75 and not Part 20.

Section 20.1003, Definitions

Issue 1: Were Any Changes Made to This Section Between the Proposed and Final Rule?

Response. Yes. The NRC made corresponding changes to the definitions for occupational dose and public dose to clarify that these doses do not include doses received by individuals exposed to patients who were released by the licensee under the provisions of § 35.75. Specifically, we amended these definitions to replace the phrase ''from exposure to individuals administered radioactive material and released in accordance with § 35.75'' with the phrase ''from exposure to individuals administered radioactive material and released under § 35.75.'' The rationale for these changes is discussed in depth under § 20.1002, above.

Section 20.1301, Dose Limits for Individual Members of the Public

Issue 1: Who Should Approve Whether a Visitor Is Allowed To Receive a Dose Up to 5 mSv (0.5 rem)?

Comment. A commenter suggested that the RSO, not the AU, should be the appropriate individual to approve the merits of allowing a visitor to receive up to 5 mSv (0.5 rem).

Response. AUs have the primary responsibility for the health and safety of their patients. They are also responsible for determining, depending on the patient's condition, whether individuals can visit patients and with what limitations. Therefore, the NRC believes that the AU should approve whether a visitor is allowed to receive a dose up to 5 mSv (0.5 rem). However, the AU may consult with the RSO at any time regarding visitor control.

Issue 2: Should Visitors be Allowed To Receive a Dose Up to 5 mSv (0.5 rem)?

Comment. The commenter stated that the proposed rule did not meet any standard for justifying an increased exposure to someone visiting a hospitalized (confined) patient. The commenter indicated that one of the reasons for the increased dose limit in § 35.75 was the economic benefit of allowing the patient or human research subject to be released from control earlier. He went on to state that in the case of the proposed revision to § 20.1301, there was no economic benefit to the licensee and that NRC was basing this change on an emotional benefit to the patient rather than an economic benefit.

Response. The justification for this change was discussed in detail in the Statements of Consideration for the proposed rule (63 FR 43516; August 13, 1998) and in the associated draft Regulatory Analysis. It is restated in Section III, Part III of the **SUPPLEMENTARY INFORMATION** in this document and in the final Regulatory Analysis. Overall, the NRC believes that the emotional benefit to the patient or the visitor outweighs the increase in radiation risk to the visitor. AUs should have the flexibility to make a determination, based on their judgment, as to whether a patient or human research subject would benefit from allowing a visitor to receive a dose up to 5 mSv (0.5 rem). The AU must consider the patient's condition when determining whether it is appropriate to allow a visitor to receive a dose up to 5 mSv (0.5 rem). We changed the regulatory text in § 20.1301(c)(2) to clarify that the authorized user must make the determination whether the visit is appropriate before the visit occurs.

Issue 3: Were Any Changes Made to This Section Between the Proposed and Final Rule?

Response. Yes. The NRC changed the regulatory text in § 20.1301(a)(1) to indicate that the dose to individual members of the public from a licensed operation does not include doses received by individuals exposed to patients who were released by the licensed operation under the provisions of § 35.75. Specifically, we replaced the phrase ''from exposure to individuals administered radioactive material and released in accordance with § 35.75'' with the phrase ''from exposure to individuals administered radioactive material and released under § 35.75.'' The rationale for this change is discussed under § 20.1002.

Part 32—Specific Domestic Licenses of Broad Scope for Byproduct Material

Section 32.72, Manufacture, Preparation, or Transfer for Commercial Distribution of Radioactive Drugs Containing Byproduct Material for Medical Use Under Part 35

Issue 1: Were There Any Changes Made in This Section Between the Proposed and Final Rule?

Response. Yes. The NRC corrected the reference to ''paragraph (b)(2) and (b)(3)'' in § 32.72(b)(1) to read ''paragraphs (b)(2) and (b)(4).''

Part 35—Medical Use of ByProduct Material

Subpart A—General Information

Section 35.1, Purpose and scope.

Issue 1: How Does This Rule Provide for the Radiation Safety of Patients?

Comment. Commenters did not believe that Part 35 should address the radiation safety of patients because it would necessitate NRC making medical judgments. Commenters noted that physicians are trained to make informed decisions on behalf of patients. They believed that the NRC should ensure that those practicing nuclear medicine are adequately trained in nuclear science, thus ensuring that the radiation safety of patients is provided for.

Response. The NRC made no changes to the regulatory text in this section. We believe that the NRC should provide for the radiation safety of the public, workers, and patients. The Commission's goal in regulating nuclear material safety, as stated in its September 1997 ''Strategic Plan'' (NUREG–1614, Vol. 1), is to ''prevent radiation-related deaths or illnesses due to civilian use of source, byproduct material, and special nuclear material.'' The radiation safety of the public, workers, and the patient is central to the fulfillment of the Commission's statutory mandate to ''protect health and minimize danger to life.''

The Commission has decided to retain its long-standing medical use regulatory program. However, it is doing so with improvements, including decreased oversight of low-risk activities and continued emphasis on high-risk activities. The Commission has long recognized that physicians have the primary responsibility for the diagnosis and treatment of their patients. NRC regulations are predicated on the assumption that properly trained and adequately informed physicians will make decisions that are in the best interest of their patients. However, the NRC has a secondary, but necessary, role with respect to the radiation safety of patients. The NRC will, when justified by the risk to patients, regulate their radiation safety, primarily to ensure that the use of radionuclides is in accordance with the physician's directions.

Issue 2: Were There Any Changes Made in This Section Between the Proposed and Final Rule?

Response. Yes. The NRC replaced the word ''prescribes'' with the phrase ''contains the'' in the first sentence of the section because Part 35 contains the requirements and provisions for the medical use of byproduct material and for issuance of specific licenses authorizing medical use.

Section 35.2, Definitions

The NRC received numerous comments on the definitions. Commenters asked us to revise, delete, or add definitions for terms used in the rule. We also added some new terms in this section because of changes made in other sections of the rule. Public comments and our response to the comments, as well as the reasons for other changes to this section, are presented below, in alphabetical order of the terms.

Address of use.

Issue 1: Were There Any Changes Made in This Definition Between the Proposed and Final Rule?

Response. Yes. The NRC added the word ''preparing'' to the definition to recognize that licensees not only receive, use, and store byproduct material but, in the case of a medical licensee, they may also prepare the material for use.

Area of use.

Issue 1: Were There Any Changes Made in this Definition Between the Proposed and Final Rule?

Response. Yes. The NRC added the word ''preparing'' to the definition to recognize that licensees not only receive, use, and store byproduct material but, in the case of a medical licensee, they may also prepare the material for use.

Authorized Medical Physicist.

Issue 1: Should the Term ''Medical Physicist'' Be Used in the Rule?

Comment. Commenters believed that a ''medical physicist'' would better be defined by a unique term, similar to ''Authorized User,'' which has no meaning outside the regulations. They stated that use of the term ''authorized physicist'' would be consistent with ''authorized user.''

Response. The NRC retained the term ''authorized medical physicist'' in the final rule. This was done to maintain consistency with other terms used in Part 35 (AU and ANP). We also believe the term ''authorized physicist'' may be too broad, and we would like to make it clear that this individual has experience as a medical physicist.

Issue 2: Can an AMP Be an AU?

Comment. Commenters questioned whether a medical physicist could be the AU and, if so, whether there would be a need to have a physician listed on a nuclear medicine license?

Response. It is always necessary to name an AU on the Part 35 license because only an AU can prescribe dosages or doses of byproduct material for medical use under Part 35. An AU for medical use under §§ 35.100, 35.200, 35.300, 35.400, and 35.600 must be a physician. An AU for medical use under § 35.500 may be a physician, dentist, or podiatrist. An AMP could only be an AU, named in the license, if the AMP meets the criteria in the definition of AU in § 35.2, including the training and experience criteria cited in that section.

Issue 3: Were There Any Changes Made in This Definition Between the Proposed and Final Rule?

Response. Yes. In addition to restructuring the definition, to make it more readable, the NRC substituted the word ''individual'' for the word ''physicist.'' This change has been made so that the definition of the term would be similar to the definition for an RSO.

We also amended the definition for the AMP to include individuals identified as an AMP on a medical use permit issued by a Commission master material licensee, or a permit issued by a Commission master material license broad scope medical use permittee. This change, which was also made to the definitions of ''ANP,'' and ''AU,'' accounts for the fact that an AMP may be named on a permit issued by a master material licensee. For example, in the first case identified above, if a master material licensee has issued a permit that recognizes a particular individual as an AMP, under the revised definition the individual would continue to meet the requirements for an AMP under an NRC license. In the second case, if a master material licensee chooses to issue a broad scope permit to a hospital and that hospital has authorization to issue permits designating AMPs, under the revised definition an AMP on the permit would also meet the requirements for an AMP under an NRC license. For a definition and description of master materials licenses refer to NUREG–1556, Vol. 10, ''Consolidated Guidance About Materials Licenses: Program-Specific Guidance About Master Materials Licenses.''

Authorized Nuclear Pharmacist.

Issue 1: What Are the Duties of an ANP?

Comment. A commenter stated that the responsibilities and duties of the ANP were not codified.

Response. The NRC did not change the regulatory text in response to this comment. We have used the definitions section to provide an understanding of what we mean by a term. We do not believe it is appropriate to list the responsibilities and duties of the ANP either in the definitions section or elsewhere in the rule. In most cases, we have not specified who must perform a particular duty. This was done to give the licensee flexibility in how it implements its radiation protection program. However, where justified by risk, we have specified who must perform specific duties in a limited number of cases. For example, the full calibration measurements on remote afterloader must be performed by an AMP (§ 35.633(h)).

Issue 2: Why Do Nuclear Pharmacies Have the Authority To Approve ANPs?

Comment. A commenter did not believe that nuclear pharmacies should be authorized to approve ANPs.

Response. This commenter objected to one way by which an individual may be qualified to be an ANP, i.e., approval by a nuclear pharmacy authorized to approve ANPs. This pathway to be a qualified ANP was added to the final rule for two reasons. One, the current definition needs to recognize that § 32.72(b)(4) allows nuclear pharmacies to designate a pharmacist as an ANP if the individual meets certain requirements. Specifically, § 32.72(b)(4) contains a ''grandfathering'' provision permitting certain Part 32 nuclear pharmacy licensees to designate a pharmacist as an ANP, if the individual is identified, as of December 2, 1994, as an AU on a nuclear pharmacy license issued by the Commission. [If you would like additional information on § 32.72, refer to the regulatory history of the radiopharmacy rule (58 FR 33396; December 2, 1994, see page 33400).] Second, this change is needed because some nuclear pharmacies have a license amendment that allows them to approve ANPs if the individual meets the training and experience requirements in Part 35. Without this corresponding change in Part 35, the individual would not be allowed to function as an ANP regardless of the nuclear pharmacy's approval.

Issue 3: Were There Any Changes Made in This Definition Between the Proposed and Final Rule?

Response. Yes. The definition was restructured to make it more readable. The NRC also amended the definition for the ANP to include pharmacists identified as ANPs on a permit issued by a Commission master material licensee that authorizes medical use or the practice of nuclear pharmacy or a permit issued by a Commission master material license broad scope medical use permittee that authorizes medical use or the practice of nuclear pharmacy, or designated as an ANP in accordance with § 32.72(b)(4). This change, which parallels changes made to the definitions of ''AMP'' and ''AU,'' accounts for the fact that an ANP may be named on a permit issued by a master material licensee. In addition, the definition was amended to include ANPs that have been identified by a commercial nuclear pharmacy which has been given authorization to identify ANPs. In the first case identified above, if a master material licensee has issued a permit that recognizes a particular individual as an ANP, under the revised definition the individual would continue to meet the requirements for an ANP under an NRC license. In the second case, if a master material licensee chooses to issue a broad scope permit to a hospital and that hospital has authorization to issue permits designating ANPs, under the revised definition an ANP on the permit would also meet the requirements for an ANP under an NRC license.

Authorized User.

Issue 1: What Does an AU Do?

Comment. A commenter recommended that the definition of ''Authorized user'' include the duties of an AU.

Response. The NRC did not change the regulatory text to include the duties of the AU in the definition. We have used the definitions section to provide an understanding of what we mean by a term, as it is used in Part 35. Duties that must be performed by the AU are stated in regulatory text, where appropriate. The issue of whether the duties of a licensed individual belong in the definition section is discussed in more detail under the term ''authorized nuclear pharmacist.''

Issue 2: Does the Rule Distinguish Between Different Types of AUs?

Comment. A commenter recommended we clarify each type of

AU, or distinguish between AUs involved in diagnostic versus therapeutic medical uses.

Response. The NRC does not believe the definition of AU should be modified in this way. Other requirements in this part address the safety requirements for the different types of medical uses and the AU's actual duties. For example, the training and experience requirements for AUs, as well as other requirements in the regulations, differentiate between diagnostic and therapeutic medical uses of byproduct material. The training and experience requirements for an AU who would like to use unsealed byproduct material for uptake, dilution, and excretion studies (§ 35.290) differ from the training and experience requirements for an AU who would like to use unsealed byproduct material for therapy (§ 35.390). Also, radiation safety requirements are not the same for diagnostic medical uses as compared to therapeutic medical uses. Finally, the medical use license indicates what materials can be used by an AU.

Issue 3: Can Non-Physicians Be AUs?

Comment. A commenter noted that although the definition of ''AU'' refers to ''any prescriber,'' (i.e., physician, dentist, or podiatrist),'' the proposed rule language (in §§ 35.100, 35.200, and 35.300) refers only to a physician. The commenter indicated that if dentists and podiatrists cannot be AUs, the regulations should state this.

Response. Section 35.2 contains a general definition of an AU. Specific training and experience requirements for AUs are contained elsewhere within the regulatory text of Part 35. Where appropriate, the rule does specify when an AU must be a physician. An AU of materials authorized in §§ 35.100, 35.200, 35.300, 35.400, and 35.600 must be a physician. An AU using materials authorized under § 35.500 can be a physician, dentist, or podiatrist, if that individual meets all of the training and experience requirements for this type of use.

Issue 4: Were There Any Changes Made in This Definition Between the Proposed and Final Rule?

Response. Yes. The NRC also amended the definition for the AU to include physicians, dentists, or podiatrists identified as AUs on a permit issued by a Commission master material licensee that is authorized to permit the medical use of byproduct material, or a permit issued by a Commission master material license broad scope medical use permittee that is authorized to permit the medical use of byproduct material. This change, which was also made to the definitions of ''ANP,'' and ''AMP,'' accounts for the fact that an AU may be named on a permit issued by a master material licensee. For example, in the first case identified above, if a master material licensee has issued a permit that recognizes a particular individual as an AU, under the revised definition the individual would continue to meet the requirements for an AU under an NRC license. In the second case, if a master material licensee chooses to issue a broad scope permit to a hospital and that hospital has authorization to issue permits designating AUs, under the revised definition, an AU on the permit would also meet the requirements for an AU under an NRC license.

We also added a reference to new sections in the final rule that list the training and experience requirements for individuals using only I–131 in quantities that would require a written directive (§§ 35.392 and 35.394) and for individuals using strontium-90 for ophthalmic treatments (§ 35.491).

Brachytherapy.

Issue 1: Were There Any Other Changes Made in This Section Between the Proposed and Final Rule?

Response. Yes. The NRC added a definition for brachytherapy. We believe it is important to define such a term as it is used in Part 35 so that the regulated community and regulatory agencies have a clear understanding of what we mean when we use the term in the rule.

Brachytherapy source.

Issue 1: Were There Any Changes Made in This Definition Between the Proposed and Final Rule?

Response. The NRC did not receive any public comment on this definition. However, we did delete the word ''sealed'' in the definition. This was done in order to include sources which do not meet the definition of ''sealed source'' (i.e., ''radioactive plated, embedded, and activated'' sources).

Client's address.

Issue 1: Were There Any Other Changes Made in This Section Between the Proposed and Final Rule?

Response. Yes. The NRC added a definition for client's address because we now use it in § 35.80, ''Provision of mobile medical service.'' The term ''client's address'' encompasses an area of use, as well as a temporary job site. Use of this term in the rule is explained in greater depth under the discussion of § 35.80.

Diagnostic clinical procedures manual.

Issue 1: Is This Term Needed?

Comment. Commenters recommended this term be deleted because it is too prescriptive and should be replaced with the term ''radiopharmaceutical prescription/order.'' A radiopharmaceutical prescription/order can either be written for an individual patient (e.g., a written directive for therapeutic radiopharmaceuticals) or be in the form of specific standing orders. The commenter was concerned that use of the term ''clinical procedures manual'' may limit a licensee's ability to compound radioactive drugs. As such, according to the commenter, the term raises a clinical medical practice issue under state law regarding the practice of medicine and pharmacy. The commenter believed that it would be more appropriate for the NRC to require a general description of the radiation safety procedures used to protect workers, the public, and other patients from unintentional exposures. The commenter indicated the procedure manuals are written by physicians and should only be considered as informational or guidance documents for technologists.

Response. In response to this comment, the NRC deleted ''diagnostic procedures manual'' both as a defined term in § 35.2 and from the definition of ''prescribed dosage'' in § 35.2. Also, because this term is not used in the regulatory text, we no longer need to define it.

As modified, the rule is less prescriptive and does not limit a licensee's ability to compound certain radioactive drugs. Sections 35.100, 35.200, and 35.300 permit certain uses of unsealed byproduct material which are prepared by an ANP, a physician who is an AU (meeting certain requirements), or an individual under their supervision.

Health physicist.

Comment. A commenter asked that we add a definition for ''health physicist.'' This individual would be defined as ''a person qualified in the art, science, and professional practice of radiation safety as evidenced by current certification by the American Board of Health Physics (ABHP) or an equivalent certifying body with substantially the same requirements.'' The commenter believed that NRC, when identifying physicists, was defining a specific position too narrowly, with delineated duties and responsibilities that represent only a portion of the duties and responsibilities of physicists who are involved in radiation safety.

Response. The NRC has not defined the term in Part 35 because it is not used

in Part 35. Physicists meeting the requirements for an ''authorized medical physicist'' or ''Radiation Safety Officer'' would be recognized on the license as either an AMP or RSO, respectively.

High dose-rate remote afterloader and low dose-rate remote afterloader.

Issue 1: Should There Be Another Category of ''Afterloader,'' Such as a ''Non-Remote'' or ''Beta-Only'' Afterloader?

Comment. A commenter stated that the proposed afterloader definitions don't distinguish between the beta device that delivers more than 2 Gray/hour (Gy/h) to a target tissue and less than 0.002 Gy/h to the remainder of the body from the afterloader capable of delivering a lethal whole body dose. The proposed definitions will result in confusion for licensees and inspectors. The commenter recommended that another category of afterloaders, such as ''non-remote'' or ''beta-only'' afterloaders, be developed.

Response. The NRC has not distinguished between beta and photon-emitting remote afterloaders in the definition. The purpose of the definition is to categorize afterloaders into different groups based on the dose rate (i.e. high, medium, or low) of the remote afterloader. Requirements for the devices are found in Subpart H. The final rule only addresses use of photon-emitting afterloaders. Use of beta-emitting afterloaders is being addressed on a case-by-case basis at this time because use of these types of afterloaders is relatively new and both regulators and licensees continue to identify elements of safe operation.

Issue 2: Were There Any Other Changes Made in This Definition Between the Proposed and Final Rule?

Response. Yes. The definition for a high dose-rate remote afterloader (HDR) was amended to state that it means a brachytherapy device that remotely delivers a dose rate in excess of 12 gray (1200 rads) per hour at the point or surface where the dose is prescribed, rather than a dose rate in excess of 2 gray (200 rads) per hour. The definition for a low dose-rate remote afterloader (LDR) was also amended to state that it means a brachytherapy device that remotely delivers a dose rate of less than or equal to 2 gray (200 rads) per hour at the point or surface where the dose is prescribed, rather than a dose rate of less than 2 gray (200 rads) per hour. These changes were needed because the final rule includes a definition for medium dose-rate remote afterloader (MDR).

Licensee.

Issue 1: Should This Term Be Defined?

Comment. A commenter asked that this term be defined.

Response. The NRC did not define the term in Part 35 because ''licensee'' is defined in 10 CFR 20.1003, ''Definitions,'' as the holder of a license. Wherever possible, we have tried to rely on the definitions in other parts of 10 CFR Chapter I that apply to medical licensees, rather than duplicate the definitions in Part 35.

Management.

Issue 1: Who Is ''Management''?

Comment. A commenter asked that we clarify what we mean when we use the term ''management.'' The commenter wanted to know whether management could be the chief executive officer or the head of one or all departments?

Response. The NRC clarified the regulatory text to define management as the Chief Executive Officer (CEO) or other individual having the authority to manage, direct, or administer the licensee's activities, or those persons' delegate or delegates. If the head of one or all departments is a delegate(s) of the CEO or if the individual has the authority to manage, direct, or administer the licensee's activities, that person(s) would be considered to be part of ''management.''

Manual brachytherapy.

Issue 1: Should the Term ''Manual Brachytherapy'' Be Defined?

Comment. A commenter asked that we define this term because it is not a common or standard term and it is used as a subpart title.

Response. The NRC added a definition for manual brachytherapy. As used in this part, manual brachytherapy has been defined to be a type of brachytherapy in which the brachytherapy sources (e.g., seeds, ribbons) are manually placed topically on or inserted either into the body cavities that are in close proximity to a treatment site or directly into the tissue volume.

Medical use.

Issue 1: Should the Definition of the Term ''Medical Use'' Include the Term ''Byproduct Material''?

Comment. A commenter recommended that the term ''byproduct material'' be deleted from the definition of the term ''medical use'' because the regulations use the phrase ''byproduct material for medical use,'' which is redundant. The commenter did not believe it necessary to include the term ''byproduct material'' in the definition of ''medical use'' and then to modify the term ''medical use'' with the phrase ''byproduct material'' in the regulations. The commenter stated that deleting the term ''byproduct material'' from the definition ''requires the least amount of correction and simplifies compatibility by Agreement States.''

Response. The NRC recognizes that there is some redundancy in using the phrase ''Medical use of byproduct material.'' However, we believe that this level of redundancy in some requirements is not objectionable, if it helps to clarify NRC's implementation of specific requirements of the AEA.

Medium dose-rate remote afterloader.

Issue 1: Is There a Need for a Definition of the Term ''Medium Dose-Rate Remote Afterloader''?

Comment. Commenters were divided in response to our request for comment on whether the rule should define the term ''medium dose-rate remote afterloader.'' Some commenters recommended that the term be defined because, although the regulatory requirements for ''high'' and ''medium'' dose-rate afterloaders are very similar, the radiation safety precautions are different and, thus, these terms require different definitions. Commenters who did not support a definition for an MDR cited various reasons for their position. Some commenters believed that the regulatory requirements for HDR and MDR should be identical, and, therefore, there was no need to define an MDR. This position is based on the opinion that the risks to patients from high, medium, pulsed and low dose-remote afterloaders, capable of whole body irradiation, are indistinguishable. Other commenters were concerned that the definition for an MDR could lead to confusion because the definition would overlap with the current definition of ''high dose-rate remote afterloader.''

Response. The NRC included a definition for an MDR in the final rule because the final rule contains requirements that apply to MDRs. The definitions of an HDR and an LDR were revised so there is no overlap between the definitions.

Mobile medical service.

Issue 1: Were There Any Changes Made in This Definition Between the Proposed and Final Rule?

Response. The NRC did not receive any public comment on this definition. However, we did change the term from ''mobile service'' to ''mobile medical service.'' This was done because we wanted to state clearly that the mobile service provisions apply only to medical

use. The final rule defines ''mobile medical service'' as the transportation of byproduct material and its medical use at the ''client's address,'' which includes the ''area of use'' or a ''temporary job site.'' In addition, the definition of this term no longer contains the phrase ''by the same licensee'' because that phrase unduly limited the transportation and medical use of the byproduct material to one licensee.

Output.

Issue 1. Were There Any Changes Made in This Definition Between the Proposed and Final Rule?

Response. The definition for output was amended to also refer to the exposure rate or dose rate from a brachytherapy source, remote afterloader, or gamma stereotactic radiosurgery unit. The proposed rule only addressed the output from a teletherapy unit. This was done because various sections in Subpart H reference output from these other units.

Patient intervention.

Issue 1: Were There Any Other Changes Made in This Section Between the Proposed and Final Rule?

Response. Yes. The NRC added a definition for patient intervention. We believe this definition is needed to state clearly what we mean when we use the term in § 35.3045. Discussion of patient intervention is found in the section of this document responding to comments on § 35.3045.

Preceptor.

Issue: Should the Term ''Preceptor'' Be Defined?

Comment. Commenters recommended that the term be defined and that the definition distinguish between low-dose radiopharmaceuticals (diagnostic) and high-dose radiopharmaceuticals (therapeutic). The former would include ''persons designated as authorized physician users of low-dose radiopharmaceuticals.'' Preceptors of ''high-dose radiopharmaceuticals'' must be ''program directors of structured educational programs in medical teaching institutions that consist of didactic training and practical experience.'' Commenters believed that the ''preceptor'' should not be limited to someone in the medical, dental, or podiatry profession.

Commenters believe the term ''preceptor'' should be defined as an individual who is listed on a license, such as an AU or RSO, or is appointed by licensee management to act in the capacity of a preceptor for the purpose of documenting that an individual has completed a structured educational program and/or practical experience. The preceptor must have demonstrated training and experience that is at least equal to the training and experience of the individuals being trained.

Response. The NRC agrees the term ''preceptor'' should be defined because the term is used throughout the training and experience requirements in the revised Part 35. A preceptor is defined as someone who provides or directs the training and experience required for an individual to become an AU, AMP, ANP, or RSO. In addition, we agree that the preceptor must have training and experience that is at least equal to the training and experience required by the AU, AMP, ANP, or RSO, as appropriate. This is reflected in the paragraphs that require the preceptor certification in the training and experience requirements in Subparts B and D through H.

Prescribed dosage.

Issue 1. Were There Any Changes Made in This Definition Between the Proposed and Final Rule?

Response. Yes. The NRC amended the definition for ''prescribed dosage'' to allow the AU to direct the administration of a range of activity and to delete the reference to the ''diagnostic clinical procedures manual.''

Prescribed dose.

Issue 1. Were There Any Changes Made in This Definition Between the Proposed and Final Rule?

Response. Yes. The NRC amended the definition for ''prescribed dose'' to clarify that item (3) refers to manual brachytherapy and item (4) refers to remote brachytherapy afterloaders.

Pulsed dose-rate remote afterloader.

Issue 1. Were There Any Changes Made in This Definition Between the Proposed and Final Rule?

Response. Yes. The NRC restructured the definition of pulsed dose-rate remote afterloader (PDR) to make it easier to read and clarified that it refers to a remote afterloading brachytherapy device. We also added a statement that the device uses a single source that is capable of delivering dose rates in the ''high dose-rate'' range, but is approximately one-tenth of the activity of typical HDR sources.

Radiation Safety Officer.

Issue 1: Were There Any Changes Made in This Definition Between the Proposed and Final Rule?

Response. Yes. The NRC restructured the definition to make it more readable. We also amended the definition for the RSO to include individuals identified as an RSO on a medical use permit issued by a Commission master material licensee. This change, which was also made to the definitions of ''ANP,'' ''AMP,'' and ''AU,'' accounts for the fact that an RSO may be named on a medical use permit issued by a master material licensee. If a master material licensee has issued a permit that recognizes a particular individual as an RSO, under the revised definition the individual would continue to meet the requirements for an RSO under an NRC license.

Radionuclide or radiopharmaceutical.

Comment. Commenters opposed the use of terms like ''radionuclide,'' or ''radiopharmaceutical'' in Part 35 because these terms are not defined as specifically containing byproduct material. They indicated that this was very important because NRC's statutory authority for regulating medical use under Part 35 is limited to byproduct material. They recommended that the regulation should use terms that have been defined to mean ''byproduct material radionuclide'' or ''byproduct material radiopharmaceutical.''

Response. Section 35.1, Scope, specifies that ''this part contains the requirements and provisions for the medical use of byproduct material and for the issuance of specific licenses authorizing the medical use of this material.'' In addition, medical use is defined in § 35.2, to mean the intentional internal or external administration of byproduct material or the radiation from byproduct material to patients or human research subjects under the supervision of an AU.

The word ''radiopharmaceutical'' is only used in §§ 35.204 and in 35.2063. In both cases, it is clear that the requirement applies to radiopharmaceuticals containing byproduct material. The word ''radionuclide'' is used in §§ 35.13, 35.40, 35.2067, and 35.3067 and is also used in the training and experience sections in Subparts B and D through H. Again, it is clear that the requirements in §§ 35.13, 35.40, 35.2067, and 35.3067 apply to radionuclides containing byproduct material, and it would be redundant for the rule text to restate the phrase ''containing byproduct material.'' In the case of the training and experience sections, we have chosen to allow an individual ''to take credit for'' experience obtained with handling nonbyproduct and byproduct material in meeting the training and experience requirements because there is very little difference between how byproduct and nonbyproduct materials are handled.

Sealed source.

Issue 1: Are Epoxy Vials Used for Testing Dose Calibrators ''Sealed Sources''?

Comment. A commenter asked that we clarify whether the epoxy vials used for testing dose calibrators are ''sealed sources.'' The commenter stated that epoxy vials are more correctly characterized as monoliths and should not be subject to leak testing.

Response. A ''sealed source'' is defined in § 35.2 as ''any byproduct material that is encased in a capsule designed to prevent leakage or escape of the byproduct material.'' Under this definition, epoxy vials used for testing dose calibrators are typically considered sealed sources. However, it is the licensee's responsibility to verify that a particular manufacturer's vial is considered by the relevant regulatory agencies to be a sealed source. This can be done by referencing the SSDR.

Stereotactic radiosurgery.

Issue 1: Were There Any Changes Made in This Section Between the Proposed and Final Rule?

Response. Yes. The definition was amended to clarify that stereotactic radiosurgery devices deliver therapeutic doses.

Teletherapy.

Issue 1: Were There Any Changes Made in This Section Between the Proposed and Final Rule?

Response. The NRC added a definition for teletherapy. This was done because we believed it is important to define this term as it is used in Part 35 so that the regulated community and the regulatory agencies have a clear understanding of how we have used a term within the rule.

Therapeutic dosage and therapeutic dose.

Issue 1: Were There Any Other Changes Made in This Section Between the Proposed and Final Rule?

Response. The NRC added definitions for the terms ''therapeutic dosage'' and ''therapeutic dose'' because both terms are used in § 35.40, ''Written directives.'' In addition, we believe these definitions are needed to eliminate any confusion about when a written directive is needed.

Type of use.

Issue 1: Were There Any Other Changes Made in This Section Between the Proposed and Final Rule.

Response. Yes. The NRC added a definition for the term ''type of use.'' This term replaced the term ''clinical procedure'' in § 35.13(a). We believe this term makes it clear that we are discussing ''uses'' in Part 35 (e.g., a use of byproduct material as specified in §§ 35.100, 35.200, 35.300, 35.400, 35.500, 35.600, and 35.1000), rather than ''clinical procedures'' (e.g., a bone scan, liver scan, or whole body scan).

Unit dosage.

Issue 1: Is Manipulation of ''Unit Dosages'' Permitted Under the Definition of This Term?

Comment. A commenter asked to what extent the ''end user'' would be allowed to manipulate a ''unit dosage.'' The commenter indicated that the greater the manipulation of the dosage, the greater the chance of an error being made in calculating the activity.

Response. The NRC amended the definition of unit dosage to make it clear that unit dosages cannot be manipulated after being initially prepared because any manipulation could change the activity in the dosage.

Issue 2: Were There Any Other Changes Made in This Definition Between the Proposed and Final Rule?

Response. Yes. The NRC amended the definition to stipulate that unit dosages must be prepared for medical use for administration as a single dosage to a patient or human research subject without any further manipulation of the dosage after it is initially prepared. This change acknowledges that preparation of a unit dosage is not limited to a manufacturer or preparer licensed under § 32.72 or equivalent Agreement State requirement. It also highlights that a unit dosage is intended for administration to a patient or human research subject without any further manipulation.

Written directive.

Issue 1: Does the Definition of ''Written Directive'' Recognize ''Computerized Directives''?

Comment. A commenter asked that the definition of written directive be revised to recognize that many facilities are using computerized systems and are not relying on written documents.

Response. The NRC did not change the definition. The intent of the definition of ''written directive'' and the requirements in § 35.40 are to distinguish between an AU's written versus oral direction for the administration of byproduct material, rather than between written (hard copy) and electronic directions. As used in Part 35, ''written'' includes information recorded in a computerized system. If a written directive is generated or stored in a computerized system, the licensee must have a method of authenticating the AU's signature. Refer to the discussion of § 35.5 for additional information on maintenance of records.

Section 35.5, Maintenance of records

Issue 1: Can Required Records, Other Than Originals, Be Authenticated?

Comment. A commenter asked how a copy or microform is authenticated by authorized personnel. The commenter indicated there is no requirement to authenticate records stored in electronic media. The commenter believed that all records should be required to be authenticated in writing when provided for legal purposes, or verbally when being reviewed during an inspection.

Response. Any record required by Part 35 must be maintained in accordance with § 35.5. These records must be authenticated regardless of the storage media. The issue of authenticating records was addressed by the NRC under a separate rulemaking, published in the **Federal Register** on May 27, 1988 (53 FR 19240). The following explanation of ''authenticated,'' as stated in that final rule, applies to all records retained under NRC's regulatory authority: '''Authenticated' denotes that the data has been verified for completeness and accuracy by an authorized individual and that it is a true representation of the original data'' (see page 19243).

Issue 2: Were There Any Changes Made in This Section Between the Proposed and Final Rule?

Response. Yes. The NRC made an editorial change in the second sentence to replace the phrase ''original, or a reproduced copy or a microform,'' with the phrase ''original, reproduced copy, or microform.''

Section 35.6, Provisions for Research Involving Human Subjects.

Issue 1: Should § 35.6 Include a Requirement That Licensees Develop, Implement, and Maintain Procedures for Evaluating When a Medical Procedure Would be Considered To Be a Research Procedure?

Comment. The NRC received a comment in support of the requirement, as well as comments opposed to the requirement. The commenter who wrote in favor of requiring such procedures stated there are occasions when a clear definition of what constitutes research would be useful in deciding which procedures must be approved by the Institutional Review Board (IRB) or RSC.

Commenters opposed to a requirement for procedures indicated that FDA regulates research through IRBs. They believed that existing regulations and guidelines provided

adequate oversight of research and that decisions regarding research should be left to the individual licensee and the licensee's IRB. They noted that the IRB must follow the Federal Policy for the Protection of Human Research Subjects. As a result, they believed that research that is approved by an IRB and is within the scope of the authorized inventory should be permitted. Commenters also noted that similar procedures are not required in other areas of medicine. Finally, commenters indicated that a requirement for procedures would not increase public health and safety.

Response. The NRC does not believe it is necessary to include a separate definition of the term ''research'' in Part 35 because Section 102 of the Federal Policy for the Protection of Human Research Subjects defines the term ''research.'' (Further information on this can be found in the **Federal Register** (56 FR 28003; June 18, 1991, see page 28013). In addition, we consider research conducted by NRC medical use licensees involving human subjects, which is also regulated by FDA, to be within the scope of § 35.6(b). Therefore, it is not necessary for such a licensee, prior to conducting such research, to apply for and receive a specific amendment to its NRC license. However, under §§ 35.6 and 35.7, the licensee is not relieved from complying with FDA or other requirements applicable to such research.

We agree with the comment that the NRC should not add a requirement in Part 35 for licensees to develop, implement, and maintain procedures for evaluating when a medical procedure would be considered to be research. We believe that the issue of ensuring that all medical procedures and studies that should be subject to the policy are recognized as ''research'' and are reviewed by an IRB should be resolved as a matter of common policy, rather than in any separate effort by NRC. However, in reaching this conclusion, we do not believe that we must be guided by whether, for any given Commission requirement, there is a comparable requirement for other areas of medicine. The regulatory history of Part 35 shows that the Commission has operated under the assumption that Congress intended a disproportionate degree of Federal regulatory control be exercised over the medical use of nuclear materials, as compared to the medical use of other sources of radiation (e.g., x-rays or accelerator-produced isotopes) (44 FR 31701; May 14, 1980, see page 31702). The issue of why similar procedures are not required in other areas of medicine is outside the scope of this rulemaking.

Issue 2: Do Broad Scope Licensees Need a License Amendment Before Conducting Research?

Comment. A commenter recommended that broad scope licensees be exempted from the requirement to amend their licenses before conducting research involving human subjects using byproduct material.

Response. The NRC believes that broad scope medical use licensees should be required to comply with § 35.6. This section is designed to protect the rights of human research subjects by requiring all licensees to obtain the informed consent of the subjects and by requiring an IRB to give prior review and approval of the research.

Issue 3: Were There Any Changes Made in This Section Between the Proposed and Final Rule?

Response. Yes. The NRC restructured the section to make it easier to read. We also added an introductory paragraph to make it clear that research permitted under § 35.6 may only be performed using byproduct material that is already authorized for medical use by the license. For example, if a licensee is authorized to use byproduct material under §§ 35.100, 35.200, and 35.300, it could not conduct research using a remote afterloader. However, the same licensee could conduct research using materials authorized in §§ 35.100, 35.200, or 35.300.

We also added a new paragraph (d). This paragraph codifies the Commission's intent that § 35.6 does not relieve licensees from complying with other provisions in Part 35. In other words, as stated in the regulatory history of § 35.6, the relevant radiation safety provisions of Part 35 are applicable to research involving human subjects. For further information on this issue, you may want to refer to the December 2, 1994, **Federal Register** (59 FR 61767).

Section 35.8, Information Collection Requirements: OMB Approval

Issue 1: Were There Any Other Changes Made in This Section Between the Proposed and Final Rule?

Response. Yes. Paragraph (b) was amended to add references to §§ 35.19, 35.190, 35.392, 35.394, 35.433, 35.491, 35.615, 35.1000, 35.2041, 35.2433, and 35.2610 and to delete references to §§ 35.62, 35.292, 35.644, and Appendix A. These were conforming changes needed because of changes made in the regulatory text between the proposed and final rule.

Section 35.10, Implementation

Issue 1: Should the Time Period for Implementation of the Final Rule Be Extended?

Comment. Commenters asked that the implementation period for the new rule be extended up to 1 year from its publication to allow licensees and applicants sufficient time to adjust their budgets for any increased expenditures needed to implement the rule.

Response. The NRC has maintained a 6-month implementation period for all sections of the final rule. We believe that 6 months provides adequate time for licensees to develop and implement any changes in their radiation safety programs.

Issue 2: Should the Rule Provide Relief From Restrictive Requirements in the Rule or License?

Comment. A commenter recommended that § 35.10(e) be revised because otherwise it will maintain the most restrictive requirements of either the revisions of Part 35 or the licensee's current license conditions. The commenter was concerned if a license condition cites a deleted requirement in Part 35, the license condition remains in effect unless the license is amended in order to remove the needless requirements. The need for a license amendment would diminish the projected cost saving of the rule.

Commenters also raised the issue of whether there is a ''duality'' of the new Part 35 and existing license conditions, thus raising a concern about inspection and enforcement. Licensees will have to make significant amendments comparable to submitting a license renewal. Commenters believed that, if feasible and upon written request, licensees should be permitted to comply with the ''new'' Part 35 without regard to the restrictive nature of the license and without requiring a license amendment. If NRC believes that a regulation can be relaxed or eliminated without a reduction in radiation safety, the NRC should allow licensees to change their programs accordingly.

Response. The NRC modified the text of § 35.10 to allow for relief from the current rule and, in some cases, license conditions. The following discussion explains and summarizes the changes made in this section.

Paragraph (a) requires licensees to implement the provisions in the rule 6 months after the final rule is published in the **Federal Register**, except as stated in paragraph (b) of this section.

Paragraph (b) allows certain training and experience requirements to be

implemented on or before 2 years after the effective date of the final rule.

Paragraph (c) allows, prior to the date 2 years after the effective date of the final rule, licensees to have the option of complying either with Subpart J or Subparts B and D–H.

Paragraph (d) states if a license condition exempted a licensee from a provision in the current Part 35, that license condition continues to exempt the licensee from the requirements in the corresponding provision in §§ 35.1–35.4002 of Part 35. As shown in the following example, a corresponding provision may not always have the same numerical section reference. For example, if a licensee is exempted from the requirements in current § 35.57(c), Authorization for calibration and reference sources, the licensee will be exempted from the corresponding requirements in the final § 35.65(c), Authorization for calibration, transmission, and reference sources.

Paragraph (e) states that when a regulatory requirement in Part 35 differs from the requirement in an existing license condition, the requirement in Part 35 governs. This paragraph primarily applies to those licensees that committed to follow the procedures in Regulatory Guide 10.8, ''Guide for the Preparation of Applications for Medical Use Programs.'' When the final rule becomes effective, licensees will follow the requirement in Part 35 if it differs from the requirement that the licensee committed to by referencing the Regulatory Guide. For example, most licensees have committed to calibrate their dose calibrators using the procedures in Regulatory Guide 10.8, Appendix C, ''Model Procedure for Calibrating Dose Calibrator.'' These procedures are very prescriptive. The final Part 35 only requires licensees to calibrate instruments used to measure the activity of unsealed byproduct materials in accordance with nationally recognized standards or the manufacturer's instructions. Therefore, after the effective date of the final rule, a licensee must calibrate its dose calibrators in accordance with nationally recognized standards or the manufacturer's instructions, rather than being tied to using the procedures in Regulatory Guide 10.8.

Paragraph (f) states that the licensee shall continue to comply with any license condition that requires it to implement procedures for spot-checks on teletherapy, photon-emitting remote afterloaders, or gamma stereotactic radiosurgery units and to implement emergency procedures for photon-emitting remote afterloaders, teletherapy units, or gamma stereotactic radiosurgery units until there is a license amendment or renewal that modifies or removes the condition. Specifically, licensees must continue to follow any emergency response and spot-check procedures for teletherapy, remote afterloaders, and gamma stereotactic radiosurgery units that were submitted to NRC in support of a licensing action because of the high radiation risk associated with this type of use of byproduct material.

Issue 3: Were There Any Other Changes Made in This Section Between the Proposed and Final Rule?

Response. Yes. Paragraph (b) was amended to add references to §§ 35.190(a), 35.392(a), and 35.394(a), and to delete reference to § 35.292(a). Paragraph (g) was deleted. Reference the General Training and Experience discussion in the beginning of this section of the **SUPPLEMENTARY INFORMATION** for more information.

Section 35.11, License Required

Issue 1: Should the Term ''Person'' Be Used in Lieu of ''Individual''?

Comment. A commenter noted that the word ''person'' was used in paragraph (a), while in paragraphs (b) and (c), the word ''individual'' was used. They recommended that the word ''person'' in paragraph (a) be changed to ''individual.''

Response. The NRC did not change the regulatory text of § 35.11. The term ''person'' is used in § 35.11(a) because licenses are issued to ''persons'' as defined in 10 CFR 30.4. Section 30.4 states that a person includes not only individuals (defined in 10 CFR 20.1003 as ''any human being''), but also corporations, government agencies other than the Commission, and States. Paragraphs (b) and (c) of § 35.11 use the term ''individual'' because the activities authorized by those sections are performed by ''individuals'' (under the supervision of an ''authorized user'' or ''authorized nuclear pharmacist''), but not necessarily by all of the entities which constitute ''persons.''

Issue 2: Can There Be Transfer of Sources Among Licensees?

Comment. A commenter indicated that changes in the health care environment have created affiliations between hospital groups which may or may not be under a single NRC license. The commenter believed that this regulation could prohibit the cost savings created by these affiliations. The commenter believed that if sources are received from a licensed distributor and handled properly, there should be some flexibility in transferring the sources between licensees.

Response. The NRC did not change the regulatory text in this section. However, we did change the regulatory text of § 35.49 to address this comment. Section 35.11 references conditions of a specific license issued by the Commission or an Agreement State. This license would require the licensee to comply with all provisions of Part 35. Section 35.49 has been modified to state that a licensee may use sealed sources or devices for medical use which are non-commercially transferred from a Part 35 licensee, i.e., if two licensees are authorized to possess sealed sources for medical use, they may transfer the sources from one to the other.

Issue 3: Were There Any Other Changes Made in this Section Between the Proposed and Final Rule?

Response. Yes. ''Prepare'' was added to paragraph (a) in recognition that medical licensees may also prepare byproduct material for medical use and need a license to do so. In addition, the section was restructured to make it easier to use. Paragraphs (b) and (c) were combined into one paragraph because they both provide information on when a specific license is not needed.

Section 35.12, Application for License, Amendment, or Renewal

Issue 1: Who May Apply for a License?

Comment. The commenter believed that the requirements in the current § 35.12(a) are inconsistent. According to the commenter, under the current rule, any person may apply for a license for medical use not sited in a medical institution, while only a medical institution's management may apply for a license for medical use sited in a ''medical institution.'' The commenter recommended that the NRC issue the license to a ''responsible person'' no matter what the license type. The commenter further recommended that the text of the rule be changed to reflect that the NRC will only accept a license application from a financially and/or legally responsible person.

Response. The NRC did not make any changes between the proposed rule and the final rule in response to this comment. Section 35.12(a) of the final rule requires that the license application be signed by the applicant's or licensee's management, regardless of the types of use applied for or authorized. For a sole practitioner, the ''management'' could be the same as the AU. This paragraph clarifies that ''management,'' by signing the

application, is responsible for the license, regardless of the size of the licensee.

Issue 2: Is There a Need for a Separate License for Medical Uses Covered by § 35.600?

Comment. Commenters stated that license applicants should be permitted to submit one license application covering several uses of radioactive material, as long as the activity is under both the same management and a qualified RSO. Commenters asked that we justify the inconsistent and separate licensing of a medical device such as a cobalt-60 machine because neither the administrative nor the technical requirements of the radiation safety program are going to be unique for the cobalt-60 unit. Commenters believed that a licensee should not be assessed a separate annual fee just for a medical device. The additional cost will only place a greater burden on the health care delivery system.

Response. NRC agrees with the commenter that licensees should be permitted to submit one application covering all medical uses. We have amended the regulatory text to require only one application for a Part 35 license, regardless of which medical use modalities the licensee will be performing. It will not be necessary for a licensee or applicant to file a separate application for each medical use of byproduct material, as described in §§ 35.600 or 35.1000. Licensees who currently hold separate licenses may request that the licenses be combined.

The commenter's suggestion that a single fee be assessed for all medical uses covered by a license would require a revision to Parts 170 and 171. The NRC will address this issue in an annual fee rulemaking subsequent to the issuance of this revision to 10 CFR Part 35.

Issue 3: Can Licenses Be Combined at Facilities?

Comment: Commenters believed that it would be advantageous for larger licensees that employ a full-time RSO and that have several existing licenses to unify all specific licenses into a single license. Commenters believed that the RSO should have the freedom and flexibility to manage resources to control all types of use without describing all the individual radiation safety procedures for the NRC. The RSO could appoint specialty RSOs, if needed, to manage the daily radiation safety program in specialty areas, *e.g.,* nuclear medicine, cardiology, radiation therapy, or individual campuses. For example, universities or large hospitals with several campuses could issue sub-licenses under a unified license. The RSO could authorize individual users who qualified under the training and experience criteria, without notifying NRC. This would be appropriate for authorizing physicians for emerging technologies, as well.

Response. The NRC agrees that licensees should have the flexibility of combining several licenses into one license. This will help to foster a more unified radiation protection program at the licensee's facility. Section 35.12 has been amended to allow applicants to apply for one license for all types of medical uses. For example, it is no longer necessary to have separate licenses for medical uses such as teletherapy, gamma stereotactic radiosurgery, or diagnostic nuclear medicine. Licensees have flexibility in structuring their radiation protection program to include specialty RSOs but the Commission holds the RSO named on the license responsible for the radiation protection program. Licensees do not have authority to issue any type of license. Under § 35.24, only licensee management can approve AUs.

Issue 4: Should Licensees Be Required To Submit Operating Procedures to NRC for Review and Approval as Part of the License Application?

Comment. The NRC received comments recommending that we review operating procedures as part of the license application. We also received comments indicating that we did not need to review procedures and that licensees should have flexibility in program management.

Some commenters recommended that we should not abandon our practice of reviewing a licensee's or applicant's procedures before issuing a license. These commenters believed it is important for NRC to review procedures as part of the licensing process. This is important because licensee management, AUs, workers, and NRC staff must have a common understanding of what is in the procedures. They believed that this would avoid enforcement problems during subsequent inspections.

Commenters believed licensees should have the flexibility to change certain procedures, even if the procedures had been submitted to the NRC, as long as the spirit of the rule is met. Once the procedure is incorporated into the license, the regulatory agency and the licensee know what to expect. NRC review of procedures during the license application or renewal process is a good way to see if the licensee has established procedures in compliance with NRC requirements. Other commenters asked that this section be changed to include the requirement that applicants either (1) commit to adopting the model procedures contained in NUREG–1556, Volume 9(draft), or (2) submit with the application the procedures they wish to use for review and approval by the Commission. These commenters did not believe inspectors have the time or resources during an inspection to both conduct the inspection and determine the adequacy of the licensee's procedures.

Other commenters suggested that the NRC review procedures only at the time of the initial application or when the license is periodically renewed. Procedures would not need to be submitted for license amendments. They believed that this approach would be helpful for smaller licensees that do not employ a full-time RSO and who usually rely on a consultant to write their standard operating procedures.

We also received comments that did not support NRC review of procedures. These commenters indicated that the NRC must recognize that there are many acceptable procedures to accomplish a specified goal. A licensee should be able to use any one of a large number of procedures as long as the performance standard is met. No written procedures of any kind need to be submitted to the NRC for review or be required as license conditions. Commenters also indicated that because the level of radioactivity involved in diagnostic medical uses of byproduct material is so low, compliance with the requirement for licensees to develop, maintain, and implement procedures provides no additional safety. Such a requirement would only increase the cost to the patients without any corresponding increase in the safety of the patient, hospital worker, or physician. Finally, commenters stated that this licensing approach should be extended to other uses outside Part 35, such as radiography (Part 34) and irradiator (Part 36) licenses.

Response. The NRC has amended the various provisions in the rule to delete, with one exception, the requirement for licensees to develop, implement, and maintain procedures (*e.g.,* § 35.24). We have also modified § 35.12 to state that only procedures required under §§ 35.610, 35.642, 35.643, and 35.645, as applicable, must be submitted to NRC for review as part of the license or amendment application. We agree that submittal of a licensee's operating procedures for NRC review and approval is necessary for certain higher risk medical uses such as those authorized in Subpart H, but is not

necessary for low risk uses, such as in diagnostic nuclear medicine. The lack of a procedure for the high risk modalities could result in situations where the public, workers, or patients could be exposed to unnecessary radiation. Overall, the final rule reduces the amount of documentation, including operating procedures, that an applicant must submit for either a license or amendment.

Issue 5: What Are the Information and Licensing Requirements for ''Emerging Technology''?

Comment. Commenters were concerned that significant resources may be expended by companies for clinical research for ''emerging technologies,'' without knowing what the actual regulatory requirements will be. Commenters asked that provisions be made for protection of confidential and proprietary information which licensees are required to submit in accordance with § 35.12(d)(1). Commenters also asked whether NRC would be open to a petition for rulemaking proposing an appropriate way to license an ''emerging technology,'' such as brachytherapy.

Response. The NRC clarified the regulatory text in § 35.12(d) to make it clear that the information in paragraph (d)(1) must be submitted in addition to the information required by other paragraphs in this section. Paragraph (d) was added because the current rule does not provide for the efficient licensing of ''emerging technologies'' (*i.e.,* those medical uses that are not specifically included in Subparts D through H). Paragraph (d)(1) provides a generic list of all the information needed by NRC to approve a medical use that is not specifically addressed in those Subparts. The specified information is needed because we must verify that the byproduct material will be handled safely. At this time, and because of the evolving nature of ''emerging technologies,'' it is not possible to be more specific about the necessary information. Applicants for ''emerging technology'' licenses are encouraged to consult with the NRC staff about the required information during the application process. Of course, licensees for these technologies would also be required to comply with all the applicable sections in Part 35 and 10 CFR Chapter I (*e.g.,* Parts 30 and 71).

Provisions are already in place for the protection of trade secrets or privileged or confidential information. Section 2.790(b)(1) contains procedures under which any person who proposes to withhold a document (or a part of it) from public disclosure on the ground that it contains trade secrets or privileged or confidential information may file an application for withholding accompanied by an affidavit.

Any ''interested person'' may file a petition for rulemaking under 10 CFR 2.802. During the NRC review of the petition, the NRC staff will review the interested person's request and determine whether a rulemaking is needed to address the issue. In some cases, there may be existing regulatory requirements that adequately address the petitioner's request; in other areas, the petitioner's request may result in development of a new rule or revision of an existing rule.

Although any ''interested person'' may file a petition for rulemaking in accordance with 10 CFR 2.802, such a petition should not be necessary for licensing ''brachytherapy.'' Licensing medical use involving brachytherapy is covered in the final rule in Subpart F, ''Manual Brachytherapy,'' and Subpart H, ''Photon Emitting Remote Afterloader Units, Teletherapy Units, and Gamma Stereotactic Radiosurgery Units.'' If an applicant believes that the use is not covered in either Subparts F or H, the applicant may request use under § 35.12(d) and Subpart K, ''Other Medical Uses of Byproduct Material or Radiation from Byproduct Material.'' Subpart K provides a means for licensing medical use of an ''emerging technology.''

Issue 6: Does a Broad Scope Licensee Need To Amend Its License for Medical Use of an Emerging Technology?

Comment. A commenter stated that broad scope licensees should not be required to amend their licenses simply for medical use of emerging technologies. The commenter asked that this section be clarified or added to the list of exemptions for broad scope licenses in § 35.15.

Response. The NRC agrees with the commenter's recommendation. We amended § 35.15 to relieve a broad scope licensee from the requirement to file a request for a license or amendment for medical use of byproduct material, as described in § 35.1000. This regulatory relief only applies if the broad scope licensee is already authorized to possess the type and form of byproduct material used in the emerging technology.

Issue 7. Were There Any Other Changes Made in This Section Between the Proposed and Final Rule?

Response. Yes. Section 35.12(a) was amended to delete the phrase ''of the facility.'' The proposed rule required that the application be signed by the management of the facility. The final rule requires that the application be signed by the applicant's or licensee's management. The addition of the words ''applicant's or licensee's'' is discussed under Issue 1 of this section. The NRC deleted the phrase ''of the facility'' because the word ''management'' clearly ties the requirement to activities performed by the licensee. (Refer to the definition of ''management'' in § 35.2.)

Paragraph (c) was amended to recognize that the application may be either in a letter format or on NRC Form 313, consistent with the current regulations.

Paragraph (d) was amended to delete the requirement to submit information on the training and experience of proposed users of an emerging technology. This requirement was redundant of the requirement in paragraph (b) for applicants to submit the training and experience qualifications of AUs.

Section 35.13, License Amendments

Issue 1: Why Would a License Amendment Be Necessary for a Type of Use Not Authorized in the License?

Comment. A commenter was concerned that this section implies the NRC will be regulating medical procedures through the licensing process, *i.e.,* NRC will use license conditions to prevent the clinical use of certain isotopes. According to the commenters, physicians should not have to wait for the NRC to grant an amendment in order to practice medicine.

Response. The NRC has not made any changes in the regulatory text as a result of these comments. Requiring a licensee to obtain a license amendment for a type of use permitted under Part 35, but not authorized on the licensee's current license, is not intended to prevent the medical use of certain radionuclides. A licensee must apply for and receive an amendment for such a type of use because it may change the licensee's byproduct material program and might increase the potential for radiation exposure to workers and the general public. For example, a licensee would need to amend its license if it is only authorized to use byproduct material for imaging and localization studies and it would like to use a remote afterloader. These types of changes in the byproduct material program are potentially significant and require a license amendment because:

(1) The NRC must be assured that the licensee has adequate training and experience and facilities before authorizing a change in the type of

medical use or the amount of byproduct material used; and

(2) Such a change might also indicate a need for increased inspection frequency.

Issue 2: Should There Be a Provision for a Temporary RSO?

Comment. A commenter asked if we planned to add language to this section to codify the discussion in the Statements of Consideration for the proposed rule on § 35.13(c) (53 FR 43516; August 13, 1998) regarding using an AU to fill the RSO position, if the RSO leaves with little or no warning. This commenter recommended that we add the following phrase to § 35.13(c): ''changes permanent Radiation Safety Officer.'' Commenters recommended that we allow an ANP or AMP to function as the RSO because either of these individuals would meet the qualifications of an RSO in § 35.50.

Response. The NRC addressed these comments by adding a provision for a ''temporary RSO'' in § 35.24(c). As stated in § 35.24(c), and discussed in greater detail under the Statements of Consideration for § 35.24, an AU or an individual qualified to be an RSO may function as the temporary RSO. The broader issue of who can be an RSO is discussed in greater detail in the response to comments on § 35.50. A licensee would not need to amend its license for a temporary RSO.

Issue 3: Were There Any Other Changes Made in This Section Between the Proposed and Final Rule?

Response. Yes. Paragraph (a) was amended to clarify that a licensee must apply for a license amendment before it ''prepares'' byproduct material for a type of use that is not authorized on the licensee's current license.

The NRC amended paragraph (b) to include ANPs identified on a permit issued by a Commission master material licensee that is authorized to permit the use of byproduct material in medical use or in the practice of nuclear pharmacy, or identified by a commercial nuclear pharmacy that has been given authorization to identify authorized nuclear pharmacists. This change has been made so that this section is consistent with the revised definition of ANPs in the final rule.

We also made minor editorial changes to the regulatory text in paragraph (b) to make the rule easier to read. For example, we started each requirement by stating to whom the requirement applies, *e.g.,* we replaced the phrase ''An authorized user who meets the requirements in * * * '' with ''For an authorized user, an individual who meets the requirements in * * * ''

In addition, paragraph (b) was amended to add references to §§ 35.190(a), 35.392(a), and 35.394(a); and to delete § 35.292(a). These actions are considered conforming changes needed for other changes made to the regulatory text between the proposed and final rule. In addition, paragraphs (b)(4) and (5) were combined to make the rule easier to use.

We also amended paragraph (d) requiring the licensee to apply for and receive a license amendment before it receives byproduct material in excess of the amount, in a different form, or a different radionuclide than is authorized in the license. This change makes the regulatory text clearer.

A new paragraph (g) was added that requires a licensee to apply for a license amendment if it revises the procedures that must be submitted in accordance with § 35.12(b)(2), where such revision reduces radiation safety. This applies to procedures required by §§ 35.610, 35.642, 35.643, and 35.645, as applicable.

Section 35.14, Notifications

Issue 1: Is the Purpose of Notification To Initiate a License Amendment?

Comment. A commenter recommended the title of this section be changed to ''Thirty-day Notifications for Amendments.'' In addition, the commenter stated that an introductory sentence should be added to the section indicating that the notifications should be made to initiate license amendments. Without this sentence, it is not clear that the purpose of the notification is to initiate an amendment.

Response. The NRC has not changed the regulatory text. The purpose of § 35.14 is to identify when a licensee must notify NRC of changes in its program for which it does not need to apply for a license amendment. For example, if an AU, AMP, or ANP is certified by a specialty board recognized by NRC, the licensee may allow that individual to begin work immediately (without first seeking and obtaining a license amendment). All the licensee must do is notify the NRC, within 30 days, that the individual has begun working.

Issue 2: Is There a Conflict Between the Requirements in §§ 35.13(b)(1) and 35.14(b)(1)?

Comment. A commenter indicated that this section was confusing because it was not clear whether the board certifications mentioned in § 35.14(a)(1) meant only those boards ''adopted by regulation'' or those certifying organizations listed in Appendix A. The commenter also believed the section conflicted with § 35.13(b)(1), which permits persons to act as an AU if they meet the training and experience requirements in §§ 35.290(a), 35.292(a), 35.390(a), 35.490(a), 35.590(a), or 35.690(a) and § 35.59 and §§ 35.910, 35.920, 35.930, 35.932, 35.934, 35.940, 35.941, 35.950, 35.960 and § 35.49.

Response. Section 35.13 provides information on when a licensee must apply for a license amendment. Section 35.14 provides information on when a licensee must notify NRC of a change in its program. In order to provide some regulatory relief to licensees and to allow individuals to begin work immediately, the NRC structured these provisions as two parts that address two different groups of people—those who are certified by a board recognized by NRC and those who are not certified by a board recognized by NRC. In the case of an AU, a licensee would not need to amend its license before allowing an individual to begin work if the individual is certified by a board whose certification process has been recognized by NRC. However, the licensee would need to notify us within 30 days of having allowed that individual to work as an AU. Conversely, a licensee would need to amend its license if the individual is NOT certified by a board that has been recognized by NRC.

We have deleted any references to boards by name in the final rule. In addition, Appendix A to the proposed rule was not included in the final rule. More detailed information on these changes can be found under the discussion of ''General training and experience,'' in Part II, General Issues, at the beginning of this section.

Issue 3: Is It Necessary To Name an AMP on a License?

Comment. A commenter recommended that NRC need only allow individuals who meet the training and experience requirements for an AMP to function as an AMP.

Response. The NRC believes that the requirements for naming an AMP and AU in the license should be the same. In order to be considered an AMP, the individual must meet the training and experience qualifications in § 35.51. If the individual is certified by a board whose certification process has been recognized by NRC, the licensee may allow that individual to begin work immediately and notify us within 30 days that the individual has begun work. If the individual is not certified by a board whose certification process

has been recognized by NRC, the licensee must apply for and obtain an amendment of its license before it allows that individual to begin work as an AMP.

Issue 4: Were There Any Other Changes Made in This Section Between the Proposed and Final Rule?

Response. Yes. The NRC revised paragraph (a) to include AUs, AMPs, and ANPs that are identified on a permit issued by a Commission master material licensee or a permit issued by a Commission master material license broad scope permittee. This change has been made so that this section is consistent with the revised definition of AUs, AMPs, and ANPs in the final rule. Paragraph (b)(4) was amended to state that the licensee must notify NRC when it adds to or otherwise changes the areas where byproduct material is used in accordance with §§ 35.100 and 35.200. This change has been made to clarify the regulatory text.

Section 35.15, Exemptions Regarding Type A Specific Licenses of Broad Scope

Issue 1: Were There Any Changes Made in This Section Between the Proposed and Final Rule?

Response. Yes. A new paragraph (f) was added that exempts broad scope licensees from the requirement to notify NRC when there are additions to or changes in the areas of use identified in the application or on the license where byproduct material is used in accordance with §§ 35.100 and 35.200. This exemption is consistent with the current exemption that these licensees have from the requirement to apply for a license amendment when there are additions to or changes in the areas of use only at the addresses specified on the license. The exemption was inadvertently omitted from the proposed rule.

Section 35.19, Specific Exemptions

Issue: Shouldn't This Section Provide an Exemption for Diagnostic Nuclear Medicine?

Comment Some commenters believed that essentially all diagnostic nuclear medicine procedures should be exempted from regulation because they would not endanger life or property or the common defense or security and are otherwise in the public interest.

Response. The NRC did not make any changes in this section. Section 35.19 recognizes that an applicant for a license or licensee filing an amendment request may seek to be exempted from a specific requirement in this part (50 FR 30616; July 26, 1985, see page 30624). However, this provision does not provide the basis for a ''blanket'' exemption of an entire category of medical use such as ''diagnostic nuclear medicine procedures'' from Part 35. Nevertheless, consistent with making Part 35 more risk-informed, we have decreased the regulatory burden on licensees administering or preparing byproduct material for most diagnostic uses by decreasing the requirements imposed on them in Part 35.

Subpart B—General Administrative Requirements

Section 35.20, ALARA Program

Issue 1: Should the Current Part 35 Requirements Related to ALARA Programs Be Deleted?

Comment A commenter supported the deletion of the current Part 35 requirements related to the ALARA program. However, another commenter believed that the requirements in Part 35 related to the ALARA program should be retained. This commenter stated that keeping this regulation in Part 35 is appropriate because Part 20 regulations are not specific enough.

Response. The NRC deleted § 35.20, which includes prescriptive requirements related to the ALARA program, in its entirety from the revised Part 35. Medical use licensees will continue to be required to comply with § 20.1101 that includes a requirement to implement an ALARA program designed to keep doses as low as reasonably achievable. We believe that deletion of the prescriptive ALARA requirements that are in the current § 35.20 will provide licensees flexibility in developing and implementing their ALARA programs.

Section 35.24, Authority and Responsibilities for the Radiation Protection Program

Issue 1: Can Licensee Management Delegate Its Responsibility To Approve Individuals Before Allowing Them To Work as an AU, ANP, or AMP?

Comment Several commenters said that mandating that licensee management approve individuals before allowing them to work as AUs, ANPs, or AMPs is excessive. Normally, management does not approve other individuals to work in non-NRC licensed areas. The approval to work generally comes from the department chief or the hospital credentialing committee. Therefore, the commenters suggested inserting ''or management designee'' after ''management'' in paragraph (a)(2) of this section to allow management to delegate the responsibility for approving individuals to either a responsible individual in the department or the hospital credentialing committee.

Response. In the current Part 35, the RSC has the responsibility to approve AUs, ANPs, and teletherapy physicists before allowing them to work. In the new § 35.24(a)(2), licensee management is given this responsibility for several reasons. First, licensee management has the ultimate responsibility for the radiation protection program in the revised rule. Second, not all licensees are required to have an RSC. Therefore, giving licensee management the responsibility for approval of individuals makes the requirement uniform for all medical licensees, i.e., the authority for approving individuals is not dependent on whether or not a licensee has an RSC.

As defined in § 35.2, management means the chief executive officer or other individual having the authority to manage, direct, or administer the licensee's activities, or those persons' delegate or delegates. Thus, licensee management could delegate the task of approving individuals before allowing them to work.

Issue 2: Is There a Need for a Requirement for the RSO To Acknowledge Responsibility for Implementing the Radiation Protection Program in Writing?

Comment The NRC received comments in response to the Commission's question as to whether a requirement for the RSO to acknowledge in writing responsibility for implementing the radiation protection program would impact the licensee's effectiveness in carrying out its radiation protection program. These comments both agreed and disagreed with the requirement in paragraph (b) of this section that an RSO agree in writing to be responsible for implementing the radiation protection program. One commenter supported this requirement, especially in cases where the RSO position is assigned to a junior medical staff member who has significantly more pressing obligations. Another commenter supported the requirement because it enhances the visibility of the RSO position. Several commenters noted that National Council on Radiation Protection and Measurements (NCRP) Report No. 127, Operational Radiation Safety Program (1998), Section 3 on Organization and Administration, includes recommendations for the RSO's responsibilities for the radiation safety program.

Other commenters questioned why the RSO should be required to sign off on his or her duties when the AU, AMP, and ANP are not required to do so. One commenter said that a written agreement seems more appropriate between management and the AUs, or between the AUs and NRC. Increasing the responsibilities of the AUs would provide more incentive for them to become familiar with the details of the radiation safety aspects of the licensed activities. Another suggestion was that there be a requirement for the licensee and AUs to commit in writing to follow the radiation protection program, instructions, and procedures, as formalized/approved by the RSO.

Other commenters questioned why there needs to be a paper trail of the RSO's agreement to be responsible for implementing the radiation safety program. They questioned whether there is a concern that management may assign the RSO duties to someone who is unaware of their responsibilities or there is a concern because unqualified, uncommitted RSOs have been named in the past. A commenter believes that if an individual agrees to assume the RSO's duties and his or her name is on the license as the RSO, a written statement from the RSO is redundant and unnecessary. Instead, the Commission should require that the individual appointed to be the RSO sign the license amendment naming him or her as RSO, which would not only provide documentation of their acceptance of the RSO duties, but would also provide the licensing staff with a copy of the RSO's signature for future reference.

Another commenter was concerned that the written agreement seems to be more of a legal, contractual matter than it is a radiation safety matter, and it could be later used by management against the RSO.

Response. After reviewing and evaluating the public comments, the NRC retained the requirement in paragraph (b) of this section for the RSO to acknowledge, in writing, responsibility for implementing the radiation protection program. We believe that future confusion over the responsibilities for the radiation protection program can be prevented by having a clear, written agreement between licensee management and the RSO. The final rule explicitly gives the RSO the responsibility for implementing the radiation protection program. Therefore, we believe it is more appropriate for that individual, rather than the AU, ANP, or AMP, to agree to that responsibility in writing.

Issue 3: Why Does the Rule Increase Management Oversight of, and Consequently Limit the RSO's Authority Over, the Radiation Safety Program?

Comment. Commenters believe that the proposed rule is very prescriptive about the relationship between the RSO and licensee management. The rule implies that licensee management gives the responsibility for maintaining the radiation safety program to the RSO, but does not allow the RSO the authority needed to manage the program. No other radiation protection program in 10 CFR Chapter I has as much management oversight as the medical use program. The NRC should also stipulate that the RSO report directly to senior management.

Response. The requirements in paragraphs (e) and (g) of § 35.24 that are associated with the RSO's authority are also in the current § 35.23. The revised rule retains all of the RSO's current authority, plus provides the RSO with additional authority to stop unsafe operations. The NRC did not address whether there is the same level of management oversight of other NRC licensees' radiation protection programs because that issue is beyond the scope of this rulemaking. We believe that the requirements for both the RSO's authority and for management oversight are more risk-informed and, therefore, appropriate for the risk associated with the medical use of byproduct material.

Issue 4: Should There Be a Provision for a Temporary RSO?

Comment. As noted in Issue 2 under § 35.13, License amendments, a commenter asked if we planned to add regulatory text to allow a licensee to use an AU to fill the RSO position when the RSO leaves a facility with little or no advance warning. Commenters also recommended that we allow an ANP to function as the RSO if the individual meets the qualifications for an RSO in § 35.50.

Response. The NRC added a new provision in paragraph (c) of § 35.24 that allows a licensee to have a temporary RSO for up to 60 days a year if the licensee meets the requirements for RSOs in paragraphs (b), (e), (g), and (h) of this section and notifies the Commission in accordance with § 35.14(b). The temporary RSO must meet the training and experience requirements in §§ 35.50 and 35.59. This new provision was added so that licensees can appoint someone in a timely manner to fulfill the duties and responsibilities of the RSO following the sudden departure of the permanent RSO named on the license. We also added a new paragraph (d) that allows a licensee to simultaneously appoint more than one temporary RSO, if needed, to ensure that the licensee has an individual that is qualified to be an RSO for each of the different types and uses of byproduct material permitted by the license. Even though we have added a provision for a temporary RSO, a licensee is expected to fill the position of permanent RSO as soon as possible.

Issue 5: Would the Proposed Deletion of the Requirement for a Radiation Safety Committee (RSC) Impact the Licensee's Effectiveness in Carrying Out Its Radiation Protection Program?

Comment. The NRC received a substantial number of comments on whether the proposed deletion of the RSC would impact the licensee's effectiveness in carrying out its radiation protection program. The majority of the comments supported retaining the current requirement for an RSC at medical institutions because the RSC is a valuable resource in this case. The decision to eliminate the RSC could be detrimental to the institution's radiation safety program, especially with the proposed reduction in the training and experience hours for some AUs. Commenters noted that, in a medical institution, the RSC provides a valuable forum with expertise from all aspects of the licensee's medical use operations. The RSC performs many functions, such as developing and mandating the implementation of radiation protection policies and procedures, peer reviewing the radiation safety aspects of research protocols, and responding to enforcement or infractions of radiation safety practices. In addition, it provides the RSO support, authority, and access to management. It is incorrect to assume that other hospital committees will encompass the area of radiation safety compliance. An accountable RSC, and documentation of its activities, will assure that decisions are made in the interest of radiation safety and regulatory compliance.

Several commenters noted that NCRP Report No. 127, Operational Radiation Safety Program, clearly supports the RSC, especially in the formulation of policies, review and audit of program effectiveness, and guidance of the RSO.

Other commenters supported retaining the requirement for an RSC, but not specifically tying the requirement to medical institution licensees. One recommendation was to retain the RSC for complex, multiple discipline, multi-department, and multi-use licensees. Another recommendation was for eliminating the requirement for

small operations authorized under §§ 35.100 and 35.500, and possibly under § 35.200, but making the requirement mandatory for activities under §§ 35.300, 35.400, and 35.600 and for larger operations involving imaging. Other recommendations included modifying the definition of medical institution to only include those facilities that perform more than one radioactive material modality; and requiring an RSC for facilities with inpatients. Commenters also said that any requirement for facilities with multiple modalities should be qualified by ''within the same speciality'' because there is no benefit to having physicians who use completely separate modalities communicating regularly.

Some commenters supported deletion of the RSC. According to one commenter, there is no evidence that the absence of an RSC jeopardizes public and occupational health and safety. Another commenter noted that, in some cases, other Federal agencies, such as the FDA, have committee requirements that meet radiation safety objectives. Also, facilities comply with Occupational Health and Safety Administration or Environmental Protection Agency regulations without a requirement for a committee. Therefore, deletion of the RSC would not reduce the effectiveness of the program, but would allow the licensee flexibility in meeting radiation safety objectives and in organizing its operations in the most efficient manner. However, another commenter said that removing the RSC may increase the burden on licensees, especially in conjunction with not requiring procedures to be submitted for review by licensing staff.

Another commenter suggested that rather than eliminating the entire requirement for an RSC, it might be more appropriate to reduce the more prescriptive requirements, such as the meeting, quorum, recordkeeping, and membership requirements.

Response. Based on public comments, the NRC retained the current requirement, with modifications, for certain medical licensees to have an RSC to oversee all the uses of byproduct material permitted by the license. In the final rule, only licensees that are authorized for two or more different types of uses of byproduct material under Subparts E, F, and H, or two or more types of therapy units under Subpart H, are required to establish an RSC. Examples of such licensees are those authorized to use therapeutic quantities of unsealed byproduct material (§ 35.300) and manual brachytherapy (§ 35.400), or manual brachytherapy (§ 35.400) and LDR units (§ 35.600), or teletherapy units (§ 35.600) and gamma stereotactic radiosurgery units (§ 35.600). An example where an RSC would not be required would be a licensee authorized for use of unsealed byproduct material for uptake, dilution, and excretion studies for which a written directive is not required (§ 35.100) and for use of unsealed byproduct material for imaging and localization studies for which a written directive is not required (§ 35.200). However, we believe that, based on public comments, many other medical use licensees will also continue to use an RSC to oversee the use of byproduct material, even if they are no longer required to do so. Licensees should note that the requirement for an RSC is no longer tied to medical institutions, which means that it now also applies to ''free-standing clinics.''

We have deleted most of the prescriptive list of administrative requirements and committee tasks that are specified in the current rule. For example, the final rule does not include specific requirements for the frequency of meetings, the content of the meeting minutes, or the tasks that the RSC must perform to oversee the use of licensed material. However, based on public comment, we have specified the membership of the committee, as discussed in Issue 6.

Issue 6: If an RSC Is Required, Who Should Be Members of the Committee?

Comment. The Commission asked whether the regulatory text should explicitly require that the RSO be a member of the RSC, if a requirement for a committee to oversee the radiation safety program was included in the final rule. Several commenters said that the membership of the RSC is best left to the licensee. While most licensees would make their RSO a member, there is no obvious reason to require this action. Some commenters said that the RSO should be allowed to decide the committee membership, and then submit the specialties of the membership to the NRC.

Most commenters agreed that both the RSO and a representative of the licensee's upper management should be explicitly named as members. Commenters also recommended that representatives of the different users and the nursing staff be on the committee, if the facility is licensed for inpatient therapies. While the RSO is responsible for implementing the radiation safety program, a successful committee requires both management backing and resources, and user support.

Response. As discussed in Issue 4, the final rule includes a requirement for certain medical licensees to have an RSC. We essentially agree with the commenters' recommendations for the membership of the RSC. We have included a requirement in the final rule that the membership of the RSC must include an AU for each type of use authorized by the license, the RSO, a representative of the nursing service, a representative of management, and other members the licensee considers appropriate.

Issue 7: Were There Any Other Changes Made in This Section Between the Proposed and Final Rule?

Response. Yes. Paragraph (b) was amended to delete the phrase ''in the daily operation of the licensee's radiation protection program.'' This phrase did not add anything to the requirement and was awkwardly worded.

Section 35.26, Radiation Protection Program Changes

Issue 1: What Is Meant by Changes in a Licensee's Radiation Protection Program That ''Do Not Reduce Radiation Safety?'

Comment. Several commenters said that the provision in the proposed § 35.26(a)(2), that radiation protection program changes can be made if the revisions ''do not reduce radiation safety,'' was ambiguous and subjective and would invite second-guessing by NRC inspectors. There should be objective measures for acceptable changes, such as changes that do not result in a licensee exceeding the limits in Part 20 or only changes that comply with all applicable regulations and license conditions.

Response. The NRC intended for this provision to provide licensees with as much flexibility as possible in making changes in their radiation protection program, without seeking Commission approval. However, in response to comments that the proposed wording was not clear when applied to minor (ministerial) changes to the licensee's radiation protection program, we revised the rule to allow licensees to make revisions in their radiation protection program that are ''in compliance with the regulations and the license.''

Issue 2: Why Is There a Requirement To Instruct Individuals on Changes in the Radiation Protection Program?

Comment. Commenters said that the requirement to instruct individuals on changes in the radiation protection program should be removed. This

requirement only adds work for licensees, with no resultant increase in safety, and is not consistent with the Commission's philosophy of more risk-informed regulations.

Response. This requirement has been retained in the final rule because the NRC believes that it is important to instruct individuals on radiation protection program changes before they are implemented, so that individuals have a clear understanding of those changes in the radiation protection program that may affect them. This instruction may be provided in writing, or orally, and may be conducted on either an informal or formal basis. For example, the instruction could be provided at an informal staff meeting.

Section 35.27, Supervision

Issue 1: Why Does This Section Include Requirements for Supervising Individuals?

Comment. Commenters had a number of concerns about the requirements for supervising individuals in this section. One concern was that there is no requirement for a licensee to notify the NRC that it operates in the manner permitted by this section, i.e., a licensee does not have to inform NRC when it allows supervised individuals to use byproduct material. Therefore, this section is not consistent with other sections in the regulations that only allow licensees to conduct activities that are permitted by their licenses. This section should be deleted or changed to require licensees to apply for a supervised user program within their license applications. In addition, commenters noted that if NRC is not made aware of this type of activity, it is not conducive to inspection activities.

Another concern was that this section permits individuals, including physicians, to use byproduct material without completing the training and experience requirements for AU status. This also allows a physician who does not meet the training and experience requirements for an AU to perform the duties of the AU without the AU being present. If the training and experience required to become an AU is necessary, the supervising AU should be required to be present (e.g., during the administration and reading of films), and the supervised physician should be required to attain licensure in a specified period of time.

Another commenter also said that this section should be deleted, but said that if the section is retained it should be revised to meet minimal ACGME teaching requirements for physicians. Recommended changes relate to whether: the supervising physician and the supervised physician must be within the same city (and preferably in the same building); the number of physicians supervised at one time should be limited; the duration of a physician working under the supervision of an AU should be limited; the NRC should verify the ability of the supervising individual to teach; the supervised program should have a curriculum, goals, objectives, handouts, and testing; and the NRC should be notified that a supervised physician program is in effect.

Some commenters said that there was no need for this section because its provisions are covered in other sections of Part 35. For example, proposed § 35.11 (b) and (c) state that a specific license is not needed for individuals receiving, possessing, using, transferring, and preparing byproduct material under the supervision of an AU or ANP, respectively. In addition, commenters said that paragraphs (a) and (b) of this section, that contain requirements for supervised individuals to follow the instructions of the supervising AU or ANP, should be deleted. If there is a failure to properly supervise, the licensee, not the supervisor, will ultimately be responsible because paragraph (d) of this section holds the licensee responsible for the acts and omissions of supervised individuals.

In addition, one commenter said that the ANP should be added to paragraph (a) because, in order to prepare material, the material must first be received, possessed, and used.

Response. Under part 35, only AUs and ANPs identified on a medical use license are allowed to use or prepare, respectively, byproduct material in the practice of medicine. It is frequently necessary for an AU or an ANP to delegate specific tasks associated with using or preparing byproduct material to other individuals who do not have the same training in the use or preparation of the byproduct material for medical use. This section allows for that delegation, if the individuals are properly supervised and instructed. The supervised individuals must also be required to follow the instructions of the supervisor for medical uses of radioactive material or for preparation of byproduct material for medical uses, the licensee's written radiation protection program procedures and written directive procedures, the license conditions, and the regulations of this chapter. These provisions do not require prior notification of the NRC that a licensee has delegated tasks associated with the medical use of byproduct material, e.g., tasks such as package receipt, administration, and disposal of the radioactive waste. Such a requirement would be an unnecessary burden and negate the flexibility afforded to licensees in conducting their medical use programs.

The AUs and ANPs are best suited to determine what tasks supervised individuals are capable of performing and the degree of supervision that each needs. Consequently, this section does not include prescriptive requirements for training or list delegatable tasks. The NRC believes that the requirements in this section provide the best balance between NRC's responsibility to assure the public health and safety and the licensee's responsibility for the safe use of byproduct material.

We have not added ANP to paragraph (a) of this section because this requirement is tied to § 35.11(b)(1), which only allows individuals to receive, possess, use, or transfer material under the supervision of an AU. Section 35.11(b)(2) permits the preparation of byproduct material for medical use under the supervision of an AU or ANP, unless prohibited by license condition.

Issue 2: Is There a Need for Licensees To Have a Policy for Supervised Individuals To Request Clarification From AUs or ANPs About Procedures or Instructions (proposed § 35.27(c))?

Comment. Commenters said that the requirement for licensees to have a policy for supervised individuals to request clarification if they do not understand procedures or instructions should be deleted. This requirement will not stop a misadministration which may be caused by other factors, such as human error or poor management. One commenter said that there were no data demonstrating that the failure to ask clarifying questions had resulted in a misadministration associated with either nuclear medicine or radiation oncology. If misadministration data are being used to justify the requirement, then it should not apply to diagnostic nuclear medicine because there has probably never been an instance where a diagnostic misadministration was the result of someone not understanding procedures or instructions.

Response. The NRC deleted the proposed paragraph (c) of this section that required licensees to have a policy for supervised individuals to request clarification if they do not understand procedures or instructions. Licensees should have flexibility in establishing communication programs that are tailored to their facilities. Appendix S, in NUREG–1556, Vol. 9 (draft),

discusses the importance of instructions being clearly communicated to professional team members, with constant attention devoted to detail during the treatment process. The guidance document states that licensees should instruct all workers to seek guidance if they do not understand how to carry out a written directive. Based upon actual case histories, the NRC believes that some types of medical events can be prevented if workers ask questions about what to do or how it should be done, before administering a dose or dosage, rather than continuing the procedure when there is any doubt.

Issue 3: What Is the Purpose and Intent of the Statement in the Proposed § 35.27(d) That Licensees Are Responsible for the Acts and Omissions of Supervised Individuals?

Comment. Commenters raised a number of concerns about the statement in paragraph (d) of the proposed rule that licensees that permit supervised activities are responsible for the acts and omissions of supervised individuals. By explicitly stating that the licensee is responsible for the acts and omissions of supervised individuals, the implication is that the licensee is not responsible for the acts and omissions of AUs, ANPs, AMPs, or the RSO. State laws hold the supervising physicians and pharmacists responsible for the actions of all health professionals working under their supervision. Another concern was that licensees would be held responsible for willful actions and omissions of supervised individuals against established policies and/or procedures. One commenter requested a definition of the term ''supervising AU.'' This term appears to imply that the ''AU'' is responsible for supervision, while other statements in Part 35 give the authority for supervision to management. In addition, some commenters suggested that this requirement be deleted because it states the obvious and is unnecessary.

Response. This statement of the licensee's responsibility for the acts and omissions of supervised individuals is in the current § 35.25(c). According to the Statements of Consideration for this provision, it was added to make it clear that a ''licensee can not delegate responsibility to supervised individuals. If a supervised individual, through misunderstanding, negligence, or commission, acts contrary to the requirements of the license, the regulations, or an order, the licensee remains responsible'' (51 FR 36932; October 16, 1986). This is still an accurate statement of the Commission's intent in retaining this provision for supervision by an AU or ANP.

As used in this section, a ''supervising AU'' is simply an AU who supervises an individual using byproduct material. Even though an individual may be supervised by an AU, the licensee is ultimately responsible for the acts and omissions of supervised individuals.

Issue 4: Should ''Telesupervision'' Be Allowed for Part 35 Licensees?

Comment. One commenter said that the Part 35 rulemaking should address the issue of ''telesupervision.'' With present technology, AUs can stay in their offices and supervise medical procedures at facilities that are miles away. Due to all of the upcoming challenges of emerging technologies, the NRC should address this issue to ensure protection of public health and continued radiation safety.

Response. The NRC has not addressed ''telesupervision'' during the revision of Part 35 because the need for the AU or a medical physicist to be present during the medical use of byproduct material is dependent on the risk associated with the particular modality. For example, the use of remote afterloader units requires onsite supervision by individuals who are knowledgeable of the radiological hazards associated with the use of that material.

Issue 5: Were There Any Other Changes Made in This Section Between the Proposed and Final Rules?

Response. Yes. The phrase ''in addition to the requirements in § 19.12'' was added to both paragraphs (a)(1) and (b)(1) of this section. This addition to § 35.27 has been made as a reminder to licensees that they must also comply with the requirements for supervision in § 19.12, Instructions to workers.

The phrase ''written directive procedures'' was added to paragraph (a)(2) because it is important that supervised individuals follow the licensee's procedures for written directives.

Paragraph (b)(1) of this section was amended to read ''individual's involvement with byproduct material,'' rather than ''use of byproduct material,'' because the requirement also applies to individuals who prepare byproduct material for medical use under the supervision of an ANP.

Section 35.40, Written directives

Issue 1: Why Does Part 35 Need To Include Requirements for Written Directives?

Comment. Several commenters agreed that the NRC should require licensees to prepare written directives, especially for those procedures that create the greatest risk to the patient from errors and those procedures that are performed by supervised individuals. However, if the written directive is really meant to be a tool for communication between the AU and other health care staff, the proposed requirements for written directives should be revised to allow licensees more flexibility in defining what information must be included in written directives. For example, an AU should be allowed to determine what information is necessary for a supervised individual to administer the byproduct material. One commenter said that the NRC should only require that a written directive be prepared before a treatment to a patient is delivered and should not define even the essential elements of the directive.

Another group of commenters opposed both the use of the term ''written directive'' and the need for written directives for administrations of unsealed byproduct material in medicine. Written directives, as described in the proposed rule, are ''prescriptions,'' which are the standard of practice in medicine and pharmacy. Prescriptions are already controlled by the State Board of Medicine and Pharmacy and the Attorney General of each state. Licensees should be allowed to create records that are consistent with other requirements for medical practice and pharmacy, rather than duplicating a ''prescription.'' The NRC should cite data demonstrating that the traditional method of prescribing medicine is not adequate. If the requirement for a written directive is retained, ''radiopharmaceutical'' in § 35.40(a) should be qualified by adding ''containing byproduct material'' because no other radiopharmaceuticals fall under NRC's jurisdiction.

Response. The NRC believes that the requirements for written directives in this section only include what is essential to provide high confidence that the byproduct material will be administered as directed by the AU. Licensees have the flexibility to include additional information that they feel is necessary for a supervised individual to perform a procedure according to the directions of the AU. Records that include the information specified in § 35.40 and are used to demonstrate compliance with other requirements are acceptable.

During the Quality Management and Misadministrations rulemaking (56 FR 34104; July 25, 1991), several medical societies recommended that NRC use the term ''written directive'' to avoid confusion with the term ''prescription''

in medical and pharmacy practices. We have retained the use of the term ''written directive'' so that there continues to be a clear distinction between NRC's requirements and other requirements for a ''prescription.''

This section neither prevents licensees from keeping or creating other pharmacy or medical records, nor requires licensees to create records that duplicate prescriptions. Written directives are not duplicative of prescriptions. They must include information necessary to ensure that byproduct material is administered as directed by the AU. This may require different or more detailed information than is in a prescription.

Most diagnostic procedures are low risk. Therefore, licensees are not required to prepare written directives for most administrations of unsealed byproduct material. This section only requires written directives for the higher-risk administrations, such as sodium iodide I–131 in quantities greater than 1.11 MBq (30 μCi). We also agree that the NRC's jurisdiction only covers radioactive drugs containing byproduct material, so we have replaced the word ''radiopharmaceutical'' with ''radioactive drug containing byproduct material'' throughout Part 35.

Issue 2: Does a Written Directive Need To Be Prepared If the AU Physician Performs or Is Present During the Administration?

Comment. Several commenters questioned the need for a written directive when the AU physician performs or is present during the medical use of the byproduct material. In particular, they questioned the benefit of a physician in such a situation having to prepare a written directive, if the primary purpose of written directives is to prevent misadministrations in carrying out the physician's directions. Commenters also questioned whether physicians were expected to prepare or revise written directives while simultaneously performing administrations.

Response. Written directives must be prepared in accordance with § 35.40 whether or not the AU physician performs or is present during the procedure that involves the medical use of byproduct material. The NRC does not expect physicians to either prepare or revise written directives while performing medical procedures. We agree with the commenter that the main reason for requiring written directives is to provide high confidence that the administration is according to the directions of the AU physician, i.e., that there is no misinterpretation of the physician's directions by another physician, pharmacist, or supervised individual.

Licensees are required to retain copies of written directives for 3 years. These copies provide documentation that the actual administrations were according to the written directives prepared before the administrations. Licensees are required to report medical events, in accordance with § 35.3045, based on the differences between the information in the written directives and the actual administrations. Therefore, if written directives, or copies of them, are not available for all administrations for which they are required (e.g., if written directives were not prepared when physicians were present during the administrations) licensees will not be able to demonstrate compliance with either § 35.40 or § 35.3045.

Issue 3: What Are the Requirements for the AU's Signature on Written Directives?

Comment. One commenter agreed that the requirement for the AU to sign the written directive should be retained. The AU checks the written directive for ''appropriateness of study'' before signing the document before treatment. This practice is part of the Quality Assurance Program developed by the Joint Review on Accreditation of Hospital Organizations.

Several commenters requested clarification of the requirements and policies associated with signatures on written directives. One commenter said that the requirement for preparing, signing, and dating written directives has been interpreted differently by regulators in the past. The regulations should explicitly state whether a written directive must be signed by an AU, or whether a physician under the supervision of the AU may sign the written directive. Another commenter questioned whether ''electronic signatures'' or ''signatures on file'' would be accepted on written directives.

Response. This section allows an individual under the supervision of an AU to prepare a written directive, but requires an AU to sign and date it. The NRC requires the signature of the AU on a written directive so that there is a record that the AU has reviewed and approved the information on the written directive.

Section 35.5 allows records to be maintained electronically. Therefore, AUs may use their own electronic signatures if they are signing an electronic version of a written directive. However, licensees may not use the ''signature on file'' notation on written directives because another individual may add it to a written directive and, therefore, it may or may not mean that the AU has reviewed and approved the written directive.

Issue 4: How Soon Should Oral Directives or Oral Revisions to Written Directives Be Documented in Writing?

Comment. One commenter recommended that written documentation of oral directives or oral revisions to written directives should be made the next working day. The current requirement for written documentation within 48 hours is unnecessarily restrictive in some cases (e.g., over a weekend) and too lenient in other cases (e.g., during the week).

Response. In situations where a delay in order to revise a written directive or to prepare a written directive would jeopardize the patient's health, the current requirements in § 35.32(a)(1) allow for revisions of written directives to be signed by the AU within 48 hours of the oral revision and for written directives to be prepared within 24 hours of oral directives. In both the proposed and final requirements, NRC has decreased the regulatory burden on licensees by allowing licensees to document both oral directives and oral revisions to written directives within 48 hours. The 48-hour requirement provides more flexibility for AU physicians and also allows them to prepare any written documentation during the workweek, unless they choose to do otherwise.

Written directives are essential to providing high confidence that the byproduct material is administered as directed by the AU. Therefore, we do not believe that the requirement should allow for written documentation of the administration ''the next working day.'' This could potentially result in a delay of over 80 hours before an error in the administration is identified, if the administration is made early Friday and the written directive is not prepared until late Monday.

Issue 5: Do the Requirements for Written Directives Allow for Prescribing Doses or Dosages in a Range?

Comment. Several commenters said that the NRC should allow AU physicians to prescribe a range of doses and dosages in a written directive. At the time that written directives are prepared, physicians are not always aware of how much radioactive drug will be taken up or how many seeds will actually be implanted. One commenter suggested that an alternative to a dose range in manual brachytherapy is not to specify a dose. This allows the

physician to make a guess at the number of seeds of a certain strength to implant and when the implant is completed to document the number of seeds actually implanted. If this is acceptable, the dosimetry could be done later.

Response. The regulations allow for AU physicians to prescribe a range of dosages, but not doses, in written directives. Section 35.2 states that prescribed dosage means the specified activity or range of activity of unsealed byproduct material. The definition of prescribed dose in § 35.2 is dependent on the modality.

In addition, paragraph (b)(6)(ii) of this section allows the physician to change the written directive after the brachytherapy sources (other than HDR) are implanted, but before completion of the procedure, to more accurately reflect what actually took place (e.g., number of sources used, total source strength, exposure time, etc.).

Issue 6: What Is the Basis for Requiring Written Directives for Administrations of Greater Than 1.11 MBq (30 μCi) of Sodium Iodide I–131?

Comment. One commenter questioned why the threshold for preparing a written directive for administrations of sodium iodide I–131 is set at greater than 1.11 MBq (30 μCi) when the patient release criteria in § 35.75 indicates that hundreds of millicuries in a patient do not pose undue harm. Another commenter said that the threshold for I–131 should be increased.

Response. The threshold for preparing a written directive for administrations of sodium iodide I–131 was set at 1.11 MBq (30 μCi) because it results in a 0.5 sievert (Sv) (50 rem) dose to the thyroid. The Commission, with the recommendation of the ACMUI, adopted an organ dose of 0.5 Sv (50 rem) as one threshold for identifying medical events (previously ''misadministrations'') during the Quality Management Program and Misadministrations rulemaking (56 FR 34104; July 25, 1991). We cited NCRP Commentary No. 7, Misadministrations of Radioactive Byproduct Material-Scientific Background (July 1991), as stating that this threshold was considered to be well below the onset of acute, clinically detectable adverse effects that may be caused by ionizing radiation. We believe that the current threshold for preparing a written directive for sodium iodide I–131 is appropriate. Therefore, we have retained it in the final rule.

The criteria for licensees to authorize the release of patients in § 35.75 are based on the potential dose to the maximally exposed individual, not on the quantity of byproduct material associated with the administration to the patient. Under § 35.75, a licensee may authorize the release of any individual from its control who has been administered radioactive drugs or implants containing byproduct material, if the total effective dose equivalent to any other individual from exposure to the released individual is not likely to exceed 5 mSv (0.5 rem).

Issue 7: Should There Be Any Changes to the Proposed List of Information That Is Required To Be Included in Written Directives?

Comment. For any administrations of quantities greater that 1.11 MBq (30 μCi) of sodium iodide I–131, the name of the radiopharmaceutical and the route of administration should be provided so that the requirements for written directives for all unsealed byproduct material are consistent.

Response. The requirements are not consistent because there is no need to specify either the name of radiopharmaceutical or the route of administration when sodium iodide is used. Sodium iodide is the name of the radioactive drug administered and it concentrates in the thyroid regardless of the route of administration.

Comment. For gamma stereotactic radiosurgery, the total treatment volume should be deleted because there is no way of determining it numerically.

Response. The NRC agrees with the comment and has deleted the requirement in paragraph (b)(3) of this section to include the total treatment volume in written directives for gamma stereotactic radiosurgery.

Comment. For teletherapy, the inclusion of the overall treatment period is not necessary. Extending the treatment time for one or two missed fractions has no impact on the overall effectiveness of the treatment.

Response. The NRC agrees that it is not necessary to include the overall treatment period in written directives for teletherapy. The requirement for overall treatment period has been deleted from paragraph (b)(4) of this section.

Comment. For HDR brachytherapy, the number of fractions and dose per fraction can be used to calculate the total dose. The requirement for total dose should be deleted so that there is no confusion if two different doses (dose per fraction and total dose) are required on the written directive.

Response. The NRC retained the requirement for the written directive for HDR brachytherapy to specify the total dose because the treatment time is very short compared to other types of brachytherapy.

Comment. For all other brachytherapy, several commenters suggested revision of the requirements for written directives for brachytherapy. One commenter said there was no need to require the dose to be stated if the number and source strengths were included, while another commenter said the opposite. Another commenter suggested separate requirements for permanent and temporary brachytherapy implants.

Response. Following discussion of the comments with the ACMUI, the NRC deleted the requirement in paragraph (b)(6)(i) of this section to provide the number of sources and source strengths before implantation. We do not believe that there needs to be different requirements for permanent and temporary brachytherapy because the rule allows the AU to document certain information after implantation, but before the procedure is completed.

Issue 8: Can the Footnote Be Incorporated Into the Regulatory Text of This Section?

Comment. One commenter suggested that the footnote in this section be incorporated into the body of the rule text.

Response. The NRC agrees and has incorporated the footnote, in its entirety, into the body of the text. That footnote contains important information about preparing written directives when a patient's health could be jeopardized by any delay in providing medical care. The requirements for written documentation of an oral directive and documentation of a revision to a written directive now appear in paragraphs (a)(1) and (c)(1) of this section, respectively.

Issue 9: Were Any Other Changes Made to This Section Between the Proposed and Final Rules?

Response. Yes. Paragraph (a) was amended to delete the requirement for an AU to prepare a written directive. The change recognizes the fact that written directives are often prepared by supervised individuals.

Paragraph (b)(2) was revised to make it clear that the requirements in this paragraph apply to an administration of a *therapeutic* dosage of unsealed byproduct material.

The requirements for written directives for gamma stereotactic radiosurgery in paragraph (b)(3) were amended to delete ''the target coordinates (including gamma angle), collimator size, plug pattern, total dose for the treatment, and the total treatment

volume'' and to add ''the total dose, treatment site, and values for the target coordinate settings per treatment for each anatomically distinct treatment site.'' These changes were made to ensure that written directives for gamma stereotactic radiosurgery include the essential information.

Paragraph (b)(5) was revised to make it clear that the requirements in this paragraph apply only to high dose-rate brachytherapy.

Paragraph (b)(6) was revised to make it clear that the requirements in this paragraph apply to all other brachytherapy, including low, medium, and pulsed dose-rate remote afterloaders.

Paragraph (b)(6)(i) was amended to delete the requirement for written directives for brachytherapy, before implantation, to include the number of sources and source strengths. The number of sources used is often not known until the procedure is performed.

Paragraph (b)(6)(ii) was revised to include a requirement for written directives for brachytherapy, after implantation but before completion of the procedure, to document the number of sources. The number of sources used is determined during the procedure.

Paragraph (d) was amended to include the words ''a copy of'' the written directive to conform with the text of § 35.2040.

Section 35.41, Procedures for Administrations Requiring a Written Directive

Issue 1: Is There a Need for Medical Licensees to Have a Quality Management Program (QMP)?

Comment. Most of the commenters favored deletion of the QMP, as it appears in the current Part 35. The commenters felt that the provisions of the QMP were redundant with requirements that are already in place because of State pharmacy laws or with regulations codifying the routine ''standard of care'' in medicine. They also noted that the data collected on misadministrations do not show that QMPs have any impact. In particular, there were no data that showed patient identification is a problem. Therefore, the issue of incorrect patients being administered dosages of byproduct material has been exaggerated. Several commenters noted that regulations cannot prevent misadministrations (medical events) that are due to human error, purposeful misconduct, or failure of a supervised individual to ask questions. In addition, commenters welcomed the paperwork relief provided by deletion of some of the QMP review and reporting requirements.

Several commenters favored retention of the current QMP requirements. One commenter said that the requirement for a QMP reinforces the need for a quality improvement committee (QIC) in his institution. The QIC reviews patient records and plans, investigates, checks, and acts on issues of quality improvement. In addition, the QIC periodically reviews compliance with all aspects of the QMP, prepares a report that summarizes the findings of the review and identifies the corrective actions taken, and then submits it to the RSO. Therefore, the QMP can be important in assisting licensees to maintain good radiation protection programs. Another individual supported retention of the QMP for the following reasons: licensees have already developed QMPs that meet the regulations; the annual reviews of the QMPs evaluate the effectiveness of the therapy programs; QMP program reviews are documented and distributed to management; and they provide a mechanism to identify precursor events.

Several commenters favored a more balanced approach. They would delete some of the prescriptive QMP requirements, such as submittal of the QMP plans to NRC for review, but retain some essential requirements, such as identifying the patient and ensuring that each administration is in accordance with the written directive.

Response. The NRC has not retained the current § 35.32, Quality management program, in the final rule. We have decided that only certain essential requirements are necessary to provide high confidence that byproduct material will be administered as directed by the AU. For any administration that requires a written directive to be prepared in accordance with § 35.40, licensees must develop, implement, and maintain written procedures to assure that the patient's or human research subject's identity is verified before each administration and that each administration is in accordance with the written directive. These procedures must address certain items applicable to the licensee's use of byproduct material. Beyond these requirements, the final rule allows licensees the flexibility to develop procedures to meet their needs. In addition, there is no requirement for submission of these procedures to NRC for its approval, as was previously required by the quality management rule.

Issue 2: What Is the Commission's Intent in Requiring Procedures for Administrations Requiring a Written Directive in § 35.41(a)?

Comment. One commenter noted that the emphasis in § 35.41 seems to be on development of the procedures, rather than on what the Commission is trying to accomplish with the procedures. Another commenter was in favor of the proposed requirements in paragraph (a) if the intent is to permit licensees to develop their own policies and procedures to prevent patient misadministration, rather than submitting QMP programs requiring prior approval by the NRC.

Response. The NRC's intent in requiring procedures to provide high confidence that the administration will be as directed by an AU is to avoid burdening licensees with an absolute requirement that this objective be met. We do not intend to imply that all errors in the administration of byproduct material can be prevented. For additional information refer to the regulatory history of Part 35 (56 FR 34104; July 25, 1991, page 34115). Paragraph (a) provides licensees with some flexibility to develop procedures that are appropriate for their uses of byproduct material. We recognize that there is no ''absolute'' way to achieve the objectives of these procedures, e.g., verifying the patient's or human research subject's identity. However, NRC does require that these procedures be sufficient to provide high confidence that the patient's or human research subject's identity is verified. For example, just asking an individual his name may not provide high confidence that the administration was given to the correct individual. Although the procedures do not have to be submitted for NRC review and approval, licensees may be requested to make them available for review during an inspection or, following a medical event, to demonstrate that they provide the requisite high degree of confidence.

Issue 3: Does § 35.41(b) Include the Appropriate Items That Should Be Addressed in Procedures for Written Directives?

Comment. Commenters differed on whether the list of items that must, at a minimum, be addressed in the written procedures was too prescriptive or too vague. Commenters noted that if a licensee has procedures that provide high confidence that the patient's identification is verified and that the administration is in accordance with the written directive, the procedures will have to include the appropriate

information in paragraph (b). Another commenter said that not all of the items to be addressed in paragraph (b) are applicable to all of the uses of byproduct material that require a written directive.

A commenter said that the requirement in paragraph (b) to have procedures for checking the manual and computer-generated dose calculations and verifying that any computer-generated dose calculations are correctly transferred into the consoles of therapeutic medical units is vague and does not state how these should be done. Another commenter recommended adding an ''/or'' after the word ''and'' in paragraph (b)(3) to acknowledge that there could be either manual or computer-generated dose calculations.

Response. Paragraph (b) has been retained in the final rule because the Commission believes that these are the minimum items that should be addressed in procedures to provide high confidence that the patient's identification is verified and that the administration is in accordance with the written directive. The commenter correctly noted that not all of the items in paragraph (b) are applicable to all of the uses of byproduct material that require a written directive. Therefore, paragraph (b) of this section was revised to read that the procedures ''must address the following items that are applicable to the licensee's use of byproduct material.'' Paragraph (b)(2) of this section was revised to read ''treatment plan, if applicable.'' Both of these changes were made because all of the items listed in paragraph (b) may not be applicable to the licensee's use of byproduct material. The NRC amended paragraph (b)(3) to state more correctly that ''both manual and/or computer-generated dose calculations'' should be checked. We have not been more specific in order to provide the licensee flexibility in determining how these items should be addressed in the procedures for his or her modality or unit.

Issue 4: Were There Any Other Changes Made in This Section Between the Proposed and Final Rules?

Response. Yes. Paragraph (b)(2) of this section was amended to read ''verifying that the administration is in accordance with the treatment plan.'' The phrase ''the specific details'' was deleted because they are not provided in the regulations.

Paragraph (b)(4) of this section was amended to read ''therapeutic medical units'' to correspond to the use of ''units'' in Subpart H.

Paragraph (c) of this section was added to refer licensees to the record keeping requirements in § 35.2041.

Section 35.49, Suppliers for Sealed Sources or Devices for Medical Use

Issue 1: Are the Sealed Sources and Devices Covered by This Section Only Supposed to Be for Medical Uses?

Comment. As worded, one commenter said that the proposed regulation could be interpreted to mean that the sealed sources or devices manufactured, labeled, packaged, and distributed in accordance with a Part 30 and § 32.74 license may be used only for medical use. If the latter interpretation is used, cesium-137 (Cs-137) brachytherapy sources could not be used for shielding evaluations because this is not a medical use.

Response. The intent of the regulatory text is for licensees to use only the sealed sources and devices listed in paragraphs (a), (b), and (c) for medical use. Other sealed sources and devices may not be used for medical use. Therefore, the NRC revised the regulatory text to make it clearer that licensees shall use only the sealed sources and devices that are listed in paragraphs (a), (b), and (c) of this section for medical use. This paragraph does not address what sources may be used for non-medical uses. For example, Cs-137 brachytherapy sources may be used for shielding evaluations.

Issue 2: Are iridium-192 Seeds and Ribbons Considered to Be Sealed Sources Under Part 35?

Comment. A commenter indicated that iridium-192 seeds and ribbons are not ''sealed'' sources. Are they included in the reference to sealed sources in this section?

Response. The NRC considers iridium-192 seeds and ribbons to be sealed sources, as defined in § 35.2.

Issue 3: Under What Circumstances Can Limited-Scope Licensees Participate in Medical Device Trials Conducted Under FDA-Approved Investigational Device Exemptions (IDE)?

Comment. One commenter said that § 35.49, under both the current and proposed regulations, has the effect of prohibiting medical facilities with specific licenses from participating in certain manufacturer-sponsored trials of medical devices conducted under FDA-approved IDE. The commenter recommended that § 35.49 be modified to permit the participation of limited-scope licensees in multi-site manufacturer-sponsored medical device trials conducted under FDA-approved IDEs.

Response. A specific licensee may have to amend its license before it participates in a trial with a source with an IDE in the following situations: (1) the sealed source/device design or use is changed from that documented in the SSDR; or (2) the sealed source or device was not initially distributed by a § 32.74 supplier. There are other situations where a specific licensee may use a sealed source under an IDE and not have to amend its license. For example, when the sealed source is the same as the description in the SSDR and the sealed source was originally distributed by a § 32.74 supplier, but the FDA requires an IDE because the description of the sealed source or device differs from that originally described to the FDA.

There are additional regulatory requirements for broad scope medical licensees beyond the requirements for specific licensees. Because the broad scope licensees must comply with additional requirements to ensure the safe use of byproduct material, they have more flexibility than specific licensees in the activities that may be conducted under their licenses.

Issue 4: Should This Section Also Address Distribution by § 32.72 Licensees?

Comment. One commenter questioned whether § 35.49(a) should include § 32.72 licensees as distributors of the sources.

Response. Section 32.72 applies to unsealed byproduct material distributors. Therefore, these licensees should not be included in § 35.49(a), which applies to sealed sources.

Issue 5: What Are the Regulations for the Use and Distribution of Sealed Sources and Devices From International Manufacturers?

Comment. A commenter questioned whether the rules prohibit the use of sources and devices from international manufacturers that may not have an NRC or Agreement State license to manufacture, package, and distribute these sources and devices.

Response. In order for an international manufacturer of sealed sources to distribute these sources in the United States, the manufacturer must have both a distribution license and a manufacturing license. The manufacturing license does not have to be from the US. The distribution license must be from NRC or an Agreement State and the sources to be distributed must go through the SSDR process.

Issue 6: What Other Comments Were Made on This Section in the Proposed Rule?

Comment. One commenter said that ''assembled'' needed to be added to § 35.49(a).

Response. As used in § 35.49(a), the word ''manufactured'' includes ''assembly'' of the sealed sources or devices.

Issue 7: Were There any Other Changes Made in This Section Between the Proposed and Final Rule?

The NRC added a new paragraph (b) to allow for medical use of sealed sources and devices that have been noncommercially transferred from a Part 35 licensee. ''Noncommercially transferred,'' as used in this part, means that the sources and devices are not being transferred for profit in the open market. Subsequent distribution of the sealed source or device is not subject to the requirements of this paragraph, if the source or device is distributed to licensees that have a license to possess the source or device. However, the source and device cannot be altered from the description and intended use documented in the SSDR. Currently, licensees must obtain an amendment exempting them from the requirements in this section following the initial distribution of the sealed source or device.

Section 35.50, Training for Radiation Safety Officer

Issue 1: Due to the Large Variation in Authorized Uses of Byproduct Material Under Medical Licenses, What Are Appropriate Training and Experience Requirements for RSOs Listed on Such Licenses?

Comment. Commenters expressed concern that, due to the large variation in the authorized uses of byproduct material under medical licenses, it is difficult to have one set of requirements for RSOs. Other commenters believe that the qualifications of the RSO should be specified in competencies that are commensurate with the scope and complexity of the radiation safety program that the RSO must implement. For example, the required experience in paragraph (b) should be tied to the specific medical uses that are authorized on the license. It is neither necessary nor practical to require a certified health physicist to be the RSO at a small clinical program that only involves low risk modalities, such as routine nuclear medicine procedures. Alternatively, it is inappropriate for an AU to function as the RSO at a large complex program or one which may involve a broad scope license. A related comment was that certification by the ABHP does not mean that an individual is qualified to be an RSO for a medical licensee because he or she may have no experience in a medical environment.

One commenter said that the issue of acceptable qualifications for an RSO should be dealt with both through the regulations and the licensing process. A license reviewer should be able to place additional qualifications on an RSO for a more complex byproduct material program.

Another concern was the perceived inconsistencies in the requirements. For example, board certification in paragraph (a) requires many more hours of training and experience than is listed in paragraph (b). In addition, AUs, AMPs, and ANPs are not required to obtain written certification that they have achieved a level of radiation safety knowledge sufficient to independently function as an RSO.

Response. The NRC agrees that it is very difficult to have a single set of training and experience requirements for RSOs named on medical licenses because of the wide variation in medical uses of byproduct material. Therefore, we made several changes to the current requirements for RSOs to ensure that the RSO has adequate training for the types of uses for which he or she has RSO responsibilities. The final rule requires that an RSO must have one year of full-time radiation safety experience involving similar types of uses of byproduct material and a signed preceptor statement that the individual can function as an RSO for a medical use licensee. If an AU, AMP, or ANP is named RSO, he or she must have the required experience with *similar types of uses* of byproduct material for which the individual has RSO responsibilities.

The NRC reviews the training and experience of the RSO as part of the licensing process to determine if the individual has the qualifications to be named as RSO for the medical uses authorized on that license. A major focus during the rulemaking has been to incorporate all of the requirements for medical licensees in Part 35 so that there is no need for additional requirements (via license conditions) to be placed on licensees during the licensing review.

Issue 2: What Will Be the Status of an RSO Who Satisfies the Current Training and Experience Requirements, But Not the New Training and Experience Requirements, When the Rule Becomes Effective?

Comment. One commenter said that the regulations need to accommodate older, valuable professionals with years of experience as health physicists and medical health physicists. The preceptor of such an individual may no longer be available (retired or deceased) to provide the written certification. In addition, it serves no purpose for these individuals to satisfy 200 hours of didactic training when they might well be the instructors for such programs.

Response. An individual who is currently listed on a license as an RSO will be ''grandfathered'' under § 35.57 when the rulemaking becomes final and will not have to satisfy the requirements in § 35.50. The individual will be able to continue as an RSO, including being named as an RSO on a new license application at a future date.

Issue 3: Can a Technologist Be the RSO for a Medical Licensee?

Comment. The NRC received comments that both supported and opposed technologists being RSOs for medical licensees. Some commenters think that nuclear medicine technologists are often the individuals who are most familiar with radiation safety requirements and are in the best position to carry them out. Other commenters think that technologists are more involved in clinical procedures. Therefore, technologists are not as totally oriented to radiation safety as either medical physicists or health physicists. One commenter said that certified or registered technologists would many times be better choices for RSOs than AUs. Another commenter said that one year of full-time experience as a radiation safety technologist does not provide enough opportunity to address all the issues that confront an RSO.

Response. The current Part 35 allows a technologist to be an RSO if the requirements in § 35.900, Radiation safety officer, are met. The NRC continues to believe that a technologist can be an RSO if he or she successfully completes all of the training and experience requirements in the new § 35.50, Training for Radiation Safety Officer.

Issue 4: Is the Requirement in § 35.50(b) for an RSO To Have 1 Year of Full-Time Supervised Radiation Safety Experience Involving Similar Types(s) of Use(s) of Byproduct Material Adequate?

Comment. One commenter said that 1 year of full-time experience is not adequate for an RSO to cover both nuclear medicine and therapy or to cover all aspects of a broad scope licensee's radiation safety program.

Response. The NRC has retained the requirement for 1 year of full-time

supervised experience because that requirement is in the current § 35.900(b)(2) for radiation safety technologists, and we have no evidence that the 1 year requirement has resulted in inadequate experience using byproduct material. This requirement is important because it must involve similar type(s) of use(s) of byproduct material for which the individual will have RSO responsibilities. In addition to the 1 year of full-time experience, the individual must also satisfy the other training and experience requirements in § 35.50 in order to be named as an RSO on a license.

Issue 5: Why Is There a Requirement for an RSO To Obtain a Preceptor Statement?

Comment. Several commenters questioned the need for a preceptor statement for RSOs and noted the difficulty of obtaining these statements. One commenter said that preceptors are not common in the health physics profession. RSOs often obtain their training and experience at multiple institutions. Therefore, no single individual would be able to attest to satisfactory completion of all of the training and experience requirements. Several commenters said that the requirement for a preceptor statement should allow for submission of documents such as resumes or college transcripts that are comparable to a preceptor statement. Another suggestion was that licensee management be able to sign the preceptor statement.

Response. The NRC has retained the requirement for an RSO to obtain written certification that he or she has completed the training and experience requirements in paragraph (b)(1) of § 35.50. We consider such a statement to be an important component of the overall training requirements. The requirement for a preceptor statement for an ANP is in the current Part 35. We are not aware of any difficulties an ANP may have experienced in getting the required written certification. We recognize that professionals very often get their training and experience at multiple locations and there may not be one individual who can attest to completion of all of the training and experience requirements. In that case, the preceptor would be expected to look at the transcripts or possibly check some references for the individual for whom they are preceptoring in order to certify that the individual has satisfied the requirements in paragraph (b)(1) of this section. We have required that the preceptors be RSOs because they are most qualified to judge whether the individual has achieved a level of radiation safety knowledge sufficient to independently function as an RSO for medical uses of byproduct material. Licensee management may not have the same knowledge. Therefore, the licensee may not be in the best position to judge another individual's level of radiation safety knowledge and experience. We discuss the training and experience requirements in the final rule, including the preceptor, in Section III, Part I, of the **SUPPLEMENTARY INFORMATION** of this document.

Issue 6: Should AUs, AMPs, and ANPs Be RSOs?

Comment. The NRC received a number of comments that did not agree with the provision in paragraph (c) of this section that allows AUs, AMPs, or ANPs to be RSOs. Commenters felt that there was an inconsistency between the requirements for an RSO to complete 200 hours of didactic training, and allowing AUs, with as little as 40 hours of didactic training and 20 hours of supervised training, to be RSOs.

There were no comments that recommended that the hours required for RSOs be reduced. Rather, commenters recommended that if AUs, AMPs, and ANPs are allowed to be RSOs, they should be required to satisfy the same requirements as RSOs, including 200 hours of didactic training and supervised experience in the activities listed in paragraph (b)(1)(ii). Another suggestion was to revise the training requirements for AUs to focus on requirements associated with being an RSO. One commenter said that paragraph (c) should be deleted because training and experience requirements for RSOs should be independent of AU, AMP, and ANP status.

Another concern was that physicians typically have AU status for one type, or similar types, of medical use and may not be qualified to be the RSO for other types of medical uses. For example, a physician with AU status in nuclear medicine may be qualified to be an RSO for a licensee that only provides nuclear medicine services, but he or she should not be named as RSO for a brachytherapy device licensee or a broad scope licensee.

Several commenters said that only AUs for § 35.100 and § 35.200 uses should be allowed to be RSOs, while another commenter suggested that an AU for § 35.600 uses could be an RSO for all other uses. One commenter said that, in small practices, an AU should be allowed to serve as the RSO for the modality in which they have AU status, while in broad scope institutions a ''dedicated'' RSO is necessary. One commenter said that the regulations should allow licensees to have more than one RSO, or the regulations should emphasize that an RSO must have training and experience in all of the types of uses for which he or she has RSO responsibilities.

Response. Following a review and evaluation of the public comments, the NRC retained the provision in paragraph (c) that allows AUs, AMPs, and ANPs to be RSOs. The current rule allows AUs that are identified on the licensee's license to be RSOs. Retention of this provision is important for a licensee that is a sole practitioner and must be both the AU and RSO. Not allowing such a licensee to be an RSO would result in unnecessary regulatory burden on that licensee.

The final rule also allows for AMPs and ANPs to be RSOs. This provides medical licensees even more flexibility in whom they name as their RSO. We believe that AMPs are well aware of the radiation safety issues associated with therapeutic units. In addition, we believe that the 700 hours of training and experience required for ANPs provides them with extensive knowledge of the radiation safety issues associated with the medical use of unsealed byproduct material.

Note that AUs, AMPs, and ANPs may be named as RSO only if they have experience with the radiation safety aspects of similar type(s) of use(s) of byproduct material for which the individual will have RSO responsibilities. For example, an AU of unsealed byproduct material cannot be named an RSO for therapeutic medical units, or vice versa, unless he or she has additional training and experience with these types of units.

Part 35 does not allow licensees to have more than one permanent RSO. The RSO named on the license must have training and experience with the radiation safety aspects of all types of uses of byproduct material for which the individual will have RSO responsibilities. However, § 35.24(c) in the final rule does allow licensees to name multiple temporary RSOs, if necessary. For additional information, refer to the discussion of the provision for temporary RSOs in § 35.24.

Issue 7: Were There Any Other Changes Made in This Section Between the Proposed and Final Rule?

Response. Yes. The NRC added a phrase, ''or permit issued by a Commission master material licensee,'' in paragraph (b)(1)(ii). This phrase was added to conform with the change in the definition of Radiation safety officer, in which the phrase ''a medical use permit issued by a Commission master material

licensee was added as one way to identify a Radiation Safety Officer.

The NRC added a new paragraph (b)(1)(ii)(F) that states that the RSO's experience should include the use of emergency procedures to control byproduct material. The list of RSO duties in the current Part 35 includes ''taking emergency action if control of byproduct material is lost,'' but this area was omitted in the proposed rule.

We also reworded paragraph (b)(2) of this section to state more clearly that the preceptor must certify in writing that the individual has both completed the structured educational program in paragraph (b)(1) and achieved a level of radiation safety knowledge sufficient to function independently as an RSO for a medical use licensee.

Section 35.51, Training for an Authorized Medical Physicist

Issue 1: What Is the Distinction Between a Physicist, Health Physicist, and a Medical Physicist in Part 35?

Comment. One commenter was concerned about the lack of differentiation between a physicist, a health physicist, and a medical physicist in the proposed rule. Health physics is radiation detection and radiation safety. Medical physics involves radiation detection and health physics, but with additional emphasis on treatment planning, therapy, and dosimetry. Under the new regulations, it appears that a solid state physicist with a masters degree, who had never had a course in medical physics or dosimetry, could work for 2 years on the radiation safety aspects of the tasks listed in § 35.51(b)(1), learn to calibrate an HDR, take a test on radiation safety, and be an AMP.

Response. The term ''authorized medical physicist,'' as used in Part 35, is defined in § 35.2. The NRC uses the term AMP in the new Part 35, rather than ''teletherapy physicist'' as in the current Part 35, because the regulations now include requirements for photon-emitting remote afterloader units and gamma stereotactic radiosurgery units in addition to teletherapy units. The terms ''physicist'' and ''health physicist'' are not defined in § 35.2 because they are not used in Part 35. Physicists and health physicists that meet the requirements for an AMP or RSO would be recognized on the license as an AMP or RSO, respectively.

The requirements for an AMP in this section are similar to the requirements for a teletherapy physicist in the current § 35.961, Training for teletherapy physicist. As in the current Part 35, a physicist who wants to be an AMP would have to have a master's or doctor's degree in physics, biophysics, radiological physics, or health physics; and complete 1 year of full-time training in therapeutic radiological physics and an additional year of full-time work experience under the supervision of a medical physicist at a medical institution performing the tasks in the sections listed in § 35.51(b)(1). The only new requirement is for an AMP to obtain a preceptor statement that he or she has obtained a level of competency sufficient to function independently as an AMP. We have deleted the proposed requirement for an AMP to demonstrate sufficient knowledge in radiation safety by passing an examination. We discuss the training and experience requirements in the final rule, including the deletion of the examination, in Section III, Part I, of this document.

Issue 2: Were There Any Other Changes Made in This Section Between the Proposed and Final Rule?

Response. Yes. In the lead-in sentence, a phrase ''Except as provided in § 35.57'' was added. This phrase was inadvertently left out in the proposed rule.

The phrase ''or an equivalent training program approved by the NRC'' was deleted from paragraph (b)(1) of this section because the NRC is not going to approve training programs under the revised training and experience requirements. For a more detailed discussion of the new training and experience requirements refer to Section III, Part I, of this document.

Paragraph (b)(1) was amended to include a reference to the new § 35.433, Decay of strontium-90 sources for ophthalmic use. Section § 35.433 requires that only an AMP shall calculate the activity of each strontium-90 source that is used to determine the treatment times for ophthalmic treatments.

In addition, we reworded paragraph (b)(2) to state more clearly that the preceptor must certify in writing that the individual both has completed the requirements in paragraph (b)(1) and has achieved a level of competency sufficient to function independently as an AMP. We also reworded paragraph (b)(2) to clarify that the preceptor has to be an AMP who meets the requirements in § 35.51 or equivalent Agreement State requirements for an AMP for each type of therapeutic medical device for which the individual is requesting AMP status. For example, an individual who is an AMP for only remote afterloaders can not be a preceptor for an individual who wants to be an AMP for gamma stereotactic radiosurgery units.

Section 35.55, Training for an Authorized Nuclear Pharmacist.

Issue 1: Should the Current Requirement for ANPs To Complete 700 Hours in a Structured Educational Program Be Retained?

Comment. Most commenters supported the proposal to maintain the current 700 hours of training and experience for ANPs because they believe that this training is necessary to assure the quality of nuclear pharmacy practitioners. One commenter recommended that the 700 hours of training and experience should specifically include 200 hours of didactic training.

Response. Throughout this rulemaking, the NRC reviewed and discussed the training and experience requirements in Part 35 at facilitated public meetings held both during the development of the proposed rule and during the public comment period on the proposed rule. Based on these discussions and on a review of the written comments received on the proposed rule, we made no changes to the current requirements for an ANP to complete 700 hours in a structured educational program. The current requirements are considered appropriate for the duties and responsibilities of an ANP, as defined in § 35.2.

Issue 2: Were There Any Changes Made in This Section Between the Proposed and Final Rule?

Response. Yes. In the lead-in sentence, a phrase ''Except as provided in § 35.57'' was added. This phrase was inadvertently left out in the proposed rule.

The NRC reworded paragraph (b)(2) of this section to state more clearly that the preceptor must certify, in writing, that the individual both has completed the structured educational program in paragraph (b)(1) and has achieved a level of competency sufficient to function independently as an ANP. We also reworded this section to state more correctly that the preceptor is certifying that the individual has achieved a level of competency sufficient to function independently as an ANP, rather than to independently operate a nuclear pharmacy. The amended text is consistent with the text used in the other training and experience sections.

Section 35.57, Training for Experienced Radiation Safety Officer, Teletherapy or Medical Physicist, Authorized User, and Nuclear Pharmacist.

Issue 1: Why Doesn't § 35.57 Include a Reference to § 35.55, Training for an Authorized Nuclear Pharmacist?

Comment. One commenter noted that § 35.57(a) in the proposed rule referred to experienced RSOs, physicists, and nuclear pharmacists, but only referenced the training requirements for RSOs and physicists.

Response. The NRC corrected § 35.57(a) to include the reference to § 35.55, Training for an authorized nuclear pharmacist.

Issue 2: Why Did § 35.57(b) in the Proposed Rule Reference Training Requirements for AUs in Subparts C-H, When There Are No Training Requirements for AUs in Subpart C?

Comment. One commenter noted that § 35.57(b) in the proposed rule referenced training requirements for AUs in Subparts C-H, but there are no training requirements for AUs in Subpart C.

Response. The NRC corrected § 35.57(b) to delete the reference to Subpart C, which does not include training requirements for AUs.

Issue 3: Were There Any Changes Made in This Section Between the Proposed and Final Rule?

Response. Yes. The NRC revised paragraphs (a) and (b) to include AUs and other authorized persons that are identified on a permit issued by a Commission master material licensee, a permit issued by a Commission or Agreement State broad scope licensee, or a permit issued by a Commission master material license broad scope permittee. This change has been made so that this section is consistent with the revised definition of AUs and other authorized persons in the final rule.

Section 35.59, Recentness of Training

Issue 1: How Much Related Continuing Education and Experience Does an Individual Need To Have if Their Training and Experience Has Not Been Obtained Within 7 Years Preceding the Date of the Application?

Comment. A commenter questioned that if the training and experience have not been obtained within the 7 years preceding the date of application, how much related continuing education and experience would the individual need to have, and would this be a case-by-case evaluation with input from the ACMUI.

Response. If the training and experience was not obtained within 7 years preceding the date of the application, the continuing education and experience requirements for an individual would be reviewed on a case-by-case basis, with input from the ACMUI, as necessary.

Subpart C—General Technical Requirements

Section 35.60, Possession, Use, and Calibration of Instruments To Measure the Activity of Unsealed Byproduct Materials

Issue 1: Can All Requirements for Calibration of Instruments Used To Measure the Activity of Unsealed Byproduct Material Be Combined? Is it Necessary to Have Prescriptive Calibration Requirements for these Instruments?

Comment. Commenters proposed that §§ 35.60 and 35.62 be combined into one section because both sections address calibration of instruments used to measure the activity of unsealed byproduct material. They also recommended that the prescriptive calibration requirements be deleted so that licensees have the flexibility to develop a calibration program that meets their needs.

Response. The NRC agrees that §§ 35.60 and 35.62 should be combined because both sections address instrument calibration. We also agree that the prescriptive requirements should be deleted from the section. Therefore, the regulatory text was amended to delete prescriptive calibration requirements. The section now requires that licensees calibrate instrumentation in accordance with nationally recognized standards (e.g., voluntary consensus standards, such as ANSI N42.13–1986 (R 1993), ''Calibration and Usage of Dose Calibrator Ionization Chambers for the Assay of Radionuclides.'') or with the manufacturer's instructions. This change makes the requirements for instrument calibration more flexible, more adaptable to new technology, and more performance-based.

Issue 2: Does This Section Apply To Licensees That Use Brachytherapy Sources?

Comment. A commenter asked that we revise the section to state that the section does not apply to use of brachytherapy sources.

Response. The title of this section has been amended to clarify that it only pertains to instruments used to measure the activity of unsealed byproduct material. The calibration of brachytherapy sources is addressed in § 35.432.

Issue 3: Should Licensees That Only Use Unit Dosages Be Required To Possess, Use, and Calibrate Instruments To Measure the Activity of Unsealed Byproduct Material?

Comment. Some commenters agreed that the NRC should not require unit dosages to be assayed. As a result, they did not believe that it was necessary to require licensees that only use unit dosages to possess, use or calibrate instruments to measure the activity of unsealed byproduct material. Other commenters disagreed with the proposed provision that did not require direct measurement of unit dosages prior to administration. They believed that all dosages should be assayed. Therefore, all licensees should be required to comply with this section.

Response. The NRC amended the regulatory text to state clearly that this section only applies to direct measurements that are made in accordance with § 35.63, which requires licensees to assay (measurement of radioactivity) nonunit dosages except when volumetric measurements and mathematical calculations are used.

As stated in the Statements of Consideration for the proposed rule (63 FR 43533; August 13, 1998), if a licensee administers only unit dosages from manufacturers (or preparers) and uses decay methods to determine the dosages, the licensee is not required to have a measurement instrument and, thus, is exempt from the calibration requirements of this section. However, if a licensee administers unit dosages but chooses to reassay a unit dosage, the licensee must comply with this section. If an instrument is used to measure dosages, it is extremely important that it is calibrated.

Issue 4: Is It Necessary To Keep a Record of Instrument Calibrations?

Comment. Some commenters did not believe that it was necessary to keep a record of the instrument calibrations.

Response. The NRC retained the requirement to maintain calibration records because they are needed to document that the instruments have been calibrated. However, we have simplified the recordkeeping requirements in § 35.2060 of the final rule by requiring that the licensee record the model and serial number of the instrument, the date of the calibration, the results of the calibration, and the name of the individual who performed the calibration. These changes are further discussed in § 35.2060.

Section 35.61, Calibration of Survey Instruments

Issue 1: Is This Section Needed in Part 35?

Comment. A commenter believed that this section should be deleted from Part 35 because survey instrument calibration is addressed in 10 CFR 20.1501.

Response. The NRC has not deleted this section. Section 20.1501 requires that licensees calibrate survey instruments periodically, but it does not provide specific requirements for calibrations of survey instruments. Specific requirements are needed for Part 35 licensees to ensure that their radiation survey instruments are properly calibrated. An accurate survey instrument is important because individuals rely on the instrument output to assess radiation levels in areas in or adjacent to nuclear medicine or radiation therapy departments where patients or the public may have access.

Issue 2: Is It Necessary To Require That Survey Instrument Operability Be Determined With a Check Source?

Comment. A commenter stated that the NRC should retain the requirement in the current rule that requires licensees to check survey instrument operability with a dedicated check source. Another commenter indicated that the word ''check'' should be deleted in the section title because the regulatory text did not include a requirement for an instrument ''check.''

Response. The requirement to check survey instrument operability with a dedicated check source was not included in the proposed or final rule because the NRC believes that licensees should have flexibility in how they determine that instruments are operating properly. We deleted the word ''check'' from the title because the section does not include a requirement for an instrument ''check.''

Issue 3: How Often Should a Survey Instrument Be Calibrated?

Comment. Commenters suggested various frequencies for instrument calibrations. Some commenters suggested that instruments be calibrated every 6 months. Others agreed with the 1-year interval in the proposed rule and still others suggested a 2-year interval.

Response. The NRC believes that survey instruments should be calibrated before first use, annually, and following any repair that affects the calibration of the instrument. A 1-year calibration frequency is consistent with nationally recognized standards, such as ANSI (ANSI–N323A–1997).

Issue 4: Were There Any Other Changes Made in This Section Between the Proposed and Final Rule?

Response. Yes. In paragraph (a), the NRC added the phrase ''that affects the calibration.'' This was done to clarify that the licensee does not need to recalibrate an instrument if the repair did not affect the calibration. For example, if the licensee replaced the batteries in the instrument, the licensee would not need to calibrate it. In paragraph (a)(2), we added the word ''decade'' to account for instruments with digital readouts.

Proposed paragraph (b) was deleted from the final rule. We believe the licensee should have flexibility in how it documents information on the status of survey instrument calibrations. Our primary concern is that the instrument is reading accurately. Proposed paragraph (c) stated that a licensee may not use a survey instrument if the difference between the indicated exposure rate and the calculated exposure rate exceeds 20 percent. Therefore, we do not believe the requirement in the proposed paragraph (b) for a licensee to attach a correction chart is needed. A statement regarding when a licensee shall consider a point calibrated is unnecessary. Because of the deletion of proposed paragraph (b), proposed paragraphs (c) and (d) have been redesignated as paragraphs (b) and (c) in the final rule.

Section 35.62, Possession, Use, Calibration, and Check of Instruments To Measure Dosages of Alpha- or Beta-Emitting Radionuclides

Issue 1: Can This Section Be Combined With § 35.60?

Comment. Commenters proposed that this section be combined with § 35.60.

Response. The NRC agreed that §§ 35.60 and 35.62 could be combined because Part 35 requirements for instrument calibrations are the same for all types of instruments. (See the response to similar comments under § 35.60.)

Section 35.63, Determination of Dosages of Unsealed Byproduct Material for Medical Use

Issue 1: Can This Section Be Combined With § 35.60?

Comment. A commenter proposed that this section be combined with § 35.60.

Response. The NRC did not combine § 35.60 with § 35.63 because these sections have different purposes. Section 35.60 contains the requirements for calibrating instruments used to determine the activity of a dosage. Section 35.63 contains the requirements for determining the activity of a dosage.

Issue 2: Should Unit Dosages Be Reassayed Before Administration?

Comment. Some commenters supported the lack of a proposed requirement for the licensee to reassay unit dosages. These commenters believed that the administered activity could be based on the activity reported by the nuclear pharmacy. Other commenters did not support the proposed rule. They believed that all dosages should be assayed by the licensee before administration.

Response. The NRC believes that a licensee should determine and record the activity of each dosage before medical use. For unit dosages, this determination must be made by direct measurement of radioactivity or by a decay correction based on the activity or activity concentration. The provision for licensees to determine the activity of the unit dosage by direct measurement of radioactivity was added to the final rule. The activity or activity concentration must have been determined by a manufacturer or preparer licensed under § 32.72 or equivalent Agreement State requirement or by an NRC or Agreement State licensee for use in research in accordance with an RDRC-approved protocol or an Investigational New Drug (IND) protocol accepted by FDA. Because the unit dosages have been assayed by the Part 32 licensee or by a licensee for use in research in accordance with an RDRC-approved protocol or an IND protocol accepted by FDA, we do not believe the Part 35 licensee should be required to reassay the dosage. Licensees should note that, if a unit dosage has been changed or manipulated in any way, it is no longer considered to be a unit dosage and will need to be reassayed before it is administered.

Issue 3: Can Volumetric Measurements Be Used To Determine the Activity of a Dosage?

Comment. Commenters asked that we clarify whether the phrase ''combination of measurements and calculations'' would allow a licensee to base the administered activity on the radioactivity measurement made by a manufacturer (or a preparer), with volume measurement and calculation by a licensee. Commenters also asked that we clarify whether the term ''direct measurement'' means that the activity of the dosage must be based on a measurement of the radioactivity.

Response. The NRC agrees that the terms ''direct measurement'' and

''combination of measurements and calculations'' in the proposed rule text needed to be clarified. In the final rule, we made two changes:

1. We replaced the term ''direct measurement'' by ''direct measurement of radioactivity,'' and
2. We added an alternate method for determining dosage by using the radioactivity measured by a manufacturer or a preparer, with volume measurement and calculation by a licensee.

Issue 4: Should the Administered Dosage Be Allowed To Deviate From the Prescribed Dosage?

Comment. Commenters recommended that we delete the requirement in § 35.63(d) that states: ''a licensee shall not use a dosage if the dosage differs from the prescribed dosage by more than 20 percent.'' Many commenters believed that this was an overly prescriptive requirement. They stated that it is the AU's responsibility to determine the proper dosage or dosage range for patients.

Response. The NRC believes that the requirement should be maintained in the final rule with some modification to address prescribed dosage ranges. AUs are responsible for prescribing the dosage or dosage range. AUs may prescribe a dosage range greater than 20 percent. This range can be case specific or can be a ''blanket'' range that would cover all administrations of unsealed byproduct material. For example, the AU could establish a policy where all administered dosages may deviate from the prescribed dosage by plus or minus ''xx'' percent.

In cases where the AU has not prescribed a dosage range, we believe that the regulation should allow for some deviation from the prescribed dosage. Without this 20 percent ''default'' range, all administered dosages would need to exactly match the prescribed dosage at the time of administration. We believe that a 20 percent deviation is reasonable in consideration of current technology. We have not allowed a deviation outside of the prescribed range because the AU has the flexibility of establishing the acceptable range under this provision.

Issue 5: Is It Necessary To Perform a Decay Correction for Long-Lived Radionuclides?

Comment. Commenters asked that the rule be modified so that licensees are not required to perform a decay correction for long-lived radionuclides.

Response. The NRC does not believe that the rule should specify when, based on half life, a decay correction should be performed. We believe the rule addresses this issue by permitting a licensee to administer a dosage if the dosage activity is within 20 percent of the prescribed dosage or is within the prescribed dosage range. This requirement gives the licensee responsibility for determining when it is appropriate to perform a decay correction. In the case of a long-lived radionuclide, the licensee may make a determination that a decay correction is not needed to verify that the dosage is within 20 percent of the prescribed dosage or is within the prescribed range because of the long half life of the byproduct material.

Section 35.65, Authorization for Calibration, Transmission, and Reference Sources

Issue 1: Are Medical Licensees Authorized To Receive Calibration Sources From Licensees That Are Licensed Under §§ 32.72 and 32.74?

Comment. A commenter asked that this section be revised to allow licensees to receive calibration and reference sources from licensees that are licensed under § 32.72, Manufacture, preparation, or transfer for commercial distribution of radioactive drugs containing byproduct material for medical use under Part 35, and § 32.74, Manufacture and distribution of sources or devices containing byproduct material for medical use.

Response. NRC has added a new paragraph (b) to address the issue of whether medical use licensees can receive calibration, transmission, and reference sources from § 35.72 and/or § 32.74 licensees. Paragraph (a) of the current regulations has been reworded to state more clearly that licensees can receive sealed sources, not exceeding 1.11 GBq (30 mCi) each, manufactured and distributed by a person licensed under § 32.74 of this chapter or equivalent Agreement State regulations. A new paragraph (b) has been added to allow medical use licensees to receive sealed sources, not exceeding 1.11 GBq (30 mCi) each, redistributed by a licensee authorized to redistribute the sealed sources manufactured and distributed by a person licensed under § 32.74 of this chapter, providing the redistributed sealed sources are in the original packaging and shielding and are accompanied by the manufacturer's approved instructions. This permits the sources to be received from any licensee with redistribution authorization, which codifies current practice.

Issue 2: Were There Any Other Changes Made in This Section Between the Proposed and Final Rule?

Response. Yes. The NRC inserted the word ''transmission'' in the section title. This was done to clarify that licensees may receive, possess and use transmission sources that do not exceed the quantity limits in this section.

We corrected an error in paragraphs (a) and (b). Paragraph (a) should have referred to ''1.11 GBq (30 mCi)'' rather than ''1.11 kilobecquerel (kBq) (30 mCi)'' and paragraph (b) (final rule paragraph (c)) should have referred to ''0.56 GBq (15 mCi)'' rather than ''0.56 MBq (15 mCi).'' In addition, paragraph (c) (final rule paragraph (d)) was clarified. Our intent is to allow the licensee to receive, possess, and use byproduct material with a half-life longer than 120 days provided individual amounts do not exceed the smaller of 7.4 MBq (200 μCi) or 1000 times the quantities in Appendix B of 10 CFR Part 30.

Section 35.67, Requirements for Possession of Sealed Sources and Brachytherapy Sources

Issue 1: When Are Leak Tests Required?

Comment. Some commenters believed that leak tests should only be required if a radioactive source has been abused, misused, or retrieved after being lost. Other commenters questioned whether the rule requires leak testing of small check sources. In addition, some commenters believed that sources should be leak tested annually. Others supported semiannual leak testing. Finally, some commenters believed the rule should not require a licensee to leak test certain sources, such as dry radionuclides embedded in acrylic.

Response. Section 35.67(b) contains the leak test requirements for sealed sources. The NRC believes that sealed sources should be leak tested semiannually or in accordance with the interval approved by the Commission or an Agreement State in the SSDR. A semiannual leak testing requirement is consistent with recommendations in ANSI–N542. If licensees are unsure whether a source meets the definition of a sealed source, they should reference the SSDR. This registry may be accessed at *http://www.hsrd.ornl.gov/nrc/ssdr/ssdrindx.htm.*

We have not included a requirement for a source to be leak tested if it has been ''abused, misused, or retrieved after being lost'' because the licensee is responsible for assuring that the dose limits in Part 20 are not exceeded. If the licensee suspects that a source may be leaking or could have been damaged, it

should evaluate whether a survey (leak test) should be performed.

Paragraph (f) lists the sources that do not need to be leak tested. In particular § 35.67(f)(3) states sources containing 3.7 MBq (100 μCi) or less of beta or gamma-emitting material or 0.37 MBq (10 μCi) or less of alpha-emitting material need not be leak tested. If a source contains less than this quantity of material, a leak test is not needed.

We believe leak tests are needed for sources such as dry radionuclides embedded in acrylic because removable contamination could exist due to:

1. Radioactivity contained at the surface of the acrylic;
2. Interaction between any chemicals or solvents that may accidently come into contact with the acrylic;
3. Aging of the acrylic; or
4. Radiation damage to the acrylic.

(Note: if the radioactivity of the acrylic source is less than the quantities in § 35.67(f)(3), leak testing would not be necessary.)

For example, a common dose calibrator source which is embedded in cast epoxy resin matrix, sometimes referred to as an ''E Vial,'' meets the definition of a sealed source and would have to be leak tested in accordance with the requirements in this section. However, E vials containing no more than 3.7 MBq (100 μCi) of a gamma-emitting material are exempt from leak testing under § 35.67(f)(3).

Issue 2: When Should an Inventory of Sealed Sources and Brachytherapy Sources Be Performed?

Comment. Commenters suggested that inventories of sealed sources should be performed quarterly, others suggested semiannually, as in the proposed rule. Other commenters believed that sealed sources that are exempt from leak testing should not be subject to inventory requirements. Another commenter questioned whether extra brachytherapy seeds should be subject to inventory requirements.

Response. Sealed source inventories should be performed semiannually. A review of events where sources have been lost or stolen in the past 10 years indicated that quarterly inventories would not have had a significant impact on preventing the incidents. The change from a quarterly frequency to a semiannual frequency would reduce unnecessary regulatory burden and radiation exposure for individuals performing the inventories.

The NRC believes sealed sources that are not required to be leak tested should be inventoried because handling sources listed in paragraph (f) would not necessarily be considered low risk. For the same reason, extra brachytherapy sources should be inventoried. If one of these sources were lost and were picked up by an individual, the radiation dose received by the individual may exceed the Part 20 limits.

Issue 3: What Is the Appropriate Time Period for Reporting a Leaking Source?

Comment. A commenter suggested that the time period for reporting a leaking source should be changed from ''within 5 days'' to ''within 15 days.''

Response. The NRC has not changed the time period for reporting a leaking source. We continue to believe that it is important to inform NRC promptly when a licensee discovers that a source is leaking.

Issue 4: Were There Any Other Changes Made in This Section Between the Proposed and Final Rule?

Response. Yes. The NRC amended paragraph (a) to delete the requirement to maintain a copy of the radiation safety and handling instructions supplied by the manufacturer for the duration of source use because it was overly prescriptive. We believe that this change makes the regulation more performance-based. However, deletion of the requirement does not prohibit the licensee from maintaining the instructions.

Paragraphs (d) through (f) were amended by replacing the term ''leakage test'' with the phrase ''leak test.'' This change reflects common use of the term ''leak test.''

Paragraph (f) was revised to indicate clearly that a stored source is exempt from the leak testing requirements in this section, regardless of the length of time that it has been in storage. The current rule does not contain a requirement to leak test stored sources after 10 years. The provision for leak testing after 10 years was added to the proposed rule because, at that time, we believed that leak testing was appropriate given the time of storage and the potential for contamination. At this time, we do not think this prescriptive requirement is warranted because the licensee must test each stored source for leakage before any use or transfer unless it has been leak tested within 6 months before the date of use or transfer.

Section 35.69, Labeling of Vials and Syringes

Issue 1: Can This Section Be Deleted?

Comment. Commenters suggested that this section should be deleted because appropriate labeling is the standard of medical and pharmacy practice and is adequately regulated by the FDA, the State Boards of medicine and pharmacy, and the US Pharmacopeia. Syringe shields can be used to maintain exposures ALARA. Under certain circumstances, syringe shields can be hazardous to patients because they could obscure subtle visualization of the syringe content.

Response. The NRC does not think this section should be deleted in its entirety. In addition, we do not believe that this requirement duplicates the requirements of the FDA, State Boards of Medicine and Pharmacy, and the U.S. Pharmacopeia. The labeling requirements in Part 35 are limited to two very specific purposes: to provide information to physicians or technologists that indicates the contents of the syringe to ensure that the administration is in accordance with the written directive; and to warn workers that the syringe contains byproduct material, i.e, radiation protection from the medical use of byproduct material. Labeling requirements of the other organizations have different purposes and, consequently, may result in different information on the labels. Any other labeling that contains the same information required by this section is acceptable. If another labeling requirement does not specify all of the information required by § 35.69, the additional information may be included on that label.

We deleted the requirement for the licensee to develop, implement, and maintain written procedures for labeling each syringe, syringe shield, or vial shield that contains a radiopharmaceutical and for shielding vials and syringes. We also deleted the requirement to provide individuals with instructions on these procedures. Both requirements have been deleted because we believe the rule should focus on labeling the vial or syringe, rather than on procedures.

Syringe or vial shields can be used to maintain exposures ALARA. However, we believe licensees should have flexibility to determine whether syringe or vial shields should be used. Thus, we have deleted the requirements to shield the syringe or vial. However, deletion of the requirement does not prohibit the licensee from using syringe or vial shields. When syringe shields or vial shields are used by a licensee, the final rule requires the licensee to label the shields, if the label on the syringe or vial is not visible.

Section 35.70, Surveys for Ambient Radiation Exposure Rate

Issue 1: Is This Section Needed?

Comment. Some commenters did not believe this section was needed because it was up to the licensee, through the RSO, to ensure radiation safety. Some commenters agreed that surveys should only be required when byproduct material requiring a written directive is used. Other commenters believed that the rule should require surveys of all areas where byproduct material is used.

Response. This section is needed to ensure that a radiation survey is conducted in areas where unsealed byproduct material that requires a written directive was prepared or administered. The NRC believes that a radiation survey, at the end of each day, should be required in Part 35 because patients and other individuals could be present near a nuclear medicine or radiation therapy department. Without surveying ambient radiation levels, it is possible for patients or other individuals to receive unnecessary or excessive radiation exposures.

In order to make the rule more risk-informed, we do not believe all areas need to be surveyed. However, licensees must be prepared to show compliance with the public and occupational dose limits in Part 20.

Issue 2: When Should Surveys Be Performed?

Comment. Some commenters believed that surveys should be performed after preparation or administration of byproduct material, rather than at the end of the day. Some opposed removing the existing requirements to survey areas where radiopharmaceuticals or waste is stored and to survey for removable contamination. Finally, one commenter asked that the NRC clarify whether the requirement for surveys in paragraph (b) applies only to patients' rooms or whether it also applies to the area where the patient's dosage was prepared.

Response. The general survey requirements are in Part 20. In addition to these requirements, the NRC believes that medical use licensees should be required to perform radiation surveys at the end of the day in areas where unsealed byproduct material requiring a written directive was prepared for use or administered. A medical use licensee, such as a hospital, prepares and administers byproduct material to multiple patients or human research subjects throughout the day. If a survey were required after each preparation or administration of byproduct material, there would be a significant increase in the licensee's burden to comply with this requirement without an associated safety benefit. We believe that a survey at the end of each day of use is sufficient to detect elevated radiation levels. If elevated levels are detected, corrective action, if warranted, could be taken. However, licensees always have the flexibility of performing more frequent surveys.

We do not believe a requirement for weekly surveys for removable contamination is needed because licensees are required to show compliance with public and occupational dose limits in Part 20 of this chapter. In addition, the licensee will need to be able to show compliance with Part 20, Subpart F, Surveys and Monitoring.

We have clarified paragraph (b) to indicate that the licensee does not need to perform the surveys required by paragraph (a) of this section in areas where patients or human research subjects are confined when they cannot be released under § 35.75. In this case, the licensee must be prepared to show compliance with the Part 20 requirements.

Section 35.75, Release of Individuals Containing Radiopharmaceuticals or Implants

Issue 1: Should Any Changes Be Made to the Criteria for Release of Individuals Containing Pharmaceuticals or Implants?

Comment. Some commenters supported the dose-based release criteria in the proposed rule, while others asked that the criteria be revised. Those commenters that supported the 5 mSv (0.5 rem) release limit believed that § 35.75 provided regulatory relief to the medical profession without an associated increase in radiation risk to the public. These commenters recognized that one of the major obstacles to allowing the release of individuals in accordance with § 35.75 is a possible increase in radiation alarms at landfills. However, they believed the issue of landfill alarms should be addressed in other ways, such as raising the threshold for the alarms to a ''more practical'' level, rather than revising the release criteria in § 35.75. Commenters also indicated that several studies had been conducted that indicated that radiation exposures to family members from released patients were less than the 5 mSv (0.5 rem) limit. As a result, they asked that NRC reevaluate information provided in the guidance associated with this requirement.

Other commenters asked that the release criteria be revised because they believed that the criteria were based solely on economics and not on radiation risk. They were also concerned that household waste from an individual who had been released from the hospital could be contaminated and could trigger radiation alarms at landfills. This situation would affect State radiation protection programs because the States would have to investigate incidents in which the alarms had been activated.

Response. The NRC does not believe that any changes are needed to this section as a result of the public comments. We acknowledge that some States have reported an increase in the number of alarms at landfills. However, we have no documentation indicating that the exposure rates to the maximally exposed individuals have exceeded the dose limit in § 35.75. The NRC does not have regulatory jurisdiction over the landfill operators, nor over the alarm set points for radiation detectors at landfills. However, we do encourage continued communication between regulatory bodies and landfill operators to resolve this issue.

We believe that the release criteria provide licensees with needed flexibility in program management. A dose limit of 5 mSv (0.5 rem) to individuals knowingly exposed while voluntarily helping in the care, support, and comfort of patients provides adequate protection of these individuals. In addition, licensees are required to provide instructions to the released individual, or the individual's parent or guardian, on actions recommended to maintain doses to other individuals as low as reasonably achievable (ALARA) if the total effective dose equivalent to any other individual is likely to exceed 1mSv (0.1 rem). Licensees should consider this latter provision regarding instructions on maintaining exposures ALARA in situations where the individual has been released under § 35.75 but remains hospitalized for other reasons. In this case, the maximally exposed individual may be a member of the licensee's staff. The dose limit of 5 mSv (0.5 rem) to individuals comforting patients is consistent with the recommendations of the NCRP and the International Commission on Radiological Protection (ICRP). For additional information on the background of this section, refer to 62 FR 4120 (January 29, 1997).

Finally, we recognize that the values presented in NUREG–1556, Volume 9, for release of patients are based on some conservative values. The licensee may use case-specific information in place of the values used in the guidance document.

Issue 2: What Other Changes Were Made in This Section Between the Proposed and Final Rule?

Response. In paragraph (b), the term ''breast feeding infant'' was replaced with the term ''nursing infant.'' This was done to maintain consistency within Part 35. Paragraph (d) was revised to state that records of the instructions provided to breast-feeding females should be made in accordance with § 35.2075(b) rather and § 35.2075(c). This change was needed because of a change in the codified text of § 35.2075. For additional information refer to the discussion of § 35.2075.

Section 35.80, Provision of Mobile Medical Service

Issue 1: Should Mobile Medical Service Licensees Be Allowed To Operate Under Reciprocity in Other Regulatory Jurisdictions?

Comment. Commenters indicated that mobile medical services are currently operating under reciprocity in some States. Some Agreement States indicated they do not allow medical licensees to operate under reciprocity, while other Agreement States said they permit mobile medical services to come to their State under reciprocity.

Response. Agreement States have the flexibility of determining whether they will issue mobile medical licenses and whether they will allow NRC or other State licensees to operate in their State under reciprocity. Under reciprocity, an Agreement State may allow a specific licensee from another Agreement State (or the NRC) to work within the Agreement State without requiring the licensee to obtain a license in that State. Similarly, under reciprocity, a specific licensee from an Agreement State may work in NRC jurisdictions, provided the requirements in 10 CFR 150.20, Recognition of Agreement State Licensees, are met. Specifically, NRC allows Agreement State mobile medical service licensees to operate in areas under NRC jurisdiction provided they comply with all the requirements in § 150.20, including submittal of the information required in that section.

Issue 2: Should NRC Allow Byproduct Material To Be Delivered to a Client's Address of Use?

Comment. A commenter recommended that the NRC permit byproduct material to be delivered to the client's address.

Response. Byproduct material may only be transferred to an NRC or Agreement State licensee because the licensee is responsible for the safe handling of the material. In almost all cases, the client is neither an NRC nor an Agreement State licensee. Therefore, the material must only be transferred to the licensed mobile medical service. Byproduct material may be delivered to the mobile medical service licensee at the mobile site (i.e., mobile van) if the byproduct material is secured against unauthorized removal (§§ 20.1801 and 20.1802).

Issue 3: What Checks Should Be Performed on Instruments Used To Measure the Activity of Unsealed Byproduct Material at a Client's Address?

Comment. A commenter recommended that the check for instrument operation at the client's address be limited to a constancy check.

Response. Licensees must check the operation of instruments used to measure the activity of unsealed byproduct material to ensure that the instrument is functioning properly. This section was revised to require that licensees check instruments used to measure the activity of unsealed byproduct material for constancy before medical use at each client's address or on each day of use, whichever is more frequent. In the case of a mobile medical service, we believe that a constancy check must be performed to ensure that the instrument is functioning properly. The need for additional testing on the instruments is determined by how the licensee addresses compliance with § 35.60.

Issue 4: Is it Necessary To Check a Survey Instrument With a Dedicated Check Source?

Comment. A commenter recommended that the requirement to check the survey instrument with a dedicated check source be deleted because this check was no longer included in § 35.61.

Response. The NRC does not believe that the requirement to check survey instruments with a dedicated check source should be deleted from § 35.80. While we have deleted the requirement from § 35.61, we believe it is needed in § 35.80 because there is a greater likelihood that a survey instrument in a mobile unit may become damaged or uncalibrated as a result of extensive movement.

Issue 5: Do Mobile Medical Service Licensees Need To Collect Contaminated Waste Generated by Patients After Administration of the Byproduct Material?

Comment. A commenter asked that NRC clarify whether mobile medical service licensees need to return to the client's address to collect contaminated waste generated by patients after the administration of the byproduct material.

Response. The mobile medical service licensee does not need to return to the client's address to collect contaminated waste generated by the patient after the administration. The waste is no longer considered under the licensee's control because the patient would have been released from licensee control under § 35.75.

Issue 6: What Other Changes Were Made Between the Proposed and Final Rule?

Response. The NRC amended this section to use the term ''mobile medical service'' rather than ''mobile service'' to indicate clearly that the provisions in this section only apply to medical use. In addition, in paragraphs (a)(1) through (a)(4), ''client's address of use'' was replaced by ''client's address,'' which is defined in § 35.2. This was done to recognize that mobile medical service may be provided at an area of use or a temporary job site. (Area of use is defined as a portion of an address of use that has been set aside for the purpose of receiving, preparing, using, or storing byproduct material.)

Paragraph (a)(1) was also amended by replacing the term ''each entity'' with the phrase ''the licensee and the client.'' We believe this more clearly states our intent that the mobile medical service obtain a letter from each client that delineates the authority and responsibility of the licensee and the client.

Paragraph (a)(2) was amended to clarify that the instruments referred to in this paragraph refer to those instruments used to measure the activity of unsealed byproduct material.

In paragraph (b), ''the client's address of use'' was replaced by ''the client.'' This was done to clarify that byproduct material cannot be delivered to the client unless the client has a license allowing possession of the byproduct material.

Section 35.92, Decay-In-Storage

Issue 1: Should This Section Be Moved to Part 20?

Comment. Commenters believed that decay-in-storage should be addressed in Part 20 rather than in Part 35.

Response. Part 20 provides the general requirements for various waste disposal methods, including the decay-in-storage method. Currently, detailed procedures for decay-in-storage are in license conditions. The NRC believes the specific provisions for decay-in-storage that apply to a medical licensee should be codified in Part 35.

Issue 2: Should the Rule Continue To Require That Byproduct Material Be Held for 10 Half-Lives Before Disposal As Nonradioactive Material?

Comment. Commenters were divided in response to the NRC's request for specific comment on whether byproduct material should be held for a minimum of 10 half-lives. Commenters in favor of retaining the requirement believed that it would help ensure that the waste is not prematurely disposed of as nonradioactive material due to human error or instrumentation malfunction. They also believed that licensees may not have adequate survey instruments to survey low-energy beta emitters, such as sulfur-35 (S–35).

Commenters supporting the deletion of the requirement indicated that holding the byproduct material for 10 half-lives was in no way a guarantee that the waste could be disposed of as nonradioactive material. They believed that deletion of the requirement to hold the material for 10 half-lives would improve sanitary conditions and provide for more efficient use of storage space. Finally, they indicated that although S–35 is difficult to detect with a survey instrument, S–35 is not a component in any FDA-approved radiopharmaceutical for routine use.

Response. The NRC has not included a requirement in the final rule to hold byproduct material for 10 half-lives before disposing of the material as nonradioactive material. We do not believe this requirement is needed in light of the requirement in paragraph (a)(1) that precludes disposal of byproduct material without regard to its radioactivity until radiation levels adjacent to the material do not exceed background levels.

Issue 3: Does the Requirement To Obliterate Radiation Labels Only Apply to the Outermost Container, Especially if the Material Will Be Handled as Biohazardous Material?

Comment. A commenter questioned whether the obliteration of radiation labels is only required on the outermost container. Specifically, the commenter asked whether labels needed to be defaced on inner containers if the label on the outer container had been defaced and the inner label was not visible.

Response. NRC revised the text in paragraph (a)(2) to require that all radiation labels be removed or obliterated, except for radiation labels on materials that are within containers and that will be managed as biomedical waste after they have been released from the licensee. All radiation labels must be removed or obliterated from outer containers once the radioactivity can not be distinguished from the background level. Radiation labels on biomedical waste (e.g., sharps containers or individual needles and syringes) do not have to be removed or obliterated due to the associated biohazard of retrieving such material from the outer container. Also, in many cases, the waste barrels containing biomedical waste will be incinerated.

Issue 4: What Type of Byproduct Material May Be Held for Decay-In-Storage?

Comment. A commenter asked whether radioactive ''seeds'' can be held for decay-in storage.

Response. The final rule allows a licensee to hold byproduct material with a physical half-life of less than 120 days for decay-in-storage before disposal without regard to its radioactivity. If a ''seed'' contains byproduct material with a half-life of less than 120 days, this provision applies.

Issue 5: Were There Any Other Changes Made Between the Proposed and Final Rule?

Response. Yes. Paragraph (a) was revised to indicate clearly that the provisions in this section pertain only to disposal of the material without regard to its radioactivity. Licensees must continue to comply with any other regulations that pertain to disposal of the material (e.g., Environmental Protection Agency and State biomedical waste regulations).

Subpart D—Unsealed Byproduct Material—Written Directive Not Required

General Comments

Issue 1: What Are the Correct Titles for Subparts D and E?

Comments. Commenters recommended renaming Subparts D and E to avoid use of the terms ''low dose'' and ''high dose.'' A commenter recommended renaming these sections: Subpart D—Unsealed Byproduct Material—Written Directive Not Required and Subpart E—Unsealed Byproduct Material—Written Directive Required.

Response. The NRC agrees that the titles of Subparts D and E should be renamed to avoid use of the terms ''low dose'' and ''high dose.'' Subparts D and E in the final rule have been renamed to use the requirement for a ''written directive'' as the basis for associating the use of the material to radiation risk. The new titles are Subpart D—Unsealed Byproduct Material—Written Directive Not Required and Subpart E—Unsealed Byproduct Material—Written Directive Required.

Issue 2: Are the Regulations in Part 35 (except the training and experience requirements) Needed?

Comment. Commenters proposed removing the regulations for diagnostic nuclear medicine, except for the training and experience requirements, from Part 35. The commenters believed that properly trained physicians, with the assistance of other associated nuclear medicine health care providers and the standards of radiation protection in Part 20, are all that are necessary to protect the public health and safety adequately.

Response. During the development of the proposed rule, the NRC eliminated requirements in the current Part 35 that are contained elsewhere in the Commission's regulations, such as the radiation protection requirements in Part 20. Part 35 licensees will need to comply with these requirements, such as the ALARA provisions in Part 20, but we believe there is no need to duplicate requirements.

Part 20 contains general radiation protection requirements applicable to all licensees; Part 35 contains requirements specific to medical use licensees. While some commenters believe that Part 35 should not contain any requirements associated with low risk procedures, certain radiation protection-related requirements specific to medical use are needed in Part 35 because of their contribution to risk reduction. For example, the final rule retains requirements to perform quality control tests on instrumentation used to measure the radioactivity of patient dosages before administration. These regulations are necessary to provide high confidence that the instrumentation used to measure dosages is operating properly.

In other cases, more specific requirements were kept in Part 35 where justified by risk. The majority of those requirements deal with the therapeutic uses of sealed radioactive material. We believe that the requirements in the final rule are necessary, in addition to the requirements in Part 20, to ensure that the dosage administered to a patient is as prescribed by the AU and to ensure protection of workers and the public.

Issue 3: Should the Requirements for Diagnostic and Therapeutic Uses of Unsealed Byproduct Materials for Medical Use Be Combined?

Comment. A commenter believed that the proposed rule intermingled requirements for diagnostic and therapeutic nuclear medicine and failed

to provide a regulatory scheme appropriate to each.

Response. Early in the rulemaking process, the NRC considered structuring the rule to have completely ''stand-alone'' subparts for each type of medical use. However, under this approach, there would have been significant duplication of the requirements which would make the entire rule unnecessarily voluminous. For example, if we took this approach, each subpart would have had a section that addressed when a license was needed, criteria for amending a license, or RSO qualifications.

We have structured the rule so that Subparts A, B, C, L, M, and N contain the requirements that apply to all licensees. Subparts D, E, F, G, H, and K contain the requirements that apply to a particular modality, e.g., Subpart D provides specific requirements for the use of unsealed byproduct material which does not require a written directive, and Subpart E contains the requirements for the use of unsealed byproduct material which requires a written directive. The subparts for each type of use also contain the specific training and experience requirements for the AU.

Section 35.100, Use of Unsealed Byproduct Material for Uptake, Dilution, and Excretion Studies for Which a Written Directive Is Not Required

Issue 1: Why Doesn't the NRC Eliminate or Reduce the Regulation of Certain § 35.100 Materials?

Comment. A commenter recommended eliminating or reducing regulation of materials in § 35.100 with extremely low doses (e.g., 35 μCi of I–125 iothalamate, 10 μCi of iodine-125 (I–125) albumin and 1 μCi of cobalt-57 (Co-57) cyanocobalamin) because medical use of these materials involves minimal risk.

Response. The NRC does not believe that the requirements for the medical use of byproduct material described in § 35.100 should be eliminated. If this material is not handled safely, the public or occupationally exposed individuals could receive an exposure in excess of the Part 20 dose limits. However, we have reduced some regulatory requirements that apply to this type of use, e.g., the requirements in §§ 35.24, 35.61, 35.92, and 35.290 of the final rule. Explanations for these changes can be found in the discussions of the respective sections.

Issue 2: Should §§ 35.100 and 35.200 Be Combined Because the Procedures Performed in Both Modalities Do Not Require a Written Directive?

Comment. A commenter suggested that the two types of studies listed under Subpart D in the proposed rule in §§ 35.100 and 35.200 should be combined into one category, ''unsealed byproduct material for which a written directive is not required.''

Response. Early in the development of the proposed rule, the NRC considered combining these two categories into one section. We did not do so because we believe that the training and experience requirements for individuals using byproduct material for imaging and localization should be more rigorous than such requirements for individuals who only use unsealed byproduct material for uptake, dilution, and excretion studies. This is because AUs using unsealed material under § 35.200 are allowed to compound radiopharmaceuticals and, in general, are handling multiple types of radionuclides at higher activity levels than users performing uptake, dilution, and excretion studies.

Issue 3: Is the Reference in § 35.100(b) Referring to § 35.292 Correct?

Comment. A Commenter Suggested the Cross Reference in § 35.100(b) to § 35.292 Should Be § 35.290.

Response. The cross reference in § 35.100(b) of the proposed rule to an individual who meets the criteria to become an AU for use of unsealed byproduct material for imaging and localization is correct. The requirements in the proposed § 35.292 were moved to § 35.290 in the final rule, so § 35.100(b) now references § 35.290. The NRC also added a reference to § 35.390. Sections 35.292 and 35.390 in the final rule give physicians authorization to prepare radioactive drugs using generators and reagent kits. AUs qualified under the final § 35.190 (proposed § 35.290) do not have this type of authorization.

Issue 4: Why Aren't FDA-Approved IND Pharmacokinetic Studies Addressed in the Proposed Rule?

Comment. A commenter stated that the proposed rule did not recognize pharmaceutical companies that do not have a 10 CFR Part 35 license but label compounds with byproduct material and transfer them to specific licensees for use in FDA-approved IND pharmacokinetic studies. This commenter proposed addition of a new § 35.100(c) to address this issue.

Response: The final rule addresses this comment and other omissions in the proposed rule. The proposed rule did not recognize pharmaceutical companies who do not have a Part 32 license but who label compounds with byproduct materials and transfer them to a specific licensee for use in FDA-approved IND studies. The proposed rule also did not recognize the use of unsealed byproduct material obtained from an NRC or Agreement State licensee in accordance with an RDRC protocol. Finally, § 35.100 in the proposed rule did not allow specific medical use licensees, who do not have individuals qualified under §§ 35.292, 35.55, 35.920, or 35.980, to prepare unsealed byproduct material in accordance with an RDRC or IND protocol accepted by FDA for use in research. These omissions in the proposed rule unduly restricted labeling and transfer of unsealed byproduct material to Part 35 licensees. New paragraphs (c) and (d) have been added to §§ 35.100 and 35.200 of the final rule to address all of these situations.

Section 35.190, Training for Uptake, Dilution, and Excretion.

Issue 1: Is It Necessary for Physicians Using Byproduct Materials Under § 35.100 To Be Board Certified in Nuclear Medicine?

Comment. A commenter believed that there should be an alternative training and experience pathway for individuals who are not full board certified nuclear medicine physicians, but would like to become an AU for materials authorized under § 35.100.

Response. The final rule contains three pathways for individuals to become AUs for material under § 35.100. The first pathway, § 35.190(a), requires a physician to be certified by a board recognized by NRC. The second pathway, § 35.190(b), allows AUs, qualified under §§ 35.290, 35.390, or equivalent Agreement State requirements, to use byproduct material under § 35.100. The third pathway, § 35.190(c), requires that the physician complete 60 hours of training and experience in basic radionuclide handling techniques applicable to the medical use of unsealed byproduct material for uptake, dilution, and excretion studies. The 60 hours includes classroom and laboratory training and work experience.

Issue 2: Were There Any Other Changes Made Between the Proposed and Final Rule?

Response: Yes. The training and experience requirements that were in the proposed § 35.290 were moved to § 35.190 in the final rule. This is

discussed in greater detail under the general discussion on training and experience located at the beginning of this section of the **SUPPLEMENTARY INFORMATION.**

Section 35.200, Use of Unsealed Byproduct Material for Imaging and Localization Studies for Which a Written Directive Is Not Required

Issue 1: Were There Any Changes Made in This Section Between The Proposed and Final Rule?

Response. Yes. Paragraphs (c) and (d) were added to this section in the final rule. These changes are identical to the changes made to § 35.100. The reasons for these additions are in the discussion of § 35.100, Issue 4.

Section 35.204, Permissible molybdenum-99 Concentration

Issue 1: Why Is It Necessary for NRC Regulations To Address molybdenum-99 (Mo-99) Concentrations?

Comments. Commenters argued for eliminating this section because U.S. Pharmacopeia (USP) and FDA standards already address this area. Another commenter believed that the proposed requirements were excessive and unnecessary. Some commenters supported the change in the requirement from evaluating the Mo-99 concentration for every elution, to evaluating it for only the first elution.

Response. The NRC believes that this requirement is necessary as a means to check generator eluate before medical use to ensure that the generator was not damaged in shipment. This requirement does not preclude more frequent evaluations of the Mo-99 concentrations. We revised paragraph (a) to express the permissible concentration level in SI units: ''0.15 kilobecquerel of molybdenum-99 per megabecquerel of technetium-99m (0.15 microcurie of molybdenum-99 per millicurie of technetium-99m).'' This level is identical to that used in the U.S. Pharmacopeia (USP) 23 U.S. Pharmacopeial Convention, Inc., 1995, pages 1486–1487.

Issue 2: Were There Any Changes Made in This Section Between the Proposed and final Rule?

Response. Yes. The NRC amended paragraph (c) to be more precise. We replaced the phrase ''measure molybdenum concentration'' with the phrase ''measure the molybdenum-99 concentration.''

Section 35.205, Control of Aerosols and Gases (current rule)

Issue 1: Should the Current Requirements Related to Aerosols and Gases Be Deleted?

Comment. The NRC received comments supporting and opposing the deletion of this section in the current rule. A commenter supported the deletion of the requirement because the current requirement is too prescriptive. Another commenter believed that the requirement to control radioactive aerosols and gases should be retained. This commenter stated that the requirement of having a negative pressure environment ensures that there is control over ''escaping radioactive gas.''

Response. The NRC does not believe this requirement is needed in Part 35. Part 35 licensees must comply with the occupational and public dose limits of Part 20. Additional prescriptive requirements for limiting airborne concentrations of radioactive material are not warranted in Part 35.

Section 35.290, Training for Imaging and Localization Studies

Issue 1: Should All Individuals Be Required To Have Experience With Eluting Generators?

Comment. A commenter recommended that the NRC revise the training and experience requirements in the proposed § 35.292 to state: ''To be authorized for possession and use of technetium from a generator system, the applicant must obtain supervised practical experience eluting technetium-99m from generator systems.'' The commenter is drawing a distinction between AUs that plan to limit their use to unit dosages, rather than preparing the dosages themselves. The commenter believed the requirement, as proposed, would be consistent with actual practice and good radiation safety practices. In addition, the commenter recommended that the preceptor not be required to certify that an individual has achieved a level of competency with regards to use of generators. Another commenter believed that we should delete requirements for individuals to receive training in eluting generators, measuring and testing the eluate for radiochemical purity and processing the eluate with reagent kits because unit dosages are obtained from a Part 32 licensee.

Response. The NRC has not modified the regulatory text to establish separate training and experience requirements for AUs only using unit dosages. We have also not deleted the requirement for ''eluting generator systems appropriate for preparation of radioactive drugs for imaging and localization studies, measuring and testing the eluate for radionuclidic purity, and processing the eluate with reagent kits to prepare labeled radioactive drugs.'' Physicians who meet all the qualifications in the final § 35.290 are authorized to use generator systems and reagent kits in the preparation of radioactive drugs and must be trained accordingly, even though they may elect to use only unit dosages. If a physician does not have experience in eluting generators he or she will be authorized for unit dosages only. For the same reason, we believe that the preceptor should certify that the individual has achieved a level of competency with regards to use of generators. We would unduly limit where a licensee may obtain unsealed byproduct material if we made any further revisions to the regulatory text.

Issue 2: Were There Any Other Changes Made in This Section Between the Proposed and Final Rule?

Response: Yes. The requirements in the proposed § 35.290 were moved to the final § 35.190. The requirements in the proposed § 35.292 were moved to the final § 35.290. This is discussed in greater detail under the general discussion on training and experience located at the beginning of this section of the **SUPPLEMENTARY INFORMATION.**

Subpart E—Unsealed Byproduct Material—Written Directive Required

Section 35.300, Use of Unsealed Byproduct Material for Which a Written Directive Is Required

Issue 1: Were There Any Changes Made in This Section Between the Proposed and Final Rule?

Response. Yes. Paragraph (b) was amended by changing the reference to § 35.292 in the proposed rule to § 35.290 in the final rule and adding a reference to § 35.390. The proposed rule would have allowed licensees to use any unsealed byproduct material prepared for medical use by an ANP, a physician who is an AU and who meets the requirements specified in the proposed § 35.292 (§ 35.290 of the final rule), or an individual under the supervision of either as specified in § 35.27. The NRC added the reference to § 35.390 in paragraph (b) of the final rule because a physician who meets the training requirements in § 35.390 also meets the training requirements in § 35.290.

Paragraphs (c) and (d) were added to this section. This was done because the proposed rule did not recognize pharmaceutical companies who do not

have a 10 CFR Part 32 license, but label compounds with byproduct materials and transfer them to a specific licensee for use in FDA-approved IND studies. Also, the proposed rule did not allow specific medical use licensees to prepare unsealed byproduct material in accordance with an IND protocol accepted by FDA for use in research. These omissions in the proposed rule unduly restricted labeling and transfer of unsealed byproduct material to Part 35 licensees. The final rule addresses these situations.

Sections 35.100 and 35.200 have been revised to address both the RDRC and IND approved material. Note: § 35.300, in contrast to §§ 35.100 and 35.200, does not include reference to RDRC authorizations because FDA's RDRC regulations restrict RDRC approvals to pharmacokinetic and physiological studies. Further, the dose limits for a study that can be approved by an RDRC under 21 CFR 361.1 are as follows:

(1) For a single administration of radioactive drug—whole body, gonads, blood forming organs, and lens—3 rem; all other organs—5 rem; and

(2) For multiple administrations (or annual dose commitment)—whole body, gonads, blood forming organs, and lens—5 rem; all other organs—15 rem.

Section 35.310, Safety Instruction

Issue 1: Who Must Participate in Annual Retraining on Radiation Safety?

Comments. Many commenters questioned the need for the radiation safety instruction required in § 35.310. Some commenters found this requirement to be very burdensome. A commenter suggested that posting radiation safety precautions on a patient's door or in the patient's chart could replace the training requirement. Another commenter believed that annual retraining was not needed for certified radiation therapy technologists and, therefore, recommended that the section specify annual retraining only for ''persons without specialized training in handling radioactive materials.'' Other commenters thought the requirement was too prescriptive, and that licensees should be given the freedom to decide how to assure compliance with the dose limits in § 35.75 on a case-by-case basis. According to another commenter, annual retraining should be required only for health care personnel who were not directly supervised by trained radiation safety staff. Some commenters argued against placing the radiation safety instruction requirement in Part 35, while other commenters suggested that we make the requirement only applicable to allied health workers who are not nurses. The commenter believed that the need for training should be dependent on whether the licensees needed to provide the individual with dosimetry. These commenters suggested that we revise § 35.310(a) to state: ''A licensee shall provide radiation safety instruction, initially and at least annually, to personnel, whose exposure rates may approach the limits in Part 20, caring for patient or human research subjects that have received therapy * * *''

Response. The NRC believes that it is important that personnel caring for patients or human research subjects, who cannot be released in accordance with § 35.75, receive instruction in limiting radiation exposure to the public and workers and in the radiation safety actions to be taken in the case of a medical emergency or death. We believe this provision is needed because exposure in excess of the public dose limits could result unless proper precautions are taken. We also believe this requirement is consistent with ALARA principles. We do not believe that only posting doors or a chart provides adequate information to the licensee's staff, without corresponding instruction.

The rule does not require the licensee to instruct all hospital staff. Instruction must only be provided to personnel caring for patients or human research subjects who cannot be released in accordance with § 35.75. We considered the comments regarding who should receive the training and whether the requirement should be linked to a dose limit. We decided that it is more appropriate to specify that instruction must be provided to personnel caring for patients or human research subjects, rather than tie the instruction to the dose limits in Part 20. This was done because it is possible for a licensee's staff member to receive a dose that is less than the occupational dose limits in Part 20, but take an action that could result in a dose to a member of the public that exceeds the public dose limit.

We have given the licensee flexibility on the level and detail of instruction that must be provided. The instruction need only be commensurate with the duties of the personnel. In other words, the licensee can determine the appropriate level of radiation safety instruction to be provided, depending on the level of care provided by the personnel. For example, a primary care nurse may receive detailed instructions on patient and visitor control, but the ward clerk may only need to be instructed to observe the caution signs on the patient's door.

We recognize that certified radiation therapy technologists or other individuals who have received specialized training in handling radioactive materials would have received training in the areas required by this section as part of a training program. However, we believe that refresher training is warranted because of the potential for unnecessary exposure to workers and the public if needed safety precautions are not observed.

Issue 2: Can the AU Have a Designee?

Comment: A commenter recommended that paragraph (a)(5) be revised to require that personnel be instructed to notify the RSO (or his or her designee) and the AU (or his or her designee) if the patient or the human research subject has a medical emergency or dies.

Response: The final rule provides the RSO flexibility in designating who should be notified to address radiation protection issues. However, the rule does not provide for the AU to have a designee. The AU is the individual who is responsible for the medical use and supervision of other persons using the byproduct material. Therefore, because of the type of dosages that are administered under § 35.300, we believe it is important that an AU be available to be contacted in case of a medical emergency or death.

Issue 3: Should the Current Requirements in § 35.315(a)(4) Related to Surveys Be Deleted?

Comment. A commenter indicated that removal of the current requirements in § 35.315(a)(4) to perform a radiation survey following a therapeutic administration of I–131 would be ill-advised. This commenter also believed that the requirement to perform a careful contamination room survey should not be removed.

Response. The NRC does not believe these survey requirements should be in Part 35. We believe Part 20 contains adequate information regarding radiation surveys. As required in § 20.1501, the licensee must make or cause to be made surveys that are needed to comply with the regulations in Part 20. Part 35 licensees are responsible for ensuring that the occupational and public dose limits in Part 20 are not exceeded.

Issue 4: Were There Any Other Changes Made to This Section Between the Proposed and Final Rule?

Response. Yes. In paragraph (a), the term ''radiopharmaceutical therapy'' was replaced with the phrase ''therapy with unsealed byproduct material.'' This change clarifies that this section addresses both drugs and biologics containing byproduct material. The term radiopharmaceutical does not cover both radioactive drugs and radiobiologics containing byproduct material.

Paragraph (b) of the proposed rule (paragraph (a)(5) of the final rule) was restructured to clarify our intent that, for the purpose of this section, only the RSO may have a designee.

Section 35.315, Safety Precautions

Issue 1: Does the Rule Allow the Licensee to Quarter Patients or Human Research Subjects Receiving Therapy With Unsealed Byproduct Material Together?

Comment. Commenters did not believe that the requirement to quarter a patient or human research subject, who cannot be released in accordance with § 35.75, in a private room with a private bathroom is justifiable. They believed that the requirement should be deleted, citing calculations suggesting that two patients undergoing identical radiation treatments (unsealed byproduct material) and occupying the same room would each have their total radiation dose increased by less than 1 percent due to the presence of the other patient. Others believed that allowing two patients undergoing treatment in the same room would be helpful as a means of controlling contamination and would, therefore, support ALARA principles.

Commenters also argued that allowing a nontherapy patient to share a room with a patient undergoing radiation therapy (unsealed byproduct material) was unacceptable. They said this would result in unnecessary exposure to a member of the public and would not be ALARA.

Other commenters opposed allowing the sharing of a posted restricted room with a patient who was not undergoing radiation therapy. These commenters were concerned about the radiation exposure to hospital housecleaning staff. Other commenters supported the requirement for a private room because they were concerned that medical institution management and health care insurance companies would not allow patients or human research subjects to be quartered in private rooms or in a double room (with single occupancy) because it was too expensive.

Response. The NRC revised this provision to allow the licensee to quarter a patient or human research subject in either (1) a private room with a private sanitary facility; or (2) a room, with a private sanitary facility, with another individual who also has received therapy with unsealed byproduct material and who also cannot be released under § 35.75. This requirement does not preclude the licensee from quartering the patient in a private room. This change recognizes that the exposure patients could receive from each other is insignificant in light of the exposure the patient is receiving from their administered dosages. Conversely, we do not believe that it is appropriate to allow a therapy and nontherapy patient to share a room because the nontherapy patient would not receive a radiation exposure under normal conditions.

We believe that contamination control is essential and that two patients could share the same room without negatively affecting the licensee's ability to control contamination. However, licensees should be mindful of the radiation hazards associated with different radionuclides, especially when quartering in the same room individuals who have received different radionuclides. We do not agree that sharing rooms will increase the exposure to housecleaning staff. Assuming that two patients require treatment, the exposure to the housekeeping staff should not be significantly different whether the patients are quartered in the same room or different rooms. In either situation, licensees have the responsibility to maintain the exposures below the Part 20 limits.

Issue 2: Should a Patient or Human Research Subject Be Allowed To Take Contaminated Articles Home?

Comment. A commenter asked that this section be revised to permit the licensee to package items contaminated with short-lived material so that the items could be released at the same time as the patient or human research subject. The commenter went on to state that the section should also include a requirement for the licensee to instruct the individual not to unpack the package and use anything in the package until a predetermined date. Finally, the commenter recommended that the date be calculated to ensure the activity remaining in the package is small.

Response. The NRC has not changed the rule because of the potential for unnecessary radiation exposure to the public if the material were not handled properly once it is released from licensee control. Any items contaminated as a result of medical use are the responsibility of the licensee.

Issue 3: Should Additional Requirements Be Added To § 35.315 To Address Hospitalization of Patients Who Can Be Released Under § 35.75, But Are Still Hospitalized Because of Medical Reasons?

Comment. A commenter questioned how a patient, who had been released under § 35.75, but was still hospitalized for another medical condition, should be managed. The commenter was concerned that the nursing staff could be confused by the instructions provided to the patient under § 35.75, because § 35.315 does not address the management of this type of patient. The commenter suggested that § 35.315 be revised to require licensees to implement radiation safety precautions, to include posting warning signs, whenever patients receiving therapy quantities of radiopharmaceuticals are hospitalized.

Response. It is the licensee's responsibility, under § 35.75, to control any individual who has been administered unsealed byproduct material or implants containing byproduct material if the total effective dose equivalent to any other individual from exposure to the released individual is likely to exceed 5 mSv (0.5 rem).

We do not believe that § 35.315 should be revised to specifically address patients who are released in accordance with § 35.75 but remain hospitalized for other reasons because compliance with § 35.75 ensures that the maximally exposed individual does not receive a dose in excess of 5 mSv (0.5 rem).

Issue 4: Are the Limits in § 35.315 for the Release of Material and Items Removed From the Patient's or Human Research Subject's Room Appropriate?

Comment. A commenter was strongly in favor of the revised survey requirements because the previous rules were too prescriptive and not warranted for reasons of health and safety. Another commenter believed that the release limits in § 35.315(a)(3) of the proposed rule are unnecessarily low and are not logical when compared to the annual limit of intake for I–131 and I–125.

Response. Under § 35.315 (a)(4) in the final rule, material and items from the patient's or the human research subject's room cannot be removed until the radiation levels adjacent to the items are not distinguishable from natural background, unless the material and

items are managed as radioactive waste. Because this requirement is consistent with the release requirements in § 35.92 for radioactive waste, the NRC does not believe additional modification is needed.

Issue 5: Should the Bioassay Requirements in the Current § 35.325(a)(8) Be Included in the Final Rule?

Comment. A commenter asked that the current § 35.315(a)(8) be revised and incorporated in the final rule. The commenter recommended that the following provision be added: A licensee shall measure the thyroid burden of each individual who helped prepare or administer a dosage of I–131 within 3 days after administering the dosage if there is a likelihood that the individual would receive more than 10 percent of the Annual Limit of Intake in Appendix B of Part 20.

Response. The NRC has not included bioassay requirements in the final rule. Licensees are required to comply with Part 20. As such, they must limit occupational exposure to the limits in Part 20. In addition, they must develop, document, and implement a radiation protection program commensurate with the scope and extent of licensed activities (§ 20.1101). This would include assessing whether individuals preparing or administering I–131 need bioassays.

Issue 6: Were There Any Other Changes Made to This Section Between the Proposed and Final Rule?

Response. Yes. The NRC restructured paragraph (b) to clarify our intent in the proposed rule that, for the purpose of this section, only the RSO may have a designee. This same change has been made in § 35.310. The reasons for this change are under the discussion of § 35.310, Issue 2.

Section 35.390, Training for Use of Unsealed Byproduct Material for Which a Written Directive Is Required

Issue 1: Should the Training and Experience Requirements in § 35.390 Include Instruction in Giving Radiation Safety Directions in the Event the Patient or Human Research Subject Dies?

Comment. A commenter recommended that the NRC add a requirement to § 35.390(b)(1) to require that an individual receive instruction on issuing radiation safety directions in the event the patient or human research subject dies.

Response. The NRC does not believe this change is necessary because this issue should be addressed as part of the licensee's overall radiation safety program. Licensees should have flexibility in how they address radiation safety issues associated with the death of a patient or human research subject.

Section 35.392, Training for the Oral Administration of Sodium Iodide I–131 Requiring a Written Directive in Quantities Less Than or Equal to 1.22 Gigabecquerels (33 millicuries)

Issue 1: Were There Any Changes Made in This Subpart Between the Proposed and Final Rule?

Response: Yes. The NRC added specific training and experience requirements for the oral administration of sodium iodide I–131 requiring a written directive in quantities less than or equal to 1.22 GBq (33 mCi). This addition is discussed in greater detail under the general discussion on training and experience located at the beginning of this section of the **SUPPLEMENTARY INFORMATION.**

Section 35.394, Training for the Oral Administration of Sodium Iodide I–131 Requiring a Written Directive in Quantities Greater Than 1.22 Gigabecquerels (33 millicuries)

Issue 1: Were There Any Changes Made in This Subpart Between the Proposed and Final Rule?

Response: Yes. The NRC added specific training and experience requirements for the oral administration of sodium iodide I–131 requiring a written directive in quantities greater than 1.22 GBq (33 mCi). This addition is discussed in greater detail under the general discussion on training and experience located at the beginning of this section of the **SUPPLEMENTARY INFORMATION.**

Subpart F—Manual Brachytherapy

Section 35.400, Use of Sources for Manual Brachytherapy

Issue 1: Should All Therapy Sealed Sources Be Required To Have National Institute of Standards and Technology (NIST) Traceability?

Comment. Some commenters felt that all sources used for therapeutic applications should be required by regulation to have a NIST traceable national standard. Conversely, some commenters felt that it is inconsistent to require licensees to calibrate in the absence of national standards for all clinically used sources.

Response. This comment pertains to all sources used for manual brachytherapy under Section 35.400. Section 35.432 requires that source output be measured with a dosimetry system that has been calibrated using a system or source traceable to NIST. The NRC agrees with the AAPM position that all therapy sealed sources should be calibrated using a system or sources traceable to NIST and published protocols accepted by nationally recognized bodies or by a calibration laboratory accredited by AAPM. In limited cases, a traceable standard identical to the therapy sealed source is not available. In these cases, the requirement allows the licensee the flexibility to use protocols accepted by nationally recognized bodies to meet the calibration requirement. As an example, AAPM Report No. 21—Specification of Brachytherapy Source Strength, 1987, recommends that sources used in radiation therapy have calibrations with direct or secondary traceability to national standards. AAPM defines direct traceability as ''when a source or calibrator has been calibrated either at NIST or an AAPM-Accredited Dosimetry Calibration Laboratory.'' AAPM defines secondary traceability as ''when the source is calibrated in comparison with a source of the same design and comparable strength which has direct traceability or when the source is calibrated using an instrument with direct traceability.'' In addition, AAPM TG–56 recommends that, for ''sources that do not have a national standard yet, users should develop a constancy check calibrated against the vendor's standard and use this constancy check to verify the source strength. Another option is to develop one's own secondary standard.'' This allows the licensee flexibility in the event that a direct NIST traceable standard does not exist.

Issue 2. Were There Any Changes Made in This Section Between the Proposed and Final Rule?

Response. Yes. The NRC added a new paragraph (b) to this section that allows a licensee to use therapy sources in medical research as long as the research is conducted in accordance with an active IDE application accepted by the FDA if the requirements in § 35.49(a) are met. This was done to clarify how research with sealed sources could be conducted if the medical use of the sources differed from the statements found in the SSDR for the sources. With this change, we allow the use of previously registered sources for uses other than those described in the original registration process, as long as the requirements in paragraph (b) are met.

Section 35.404, Surveys After Source Implant and Removal

Issue 1: Is the Requirement for Radiation Surveys After Brachytherapy Source Implant Necessary?

Comment. Commenters felt that a survey of the patient after brachytherapy sources have been implanted for the purpose of looking for misplaced sources would be difficult. The commenters stated that with the sources in the patient, the background around the patient is too high to detect an errant source. Additionally, some commenters believed that radiation surveys should be deleted from Part 35 because this is a Part 20 issue.

Response. The NRC agrees that Part 20 requires surveys and control of licensed material. However, in order to clarify that surveys must be conducted to locate and account for all sources that have not been implanted, the requirements for surveys have been retained in § 35.404(a). Section 20.1501 requires, in part, that each licensee shall make, or cause to be made, surveys that may be necessary for the licensee to comply with the regulations in this part and are reasonable to evaluate: the magnitude and extent of radiation levels; the concentration or quantities of radioactive material; and the potential radiological hazards that could be present. In addition, Subpart I of Part 20 requires that the licensee secure from unauthorized removal or control and maintain constant surveillance of licensed material. Because surveys under § 35.404(a) are not necessarily radiation surveys, the term ''radiation'' has been removed from the title and the text of paragraph (a) of this section. Depending on the area being surveyed and the ability to distinguish from the radiation background around the patient implanted with brachytherapy sources, these surveys may include radiation surveys of a facility room (e.g., operating room suite) after the patient with implanted sources has been removed from the room, radiation surveys in and around the patient's room after the implant, and visual surveys of the patient's bed after the implant.

Issue 2: Does Adjacent Area Include Contiguous Restricted and Unrestricted Areas?

Comment. A commenter requested that we explicitly indicate that ''adjacent area'' does not categorically include ''contiguous restricted and unrestricted areas.'' The commenter stated that the latter wording appears in the current § 35.415(a)(4). The commenter indicated there was little rationale for the current requirement and that it has been deservedly removed in the proposed rule.

Response. The NRC deleted the requirement in the current rule (§ 35.415(a)(4)) that required radiation surveys in contiguous restricted and unrestricted areas to demonstrate compliance with the requirements of Part 20. We agree that this requirement is covered by Part 20. Deleting this requirement and relying on Part 20 to ensure that adequate surveys are performed provides the licensee flexibility in performing adequate surveys. For instance, an adequate survey following a brachytherapy implant may include a radiation survey of restricted and unrestricted areas with a maximally loaded patient in a representative patient room. If the circumstances of subsequent brachytherapy patient treatments are equivalent to the initial survey conditions, we believe that the licensee may rely upon the initial survey to show compliance with Part 20.

Section 35.406, Brachytherapy Source Accountability

Issue 1: Were There Any Changes Made in This Section Between the Proposed and Final Rule?

Response. Yes. The NRC changed the title of the section from ''Brachytherapy source inventory,'' to ''Brachytherapy source accountability.'' This title more accurately reflects the regulations in this section. The inventory requirements for sealed sources or brachytherapy sources are in § 35.67 of the final rule.

Section 35.410, Safety Instruction

Issue 1: Who Must Participate in Annual Retraining?

Comment. Many commenters questioned the need for the training required in § 35.410. Some commenters found this requirement to be very burdensome. Another commenter believed that annual retraining was not needed for certified radiation therapy technologists and, therefore, recommended that the section only require annual retraining for ''persons without specialized training in handling radioactive materials.'' Additionally, one commenter stated that initial and annual training of all nurses and all hospital staff was not cost effective.

Response. The NRC believes that it is important that personnel caring for patients or human research subjects, who have received a brachytherapy implant and cannot be released in accordance with § 35.75, receive instruction. This instruction should include information on how to minimize radiation exposures to the public and workers and the radiation safety actions to be taken in the case of a medical emergency or a death. We believe this provision is needed because exposures in excess of public dose limits could result if proper precautions are not taken. We also believe this requirement is consistent with ALARA principles.

We do not require training of all hospital staff. We allow the licensee flexibility in determining the appropriate level of radiation safety instruction to be provided, depending on the level of involvement by various personnel caring for the patient or human research subject. The instruction need only be commensurate with the duties of the personnel. For example, a primary care nurse may receive detailed instructions on patient and visitor control but the ward clerk may only need to be instructed to observe the caution signs on the patient's door.

We recognize that certified radiation therapy technologists, or other individuals who have received specialized training in handling radioactive materials, may have received training in the areas required by this section as part of their training program. However, we believe that refresher training is warranted because of the potential for unnecessary exposure to workers and the public if needed safety precautions are not observed.

Issue 2: When Notifying an AU Following a Patient Emergency, Can a Physician Designee Be Notified if the AU Is Not Available?

Comment. A commenter recommended that for notifications of patient or human research subject medical emergencies, the AU, like the RSO, may not always be readily available and should also have the option to specify a designee, such as another physician.

Response. Sections 35.11 and 35.27 permit an individual to use byproduct material under the supervision of an AU. Nevertheless, an AU, and not a designee, is responsible for the medical use and supervision of the byproduct material. In the event of a medical emergency involving a patient or human research subject implanted with brachytherapy source(s), the NRC believes that, because of the doses administered under § 35.400, an AU must be notified, and this notification cannot be delegated to a designee.

Issue 3. Were There Any Other Changes Made in This Section Between the Proposed and Final Rule?

Response. Yes. The NRC restructured paragraph (a)(5) to clarify our intent that, for the purpose of this section, only the RSO may have a designee.

Section 35.415, Safety Precautions

Issue 1: Is It Necessary To List the Type and Location of Emergency Response Equipment in the Regulations?

Comment. Commenters believed that the requirement to list the contents of an emergency pack was too prescriptive and confusing. Additionally, commenters felt that the emergency equipment did not need to be specifically located in the patient's room but could be somewhere accessible in the hospital. Commenters felt that the licensee should have the freedom to adequately stock and locate an emergency pack. One commenter also felt that the phrase ''supplies necessary to surgically remove applicators'' kept in the patient's room implied that surgery should be conducted in a nonsterile environment.

Response. The NRC agrees with these comments because, in a performance-based rule, the essential objectives should be stated in the regulatory text. Therefore, we revised the regulatory text to identify the essential objective of having emergency response equipment available near each treatment room. The list of specific items that are needed for emergency responses has been deleted from this section. The licensee has the flexibility to determine the type of emergency response equipment needed to respond to a source that is either dislodged from the patient or lodged within the patient following removal of the source applicators.

We agree that the emergency equipment does not need to be maintained in the treatment room. However, it should be maintained near each treatment room in order to expeditiously respond to an emergency. The rule allows the licensee some flexibility in locating the emergency response equipment. The issue of whether to conduct surgical removals of applicators or sources within a treatment room that may not be a sterile environment is left to the licensee's discretion.

Issue 2: Can Brachytherapy Patients Be Quartered in the Same Room With a Patient Not Receiving Radiation Therapy?

Comment. The NRC solicited specific comment on the current requirement that the licensee not quarter a brachytherapy patient in the same room as an individual who is not receiving radiation therapy. The majority of commenters agreed with the requirement that would allow more than one brachytherapy patient in a room although a few commenters questioned this requirement. Some commenters believed that the final rule should retain the requirement that the licensee not quarter a patient in the same room as an individual who is not receiving radiation therapy. One commenter pointed out that a posted restricted room should not be shared with a patient not involved in the therapy. Another commenter believed that the requirement to prohibit placing a therapy patient in the same room as a nontherapy patient should apply not only to patients confined under § 35.75, but also to any patient where another individual in the room could receive over 1 mSv (0.1 rem). This commenter believed that limiting the requirement to only patients confined under § 35.75 was not ''as low as is reasonably achievable.'' Conversely, other commenters suggested that the provision for a private room be deleted.

Response. In the current Part 35, the NRC permits the sharing of a brachytherapy patient room with another ''individual undergoing radiation therapy.'' In the final rule, we clarified that the other ''individual undergoing radiation therapy'' refers to another brachytherapy patient. This is consistent with changes made to § 35.315 to allow therapy patients treated with unsealed material to share a room if they cannot be released under § 35.75.

We did not change the final rule in response to comments on the allowable exposure to the patient sharing the room or to individual members of the public. Section 20.1301 requires the licensee to conduct operations so that, in part, the total effective dose equivalent to individual members of the public from the licensed operation does not exceed 1 mSv (0.1 rem) in a year, exclusive of the dose contributions, in part, from exposure to individuals administered radioactive material and released under § 35.75. Section 35.75 allows release of patients administered byproduct material if the total effective dose equivalent to any other individual from exposure to the released individual is not likely to exceed 5 mSv (0.5 rem). Therefore, if the licensee confines a patient receiving brachytherapy and has not authorized the release of the patient under § 35.75, the licensee must limit the total effective dose equivalent to individual members of the public to less than 1m Sv (0.1 rem) in a year. Concurrent with this Part 35 rulemaking is a new provision in 10 CFR 20.1301(c) that allows a licensee to permit visitors to individuals who cannot be released under § 35.75 to receive a radiation dose not to exceed 5 mSv (0.5 rem), provided the authorized user has determined that it is appropriate. Alternatively, if the licensee authorizes the release of the patient receiving brachytherapy under § 35.75, the licensee must make the determination that the total effective dose equivalent to any other individual is not likely to exceed 5 mSv (0.5 rem). The licensee must also provide the released individual, or the individual's parent or guardian, with instructions on actions recommended to maintain doses to other individuals as low as is reasonably achievable, if the total effective dose equivalent to any other individual is likely to exceed 1 mSv (0.1 rem). In all cases, the licensee is required, under § 20.1101, to conduct operations to achieve doses that are as low as is reasonably achievable.

Issue 3: Where Should ''Radioactive Materials'' Signs Be Posted?

Comment. A commenter suggested that having the option to put ''Radioactive Materials'' signs in the chart instead of on the door was not a good idea. This commenter felt that signs should be posted on the door and in the chart.

Response. Section 35.415(a) in the current rule specifically states that the patient's door has to be posted. The NRC revised this section to require that the licensee visibly post the patient's or human research subject's room with a ''Radioactive Materials'' sign. We also revised this section to allow the licensee flexibility in determining where to place the posting so that it is visible. Notations as to where and how long visitors may stay may be placed in the patient's chart or posted on the door.

Issue 4: Why Is There a Difference in the Time Periods To Notify the AU and the RSO, or his or her Designee, if the Patient or Human Research Subject Dies or has a Medical Emergency?

Comment. A commenter suggested that the time periods for notification of a medical emergency and death should be the same.

Response. The NRC agrees with the comment. In the final rule, the notification time periods are the same whether the patient or human research subject has a medical emergency or dies. We also modified this section to require that, in the event of a medical emergency, the notification should be as soon as possible, rather than immediately, because the licensee's

primary responsibility during a patient's medical emergency is the care of the patient.

Issue 5: Following a Patient Emergency, When Should an AU Versus an RSO Be Notified and Can A Physician Designee Be Notified if the AU is not Available?

Comment. A commenter felt that the AU should be notified and the notification of the RSO should be left to the AU's discretion. Another commenter recommended that for notifications of medical emergencies, the AU, like the RSO, may not always be readily available and should also have the option to specify a designee, such as another physician.

Response. Sections 35.11 and 35.27 permit an individual to use byproduct material under the supervision of an AU. Nevertheless, an AU, and not a designee, is responsible for the medical use and supervision of the byproduct material. Therefore, under § 35.415(c) an AU and not a designee, must be notified in the event that a patient or human research subject has a medical emergency or dies. Under § 35.24, the RSO is responsible for implementing the radiation protection program. Therefore, we believe that notification of the RSO, or his or her designee, provides additional assurance that appropriate corrective actions to respond to any radiation safety hazard associated with the emergency or death are taken.

Issue 6. Were There Any Other Changes Made in This Section Between the Proposed and Final Rule?

Response. Yes. Paragraph (a) was reworded to make it clear that the requirements in § 35.75 apply to the release of individuals, not to the confinement of individuals. In addition, paragraph (c) was restructured to clarify our intent that, for the purpose of this section, only the RSO may have a designee.

Section 35.432, Calibration of Brachytherapy Sources

Issue 1: What Does the Term ''Nationally Recognized Body'' Mean and What Is the Policy for Taking Recommendations From These Bodies and Making Them Regulations?

Comment. Commenters questioned what was intended by the term ''nationally recognized body'' and stated that professional protocols may contain items that are recommended, but that were never intended to be adopted as regulations.

Response. Examples of nationally recognized bodies include ANSI, AAPM, ACR, ACMP, and NIST. Documents issued by nationally recognized bodies include multiple peer-reviews of the reports, protocols, or standards. The requirements in this subpart are based on recommendations found in AAPM TG–40 and TG–56 and are consistent with the calibration requirements for sealed sources and devices for therapy, including those found in ANSI documents. However, the NRC did not include all the recommendations made in these reports because we recognize the prescriptiveness of various reports. Instead, the regulation contains only the essential objectives for the test being required. For additional information on the use of consensus standards in developing the revision of Part 35 refer to Section I, Background.

Issue 2: What Is the Meaning of the Term ''Intervals Consistent With 1 Percent Physical Decay?''

Comment. One commenter requested that we clarify whether the requirement meant 1.0000 percent or allowed rounding down to 1 percent. Some commenters felt that 1 percent was too prescriptive because the calibration requirements are higher. Additionally, a commenter stated that correcting the output/activity at "'intervals consistent with 1 percent physical decay'' was not feasible for short half-life sources.

Response. This section requires that outputs or activities be corrected for physical decay at intervals consistent with 1 percent physical decay. ''Rounding'' is a mathematical term. ''Consistent with 1 percent'' includes from 0.51 percent to 1.49 percent. The 1 percent correction is separate from the calibration. The accuracy of the calibration must be within a given percentage provided by the published protocol used to perform the calibration. This calibration is then used to determine the dose delivered to the patient.

Issue 3: Should the Rule Contain a Requirement To Perform Calibration Measurements of Brachytherapy Sources and, if so, Can the Licensee Rely on the Manufacturer's or Distributor's Calibration?

Comment. In the proposed rule, the NRC solicited specific comment on requirements for brachytherapy source calibrations. Some commenters felt that the vendor's calibration should be verified by the licensee because use of unverified vendor calibrations poses serious hazards for the patient. Other commenters believed that the calibration of brachytherapy sources should be the manufacturer's responsibility. They also suggested that we could easily verify procedures at a few manufacturers, rather than at multiple hospitals. Some commenters also requested that we require the manufacturer to guarantee the source activity or output within 3 percent.

Response. The NRC believes that it is good practice to verify the calibration provided by the manufacturer because of the high risk associated with therapy doses to patients. Therefore, § 35.432 requires a licensee to perform calibration measurements before the first medical use of a brachytherapy source. The licensee shall determine the source output or activity using a dosimetry system that meets the requirements of § 35.630(a); determine source positioning accuracy within applicators; and use published protocols accepted by nationally recognized bodies to meet the previous two requirements.

However, we also believe that licensees should be able to use calibration measurements provided by the source manufacturer or by a calibration laboratory accredited by the AAPM as long as it was done in accordance with a published protocol accepted by a nationally recognized body using appropriately calibrated equipment. In order to ensure the reliability of the outputs or activities reported by the manufacturer, the manufacturer must perform the calibrations in accordance with the same requirements placed on the licensee. This also addresses the issue that the manufacturer guarantee the activity or output because the manufacturer must use at least the same performance standard as the licensee.

Issue 4: What is the Meaning of the Term ''Full'' in ''Full Calibration?'

Comment. A commenter suggested that the title be changed to ''Verification of calibration measurements of brachytherapy sources.'' Another commenter requested clarification of the term ''full'' in ''full calibration.'' Another commenter suggested that the term ''full calibration'' be replaced with ''spot check'' and the phrase ''spot check assay'' should be added to be consistent with terminology used in AAPM TG–40 and TG–56.

Response. The NRC agrees that the term ''full'' is confusing in the title because we do not define ''full.'' Therefore, the title of this section has been changed to ''Calibration measurements of brachytherapy sources.'' Also, the term ''full'' has been deleted from the regulatory text in this section. The terminology, including ''calibration,'' was selected to be consistent with terminology used in

Subpart H of Part 35 and in AAPM and ANSI reports.

Issue 5: When Should the Brachytherapy Sources Be Calibrated?

Comment. A commenter requested clarification on whether brachytherapy sources should be calibrated before the first medical use period or before the first medical use at a given facility.

Response. As written, the requirement is that each licensee must calibrate its brachytherapy sources before the first medical use at the licensee's facility. If the licensee is licensed for medical use at more than one facility in a single license, this calibration must only be performed once, before medical use, at any of the facilities listed in the license.

Issue 6: Does the Rule Allow Calibration of a Sampling of Sources When a Batch of Sources is Received?

Comment. Some commenters suggested that for short half-life sources and pure beta-emitting sources [e.g., I–125 and palladium–103 (Pd–103)], a sampling of the sources should be allowed.

Response. The NRC does not preclude a sampling of short half-life sources when received in a large batch. The rule requires that the calibration be performed using published protocols accepted by nationally recognized bodies, such as AAPM. The AAPM, in the report from TG–40, recommends for short half-life sources that ''for groupings with a large number of loose seeds, a random sample containing at least 10 percent of the seeds be calibrated'' and ''for a large number of seeds in ribbons, a minimum of 10 percent or 2 ribbons (whichever is larger) should be calibrated.'' However, this recommendation is made to the end user and as a verification of the source strength measurement performed by the manufacturer. The licensee must ensure that the published protocol allows for sampling of sources that have not been previously calibrated.

Issue 7: Are Sources Currently in the Possession of the Licensee Exempt From the Calibration Requirement?

Comment. A commenter suggested that we include an exemption for sources in inventory before the requirement becomes effective.

Response. Because calibration standards and methods have varied over the years, the NRC believes that to ensure that the correct dose is given to the patient, in accordance with § 35.41, the brachytherapy source output or activity must be calibrated in accordance with published protocols currently accepted by nationally recognized bodies. Therefore, we did not revise this section to include the requested exemption for sources in inventory before the effective date of the rule. Instead, we revised this section to clarify that all brachytherapy sources must be appropriately calibrated before the first medical use after the effective date of this rule. By including this date, the rule now clearly indicates that sources currently possessed by the licensee must be calibrated before the first medical use after the effective date of this rule and in accordance with a published protocol accepted by a nationally recognized body. If the source was previously calibrated in accordance with a currently accepted published protocol and using a dosimetry system that meets the requirements of § 35.630(a), the calibration would not need to be repeated after the final rule becomes effective.

Issue 8: Are the Calibration Requirements for High-Dose Versus Low-Dose Sources the Same?

Comment. A commenter requested that the calibration requirements make a distinction between high-dose and low-dose brachytherapy sources.

Response. The NRC does not believe that such a distinction is needed. We believe that when a therapeutic dose is delivered to a patient or human research subject, the licensee is responsible for ensuring that the correct dose is administered, regardless of the source strength.

Issue 9: Do the Manufacturer's Measurements Need To Be Performed Consistent With Those Required by the Licensee?

Comment. A commenter suggested that for the manufacturer's accepted measurements, the phrase ''that are made in accordance with the requirements of this section'' be deleted.

Response. This phrase has been retained in the final rule. To ensure the same level of calibration, the NRC believes that unverified calibrations performed by the manufacturer must meet the same calibration standard as the calibrations required of the licensee.

Issue 10: Is the Requirement for Source Positioning Accuracy Necessary?

Comment. Some commenters felt that the requirement for source positioning accuracy within applicators was vague and may be irrelevant or impossible to comply with.

Response. The NRC believes that, in order for the licensee to ensure further that the correct dose is delivered, the applicators used to help deliver the dose must be appropriately tested. We reviewed several standards currently available for calibration of brachytherapy sources. For example, AAPM TG–40 recommends, at a minimum, that initial tests be performed on brachytherapy applicators. TG–40 states that ''of major concern is that the applicators position the source where they are intended to be localized, and that any part of the structures which are used to attenuate the radiation (e.g., rectal and bladder shields) have not shifted.''

Issue 11: Should the Accuracy of Source Activity or Output Determination Be Stated in the Rule?

Comment. A commenter suggested that the accuracy for I–125 be changed to 10 percent because a 5 percent accuracy is not possible.

Response. The NRC deleted the reference to +/-5 percent from § 35.432(c)(1) of the proposed rule. We do not believe that the accuracy of the source activity or output measurement needs to be stated in the rule because the published protocol addresses the accuracy requirement.

Issue 12: Is New Equipment Required by Licensees To Perform Calibrations?

Comment. Several commenters indicated that the new requirement to calibrate brachytherapy sources would require licensees not currently involved in teletherapy or remote afterloader therapy to procure equipment. Additionally, a commenter requested clarification on whether a well ionization chamber (e.g., dose calibrator) was adequate for calibrating low dose rate brachytherapy sources because farmer chambers have historically been associated with § 35.630.

Response. As represented in the Regulatory Analysis accompanying this final rule, the NRC recognizes that licensees may need to procure additional equipment to meet this requirement. We believe that the additional expenditure is warranted for the licensee administering brachytherapy doses to ensure that the correct dose is administered to patients. We agree that a well ionization chamber could meet the requirement if the chamber, or source used to calibrate the chamber, is traceable to NIST or an AAPM–accredited calibration laboratory, and a published protocol accepted by a nationally recognized body is used.

Section 35.433, Decay of strontium–90 sources for ophthalmic uses

Issue 1: Were There Any Other Changes Made to This Subpart Between the Proposed and Final Rule?

Response. Yes. The NRC added this new section that requires an AMP to calculate the activity of a strontium–90 (Sr–90) source that will be used in determining the treatment time for ophthalmic uses. It also requires that the activity be calculated using the source activity determined under § 35.432.

We added this section because we are aware of numerous misadministrations involving Sr–90 for opthalmic use that were caused by individuals improperly calculating the decay of sealed sources. Given the risks associated with use of Sr–90 and the numerous misadministrations in this area, a more prescriptive requirement is warranted.

Section 35.457, Therapy-Related Computer Systems

Issue: Were There Any Other Changes Made to This Subpart Between the Proposed and Final Rule?

Response. Yes. The NRC added this new section that is consistent with the requirement found in § 35.657 for therapy-related computer systems. The new section requires brachytherapy licensees who use treatment planning systems to perform acceptance testing on the system in accordance with published protocols accepted by nationally recognized bodies.

Section 35.490, Training for Use of Manual Brachytherapy Sources

General comments on this section are summarized under the General Training topic found at the beginning of this section of the **Federal Register** notice.

Issue 1: Should Training Include Ordering and Inventory of Byproduct Material?

Comment. A commenter requested that we delete the following from work experience requirements: ''ordering'' material safely and ''maintaining running inventories of material on hand.'' The commenter believed that there was no risk associated with these procedures.

Response. Because the AU is responsible for use of byproduct material under the license, the NRC believes that experience in ordering and maintaining inventories of radioactive materials is an important component of a training program for an AU.

Section 35.491, Training for ophthalmic use of strontium–90

Issue 1: Were There Any Other Changes Made in This Subpart Between the Proposed and Final Rule?

Response. Yes. The NRC added this new section. The proposed rule had deleted specific training and experience requirements for individuals who wanted to use Sr–90 for ophthalmic use. Under the proposed rule, these individuals would need to meet the training and experience requirements in the proposed § 35.490 or § 35.940. This change was proposed because, at that time, we believed it was warranted in view of the similarities between the use of Sr–90 eye applicators and the use of sealed byproduct material in medical devices, and recent misadministrations involving Sr–90 eye applicators. Upon further review of the misadministrations, we believe that the majority of the misadministration events could have been prevented if an AMP had calculated the decay of the sources, rather than if NRC required additional training and experience for AUs who want to use Sr–90 for ophthalmic use. Therefore, we added a requirement for an AMP to calculate the activity of the source (§ 35.433) and have included a specific section that provides the training and experience requirements for an individual who would like to use Sr–90 sources for ophthalmic treatments.

This section is identical to § 35.941, Training for ophthalmic use of Sr–90 in the current rule with minor exceptions. We have deleted the phrase ''who is in the active practice of therapeutic radiology or ophthalmology.'' We believe it is important that the individual is a physician and therefore this additional level of prescriptive regulation is not warranted. We have also added a requirement for a written statement, signed by a preceptor AU, stating that the individual has satisfactorily completed the training requirements and has achieved a level of competency sufficient to function independently as an AU for use of Sr–90 for ophthalmic treatments. This change is consistent with the other training and experience sections within the revised rule. The preceptor statement is discussed in more detail under the General Training topic found at the beginning of this section. Additionally, we have added a provision that a physician who meets the requirements in § 35.490 or equivalent Agreement State requirements would automatically meet the requirements to become an AU under § 35.491.

Subpart G—Sealed Sources for Diagnosis

The NRC received comments on only three areas in Subpart G. They are: (1) SSDR; (2) availability of survey instruments; and (3) training and experience requirements. The first two topics are summarized under the ''Global Changes'' topic in the beginning of this section because the same comments pertain to multiple sections in the rule. Comments on the training and experience requirements are summarized under the ''General Training'' topic found at the beginning of this section.

Subpart H—Photon Emitting Remote Afterloader Units, Teletherapy Units, and Gamma Stereotactic Units

General Comments

Issue 1: Can This Subpart Be Revised To Eliminate Redundant and Overly Prescriptive Requirements?

Comment. A commenter suggested that Subpart H should be rewritten to eliminate redundancy and overprescriptive procedures that the NRC expects licensees to follow. The commenter felt that the licensees should have the ability to develop their own procedures instead of the NRC dictating each step.

Response. The NRC agrees that the rule should not be redundant and we have combined sections whenever possible. For example, in the final rule, we combined § 35.644, Periodic spot-checks for low dose-rate remote afterloaders, with § 35.643, Periodic spot-checks for high dose-rate and pulse dose-rate remote afterloader units. However, the full calibration requirements for all therapy units have been retained in separate sections for each type of unit to avoid confusion on the applicability of certain tests for a given therapy unit.

Subpart H contains requirements for emergency response and operating procedures, including full calibration and spot-check tests. Where warranted by risk, we maintained the prescriptive requirements in the rule. We identified the performance objectives for full calibrations and spot-checks in the rule. This decision was based on various AAPM and ANSI reports. However, the exact content of these procedures has not been specified. These procedures are required to be developed by the licensee and the AMP. Where applicable, the procedures must use published protocols accepted by a nationally recognized body. We believe that this provides the licensee more flexibility in developing its procedures.

Issue 2: How Have National Standards Been Incorporated Into the Rule?

Comment. Commenters were concerned that we are transforming recommended ''practice standards'' into excessively prescriptive and unnecessarily burdensome regulatory requirements.

Response. In many sections, the rule allows licensees to develop their own procedures in accordance with multiple peer-reviewed reports, protocols, or standards. Examples include following recommendations published by the AAPM, ACR, ANSI, and ACMP. The NRC believes this provides licensees with the flexibility needed to develop their own procedures as long as they meet the minimum regulatory requirements in this subpart.

For additional information on the use of consensus standards in the final rule refer to I, Background, in the **SUPPLEMENTARY INFORMATION.**

Issue 3: Were There Any Other Changes Made in This Section Between the Proposed and Final Rule?

Response. Yes. The NRC changed the title of this subpart and the language in § 35.600 to make it clear that the requirements in this section refer to only photon-emitting remote afterloader units, teletherapy units, and gamma stereotactic radiosurgery units.

Section 35.600, Use of a Sealed Source in a Remote Afterloader Unit, Teletherapy Unit, or Gamma Stereotactic Radiosurgery Unit

Issue 1: Should All Therapy Sealed Wources Be Required to Have NIST Traceability?

Comment. Some commenters said that all sources used for therapeutic applications should be required by regulation to have a NIST traceable national standard. Conversely, some commenters said that it is inconsistent to require licensees to calibrate such sources in the absence of national standards for all clinically used sources.

Response. Sections 35.632, 35.633, and 35.635 require that sealed source output be measured with a dosimetry system that has been calibrated using a system or source traceable to NIST and published protocols accepted by nationally recognized bodies or by calibration laboratory accredited by AAPM. The NRC agrees with the AAPM position that all therapy sealed sources should be calibrated in accordance with a traceable standard. In limited cases, a traceable standard identical to the therapy sealed source is not available. In these cases, §§ 35.632, 35.633, and 35.635 allow the licensee the flexibility to use protocols accepted by nationally recognized bodies to meet the calibration requirement. As an example, AAPM Report Number 21 recommends that sources used in radiation therapy have calibrations with direct or secondary traceability to national standards. AAPM defines direct traceability as ''when a source or calibrator has been calibrated either at NIST or an AAPM–Accredited Dosimetry Calibration Laboratory.'' AAPM defines secondary traceability as ''when the source is calibrated in comparison with a source of the same design and comparable strength which has direct traceability or when the source is calibrated using an instrument with direct traceability.'' In addition, AAPM TG–56 recommends that for ''sources that do not have a national standard yet, users should develop a constancy check calibrated against the vendor's standard and use this constancy check to verify the source strength. Another option is to develop one's own secondary standard.'' This allows the licensee flexibility in the event that a direct NIST traceable standard does not exist.

Issue 2: Were There Any Other Changes Made in This Section Between the Proposed and Final Rule?

Response. Yes. The NRC added a new paragraph (b) to this section that allows a licensee to use therapy sources in medical research if the research is conducted in accordance with an active IDE application accepted by the FDA and if the requirements in § 35.49(a) are met. This was done to clarify how research with sealed sources could be conducted if the medical use of the sources differed from the statements found in the SSDR for the sources. With this change, we allow previously registered sources to be used for uses other than those described in the original registration process as long as the requirements in paragraph (b) are met.

Section 35.604, Surveys of Patients and Human Research Subjects Treated With a Remote Afterloader Unit

Issue 1: What Is the Purpose of the Survey Required by This Section?

Comment. A commenter requested clarification of the requirement to survey the patient or human research subject and the remote afterloader with a portable radiation detection survey instrument to confirm that the source(s) have been removed from the patient or human research subject and returned to the safe shielded position.

Response. The radiation surveys are needed to ensure that a source does not remain within the patient or outside of the source shield following completion of each treatment with the unit.

Issue 2: Who May Perform the Survey?

Comment. A commenter requested that the rule be revised to allow the medical physicist to train an assistant to do the radiation surveys, required by § 35.604, when the physicist is not available.

Response. The rule does not specify who must perform the surveys required by § 35.604. The NRC believes that the licensee should have the flexibility to decide who should perform the surveys. However, the record of the survey must include the name of the individual who performed the survey, in accordance with § 35.2404.

Section 35.605, Installation, Maintenance, Adjustment, and Repair

Issue 1: Who May Repair a LDR Unit?

Comment. The NRC solicited comments on whether the restrictions in this section on who may work on a device containing a sealed source should apply to LDR units. Some commenters said that the restrictions should apply to LDR units. Other commenters believed that the restrictions should only apply to LDR units if the device manufacturer recommends the restriction for the particular device. Conversely, some commenters said that the restrictions should not apply to LDR units because the risk from these low dose-rate units is minimal enough that a trained individual knowledgeable of the unit's operation could install, perform maintenance, adjust, or repair the device. They believed that we should not ''over-regulate'' these units. Some commenters also believed that users of nonmedical devices who perform these types of services must submit procedures that show they have had appropriate training in performing these services on the specific devices. They stated that persons who perform installation, maintenance, and repair of other NRC-regulated devices (that do not apply radiation to humans) are routinely limited to services on the specific devices for which they have training and experience, e.g., fixed gauges, radiography cameras, etc. In addition, repairs of therapy devices are not just an issue of source or cable replacement, but could also include electronics and software modifications. Consequently, they believed that none of the training and experience requirements identified in the proposed

regulations provide for this kind of training. Therefore, the service provider's specific training must be evaluated by the NRC.

Response. Because of the risk associated with therapy devices, the final rule only allows an NRC or Agreement State licensed entity to install, maintain, adjust, or repair a therapy device that involves work on the source(s) shielding, the source(s) driving unit, or other electronic or mechanical component that could expose the source(s), reduce the shielding around the source(s), or compromise the radiation safety of the therapy unit or the source(s). Additionally, these regulations limit the installation, replacement, relocation, or removal of the sealed source(s) or source(s) in a teletherapy unit, gamma stereotactic radiosurgery unit, HDR, MDR, and PDR, to an entity specifically licensed by the NRC or an Agreement State for these activities. For LDR source(s), the NRC allows an AMP or a specifically licensed entity to perform these functions. This provides relief for licensees possessing LDRs when replacing decayed sources or removing and installing sources to render each individualized treatment plan. However, for work on the LDR source(s) safe, the source(s) driving unit, or other electronic or mechanical components that may expose the source(s) or compromise the radiation safety of the unit, we believe that specialized training, in addition to the training required to meet AMP status, is necessary to perform these activities. Therefore, only personnel specifically licensed by the NRC or an Agreement State may perform these activities.

Issue 2: Does Install, Maintain, Adjust, or Repair Include Assembly?

Comment. A commenter suggested that the word ''assembly'' be added to the list of activities that must be performed by a specifically licensed person.

Response. The NRC believes that ''assembly'' is included within the meaning of installation and repair. Therefore, we made no change in the regulatory text.

Section 35.610, Safety Procedures and Instructions for Remote Afterloader Units, Teletherapy Units, and Gamma Stereotactic Radiosurgery Units

Issue 1: Does the Rule Allow Individuals Other Than the Patient To Be Present in the Treatment Room?

Comment. Commenters indicated that therapy administrations in cardiac catheterization suites require the presence of other persons for the safety of the patient during the treatment, and may require that individuals have access to the patient through the treatment room doors without interruption of the treatment. In such cases, the commenters believed that the exposures to personnel were already limited by Part 20 requirements. A commenter also questioned the term ''contraindicated'' in the phrase ''ensuring that only the patient * * * is in the treatment room before initiating treatment with the source(s), unless contraindicated * * *''

Response. The NRC agrees that, in limited cases, the licensee may need to allow other individuals in the treatment room during treatment. We also agree that the scope of ''unless contraindicated'' needs to be defined. Therefore, we modified the final rule to permit individuals approved by the AU, AMP, or RSO to be present in the treatment room, during treatment with the source(s). These individuals are in the best position to determine if an individual may be present in the treatment room during a treatment. However, licensees are still required to control the exposures of workers and members of the public in accordance with Part 20.

Issue 2: Must the Console and the Console Keys Be Secured?

Comment. A commenter suggested that securing both the console and the console keys was redundant. The commenter went on to state that securing a teletherapy or a gamma stereotactic radiosurgery treatment room is unnecessary if the console or console keys are secured because it would be highly unlikely that unauthorized individuals would remove the devices given their bulk and weight. The commenter felt that, in keeping with a performance-based rule, this section should be revised to read ''prevention of unauthorized use or removal of the device when not in use or unattended.''

Response. Paragraph (a)(1) of this section specifies the mechanism for ensuring that the licensed material in therapy treatment devices is controlled when the devices are not attended or are not in use. In keeping with a performance-based rule, the NRC removed the proposed requirement for written security procedures. This allows the licensee flexibility in determining the appropriate method for meeting this requirement. General requirements for security of byproduct material are addressed in Part 20, Subpart I. However, because of the high risk posed by these sources, we believe that a more prescriptive requirement is warranted.

Issue 3: Where Should Emergency Procedures and Instructions Be Posted?

Comment. Some commenters said that requiring a copy of instructions and procedures to be posted only at the device console was too prescriptive. They suggested that the language should be revised to read ''in the immediate vicinity of the device console.'' A commenter also suggested that paragraph (c) of this section was unnecessary because it requires posting the location of the procedures, and paragraph (b) requires the procedures be posted. Another commenter suggested that, in some cases, a console may not exist.

Response. The NRC has not changed either paragraph (b) or (c) in the final rule. Paragraph (b) requires that a copy of the emergency procedures required by paragraph (a)(4) be physically located at the unit console. Paragraph (c) requires posting the location of emergency procedures and the names and telephone numbers of the emergency contacts. Because the emergency procedures for some devices (e.g., HDR units) may consist of several volumes of error codes and their meaning, we do not require that these procedures be posted. However, the actual location (e.g., specific drawer in the console) where these procedures are stored must be posted at the unit console to alert individuals about where to find the detailed emergency procedures in the event of an emergency. We agree that this does not specifically require posting the procedures on the console, but may allow, for instance, posting them on the wall in front of the console. We also believe that a console exists for ''remotely'' delivered sources because the sources must be removed from the source shielding from outside of the treatment room. For cardiac units, this may be an infusion console.

Issue 4: Should Device Operators Be Listed in the License?

Comment. A commenter felt that operator knowledge was vital to prevent a medical event, but the requirements do not address operator education, training, or experience. The commenter suggested that the operator be named in the license.

Response. It is the licensee's responsibility to ensure that operators are trained. In accordance with § 35.27, operators use licensed material and operate licensed devices, depending on the activity being conducted, under the supervision of the AU. Therefore, the NRC does not believe that NRC's prior

review of a specific operator's training is necessary.

Issue 5: What Is the Appropriate Frequency and Scope of Instruction?

Comment. Some commenters suggested that we clarify that persons not receiving annual refresher training are simply prohibited from operating the unit until the training is provided and that the individuals need not be removed from authorization in the institutional license. A commenter also felt that the instruction requirements were too prescriptive for the variety of devices. In addition, while it may be possible to perform a drill simulating the removal of a patient from a teletherapy unit, such a drill is not practical for an HDR unit. The commenter requested that the regulatory text be revised to read ''a licensee shall provide instruction and practice drills or demonstrations, initially and at least annually * * *'' Conversely, some commenters suggested that retraining was not necessary at all because the AMP and the operator routinely perform the procedures.

Response. The NRC amended the regulatory text to clarify the requirements for instruction. We believe that initial instruction and annual retraining are needed to ensure that the correct dose is administered to the patient or human research subject and to ensure that responsible individuals appropriately respond to emergencies. We also believe that emergency drills are appropriate for all devices. The requirement for training on emergency and operating procedures has been revised to clarify that the training provided is ''as appropriate to the individual's assigned duties.'' We believe that the revised rule allows the licensee flexibility in determining the appropriate level of instruction to be provided depending on the level of involvement of personnel in the operation of and emergency response for the therapy unit.

Issue 6: Were There Any Other Changes Made in This Section Between the Proposed and Final Rule?

Response. Yes. In keeping with a more performance-based rule, the NRC removed the requirement for a written procedure for preventing dual operation of radiation producing devices. This allows the licensee flexibility in determining the appropriate method for meeting this requirement.

Paragraph (g) of this section was added to refer licensees to the record keeping requirements in § 35.2610.

Section 35.615, Safety Precautions for Remote Afterloader Units, Teletherapy Units, and Gamma Stereotactic Radiosurgery Units

Issue 1: Is It Necessary To List the Type and Location of Emergency Response Equipment in the Regulations?

Comment. Commenters believed that the requirement to list the contents of an emergency pack was too prescriptive and confusing. Additionally, commenters believed that the emergency equipment did not need to be specifically located in the patient's room but could be somewhere accessible in the hospital. Commenters felt that the licensee should have the freedom to adequately stock and locate an emergency pack. One commenter also felt that the phrase ''supplies necessary to surgically remove applicators'' kept in the patient's room implied that surgery should be conducted in a nonsterile environment.

Response. The NRC agrees with these comments because, in a performance-based rule, the essential objectives should be stated in the regulation. Therefore, we revised the regulatory text to identify the essential objective of having emergency response equipment available near each treatment room. The list of specific items that are needed for emergency responses has been deleted from this section. The licensee has the flexibility to determine the type of emergency response equipment needed to respond to a source that remains in the unshielded position or is lodged within the patient following completion of the treatment.

We agree that the emergency equipment does not need to be maintained in the treatment room. However, it should be maintained near each treatment room in order to expeditiously respond to an emergency. The final rule allows the licensee some flexibility in locating the emergency response equipment but does not preclude the licensee from placing the equipment in the room. This is especially important in the situation where heavy source shields are needed. The issue of whether to conduct surgical removals of applicators or sources within a treatment room that may not be a sterile environment is left to the licensee's discretion.

Issue 2: Is This Section Applicable to Remote Afterloader Units With Beta-Emitting Sources?

Comment. The NRC solicited specific response on whether the safety precautions in this section should apply to beta-emitting sources. Some commenters felt that the requirements in this section should not apply to remote afterloader beta-emitting sources, since the lower doses from the beta-emitting sources present a very low risk. For example, some commenters felt that paragraphs (b), (c), (d), and (g) could be waived. Other commenters did not believe that we should waive the requirements in this section for remote afterloader beta-emitting sources in keeping with ALARA.

Response. The NRC amended the title of this subpart to make it clear that it only applies to photon-emitting units. We agree that when requirements for beta-emitting remote afterloader units are subsequently added to the regulations, many of the types of requirements described in this section may be appropriate. However, until the use and safety issues of beta-emitting remote afterloader units are fully understood, specific requirements for these units have not been incorporated into this subpart.

Issue 3: Who May Generate a Treatment Plan?

Comment. A commenter suggested adding a requirement that only an AMP may generate an HDR treatment plan. The commenter believed that the level of complexity and the chance for error in this area certainly warranted a requirement in this area.

Response. The NRC has not changed the final rule to state who should generate a treatment plan. We believe that licensees should determine who will generate the treatment plan. Additionally, we remind licensees that under § 35.41, Procedures for administrations requiring a written directive, the licensee must develop, implement, and maintain written procedures to provide high confidence that each administration is in accordance with the written directives, including providing the correct dose to the patient.

Issue 4: Is an Intercom System Necessary?

Comment. A commenter requested that the requirement for an intercom system be deleted because voice communication with the patient is not necessary during treatment. The commenter also suggested that the requirement to have an intercom system restricts treatments given by a deaf employee.

Response. Based on ANSI and AAPM recommendations and to help ensure patient and worker safety, the NRC retained the requirement for an intercom system in the final rule. This does not preclude additional use of

another voice activated system that can be used by a deaf operator.

Issue 5: Should the Word ''Expeditious'' Be Used in the Rule?

Comment. A commenter suggested that the term ''expeditious'' in paragraph (e) implies that, if the source is difficult to remove, the licensee will be cited. The commenter also felt that this requirement could interfere with what the physician considers to be in the best interest of the patient.

Response. The potential dose to the patient from a decoupled or jammed therapy source remaining within the patient is significant. Therefore, the NRC has retained the requirement for a licensee to only conduct treatments which allow for expeditious removal of a decoupled or jammed source.

Issue 6: Who Needs To Be Present During LDR Treatments?

Comment. A commenter felt that treatments with an LDR unit should allow for trained individuals, working under the supervision of an AU, who have been trained in the operation of the device to be physically present during treatment initiation and an AU and AMP immediately available. Another commenter felt that the AU and the AMP should be physically present during the initiation of patient treatments involving LDR devices. This commenter also asked whether the reference to a radiation oncology physician includes a resident in training. Still another commenter requested that the NRC delete the requirement for an AU and AMP to be present for continuation of LDR treatments because the treatment may last 48–72 hours and it is not possible to have someone continually available.

Response. In response to public comments, the requirements for the presence of trained personnel during LDR, MDR, and PDR treatments were amended. The final rule does not contain any requirements for the presence of trained personnel for LDR treatments. The risk associated with use of byproduct material in an LDR and manual brachytherapy are similar. Therefore, the NRC does not believe that regulatory text is needed in this area.

For MDR and PDR units, an AMP must be physically present during the initiation of patient treatments and must be immediately available during continuation of the treatments. The final rule allows an AU to permit a physician, working under his/her supervision and with training specific to operation and emergency response for the unit, to be physically present in place of the AU during initiation of patient treatment involving an MDR or PDR unit. The final rule also allows the AU to permit an individual, working under his/her supervision and with training in removing source applicator(s), to be ''immediately available'' in place of the AU during continuation of patient treatment involving an MDR or PDR unit. Because the treatment times for pulsed dose-rate treatments are significantly longer than those for high dose-rate treatments and the activities of pulsed dose-rate sources are approximately one-tenth of the activities of high dose-rate sources, the change in physician attendance during pulsed dose-rate treatments is warranted. Additionally, for normal resumption of treatment controlled by the pulsed dose-rate device during the normal continuation of the treatment, the presence of a medical professional is not required. This revision allows the licensee flexibility in determining the appropriate personnel to have physically present or ''immediately available'' for medical response to patients treated with these units.

Issue 7: Who Needs To Be Present During HDR Treatments?

Comment. Some commenters believed that a physician and a properly trained radiation therapy technologist should be present for HDR treatments. The commenters believed that the responsibility for the device is the AU's, since this is an FDA-approved device. Another commenter believed that the physical presence of an AMP is sufficient if an AU, or a physician trained to respond to an emergency, could be summoned to the HDR unit console within 2 minutes. Some commenters also requested that all remote afterloader requirements be combined because the present requirements are repetitive.

Response. The NRC believes that the requirements for HDR units should differ from the requirements for LDR, MDR, and PDR treatments because the treatment times and the source activities differ significantly. We believe that the requirements appropriately address emergency situations.

An AMP is required to be physically present during the initiation and continuation of all patient treatments involving the unit. The final rule allows an AU to permit a physician, working under his or her supervision, to be physically present in place of the AU during continuation of patient treatment as long as the physician has received operating and emergency response training for the device and as long as the AU is physically present during initiation of the patient treatment. We believe that this revision is appropriate because it allows the licensee flexibility in determining who should be physically present during treatments involving HDR units.

Issue 8: Who Needs To Be Present During Gamma Stereotactic Radiosurgery Treatments?

Comment. A commenter requested that for gamma stereotactic radiosurgery treatments, an AU or anyone trained in the setting of the coordinates and emergency procedures should be present. Another commenter suggested that emergency response could be limited to requiring the presence of a physician capable of dealing with the patient's medical needs and two individuals trained in emergency procedures particular to the unit. Still another commenter suggested that we require continuous monitoring by one trained individual and monitoring by an AU during the start and the end of the treatment.

Response. The NRC requires the physical presence of an AU and an AMP throughout all patient gamma stereotactic radiosurgery treatments to ensure appropriate response to an emergency and to ensure that the correct dose is delivered to the patient.

Issue 9: Were There Aany Other Changes Made in This Section Bbetween the Proposed and Final Rule?

Response. Yes. The NRC amended paragraph (b)(2) to delete the word ''immediately.'' We did not believe the word was needed because the text clearly indicates that the interlock system must cause the sources to be shielded when an entrance door is opened.

We also added a requirement to § 35.615 (f) that an AU and an RSO, or his or her designee, must be notified in the event the patient or human research subject has a medical emergency or dies. This notification requirement is similar to § 35.415(c) and provides consistency in the requirements for therapy devices and manual brachytherapy. In cases where an AU is physically present during the patient treatment, the notification need only be made to the RSO.

Section 35.630, Dosimetry equipment

Issue: Is Calibrated Dosimetry Equipment Needed for Low Dose-Rate Therapy?

Comment. A commenter suggested that licensees routinely do not have or have available, other than through a source provider, calibrated dosimetry equipment that is applicable to the

lower dose-rates used in standard brachytherapy. Therefore, the commenter requested that dosimetry equipment only be required for higher dose-rate procedures.

Response. As noted in the Regulatory Analysis accompanying this final rule, the NRC recognizes that licensees may need to procure additional equipment to meet this requirement. We believe that the additional expenditure is warranted for the licensee administering therapeutic doses to ensure that the correct dose is administered to patients. However, we added regulatory text on the use of the source output or activity determined by the manufacturer so that this section is consistent with the requirements in Subpart F, Manual Brachytherapy. In the final rule, a licensee using an LDR source(s) may rely on the manufacturer's calibration, and hence the manufacturer's calibration equipment, as long as the equipment and source calibration is performed in accordance with protocols accepted by nationally recognized bodies.

Section 35.632, Full Calibration Measurements on Teletherapy Uunits

Issue 1: What Does the Term ''Nationally Recognized Body'' Mean and What Is the Policy for Making Recommendations From These Bodies Into Regulations?

Comment. Commenters questioned what was intended by the term ''nationally recognized body'' and stated that professional protocols may contain items that are recommended but that were never intended to be adopted as regulations.

Response. ''Nationally recognized bodies,'' as used in Part 35, refers both to official standards consensus bodies that are identified on the NIST website and to those professional organizations that develop their reports, protocols, or standards using a consensus process and multiple peer-reviews. Examples of nationally recognized bodies include ANSI, AAPM, ACR, and ACMP. The requirements in this subpart are based on recommendations found in ANSI and AAPM reports and are consistent with the calibration requirements for other sealed sources and devices for therapy. However, the NRC did not include all the recommendations made in the ANSI and AAPM reports nor did we adopt them as regulations because we recognize the prescriptiveness of various reports. Instead, the regulation only contains the essential objectives for the test being required are listed in the rule.

For additional information on the use of consensus standards from nationally recognized bodies, refer to Section I, Background, and the discussion of industry standards in the beginning of this section.

Issue 2: What Is the Meaning of the Term ''Intervals Consistent With 1 Percent Physical Decay''?

Comment. One commenter requested that we clarify whether the requirement meant 1.0000 percent or allowed rounding down to 1 percent. Some commenters felt that 1 percent was too prescriptive because the calibration requirements are higher. Additionally, a commenter requested that the posted values be within 1 percent of the mathematically corrected values.

Response. This section in the final rule requires that outputs be corrected for physical decay at intervals not exceeding 1 month for cobalt-60, 6 months for cesium-137, or at intervals consistent with 1 percent decay for all other nuclides. ''Rounding'' is a mathematical term. ''Consistent with 1 percent'' includes from 0.51 percent to 1.49 percent. The 1 percent correction is separate from the output full calibration. The accuracy of the output full calibration must be within +/-3 percent in accordance with paragraph (b)(1) of this section. This calibration is then used to determine the dose delivered to the patient.

Issue 3: What Is the Meaning of the Term ''Calibrate'' When Referring to Timer Accuracy and Linearity?

Comment. Commenters requested the meaning of ''calibrate'' when referencing timer accuracy and linearity. The commenters suggested that, if the purpose is to measure these items to assure they are within some tolerance, this purpose should be stated in the regulation.

Response. Procedures for calibrating the timer are provided in various protocols, which include tolerances. Examples include ANSI N449 and N449–1, ''Procedures for Periodic Inspection of Cobalt-60 and Cesium-137 Teletherapy Equipment'; and AAPM TG–40. As stated in this regulation, the calibration must be performed in accordance with published protocols accepted by nationally recognized bodies. The term calibrate, as used in this context, means to perform measurements to assure that the timer is operating appropriately within a given tolerance. The tolerances may be found in reports such as AAPM TG–40. Therefore, the licensee is given flexibility in developing its calibration methods.

Issue 4: Why are repetitive output measurements necessary?

Comment. A commenter agreed with the requirement for full calibration of sources. However, the commenter suggested that repetitive output checks of long-lived sources, such as cesium, was unnecessary because the output is not going to change as long as the source is not leaking.

Response. When delivering a therapeutic dose to a patient or human research subject, the NRC believes that the licensee is responsible for ensuring that the correct dose is administered. Additionally, in accordance with § 35.41, the licensee must implement procedures to ensure that the dose is administered in accordance with the written directive. As part of ensuring that the correct dose is administered, we believe that the source output for all sources used to administer a therapeutic dose must be calibrated and verified. We also agree with published protocols, such as ANSI and AAPM recommendations, that include periodic recalibration of source activity when delivering therapeutic doses. Therefore, we retained the proposed calibration requirements in the final rule.

Section 35.633, Full Calibration Measurements on Remote Afterloader Units

Issue 1: Why Are Repetitive Output Measurements Necessary and Shouldn't the Output Test Requirements Reference the Equipment Calibration Requirements?

Comment. A commenter agreed with the requirement for full calibration of sources. However, the commenter suggested that repetitive output checks of long-lived sources, such as cesium, was unnecessary, because the output is not going to change as long as the source(s) is not leaking. Another commenter suggested that the output calibration requirement should reference the requirement for dosimetry equipment in § 35.630.

Response. When delivering a therapeutic dose to a patient or human research subject, the NRC believes that the licensee is responsible for ensuring that the correct dose is administered. Additionally, in accordance with § 35.41, the licensee must implement procedures to ensure that the dose is administered in accordance with the written directive. As part of ensuring that the correct dose is administered, we believe that the source output for all sources used to administer a therapeutic dose must be calibrated and verified. We also agree with published protocols, such as AAPM recommendations, that

include periodic recalibration of source activity when delivering therapeutic doses. Therefore, we retained the proposed calibration requirements in the final rule. However, for consistency with manual brachytherapy, which is traditionally low dose-rate, we included an allowance for LDR sources in the final rule. Paragraph (f) allows licensees using LDRs to accept the manufacturer's calibration of the unit and source as long as the manufacturer conducted the calibration in accordance with this section and with a published protocol accepted by a nationally recognized body and used a dosimetry system as described in § 35.630(a) to measure the output.

Issue 2: What System Tests and Tolerances Should Be Included in Calibration Requirements?

Comment. Commenters requested the meaning of ''calibrate'' when referencing source guide tubes, connectors, and timer accuracy and linearity. If the purpose is to measure these items to assure they are within some tolerance, the commenters suggested that this purpose be stated in the regulation. Another commenter suggested that timer accuracy is irrelevant to dosimetry as long as the timer functions the same at the time of treatment as at the time of calibration (i.e., consistency), and responds linearly. Some commenters requested deletion of: (1) Timer accuracy and linearity for LDR and PDR units; (2) guide tube calibrations; (3) connector length calibrations; (4) autoradiograph of LDR sources to verify inventory (because sources are difficult to remove from the unit); and (5) battery backup checks (should only be performed at preventative maintenance inspection conducted by the manufacturer). Additionally, a commenter suggested that a reasonable positioning accuracy was 2 millimeters for an HDR stepping source and 5 millimeters for an LDR source (reference AAPM TG–59). A commenter also requested that the NRC clarify that tests for tubes and connectors apply to tubes and connectors in use, and that no tests are required if the unit is not in use.

Response. Various professional reports provide suggested protocols for quality assurance tests on remote afterloaders. The NRC based the performance objectives for various tests in this section on recommendations made by AAPM TG–56. For instance, AAPM TG–56 suggests 1 millimeter positional accuracy for HDR, LDR, and PDR units; initial, annual, and quarterly battery backup checks; timer accuracy tests for LDR units; and autoradiograph of LDR sources. We agree with the recommendations made in AAPM reports and believe that the calibration requirements in this section are warranted to ensure that the correct dose is administered to the patient.

The terminology used in this section was chosen to reflect the current language used in practice. AAPM reports use ''timer accuracy and linearity, applicators, transfer tubes, and transfer tube-applicator interfaces.'' We noted small discrepancies in the terminology used in the proposed requirements versus in AAPM reports. Therefore, we revised the term ''source guide tube'' to ''source transfer tube'' and the term ''connector'' to ''transfer tube-applicator interface'' in the final rule. The tests apply only to units and accessories in use.

Issue 3: How Frequently Should Recalibrations Be Performed?

Comment. A commenter stated that a full calibration is always performed immediately after the source exchange. However, it is probable that the source exchange for an iridium-192 HDR source may take more than 120 days. The commenter suggested that a full calibration on the source after 120 days was not necessary if the source was not yet exchanged for a new source. Another commenter agreed with the proposed requirement that HDR units should be calibrated within 120 days and that LDR units should be calibrated annually, within 1 year. A commenter also requested clarification of the phrase ''not exceeding one quarter.''

Response. The NRC believes that, for iridium-192 (Ir-192) HDR sources, the source calibration frequency can be changed to ''at source exchange'' to allow for source exchanges that slightly exceed the 120-day period. Therefore, the frequency for full recalibration of HDR, MDR, and PDR units has been revised to quarterly for sources whose half-lives exceed 75 days. We believe that this revision will facilitate the use of sources with short half-lives. We also believe that this revision will not reduce safe use of sources whose half-lives are less than 75 days (e.g., Ir-192), because these sources are exchanged at the end of their useful life, which is approximately quarterly for Ir-192. The requirement to perform a full calibration at source exchange has been retained. The phrase ''not exceeding one quarter'' can be equated to a 3-month period.

Issue 4: Who Is Required To Perform the Decay Corrections for Source Output?

Comment. A commenter requested that dosimetrists be allowed to perform decay corrections.

Response. The AMP remains responsible for performing decay corrections because of the high consequence associated with errors in these corrections.

Issue 5: Were There Any Other Changes Made in This Section Between the Proposed and Final Rule?

Response. Yes. The NRC deleted the requirement to repeat the full calibration of the remote afterloader unit and source, whenever spot-check measurements indicate that the output differs by more than 5 percent from the output obtained at the last full calibration. We deleted this requirement because the requirement to perform output spot-checks on remote afterloader units was deleted from § 35.643.

We also revised § 35.633(b) to include patient dose delivery components for LDR units that are detailed in AAPM TG–56. Specifically, the requirements in paragraphs (b)(4), (b)(5), (b)(6), and (b)(7) were moved in the final rule so that they apply to all remote afterloaders, including LDRs. The items in these paragraphs are measurement of the length of the source transfer tubes and applicators; measurement of the timer accuracy and linearity over the typical range of use; and function tests of the source transfer tubes, applicators, and transfer tube-applicator interfaces. We believe that these changes are necessary to ensure that, during acceptance testing of the units, including LDR units, and after source replacement, these additional tests that increase patient radiation safety are performed.

Section 35.635, Full Calibration Measurements on Gamma Stereotactic Radiosurgery Units

Issue 1: What Is the Meaning of the Term ''Calibrate'' When Referring to Timer Accuracy and Linearity?

Comment. Commenters requested the meaning of ''calibrate'' when referencing timer accuracy and linearity. The commenters suggested that, if the purpose is to measure these items to assure they are within some tolerance, this purpose should be stated in the regulation.

Response. The terminology used in this section reflects the current language used in practice. AAPM reports use ''timer accuracy and linearity.'' As

stated in this regulation, calibrations must be performed in accordance with published protocols accepted by nationally recognized bodies. The term calibrate, as used in this context, means to perform measurements to assure that the timer is operating appropriately within a given tolerance. The tolerances may be found in reports such as AAPM TG–40. Therefore, the licensee is given flexibility in developing its calibration methods.

Issue 2: Can the Licensee Adopt the Manufacturer's Measurements for Relative Helmet Factors?

Comment. A commenter suggested that many users currently adopt the manufacturer's recommended relative helmet factors rather than measure them directly. The commenter stated that this was preferable because: (1) There are inherent difficulties in measuring these factors; (2) requiring users to measure their own factors could result in large errors in some situations; and (3) using the manufacturer's factors aids in sharing information among facilities conducting research protocols.

Response. The NRC believes that measurement of helmet factors is inherent in patient dosimetry. Various professional reports provide suggested protocols for quality assurance tests on gamma stereotactic radiosurgery units. The performance objectives for various tests in this section are based on recommendations in AAPM Report No. 54. For example, AAPM Report No. 54 recommends that helmet factors be measured by the end user. However, in the final rule we changed the proposed requirement for annual measurements of relative helmet factors to require only measurements before the first medical use of the helmet and following any damage to the helmet.

Issue 3: Were There Any Other Changes Made in This Section Between the Proposed and Final Rule?

Response. Yes. The NRC added the components related to the delivery of the dose to the patient that are in § 35.645, Periodic spot-checks for gamma stereotactic radiosurgery, because all patient dose delivery components detailed in the periodic spot-check section, § 35.645, were not included in the proposed full calibration requirements, and, therefore, were not required during initial quality assurance testing on the unit or after source replacement. The new paragraphs (b)(7) through (b)(10) in the final rule include tests of the treatment table retraction mechanism, helmet microswitches, emergency timing circuits, and stereotactic frames and localizing devices (trunnions). We believe that these changes are necessary to ensure that these additional tests involving patient radiation safety are performed during acceptance testing of the unit and after source replacement. These additions are consistent with the approach used in the teletherapy unit requirements for full calibration and spot-checks.

Section 35.642, Periodic Spot-Checks for Teletherapy Units

Issue 1: What Is the Meaning of the Term ''Calibrate'' When Referring to Timer Accuracy and Linearity?

Comment. Commenters requested the meaning of ''calibrate'' when referencing timer accuracy and linearity. The commenters suggested that, if the purpose is to measure these items to assure they are within some tolerance, this purpose should be stated in the regulation.

Response. Procedures for calibrating the timer are provided in various protocols, which include tolerances. Examples include ANSI N449 and N449–1, and AAPM TG–40. The term calibrate, as used in this context, means to perform measurements to assure that the timer is operating appropriately within a given tolerance. The tolerances may be found in reports such as AAPM TG–40. As stated in this regulation, the measurements must be performed in accordance with procedures established by the AMP. The licensee is therefore given flexibility in developing its spot-check methods.

Issue 2: Were There Any Changes Made in This Section Between the Proposed and Final Rule?

Response. Yes. Paragraph (f) was revised to add a reference to the procedures required by paragraph (b).

Section 35.643, Periodic Spot-Checks for Remote Afterloader Units

Issue 1: Is an Output Spot-Check Necessary?

Comment. Commenters requested deletion of the output spot-check because output is calibrated at installation and by the manufacturer, thereby satisfying all the requirements for assuring correct dosimetry and administration. A commenter also suggested that a requirement to determine the output with a dosimetry system described in § 35.630(b) be included.

Response. The NRC agrees that the full calibration output measurements are adequate. Therefore, we have deleted the proposed output spot-check requirement. We believe that a quarterly test for HDR, MDR, and PDR source output and an annual test of LDR source output are sufficient to ensure that the correct dose is delivered to the patient. In the place of the output check, we have included a requirement to check the computer decayed source activity against a precalculated decay chart to confirm that the unit has decayed the source activity properly. The output checks done in accordance with § 35.633 continue to require the use of an appropriate dosimetry system, described in § 35.630, when performing the output calibration.

Issue 2: How Frequently Should Spot-Checks Be Performed?

Comment. Some commenters suggested that the spot-checks be done each day of use, thereby insuring patient safety and not duplicating weekly checks. A commenter requested that the term ''beginning of each day of use'' be revised to ''prior to the use of the device on a given day.'' Another commenter suggested that the frequencies provided in NUREG/CR–6276, ''Quality Management in Remote Afterloading Brachytherapy'', should be used. With regard to timer constancy, a commenter felt that a monthly check was adequate for LDR units.

Response. The regulation has been amended to state ''before the first use of an HDR, MDR, or PDR unit on a given day.'' The NRC developed the frequency of the spot-checks from recommendations of AAPM TG–40 and TG–56, meetings with medical physicists, input from the Therapy Subcommittee of the ACMUI, and NUREG/CR–6276. Therefore, we believe that the frequencies of the spot-checks are appropriate.

Issue 3: What Is the Meaning of the Term ''Calibrate'' When Referring to Timer Constancy/Accuracy and Linearity?

Comment. A commenter requested that timer constancy be deleted because it is not a credible source of risk to the patient with the current timer technology. The commenter stated that this is verified at installation and needs no further monitoring. Commenters also requested the meaning of ''calibrate'' when referencing timer accuracy and linearity. The commenters suggested that, if the purpose is to measure these items to assure they are within some tolerance, this purpose should be stated in the regulation.

Response. The terminology used in this section was chosen to reflect the current language used in practice. AAPM reports use the terminology ''timer accuracy and linearity.'' The

term calibrate, as used in this context, means to perform measurements to assure that the timer is operating appropriately within a given tolerance. The tolerances may be found in reports such as AAPM TG–40. As stated in this regulation, the measurements must be performed in accordance with procedures established by the AMP. The licensee is given flexibility in developing its spot-check methods. The NRC has also retained timer checks because they are recommended by the AAPM and are similar to ANSI requirements for teletherapy units. Spot-checks of timer linearity are not required by this section because we believe that timer linearity for remote afterloaders needs only to be measured during full calibration measurements.

Issue 4: Why Must Nonexistent Source Exposure Indicator Lights Be Checked?

Comment. A commenter suggested that checks of source exposure indicator lights be deleted because these lights do not exist on a remote afterloader unit.

Response. The NRC is unaware of any remote afterloader units that do not have source exposure indicator lights. Source position indicator light checks are recommended by the AAPM and are similar to ANSI requirements for teletherapy units. Therefore, these requirements have been retained in the final rule.

Issue 5: Is It Necessary To Perform a Simulated Cycle of Treatment?

Comment. A commenter suggested that the requirement to conduct a simulated cycle of treatment should be deleted because it is vague and will not necessarily provide any higher level of assurance that the remote afterloader unit is working properly than the daily and monthly checks already performed.

Response. The NRC agrees with this comment and has deleted this requirement.

Issue 6: Does a Treatment System Have To Be Locked-Out if the System Fails Safety Tests, But a Backup System Is Available?

Comment. A commenter suggested that the NRC change the wording in this section to be more flexible. The commenter stated that, in some instances, a backup device may be available that will allow patient treatments to continue without compromising patient safety.

Response. This section does not prohibit the use of the unit if the licensee replaces the malfunctioning system before using the unit for treatment. Additionally, the requirement to arrange for prompt repair of a system has been deleted from this section. The NRC believes that the requirement to lock the control console in the off position and not use the unit until repaired is sufficient.

Issue 7: Should Door Interlocks and Audiovisual Systems Apply to LDR Units?

Comment. The NRC solicited specific comment as to whether the requirements for electrical interlocks and audiovisual systems should apply to low dose-rate remote afterloader units. Some commenters felt that LDR units may not require interlocks or audiovisual systems, depending on the dose rate and whether sources are gamma-emitters only. One commenter suggested that we always require interlocks, but require an audiovisual system only when direct visual contact is not available. Another commenter felt that we should always require interlocks and an audiovisual system for LDR units.

Response. The NRC amended the title of this subpart to clarify that it only applies to photon-emitting units. We have retained the requirements for interlocks for LDR units because they are consistent with recommendations in AAPM reports. We have not included a requirement for an audiovisual system for an LDR.

Issue 8: Were There Any Changes Made in This Section Between the Proposed and Final Rule?

Response. Yes. Paragraph (f) was revised to add a reference to the procedures required by paragraph (b).

Section 35.645, Periodic Spot-checks for Gamma Stereotactic Radiosurgery Units

Issue 1: How Frequently Should Spot-Checks Be Performed?

Comment. A commenter suggested that the requirement for monthly checks be deleted if spot-checks are performed daily. A commenter specified that the term ''beginning of each day of use'' be revised to ''prior to the use of the device on a given day.'' Another commenter suggested that the frequencies provided in NUREG/CR–6324 should be used. Other commenters said that: (1) A daily output measurement was not necessary as long as the user checks the mechanical integrity of the system through a standard run; and (2) the manufacturer recommends that the battery backup system only be tested on a monthly basis.

Response. The regulation has been amended to state ''before first use of the unit on a given day.'' The NRC developed the frequency of the spot-checks from recommendations of AAPM Report No. 54, meetings with medical physicists, input from the Therapy Subcommittee of the ACMUI, and NUREG/CR–6324, ''Quality Assurance for Gamma Knives.'' We believe that the final rule distinguishes between the checks that must be done daily or monthly. Additionally, the final rule only requires output checks and battery backup checks monthly. Therefore, we believe that the frequencies of the spot-checks are appropriate.

Issue 2: Define ''Assure Proper Operation of Stereotactic Frames and Localizing Devices?''

Comment. A commenter requested that we clarify what is meant by ''assure proper operation of stereotactic frames and localizing devices.''

Response. Various professional reports provide suggested protocols for quality assurance tests on gamma stereotactic radiosurgery units. For instance, reports from AAPM, ACR, ACMP, and ANSI may be used by the licensee in performance of these tests. The phrase ''assure proper operation of stereotactic frames and localizing devices'' means to perform quality assurance tests on these devices to assure that they operate appropriately when used to deliver a dose to a patient. The measurements must be performed in accordance with procedures established by the AMP. The licensee is, therefore, given flexibility in developing its spot-check methods.

Issue 3: What Is the Meaning of the Term ''Calibrate'' When Referring to Timer Accuracy and Linearity?

Comment. Commenters requested the meaning of ''calibrate'' when referencing timer accuracy and linearity. The commenters suggested that, if the purpose is to measure these items to assure they are within some tolerance, this purpose should be stated in the regulation.

Response. The terminology used in this section reflects the current language used in practice. AAPM reports use ''timer accuracy and linearity.'' The term calibrate, as used in this context, means to perform measurements to assure that the timer is operating appropriately within a given tolerance. The tolerances may be found in reports such as AAPM TG–40 The measurements must be performed in accordance with procedures established by the AMP. Therefore, the licensee is given flexibility in developing its spot-check methods.

Issue 4: Were There Any Other Changes Made in This Section Between the Proposed and Final Rule?

Response. Yes. The NRC deleted the requirement to check the hydraulic cutoff mechanism because we believe that checking the hydraulic backup system monthly is sufficient.

We revised the regulatory text to make the spot-checks, and associated corrective actions, consistent with the requirements in §§ 35.642 and 35.643. Paragraph (b)(1) requires that licensees perform spot-checks in accordance with written procedures established by the AMP. Paragraph (b)(2) requires that the AMP review the results of the spot-checks within 15 days and notify the licensee as soon as possible in writing of the results of the spot-checks.

Paragraph (g) was revised to add a reference to the procedures required by paragraph (b).

Section 35.647, Additional Technical Requirements for Mobile Remote Afterloader Units

Issue 1: What Are the Requirements for Discontinuing Use of a Malfunctioning Unit?

Comment. A commenter noted that this section did not contain a requirement for discontinuation of use of a malfunctioning unit and questioned whether this was an oversight.

Response. The NRC agrees with this comment. We believe that a licensee using a mobile unit must also meet the requirements described in other sections of this subpart applicable to the particular device in use. However, for clarification, we added language that prohibits the use of the unit if a safety check is failed. Paragraph (d) now reads: ''If the results of the checks required in paragraph (b) of this section indicate the malfunction of any system, a licensee shall lock the control console in the off position and not use the unit except as may be necessary to repair, replace, or check the malfunctioning system.''

Issue 2: Were There Any Other Changes Made in This Section Between the Proposed and Final Rule?

Response. Yes. Consistent with the terminology used in § 35.633, ''connectors'' was revised to ''source transfer tubes, and transfer tube-applicator interfaces.''

Section 35.652, Radiation Surveys

Issue 1: Are These Surveys Limited to Therapy Units?

Comment. A commenter questioned whether the surveys required by this section were only for therapy devices or if they included other instruments or devices used at medical facilities.

Response. The requirements of Part 35 apply only to medical uses of byproduct material. The requirements in this section apply to licenses issued for uses in this subpart. Therefore, these requirements do not include sealed sources covered by other subparts (e.g., Subparts F and G). The NRC added the phrase ''licensed under this subpart'' to this section to clarify this issue.

Issue 2: Why Do Radiation Levels Around Devices Differ?

Comment. Commenters suggested that the maximum radiation levels and average radiation levels around devices could be made a generic number, as with radiography cameras and source changers. They also suggested that it may make sense to put in the average acceptable reading for each type of afterloader unit (i.e., high dose-rate, low dose-rate, and pulsed dose-rate units).

Response. The radiation levels referenced in the SSDR differ greatly by device manufacturer. Therefore, the NRC retained the requirement in paragraph (a) of this section ''to ensure that the maximum radiation levels and average radiation levels from the surface of the main source safe with the source(s) in the shielded position do not exceed the levels stated in the Sealed Source and Device Registry.''

Section 35.657, Therapy-Related Computer Systems

Issue 1: What Is the Purpose of Acceptance Testing on Computer Operating Systems?

Comment. Commenters felt that acceptance testing of computer operating systems should be deleted because no method could guarantee that software would always operate appropriately. A commenter also said that this requirement should be deleted because it appears to be a year 2000 concern with operating systems.

Response. The NRC agrees with these concerns and has deleted the requirement to verify operability of computerized operating systems. This concern is addressed by the FDA's regulations of medical devices, which require reliability testing on computerized operating systems.

Issue 2: Should Acceptance Testing of Treatment Planning Systems Be a Requirement?

Comment. Commenters believed that the requirement for treatment planning system acceptance testing was warranted. However, they suggested that the methodology for acceptance testing should be left to the licensee. The commenters also questioned the ability to guarantee that the systems are operating appropriately and questioned our interest in the device operating system that is reviewed by the FDA.

Response. Paragraph (a) of this section in the proposed rule would have required the licensee to verify that the computerized operating system and treatment planning system are operating appropriately. Based on these comments, FDA's review of reliability testing on medical devices, and the device's associated computer operating systems, the NRC deleted these requirements from the final rule.

We agree with commenters that treatment planning system acceptance testing is warranted. Therefore, the requirement to perform acceptance testing on treatment planning systems has been retained. We believe that this requirement is appropriate and still provides the licensee flexibility in designing its acceptance testing program. We amended the regulation to incorporate the components of acceptance testing addressed in AAPM TG–56. The licensee is provided flexibility in performing acceptance testing of treatment planning systems as long as a published protocol accepted by a nationally recognized body is used and as long as the minimum testing requirements are met.

Section 35.690, Training for use of Remote Afterloader Units, Teletherapy Units, and Gamma Stereotactic Radiosurgery Units

Issue 1: Were There Any Changes Made in This Section Between the Proposed and Final Rules?

*Response.*Yes. The NRC revised paragraph (b)(3) to read ''an authorized user of each type of therapeutic unit for which the individual is requesting authorized user status.'' This change clarifies that the preceptor authorized user must certify that the individual has achieved a level of competency sufficient to function independently as an authorized user for each type of unit for which the individual would like authorized user status. However, this does not mean that the individual has to satisfy paragraphs (b)(1) and (b)(2) in their entirety for each type of unit, e.g., an individual does not need 1400 hours in a structured educational program if he or she wants to be an AU for two types of units under § 35.690.

In paragraph (b)(3) we also clarified that the preceptor AU must be an AU for each type of unit for which he or she is a preceptor.

General comments on this section are summarized under the General Training topic found at the beginning of this section.

Subpart J—Training and Experience Requirements

Issue 1: Why are There Two Sets of Training and Experience Requirements in the Revised Part 35?

Comment. One commenter noted that much of Subpart J is redundant with, but not identical to, the training and experience requirements listed in the individual sections of the other subparts. The training and experience requirements should be identical if they are included in 2 subparts within the same part, or they should only be listed once in the part.

Response. The NRC believes that Subpart J should be retained for a 2-year transition period as stated in the proposed rule (63 FR 43516; August 13, 1998). The issue of recognition of medical and other specialty boards was discussed during an ACMUI briefing of the Commission on February 19, 2002. In that meeting, two committee members expressed concern that some boards did not qualify for recognition and may not be ready to apply for recognition within 6 months after publication of the final rule. Therefore, implementation of the new Part 35, without Subpart J, could disrupt the current license authorization process for new medical personnel because many license authorizations are granted based on recognition of board certification. The Commission has considered this matter, and decided to retain the current training requirements in Subpart J for a 2-year period after the effective date of the final rule. As stated in Section IX, Implementation, during that 2-year period, licensees will have the option of complying with either the requirements of Subpart J or the requirements in Subparts B and D–H. During this transition period, the NRC will continue working with the ACMUI and the medical community to resolve any concerns with the training and experience requirements.

The Commission will consider changes to the training and experience requirements, as appropriate.

Individuals who have status as AUs, AMPs, ANPs, and RSOs at the time the rule becomes effective will be ''grandfathered'' under § 35.57, and will not have to satisfy the new training and experience requirements. For additional information on the ''deemed status'' of individuals when the final rule becomes effective refer to the general discussion of the training and experience requirements at the beginning of this section.

Issue 2: Why Were the Lists of Certifying Medical Boards in Subpart J of the Current Part 35 Not Updated During the Rulemaking to Include Other Medical Specialty Boards and Other Subspecialties?

Comment. Several commenters noted that there are other medical specialty boards and other subspecialties that should be added to the lists of certifying boards in Subpart J.

Response. The suggested updates were not made in the final rule because Subpart J will be retained for 2 years after the effective date of the final rule and there are no lists of certifying specialty boards in the new training and experience requirements in Subparts B and D through H of Part 35. Under the new regulations, the NRC will continue to review the appropriate training and experience requirements of the boards and recognize the boards that satisfy these requirements. However, we will provide the lists of recognized boards in a public document (e.g., on NRC's Internet site <www.nrc.gov>), rather than in the regulations. Before the effective date of the final rule, we encourage the certifying boards to submit their applications for recognition under the new regulations. However, the licensees will have 2 years after the effective date of the final rule to comply with the new requirements. For additional information on the recognition of specialty boards refer to the general discussion of the training and experience requirements at the beginning of this section.

Issue 3: Why Have the References to ACGME programs been retained in Subpart J?

Comment. Several commenters said that all references to ACGME programs of less than 2 years should be deleted.

Response. The NRC deleted the references to ACGME programs of less than 2 years.

Issue 4: Why Are There No Training Requirements for Endovascular Brachytherapy in Subpart J?

Comment. One commenter noted that Subpart J includes no training requirements for endovascular brachytherapy.

Response. The NRC will delete Subpart J 2 years after the effective date of the final rule. When the research on endovascular brachytherapy is completed, the standard protocol for this technology will be evaluated to determine if it is similar to the modalities currently licensed under Part 35 or if it should be licensed as an emerging technology under § 35.1000. Following this determination, the training and experience requirements for this modality will be evaluated to see if new requirements are needed for this use or if it should continue to be regulated as a sealed source therapy.

Section 35.981, Training for Experienced Nuclear Pharmacists

Issue 1: What is the Impact of Deleting This Section?

Comment. All of the commenters that responded to this question, which the NRC asked in the proposed rule, said that this section could be deleted because the requirements in § 35.57 for an experienced nuclear pharmacist are adequate.

Response. This section will be deleted, along with the other sections of Subpart J, 2 years after the effective date of the final rule.

Subpart K—Other Medical Uses of Byproduct Material or Radiation From Byproduct Material

Section 35.1000, Other Medical Uses of Byproduct Material or Radiation From Byproduct Material

Issue 1: What Is the Purpose and Scope of This Section?

Comment. There were a number of general comments on this section. Comments ranged from an endorsement of the need for this section to concerns that NRC's regulations for emerging technologies will limit the use of new technologies and radiopharmaceuticals and, consequently, affect the delivery of high quality health care.

Some commenters believed that the purpose of this section is vague, undefined, and confusing, and that there needs to be a clearer definition of an emerging technology. One suggestion was that the definition be tied to whether an IND/IRB approval is required. Another commenter said that this section should specifically exempt radiopharmaceuticals because they are regulated by the FDA under RDRC, new drug applications (NDA), biologic product license applications (PLA), and INDs. Thus, all radiopharmaceuticals should fit under Subpart D or E.

One commenter said that emerging technology uses should be reviewed on a case-by-case basis to determine their proper location in the regulations. The commenter proposed a process to determine how an emerging technology should be regulated: propose performance-based regulations for a 90-day comment period; locate the regulations in a separate subpart; and

establish that any technology placed in this subpart would have a 5–7 year sunset period at which time the regulations for this technology would be relocated in another appropriate subpart. This process would provide the opportunity for the technology to establish itself and allow the regulations to be amended, based on observed risk.

Response. The NRC added Subpart K to Part 35 so that there would be codified regulatory requirements and a more clearly defined process to obtain a license, or a license amendment, for a new medical use of byproduct material or radiation from byproduct material, i.e., an emerging technology. By adding requirements for emerging technologies to the regulations in §§ 35.12(d) and 35.1000, an applicant for a medical use that does not fit the regulatory requirements for another subpart knows the type of information to submit to NRC.

The scope of this subpart includes all new medical uses of byproduct material or radiation from byproduct material. We have not attempted to define what is included in this subpart or what is excluded from this subpart more clearly because there is no way to predict what types of medical technologies will be developed in the future. The Commission, with input from the ACMUI, as requested, will determine if the emerging technology is truly a new technology and is covered by Subpart K, or if the ''new'' technology is actually a type of use regulated under Subparts D through H.

Issue 2: What Process Will Be Used to Establish Regulatory Requirements and Evaluate Applications for Emerging Technologies?

Comment. Commenters stated that it is important to have a reasonable regulatory scheme and time frame for approving applications for new technologies. Some commenters expressed concerns about placing so much regulatory burden (e.g., too many safety constraints) on new technologies that there is an impact on the development of new products.

Emerging technologies have an undefined risk. Once the risk becomes clear, the degree of regulation that is needed to minimize the risks to the public can be defined. The NRC might be interested in the design of trials involving emerging technologies, and what kind of data are collected, in order to define the risks from emerging technologies.

A model was suggested for establishing the requirements for emerging technologies. Under the suggested model, appropriate professional societies would establish task forces to examine the issues (e.g., the training requirements) associated with the emerging technology. This model was successful in defining the standards for gamma stereotactic radiosurgery in the late 1980's when it was considered an emerging technology.

Response. The NRC agrees with these comments and will take them into consideration in setting up the process for establishing regulatory requirements and for approving applications for emerging technologies. We intend to evaluate each technology on a case-by-case basis and to work with the ACMUI, the medical community, the public, and the developers of the new technology, as appropriate, to determine the specific risks associated with the technology and any additional regulatory requirements for the medical use of the technology.

Issue 3. Will the NRC Coordinate its Regulations for Emerging Technologies With the FDA's Regulations?

Comment. One commenter has observed that the FDA process works well in addressing patient safety for investigational new drugs and devices. This commenter suggested that the NRC communicate its concerns to the FDA to assure that any radiation safety issues will be included and documented in the investigational research process.

Response. The NRC does not intend to develop requirements that are redundant with those of the FDA. FDA and NRC have different authorities and responsibilities for protection of public health and safety; FDA has the authority to approve investigational new drugs and devices; and NRC has the authority to protect the public, workers, and patients from the medical use of byproduct material. However, we have a ''Memorandum of Understanding'' with FDA under which we coordinate certain agency functions and share information (58 FR 47300; September 8, 1993 and 62 FR 15740; April 2, 1997, renewal).

Issue 4: Why Does This Section Not Include Training and Experience Requirements for AUs of Emerging Technologies?

Comment. Several commenters said that this section should provide the minimum criteria and training requirements for AUs of these new medical uses. The qualifications of individuals to use emerging technologies are pretty well established by the developers of the emerging technology, and they are aware of the radiation safety problems associated with the new technology. Whether it is an emerging technology or not, there is a need to understand the properties and hazards of the radioactive material being used, the radiobiological issues, and the measures to be taken in the event of a spill, and to demonstrate the ability to safely handle the radioactive material.

Response. Section 35.1000 does not include any training and experience requirements for AUs of emerging technologies because there is no way of knowing what training requirements will be necessary for the safe use of byproduct material in new technologies. Applicants are required by § 35.12(b) to provide the training and experience for the AU, ANP, or AMP, as appropriate, to the NRC. The training and experience will be evaluated on a case-by-case basis with input from the ACMUI and individuals who have been involved with development of the technology, as needed, and other input, as appropriate.

Issue 5: Will Cost Issues Be Considered During the Development of Requirements for Emerging Technologies?

Comment. Comments were provided on several different cost issues. One commenter said that it is very difficult to spend millions of dollars on clinical research on new technologies and have no idea what the regulatory requirements are going to be. Another commenter said that cost effectiveness needs to be considered during the development of requirements for new technologies. For example, a requirement to have multiple professionals present during a procedure would not only increase the cost of the procedure, but would also limit its availability to patients.

Response. Licensing requirements for emerging technologies will be based on the risk posed by the specific modality and when possible licensing requirements will be modeled on other medical uses with similar risk. In order for new or revised requirements to be codified in Part 35, a public rulemaking process under the Administrative Procedure Act must be followed including the development of a cost-benefit analysis made available for public comment.

Issue 6: Will Intravascular Brachytherapy Be Considered an Emerging Technology in the Revised Part 35?

Comment. Some commenters believe that intravascular brachytherapy is still experimental and covered by § 35.6 and need not be considered in § 35.1000. Other commenters believe that intravascular brachytherapy should be categorized, or specifically mentioned, as an emerging technology under the provisions described in § 35.1000.

One commenter stated that in the proposed rule the standard use of radioisotopes in patients in the field of cardiology was reclassified as experimental and cardiologists had become radiation oncologists.

Response. Section 35.6 contains some specific provisions for protection of human research subjects and does not permit the use of byproduct material for medical uses that are not authorized on the licensee's medical use license. Intravascular brachytherapy is a very complex field with a number of methodologies and radionuclides being evaluated for use. Currently, the NRC is regulating intravascular brachytherapy as a sealed source therapy. Because no single standard protocol for intravascular brachytherapy has been established, the Commission, with input from the ACMUI, the medical community, and the public, will review the technology in light of that protocol to determine if new regulatory requirements are needed for this use. Pending development of those regulatory requirements, an applicant will be able to submit a license application or amendment request, under the provisions of §§ 35.12 and 35.1000, to incorporate the new modality into their licensed program.

Issue 7. What Are the Training and Experience and Radiation Safety Requirements for Intravascular Brachytherapy?

Comment. Some commenters felt that intravascular brachytherapy should have the same training and radiation safety requirements as the rest of radiation oncology. Other commenters felt that the training and radiation safety requirements for nuclear cardiology should be reserved until the technology advances enough to develop standard protocols with the assistance of a group of experts. Still other commenters stated that the NRC should develop the training and safety requirements for intravascular brachytherapy.

Response. As we noted in Issue 6, intravascular brachytherapy is currently an evolving medical treatment composed of diverse technologies. Currently, the NRC is regulating intravascular brachytherapy as a sealed source therapy with the associated training and experience requirements for that therapy. The types of sources used vary widely in terms of the type of radiation emitted, the activity, and the level of encapsulation. In fact, intravascular brachytherapy may not evolve into either a standard protocol or a single modality. Pending receipt of additional information, we believe that it is too early to make changes in the level of training and experience for the use of intravascular brachytherapy.

Issue 8: Were There Any Other Changes Made in This Section Between the Proposed and Final Rules?

Response: Yes. The NRC corrected the wording in paragraph (a) to state that the information that is required to be submitted by an applicant for use of byproduct material under § 35.1000 is in § 35.12(b) through (d), not only in paragraphs (b) and (c).

We amended the wording in paragraph (b) to reflect a change in § 35.12(d) that allows licensees to submit an application for a license amendment, rather than an application for a separate license, for use of byproduct material under § 35.1000. This change is discussed under § 35.12.

Subpart L—Records

Issue 1: Should All the Recordkeeping Requirements Be Grouped Into One Subpart or Should They be Incorporated Into the Section Requiring the Record?

Comment. Commenters provided a wide range of responses to the Commission's question on whether all of the recordkeeping requirements should be grouped into one subpart, or whether they should be incorporated into the individual sections requiring the records. Some commenters favored having all of the recordkeeping requirements in one subpart because this format provides for easy reference, simplifies licensing, assists licensees in meeting their obligations for the radiation safety program, and simplifies compliance. Other commenters favored having the recordkeeping requirements in the individual sections because this format would place all of the requirements pertaining to a particular area of interest in one section. Therefore, licensees would know exactly what was expected of them in a particular area. They also find the similar separation in 10 CFR Part 20 to be confusing. Several commenters preferred a ''balanced approach'' in which the recordkeeping requirements would be in the individual sections and then all of the requirements would be summarized in a separate subpart.

Response. After reviewing all of the responses to this question, the NRC concluded that having all of the recordkeeping requirements in one subpart makes it easier for licensees to reference these requirements. However, the final rule is consistent with the ''balanced approach'' because each section in the final rule that is associated with a recordkeeping requirement includes a cross-reference to the specific recordkeeping requirements in Subpart L.

Issue 2: Are All of the Recordkeeping Requirements in Part 35 Needed?

Comment. Comments on the need for the recordkeeping requirements in Part 35 ranged from all of the records are needed; to the only records that are needed are those that document overexposures, exceeding environmental limits, and leaking sources; to the only records that should be required are those that have a documented history of improving radiation safety; to none of the records are needed.

Response. During preparation of the final rule, each specific recordkeeping requirement was reviewed in light of these comments and changes were made, where appropriate. These changes are noted in the discussions of the individual recordkeeping sections.

Issue 3: Are the Recordkeeping Requirements too Prescriptive?

Comment. The recordkeeping requirements in the proposed revision maintain the detailed, prescriptive elements that are in the current Part 35.

Response. All of the elements in the recordkeeping requirements in the proposed rule were considered important for documenting radiation safety issues associated with a more risk-informed regulation. During preparation of the final rule, the NRC reviewed each recordkeeping requirement in light of this comment and made appropriate changes.

Issue 4: Why Are There Different Retention Periods for the Records Required by This Subpart?

Comment. One commenter said that compliance with NRC's recordkeeping requirements would be simplified if all of the record retention periods were the same. Another commenter suggested that because most of the records have a retention period of 3 years, it would make more sense to include a separate section that states that all of the records in this subpart are to be maintained for 3 years, unless otherwise stated, than to restate the retention period in each section.

Response. The record retention periods in Part 35 were set according to either the safety significance of the action being recorded or the inspection frequency. As a result, there are several different retention periods for records in Subpart L. Because record retention periods are tied to safety considerations, the NRC believes that the regulations should specifically state the retention period for each recordkeeping

requirement even if it means repeating regulatory text.

Issue 5: How Can a Patient's Privacy and Confidentiality be Protected in Records Required by NRC?

Comment. A comment received stated that the patient's privacy and confidentiality are ''ignored'' with NRC recordkeeping requirements for records of the patient's name, social security number, and other personal information.

Response. Any records that must include the patient's name or personal information relating to the patient are to be retained by the licensee. Reports relating to medical events, which licensees provide to the NRC, explicitly must not contain the individual's name or any other information that could lead to identification of the individual.

Issue 6: Can Initials Be Used on a Record To Identify the Individual Who Performs an Activity or an Operation?

Comment. The requirement to record the ''name of the individual'' that performed a certain activity appears throughout this subpart. Several commenters said that because it is common practice to utilize initials as identifiers of individuals, the words ''name of the individual'' should be replaced with ''identification of the individual.''

Response. The NRC requires that the full name of an individual appear on a record to better ensure future identification of the individual who performed the activity or operation. It is not uncommon for several individuals to have different names, but the same initials. Also, initials are more likely to be illegibly scribbled.

Issue 7: Why Do Some Records Require a Signature, Rather Than the Name of the Individual?

Comment. Several commenters said that requiring a signature on a record is prescriptive, not performance based, and does not necessarily mean that an individual has actually read or reviewed a record.

Response. The NRC has required signatures only on those records where we feel it is important to the radiation safety program to document who approved the action, reviewed the report, performed the calibration, etc. If an individual signs a record saying, for example, that he or she performed an action, we assume that the individual actually did perform whatever action was required and is in compliance with the recordkeeping requirements in this part. Note that most of the recordkeeping requirements in Subpart L require the name of the individual, rather than a signature.

Issue 8: Do the Recordkeeping Requirements in Part 35 Allow for the Use of Electronic Signatures?

Comment. Some commenters were concerned that the requirements for signatures preclude maintaining records electronically.

Response. Section 35.5, Maintenance of records, allows records to be maintained electronically. Therefore, electronic signatures are permitted.

Section 35.2024, Records of Authority and Responsibilities for Radiation Protection Programs

Issue 1: Can the Requirements in This Section Be Made Less Prescriptive and Therefore Less Burdensome on Licensees?

Comment. Several commenters felt that the requirements in this section are too prescriptive and burdensome, especially for private practices with one physician who is also the owner/president and RSO.

Response. The NRC has retained the requirements in this section because we believe that records associated with the authority and responsibilities of the radiation protection program are fundamental to the safe use of byproduct material by all medical licensees, regardless of their size. Even single practice physicians, who may also serve as RSOs, need to be well aware of and to document their authority, duties, and responsibilities associated with being the RSO named on either an NRC or Agreement State license.

Issue 2: Why is It Necessary for Licensees to Retain Records of the Licensee's Management's Written Approval of Actions Associated With the Radiation Protection Program for 5 Years?

Comment. One commenter said that the requirement in paragraph (a) of this section to retain records for 5 years is excessive.

Response. The NRC considers the records required by paragraph (a) of this section to be important in documenting actions taken by the licensee's management that affect its radiation protection program. These records include requests for a license application, renewal, or amendment; approval of AUs, AMPs, and ANPs; and radiation protection program changes that do not require a license amendment. The 5-year retention period will ensure that the records that are key to a licensee's radiation protection program are available for review during inspection of medical use licensees. During the development of the proposed rule, we evaluated the retention period for this requirement and changed the retention period from the duration of the license to 5 years. Therefore, the recordkeeping burden for licensees to comply with the requirements in this paragraph is less than the burden to comply with the current rule.

Issue 3: Why is it Necessary for Both Licensee Management and the RSO to Sign the Authorities, Duties, and Responsibilities of the RSO?

Comment. Several commenters said that the requirement in paragraph (b) of this section for both licensee management and the RSO to sign the authorities, duties, and responsibilities of the RSO was too prescriptive. They felt that it was unnecessary to require the signature of both of them because other sections only require one signature or name. One commenter was also concerned that, if a problem occurred, the written agreement could be used by licensee management against the RSO.

Response. The NRC retained the requirement for signatures of both licensee management and the RSO because we believe it is important that there is a signed record of what the licensee management and the RSO agree are the authorities, duties, and responsibilities of the RSO. If both the licensee management and the RSO have a clear understanding of the responsibilities of the RSO for the licensee's radiation protection program, problems such as that referred to in the comment could be avoided. We explicitly state in this section that the signed document, as required by § 35.24 (b), and the responsibilities of the Radiation Safety Officer, as required by § 35.24 (e), must be retained for the duration of the license. This retention period is identical to the retention period specified in § 30.51(b), which would otherwise apply. However, without this explicit statement in Part 35, the licensee would have to reference the general recordkeeping provisions in § 30.51 for the record retention period.

Section 35.2026, Records of Radiation Protection Program Changes

Issue 1: Why is There a Requirement for Retaining Records of Changes to a Licensee's Radiation Protection Program that ''Do Not Reduce Safety,'' and Why Must These Records Be Signed by Licensee Management?

Comment. Commenters said that it is excessive and unnecessary to retain

records of radiation protection program changes that do not reduce safety. In addition, the commenters believed that it is unnecessary to have licensee management sign the records of radiation protection program changes that had already been reviewed and signed by the RSO, the licensee's radiation safety expert.

Response. Licensees are required to obtain Commission approval for changes in their radiation protection program, except for the revisions authorized by § 35.26. Because licensees are not required to submit these latter changes to NRC for approval, the records of the changes made in accordance with § 35.26 provide the Commission an opportunity to evaluate these changes during the inspection process. The NRC believes that this approach is warranted in light of the importance of changes in a licensee's radiation protection program.

The reference in proposed § 35.26(a)(2) to changes that ''do not reduce radiation safety'' resulted in many comments that this phrase was ''ambiguous'' and ''subjective.'' The proposed wording was intended to provide the licensee with as much flexibility as possible in making changes in its radiation protection program, without seeking Commission approval. However, because commenters felt that the proposed wording was not clear, we revised the text of paragraph (a)(2) to state the more objective parameter of changes that are ''in compliance with the regulations and the license.''

We have deleted the requirement in § 35.2026 for the RSO to sign the records of radiation protection program changes because licensee management is ultimately responsible for the radiation protection program. Therefore, the final rule includes a requirement for licensee management to sign these records.

Issue 2: Can the Requirements in This Section Be Made Less Prescriptive and Therefore Less Burdensome on Licensees?

Comment. Several commenters noted that the recordkeeping requirements in this section are quite prescriptive and suggested that the sentence with the list of items that must be included in the records be deleted or revised to be less prescriptive.

Response. The NRC believes that the recordkeeping requirements in this section are needed to document what changes have been made in the licensee's radiation protection program. We considered the burden on licensees during development of the final requirements for this section and believe that the requirements for radiation protection changes, and the associated records, provide the licensee more flexibility to manage its radiation protection program than in the current rule and reduce the recordkeeping burden on licensees. For example, licensees must currently retain a record of each radiation protection change until the license has been renewed or terminated. Under the final rule, licensees are only required to retain these records for 5 years.

Issue 3: Why Are Licensees Required To Retain a Copy of the Old Radiation Protection Procedures?

Comment. One commenter questioned the need to retain a copy of the old radiation protection procedures because they are immaterial to the current procedures and could be confusing to workers.

Response. The NRC believes that licensees should retain a copy of their old radiation protection procedures for 5 years so that they are available during the licensee's next inspection after the procedures were changed. If a ''problem'' or ''event'' is discovered during an inspection, the radiation protection procedures that were in place at the time of the event may be very useful in determining the cause of the event.

We suggest retaining the copy of the old radiation protection procedures in the licensee's filing system so that they are not readily available for workers to refer to by mistake.

Issue 4. Were There Any Other Changes Made In This Section Between the Proposed and Final Rules?

Response. Yes. The word ''safety'' was removed from the title of this section. This change has been made to correct an inconsistency between the regulatory text in this recordkeeping section and the corresponding § 35.26, Radiation protection program changes.

Section 35.2040, Records of Written Directives

Issue 1: Is There a Need for an NRC Requirement to Retain a Copy of Written Directives for Therapeutic Administrations of Unsealed Byproduct Material?

Comment. One commenter said that the requirement for retaining a copy of written directives should exempt radiopharmaceuticals because state laws already require retention of prescription records.

Response. Section 35.40, Written directives, contains a list of items that must be included in a written directive and requires that an AU sign and date the written directive before administration of sodium iodide I–131 greater than 1.11 MBq (30 μCi) or any therapeutic dosage of unsealed byproduct material. In other words, this section includes specific requirements for preparing written directives before administering higher dosages of unsealed byproduct material. Prescriptions for radiopharmaceuticals may or may not be signed by AUs and may or may not include all of the items that are required by § 35.40 for written directives for administrations of therapeutic dosages of unsealed byproduct material. The NRC believes that retaining copies of written directives will help ensure that administrations of therapeutic dosages of unsealed byproduct material are in accordance with the written directives. In addition, a copy of the written directive may be useful in evaluating whether a medical event was a result of a generic problem that may also affect other licensees.

Section 35.2041, Records for Procedures for Administrations Requiring a Written Directive

Issue 1: Were There Any Changes Made in This Section Between the Proposed and Final Rule?

Response. Yes. This section was added to the final rule. We explicitly state in this section that the procedures required in § 35.41 (a) must be retained for the duration of the license. This retention period is identical to the retention period specified in § 30.51(b), which would otherwise apply. However, without this explicit statement in Part 35, the licensee would have to reference the general recordkeeping provisions in § 30.51 for the record retention period.

Section 35.2045, Records of Medical Events

Issue 1: Can the Requirements in This Recordkeeping Section Be Made Less Prescriptive and Therefore Less Burdensome on Licensees?

Comment. One commenter noted that the recordkeeping requirements in this section are quite prescriptive and suggested that the list of items that must be included in the records be deleted.

Response. Section 35.2045 has been deleted in the final rule. Since licensees are required to report information about medical events to the NRC under § 35.3045, we believe that it is not necessary to require licensees to retain a record of this information under § 35.2045.

Issue 2: Should There Be a Requirement for Maintaining Records of Significant Precursor Events?

Comment. One commenter opposed the recordkeeping requirement for significant precursor events.

Response. There are no recordkeeping requirements for significant precursor events in the final rule because there are no requirements for reporting precursor events.

Section 35.2060, Records of Calibrations of Instruments Used To Measure the Activity of Unsealed Byproduct Material

Issue 1: Does This Section Address ''Calibrations'' or ''Performance Checks''?

Comment. A commenter recommended that the word ''calibrations'' be replaced with the term ''performance checks'' because the commenter believes that the tests required by the section are more accurately defined as performance checks.

Response. The NRC did not adopt this comment because this section addresses calibration of all instruments used to measure the activity of unsealed byproduct material, including dose calibrators. We believe this is the appropriate term because the term ''calibration'' is commonly used within the radiation protection profession.

Issue 2: Were There Any Other Changes Made in This Section Between the Proposed and Final Rules?

Response. Yes. The NRC changed the title of this section to state more accurately that it addresses the calibration of instruments used to measure the activity of unsealed byproduct material. In addition, we deleted prescriptive requirements from § 35.2060. This change is consistent with the revisions made to § 35.60. The licensee is only required to record the model and serial number of the instrument; the date of the calibration; the results of the calibration; and the name of the individual who performed the calibration. We believe that this information will provide adequate documentation of calibrations of instruments used to measure the activity of unsealed byproduct material.

Section 35.2061, Records of Radiation Survey Instrument Calibrations

Issue 1: Is it Necessary to Keep Instrument Calibration Records?

Comment. Commenters suggested that the requirement to retain records of radiation survey instruments be deleted. Some commenters stated that because the current calibration status and expiration date must be displayed on the instrument, they did not see a benefit to radiation safety by maintaining certificates of calibration. Other commenters stated that this section is already covered in 10 CFR 20.2103.

Response. The NRC believes records of calibration should be kept because they can be used to document that the instrument has been calibrated. This is particularly important when the calibration sticker is unreadable, missing, or in error or when an instrument that was used in a required survey cannot be located. Section 20.2103 requires that licensees maintain records of calibrations but it does not provide specific recordkeeping requirements. Therefore, this section is needed to provide medical use licensees with specific information on what items must be maintained in this record.

Issue 2: Were There Any Other Changes Made In This Section Between the Proposed and Final Rules?

Response. Yes. The NRC amended § 35.2061 to delete the requirements to include the description of the calibration procedure and the source used in calibrating the meter; the certified exposure rates from the source; the rates indicated by the instrument being calibrated; and the correction factors deduced from the calibration data. These changes are consistent with the revisions made to § 35.61. In the final rule, the licensee is required to record the model and serial number of the instrument; the date of the calibration; the results of the calibration; and the name of the individual who performed the calibration. We believe this information will provide adequate documentation of calibrations of radiation survey instruments.

Section 35.2063, Records of Dosages of Unsealed Byproduct Material for Medical Use

Issue 1: Are Records of Administered Dosages of Unsealed Byproduct Material Needed?

Comment. Commenters did not believe this recordkeeping section was needed because prescribing and dispensing records are required by state medical and pharmacy laws. Other commenters did not believe that the recordkeeping requirements should apply to byproduct material administered under §§ 35.100 and 35.200.

Response. The NRC believes that it is important to keep records of the dosages administered. These records are needed to document that the byproduct material was administered to a patient or human research subject in accordance with the written directive and to document the amount of byproduct material that was administered. However, if a licensee keeps the same records to comply with other requirements, the licensee need not retain duplicate records.

Issue 2: Should the Expiration Date of a Radioactive Drug Be Deleted From the Regulations?

Comment. A commenter indicated that the current requirement in § 35.53 to record the expiration date of a radioactive drug should not be deleted from the regulations. The commenter believed the expiration date is important because it can be used, for example, to establish time limits on sterility, dosage, and effectiveness of tagging. The commenter also believed the paperwork burden for including the expiration date is minimal.

Response. The NRC agrees that the expiration date of a radioactive drug is important. However, we believe that licensees have to comply with other regulations governing the use of drugs that include noting the expiration date because it is related to stability and sterility. Therefore, we do not believe that it is necessary to have a requirement in Part 35 for licensees to record the expiration date of a radioactive drug.

Issue 3: Should the Terms ''Prescribed Dosage'' Be Removed From the Requirement?

Comment. A commenter asked that the term ''prescribed dosage'' be deleted from § 35.2063 because there is no requirement for the AU to prescribe the dosage and, in the case of therapeutic administrations, only a written directive is needed.

Response. The NRC has not deleted the term ''prescribed dosage.'' The term is defined in § 35.2. In Part 35, only an AU may direct the administration of sealed or unsealed byproduct material for medical use.

Issue 4: Were There Any Other Changes Made In This Section Between the Proposed and Final Rules?

Response. Yes. The NRC restructured § 35.2063 to match the format used in other recordkeeping sections. We also deleted the requirements for the record to include the radionuclide, generic name, trade name, or abbreviation of the radiopharmaceutical and its lot number. These items were deleted to make the rule less prescriptive. The final rule requires that the licensee record the radiopharmaceutical; patient or human research subject's name, or

identification number, if one has been assigned; the prescribed dosage, the determined dosage, or a notation that the total activity is less than 1.1 MBq (30 μCi); the date and time of the dosage determination; and the name of the individual who determined the dosage. This information will provide adequate documentation of dosage administrations.

Section 35.2067, Records of Leak Tests and Inventory of Sealed Sources and Brachytherapy Sources

Issue 1: Why Should Licensees Maintain Records of Negative Leak Tests?

Comment. A commenter agreed with retention of positive leak test records, but not with the requirement to maintain records of negative tests.

Response. The rule requires records of all leak tests required by § 35.67(b) to show that leak tests were performed. The NRC changed the final rule to require records of the test results, but a licensee has flexibility in how it records the test results. For negative leak tests, a licensee may simply document that the measured activity is ''negative.''

Issue 2: Should This Section Make a Reference to § 35.2406, Records of Brachytherapy Source Inventory?

Comment. A commenter asked that we add a reference which states that additional brachytherapy records may be required by § 35.2406.

Response. The NRC does not believe this reference is needed. We have tried to eliminate redundancy and cross referencing in the rule unless it is needed to make the rule more understandable.

Issue 3: Were There Any Other Changes Made in This Section Between the Proposed and Final Rules?

Response. Yes. The NRC amended the title of this section to state more clearly what type of records are required by this section.

We also deleted the requirements to record the measured activity of each test sample and a description of the method used to measure each test sample in the record. These items were deleted to make the rule less prescriptive.

Section 35.2070, Records of Surveys for Ambient Radiation Exposure Rate

Issue 1: Are Contamination Surveys Included in This Section?

Comment. A commenter indicated that the requirement for records of removable contamination should be deleted because § 35.70 does not require removable contamination surveys.

Response. The commenter is correct. The NRC deleted the requirement for the licensee to record removable contamination in each area (expressed in disintegrations per minute per 100 square centimeters) and the instrument used to analyze the samples. However, the licensee must maintain records to show compliance with ALARA.

Issue 2: Are the Requirements in This Section Already Covered by § 20.2103, Records of Surveys?

Comment. Commenters did not believe this section was needed because radiation surveys are addressed in § 20.2103.

Response. 10 CFR Part 20 contains general provisions on records. Section 20.2103 requires that licensees maintain records of surveys, but it does not provide specific recordkeeping requirements. This section is needed to specify what Part 35 licensees must document in the record required by this section.

Issue 3: Were There Any Other Changes Made in This Section Between the Proposed and Final Rules?

Response. Yes. The NRC deleted the requirements to record a plan of each area surveyed; the trigger level established for each area; and the detected dose rate at several points in each area expressed in millirem per hour or the removable contamination in each area expressed in disintegrations per minute per 100 square centimeters. These items were deleted to make the rule less prescriptive. The final rule requires the licensee to record the date of the survey; the results of the survey; the instrument used to make the survey; and the name of the individual who performed the survey.

Section 35.2075, Records of the Release of Individuals Containing Unsealed Byproduct Material or Implants Containing Byproduct Material

Issue 1: Should Paragraph (b) of This Section That Requires That a Record Be Kept That Instructions Were Provided to a Breast-Feeding Woman Be Deleted?

Comment. A commenter stated that the requirements in paragraph (b) [proposed paragraph (c)] are intrusive into medical practice. The commenter believed that instructions should be left to the physician's judgment.

Response. The NRC did not make any changes in paragraph (b) of the proposed rule which requires licensees to keep a record that instructions, including written instructions, were provided to a breast-feeding female if the radiation dose to the infant or child from continued breast-feeding could result in a total effective dose equivalent exceeding 5 mSv (0.5 rem). This requirement is also in the current Part 35. We believe that providing written instructions to patients or human research subjects is necessary because they may not remember all the oral instructions. In addition, written instructions provide needed information to other family members or individuals who are caring for the patient or human research subject.

The requirement for a licensee to retain a record to demonstrate that instructions were provided to a breast-feeding female is more risk-informed. These records are associated with higher risk administrations of radiopharmaceuticals, e.g., therapeutic administrations of iodine-131.

Issue 2: Were There Any Other Changes Made in This Section Between the Proposed and Final Rules?

Response. Yes. The NRC corrected paragraph (a) of this section because it inadvertently required that licensees maintain records of all releases. This recordkeeping requirement was more restrictive than the current rule. We modified the rule to require records of the release of individuals only when the total effective dose equivalent is calculated by using the retained activity rather than the administered activity; using an occupancy factor less than 0.25 at 1 meter (3.3 feet); using the biological or effective half-life; or considering the shielding by tissue. We also amended paragraph (c) to specify that the records required by both paragraphs (a) and (b) of this section must be maintained for 3 years.

Section 35.2080, Records of Mobile Medical Services

Issue 1: Were There Any Changes Made in This Section Between the Proposed and Final Rules?

Response. Yes. The NRC amended the title of this section to state more clearly what type of records are required by this section.

We also deleted the requirement to record a plan of each area surveyed and the measured dose rate at several points in each area of use expressed in millirem per hour. These items were deleted to make the rule less prescriptive. The final rule requires the licensee to record the date of the survey; the results of the survey; the instrument used to make the survey; and the name of the individual who performed the survey. In addition, we clarified that the letter that permits the use of byproduct material must delineate the authority and responsibility of the licensee and the client.

Section 35.2092, Records of Decay-in-Storage

Issue 1: Are the Requirements in This Section Already Covered by § 20.2103, Records of Surveys?

Comment. Commenters did not believe this section was needed because radiation surveys are addressed in § 20.2103.

Response. 10 CFR Part 20 contains general provisions on records. It does not provide specific recordkeeping requirements for disposal of waste through decay-in-storage. Section 35.2092 is needed to specify what Part 35 licensees must document in the records required by § 35.92.

Issue 2: Were There Any Other Changes Made in This Section Between the Proposed and Final Rules?

Response. Yes. The NRC amended the first sentence to replace the term ''made in accordance with'' with the phrase ''as required by.'' We believe this makes the sentence more readable. We also deleted the requirement to document the name of the radionuclide that was disposed. We do not believe it is necessary for the licensee to document what material was disposed of because § 35.92 no longer requires that the material be held for 10 half-lives. However, this does not preclude the licensee from including this information in the record.

We also amended the requirement so that the record includes the name of the individual who performed the survey, rather than the name of the individual who performed the disposal. We believe that it is important to have a record of the individual who actually surveyed the material and determined that it could be disposed of without regard to its radioactivity.

Section 35.2204, Records of Molybdenum-99 Concentration

Issue 1: Can This Record Be Deleted?

Comment. Commenters suggested that this section, as well as § 35.204, be deleted. They did not believe the rule should require licensees to measure molybdenum-99 concentrations. (See comments on § 35.204.)

Response. The NRC did not delete the requirement for licensees to measure molybdenum-99 concentrations, nor have we deleted the requirement for licensees to maintain a record of the molybdenum-99 concentration tests required by § 35.204. We believe the record is needed to document that the test has been performed and that the results of the test do not exceed the levels specified in § 35.204.

Section 35.2310, Records of Safety Instruction

Issue 1: Is It Necessary To Maintain Records of Safety Instruction Given to Non-Film Badged Workers?

Comment. According to commenters, it is excessive to require licensees to maintain records of training given to non-film badged allied health care workers, who receive instruction in accordance with §§ 35.310, 35.410 or 35.610.

Response. Records of all individuals receiving safety instruction in accordance with §§ 35.310, 35.410 or 35.610 are needed to document that the instruction was provided by the licensee. The NRC believes it is important that the personnel caring for patients or human research subjects who have received radiopharmaceutical therapy (and cannot be released in accordance with § 35.75) receive instruction in limiting radiation exposure to the public or workers and what actions should be taken in the case of a medical emergency or death.

Issue 4: Were There Any Other Changes Made in This Section Between the Proposed and Final Rules?

Response. Yes. The title of this section was changed to correspond to the title of § 35.310, Safety instruction. That section includes the requirement for licensees to retain a record of individuals receiving safety instruction.

Section 35.2404, Records of Surveys After Source Implant and Removal

Issue 1: Is It Necessary To Maintain Records of Negative Surveys? Also, Can the Record Retention Requirement Be Changed from 3 Years to 1 Year?

Comment. Some commenters felt that maintenance of negative surveys for 3 years was excessive and suggested that the survey record include only an indication of the survey being performed and the results of any positive surveys. These same commenters also suggested that the record need only be kept for 1 year.

Response. The NRC simplified the recordkeeping requirements in this section by deleting the requirement to record the location of the survey and the patient identifier. These items were deleted to make the rule less prescriptive. We added a requirement to record ''the results of the survey'' because we do not believe that a requirement to record the results of the survey is excessive, even if the results are that all sources are accounted for. We have also retained the 3-year recordkeeping period to be consistent with the 3-year inspection period for most medical use licensees.

Issue 2: Could the Recordkeeping Requirements of This Section Be Less Prescriptive, Consistent With Providing More Flexibility in Running a Radiation Protection Program?

Comment. A commenter suggested that the contents of the record for radiation surveys be deleted, consistent with providing the licensee flexibility in developing, maintaining, and implementing its radiation protection program. If this cannot be done, the commenter suggested that the ''name of the individual'' be changed to ''the identity of the individual.''

Response. The NRC simplified the recordkeeping requirements in this section by deleting the requirement to record the location of the survey and the patient identifier. As discussed in Issue 6 of the general comments on this subpart, we believe that the full name of an individual must appear on a record to better ensure future identification of the individual who performed the survey.

Issue 3: Were There Any Other Changes Made in This Section Between the Proposed and Final Rules?

Response. Yes. The NRC changed both the title and regulatory text of this section to accommodate changes made in § 35.404, Surveys after source implant and removal. For example, the term ''radiation'' was struck from the section, recognizing that the survey may not necessarily be a radiation survey. The licensee may also perform a visual survey to locate and account for all sources. Other changes are discussed in the comments on § 35.404.

Section 35.2406, Records of Brachytherapy Source Accountability

Issue 1: Is It Necessary To Retain a Record of Permanent Implant Sources Returned to Storage If All Sources Were Used During the Implant?

Comment. A commenter suggested that, in some permanent implant cases, all of the sources will be utilized. The commenter proposed that the word ''unused'' be added to item (c)(2) immediately before ''sources.''

Response. The NRC changed the regulatory text in this section to require that the record include ''the number and activity of sources not implanted.'' Therefore, if all of the sources were used, the licensee would have to note that all of the sources were implanted and, consequently, none were returned to storage.

Issue 2: Were There Any Other Changes Made in This Section Between the Proposed and Final Rules?

Response. Yes. The title of this section was changed to correspond to the revised title of § 35.406, Brachytherapy source accountability. That section requires licensees to maintain accountability at all times for all brachytherapy sources in storage or use.

Section 35.2432, Records of Calibration Measurements of Brachytherapy Sources

Issue 1: Were There Any Changes Made in This Section Between the Proposed and Final Rules?

Response. Yes. The title of this section was changed to correspond to the title of § 35.432, Calibration measurements of brachytherapy sources. That section requires licensees to retain records of calibrations performed before the first medical use of brachytherapy sealed sources. Several changes were also made in this section to accommodate changes made in § 35.432. For example, the proposed rule said that the full calibration measurements must include determination of the output or activity within +/−5 percent, and the final rule says that a licensee must determine the source output or activity using a dosimetry system that meets the requirements in § 35.630(a). Other changes are discussed in the comments on § 35.432.

Section 35.2433, Records of Decay of Strontium-90 Sources for Ophthalmic Treatments

Issue 1: Were There any Other Changes Made in This Subpart Between the Proposed and Final Rules?

Response. Yes. The NRC added this section to correspond with the new § 35.433, Decay of strontium-90 sources for ophthalmic treatments. That section includes a requirement that a record be made of the activity of each strontium-90 source that is used to determine the treatment times for ophthalmic treatments. For additional information, see the discussion for § 35.433.

Section 35.2605, Records of Installation, Maintenance, Adjustment, and Repair of Remote Afterloader Units, Teletherapy Units, and Gamma Stereotactic Radiosurgery Units

Issue 1: Were There Any Other Changes Made in This Section Between the Proposed and Final Rules?

Response. Yes. The NRC amended the title of this section to state more clearly what type of records are required by this section.

We also added the word ''adjustment'' to the title and text of this section to conform them with the regulatory text. In addition, the phrase ''remote afterloader unit, teletherapy unit, or gamma stereotactic unit'' was added. This list of units was added because Subpart H in the final rule includes requirements for these types of devices, in addition to the requirements for teletherapy units which are in the current Part 35.

Section 35.2610, Records of Safety Procedures

Issue 1: Were There Any Changes Made in This Section Between the Proposed and Final Rule?

Response. Yes. This section was added to the final rule. We explicitly state in this section that the procedures required in §§ 35.610 (a)(4) and (d)(2) must be retained until the licensee no longer possesses the remote afterloader, teletherapy unit, or gamma stereotactic radiosurgery unit. Without this explicit statement, the licensees would have to reference the general recordkeeping provisions in § 30.51 for the record retention period and therefore, would have had to retain the procedures for the duration of the license.

Section 35.2630, Records of Dosimetry Equipment Used With Remote Afterloader Units, Teletherapy Units, and Gamma Stereotactic Radiosurgery Units

Issue 1: Can the Record Retention Period for This Section Be Changed From ''for the Duration of the License'' to 3 Years?

Comment. A commenter suggested that the record retention period could be changed to ''3 years after the last calibration.''

Response. The NRC has not changed the record retention period in this section. The dosimetry equipment calibrations, intercomparisons, and comparisons performed to show compliance with § 35.630 are necessary to document that the correct radiation dose is delivered to the patient or human research subject. If there is a future question about whether the correct radiation dose was delivered to a patient or human research subject, we believe that these records should be available to document that calibration of the therapy unit has been made with properly calibrated instruments.

Issue 2: Were There Any Other Changes Made in This Section Between the Proposed and Final Rules?

Response. Yes. The NRC amended the title of this section to state more clearly what type of records are required by this section.

We also amended paragraph (b)(2) to require that licensees include the manufacturer's name for the instruments that are calibrated, intercompared, or compared in accordance with § 35.630. This change is consistent with requirements in other sections to include the manufacturer's name of other types of equipment.

Section 35.2632, Records of Teletherapy, Remote Afterloader, and Gamma Stereotactic Radiosurgery Full Calibrations

Issue 1: Were There Any Changes Made in This Section Between the Proposed and Final Rules?

Response. Yes. Changes were made in this section to incorporate the requirements that were in the proposed §§ 35.2633 and 35.2635, which were deleted. Section 35.2632 in the final rule includes the recordkeeping requirements for full calibrations of teletherapy, remote afterloader, and gamma stereotactic radiosurgery units. Licensees can refer to this section for all of the recordkeeping requirements for full calibrations of the therapy units covered by Subpart H.

Section 35.2633, Records of Remote Afterloader Full Calibrations

Issue 1: Were There Any Changes Made in This Section Between the Proposed and Final Rules?

Response. Yes. This section was deleted in the final rule because the requirements were moved to § 35.2632, Records of teletherapy, remote afterloader, and gamma stereotactic radiosurgery full calibrations. This change has been made so that all of the recordkeeping requirements for full calibrations of therapy units in Subpart H would be in one place for easier reference for licensees.

Section 35.2635, Records of Gamma Stereotactic Radiosurgery Unit Full Calibrations

Issue 1: Were There Any Changes Made in This Section Between the Proposed and Final Rules?

Response. Yes. This section was deleted in the final rule because the requirements were moved to § 35.2632, Records of teletherapy, remote afterloader, and gamma stereotactic radiosurgery full calibrations. This

change has been made so that all of the recordkeeping requirements for full calibrations of the therapy units covered by Subpart H would be in one place for easier reference for licensees.

Section 35.2642, Records of Periodic Spot-Checks for Teletherapy Units

Issue 1: Were There Any Changes Made in This Section Between the Proposed and Final Rules?

Response. Yes. Paragraph (c) was added to the final rule. We explicitly state in this section that the procedures required in § 35.642 (b) must be retained until the licensee no longer possesses the teletherapy unit. Without this explicit statement, the licensees would have to reference the general recordkeeping provisions in § 30.51(b) for the record retention period and therefore, would have had to retain the procedures for the duration of the license.

Section 35.2643, Records of Periodic Spot-Checks for Remote Afterloader Units

Issue 1: Were There Any Changes Made in This Section Between the Proposed and Final Rules?

Response. Yes. Several changes were made to accommodate changes made in § 35.643.

Paragraph (c) was added to the final rule. We explicitly state in this section that the procedures required in § 35.643 (b) must be retained until the licensee no longer possesses the remote afterloader unit. Without this explicit statement, the licensees would have to reference the general recordkeeping provisions in § 30.51(b) for the record retention period and therefore, would have had to retain the procedures for the duration of the license.

Section 35.2645, Records of Periodic Spot-Checks for Gamma Stereotactic Radiosurgery Units

Issue 1: Were There Any Changes Made in This Section Between the Proposed and Final Rules?

Response. Yes. Several changes were made to accommodate changes made in § 35.645. These changes are discussed in the comments on § 35.645.

Paragraph (c) was added to the final rule. We explicitly state in this section that the procedures required in § 35.645 (b) must be retained until the licensee no longer possesses the gamma stereotactic radiosurgery unit. Without this explicit statement, the licensees would have to reference the general recordkeeping provisions in § 30.51(b) for the record retention period and therefore, would have had to retain the procedures for the duration of the license.

Section 35.2647, Records of Additional Technical Requirements for Mobile Remote Afterloader Units

Issue 1: Were There Any Changes Made in This Section Between the Proposed and Final Rules?

Response. Yes. Other changes are discussed in the comments on § 35.647.

Section 35.2652, Records of Surveys of Therapeutic Treatment Units

Issue: Can the Record Retention Period Be Changed to 3 Years, Instead of ''for the Duration of Use of the Unit?

Comment. A commenter suggested that the record retention period could be changed to 3 years.

Response. The NRC has not changed the record retention period in this section. The surveys performed to show compliance with § 35.652 are necessary to ensure that the source/device radiation level limits stated in the SSDR are not exceeded. We believe that these surveys should be retained for the duration of use of the device because of the potential radiation risks associated with these devices.

Subpart M—Reports

Issue 1: Should All the Reporting Requirements Be Grouped Into One Subpart or Should They Be Incorporated Into the Section Requiring the Report?

Comment. Commenters provided diverse responses to the Commission's question on whether all of the reporting requirements should be grouped into one subpart, or whether they should be incorporated into the individual sections requiring the reports. Commenters favored having all of the reporting requirements in one subpart because this format provides for easy reference, simplifies licensing, and assists licensees in determining their reporting requirements, which makes it easier to maintain compliance. Other commenters favored having the reporting requirements in the individual sections because this format is more orderly and informative. They find the similar separation of the actual reporting requirements and the requirements for what needs to be in the reports in Part 20 to be confusing. A number of individuals have misinterpreted sections of Part 20 simply because of the separation. Several commenters preferred a balanced approach where the reporting requirements would be in the individual sections and all of the requirements summarized in a separate subpart.

Response. After reviewing all of the comments responding to this question, the NRC concluded that having all of the reporting requirements in one subpart makes it easier for licensees to reference those requirements. However, the final rule is consistent with the ''balanced approach'' because each section in the final rule that is associated with a reporting requirement includes a cross-reference to the specific reporting requirements in Subpart M.

Section 35.3045, Report and Notification of a Medical Event

Issue 1: Do Stakeholders Think That the Term ''Medical Event'' is an Improvement Over the Use of the Term ''Misadministration'' in the Current Part 35?

Comment. Commenters supported the use of the term ''medical event.'' One commenter agreed with the change, but could see no reason for ''candy coating'' the term ''misadministration.''

Response. The NRC used the term ''medical event'' in the final rule because some believe the term ''misadministration'' has a negative connotation that implies negligence on the part of the physician or other hospital workers. The term ''medical event'' more correctly and simply conveys that the byproduct material or radiation from byproduct material was not administered as directed by the AU.

Issue 2: Are the Reporting Requirements for Medical Events Necessary?

Comment. Several commenters said that there was no need for the requirements in this section. Events that result from poor radiation protection practices are covered in the primary regulations for the use of radioactive material, e.g., inadequate survey of a patient following an HDR treatment. If such problem areas in licensees' programs are brought to their attention, licensees can correct the problems before they result in medical events.

Other commenters expressed concern that the overall wording in this section is subject to a great deal of interpretation and debate over whether specific actions are appropriate for a particular patient and whether an event is a reportable medical event. Therefore, the NRC should develop more specific language describing a medical event in order to avoid intrusion into medical judgments. It should be made clear that medical events are major deviations from a planned treatment that have or could have significant effects on the patient. These effects include either a

reduction in the possibility of tumor control or an increase in the possibility of complications. In addition, licensees should be able to appeal to medical experts if NRC staff determines that an incident is a reportable medical event.

Response. The NRC believes that the reporting and notification requirements in this section are necessary so that the NRC is aware of events that trigger the thresholds for medical events to determine what actions, if any, need to be taken to prevent recurrence; so that other licensees can be made aware of generic problems that result in medical events; and so that patients can make timely decisions regarding remedial and prospective health care. The requirements throughout Part 35 are more specific for medical use than the general requirements for the use of radioactive material in the other parts, e.g., Part 20 requirements.

During the development of the final rule, we revisited the proposed wording of all sections, including § 35.3045, to see if we could clarify the regulatory text to avoid future misinterpretations and debates about the meaning of the regulatory text. This type of clarifying change has been made to exclude reporting medical events that are due to ''patient intervention.''

Issue 3: Are the Threshold Dose Levels for Reporting Medical Events Set at Appropriate Levels?

Comment. Some commenters said that the reporting levels for medical events in the proposed § 35.3045(a)(1) cannot be justified on the basis of any real risk to either patients or the public. Reporting at these levels implies that these events result in harm to the patient, when they often result in no effect on the patient. Therefore, this is an example of a low risk requirement that the 1997 NAS–IOM Report (Radiation in Medicine: A Need for Regulatory Reform, Institute of Medicine, National Academy Press, Washington, DC, 1997) recommended be deleted. In addition, inherent risks do not justify intrusion by NRC into professional activities and the doctor-patient relationship.

Commenters said that the action level criteria for the total dose delivered from brachytherapy procedures or gamma stereotactic radiosurgery procedures should be revised from the prescribed dose to a level at which harm to patients has been demonstrated. Another commenter questioned why the threshold was not similar to FDA's requirements for reporting morbidity and mortality.

One commenter said that the reporting thresholds of 0.05 Sv (5 rem) effective dose equivalent or 0.5 Sv (50 rem) to an organ or tissue were reasonable levels because they are ''reasonably significant radiation exposures.'' Five rem is the annual limit for a radiation worker, and 50 rem to an organ is the level when one might start seeing organ effects. For example, 50 rem to the testicles will result in a decreased sperm count.

Response. The NRC made no change in the proposed threshold reporting levels for medical events. These reporting levels correspond to the annual occupational dose limits in Part 20 and the level for reporting overexposures of workers to NRC. We believe that applying these same thresholds to reporting exposures to patients is reasonable.

The NRC uses the information from the reports of medical events that exceed the dose thresholds to reduce the likelihood of other medical events. For example, information from a report may indicate a breakdown in the licensee's program for ensuring that byproduct material or radiation from byproduct material is administered as directed by the AU or may indicate a generic issue that should be reported to other licensees.

Issue 4: Should Licensees Be Required to Report Events In Which the Administration of Byproduct Material or Radiation From Byproduct Material Results in a Total Dose That Differs From the Prescribed Dose by 20 Percent or More?

Comment. Commenters said that the 20 percent difference is arbitrary, and that exceeding this limit presents little or no risk to the patient. The limit should be examined and justified. Recommendations ranged from the limit should be 100 percent, to maybe there should not be a limit and the physician can decide when to report harm to a patient, to it is inappropriate to have a single criterion for all procedures.

Commenters believe that the 20 percent limit is reasonable for external beam therapy and unsealed therapeutic radiopharmaceuticals, but that it is too restrictive for brachytherapy, gamma stereotactic radiosurgery, and unsealed diagnostic dosages. Commenters said that they were aware of clinical data that supported the 20 percent level for external beam therapy. However, they were unaware of any brachytherapy or gamma stereotactic radiosurgery data demonstrating that a 20 percent difference between the prescribed dose and delivered dose would result in harm to the patient. In addition, a few millimeters in brachytherapy can make a tremendous difference in the dose. Some provision should be made to exempt brachytherapy, or to change the 20 percent limit up to 100–120 percent.

Several commenters questioned the applicability of the 20 percent limit to uses of unsealed byproduct material. Exceeding a radiotherapy dosage by 20 percent may be significant, but reporting an administration of a diagnostic dosage that exceeds the prescribed dosage by 20 percent is overregulation.

Response. The NRC has retained the 20 percent difference that is in the current rule. According to the Statements of Consideration for the Quality Management Program and Misadministrations rulemaking (56 FR 34104; July 25, 1991), a 20 percent difference between the prescribed dose and the total dose delivered is required to be reported because it could possibly indicate a deficiency in the licensee's program, not because it necessarily indicates a significant risk to the patient. We agree with this rationale and see no reason to change the threshold.

Licensees should note that they do not have to report an event in which the total dose or dosage delivered differs from the prescribed dose or dosage by 20 percent or more unless the dose also differs from the prescribed dose or from the dose that would have resulted from the prescribed dosage by more than 0.05 Sv (5 rem) effective dose equivalent, 0.5 Sv (50 rem) to an organ or tissue, or 0.5 Sv (50 rem) shallow dose equivalent to the skin.

The NRC uses the information from the reports of medical events where the administration of byproduct material or radiation from byproduct material results in a total dose that differs from the prescribed dose by 20 percent or more to reduce the likelihood of other medical events. For example, the difference between the prescribed and administered doses may indicate a breakdown in the licensee's program for ensuring that byproduct material or radiation from byproduct material is administered as directed by the AU.

Issue 5: Does the Proposed Rule Adequately Address Wrong Treatment Site?

Comment. Commenters both agreed and disagreed on whether the proposed rule adequately addressed wrong treatment site. Two commenters said that it was unclear how wrong treatment site will be handled for therapy, especially for brachytherapy where a medical event can occur if the patient moves even a small distance. In addition, commenters questioned how the wrong treatment site criteria will be applied to permanent seed implants that migrate from the prescribed site.

Another comment was that the criteria for a medical event involving the wrong treatment site must be justified. The criteria of a 0.5 Sv (50 rem) tissue/organ dose and difference of 20 percent from the expected dose defined in the written directive are excessively restrictive. Justification can be provided that the percentage deviation could be 100 percent. At a minimum, radiobiological justification can be made for 1 Sv (100 rem) as a significant threshold. The FDA uses this threshold criteria for evaluating lengthy fluoroscopy studies that could result in skin injury.

Response. In § 35.3045(a)(3) of the proposed rule, the NRC attempted to define more clearly when exposure of a wrong treatment site is considered a medical event by including both a 0.5 Sv (50 rem) tissue/organ dose limit and a 20 percent deviation from the expected dose defined in the written directive. We believe that the proposed 0.5 Sv (50 rem) tissue/organ dose limit should be retained, but the allowable deviation from the dose in the written directive should be increased to 50 percent. Therefore, we amended paragraph (a)(3) of this section in the final rule to read ''50 percent of the dose expected * * *'' We believe that this change allows for some variation in doses to the wrong treatment site during administrations of radiation from byproduct material, and requires licensees to only report significant doses to the wrong treatment site due to the movement of the patient or source, e.g., during brachytherapy treatments. In addition, we added a statement that is in the current rule, which was inadvertently not included in the proposed rule, that excludes permanent implants of seeds that were implanted in the correct site but migrated outside the treatment site.

Issue 6: Does the Proposed Rule Adequately Address Patient Intervention?

Comments. The NRC received a range of responses to the Commission's question on whether the proposed rule adequately addressed patient intervention, i.e., actions by the patient such as dislodging or removing treatment devices or prematurely terminating treatment. Several commenters said that this issue was adequately addressed in the rule. Other commenters said that any patient intervention should not result in a medical event. One commenter said that an exemption should be provided to the licensee when the cause of a medical event is patient intervention.

A number of commenters said that the phrase in the proposed rule ''that could have been prevented by the licensee'' was ambiguous and subjective, and should be deleted because it would result in varying interpretations between NRC and licensees. In addition, decisions on what are considered ''reasonable medical practices'' for patient control infringe on the practice of medicine and should be left to the physician's professional judgment. Therefore, this requirement is in violation of Statement 2 of the proposed revision of the Medical Policy Statement: NRC will not intrude into medical judgments affecting patients, except as necessary to provide for the radiation safety of workers and the general public.

Response. As part of the medical use rulemaking, the Commission is codifying a common-sense approach to the reporting requirements for medical events that excludes incidents involving patient intervention. In the proposed rule, the phrase ''that could not have been reasonably prevented by the licensee'' was added to § 35.3045(a) in an attempt to avoid further expenditure of resources by licensees and NRC in trying to determine what constitutes patient intervention, which is not specifically addressed in the current rule. The issue has involved whether or not a licensee did everything it should to prevent patient intervention during a treatment that resulted in a medical event. Following our evaluation of the comments on patient intervention, the NRC deleted the proposed phrase from § 35.3045(a) because it did not seem to clarify when an event caused by patient intervention must be reported to NRC as a medical event.

In the final § 35.3045(b), we addressed the issue of when an event caused by patient intervention must be reported to NRC as a medical event. In addition, we added a definition of patient intervention to § 35.2. As defined, patient intervention means ''actions by the patient or human research subject, whether intentional or unintentional, such as dislodging or removing treatment devices or prematurely terminating the administration.'' We believe licensees should only be required to report serious medical events due to patient intervention. Paragraph (b) of this section in the final rule requires licensees to report any event resulting from intervention of a patient or human research subject in which the administration of byproduct material or radiation from byproduct material results or will result in unintended permanent functional damage to an organ or a physiological system, as determined by a physician. As a result of the significantly higher threshold, the NRC will only receive reports involving patient intervention for events with serious consequences, e.g., unintentional permanent functional damage.

This reporting requirement should result in decreased regulatory burden on licensees because in most situations where patients intervene in their treatment, either voluntarily or involuntarily, there is no permanent functional damage. Therefore, the revised reporting requirement should significantly reduce the resources expended by the NRC and licensees in debating what are considered reasonable medical practices for patient control because the NRC will no longer require most of the reports it currently receives involving patient intervention. In addition, it should avoid intrusion into medical judgments by the NRC because the decision on whether the administration resulted in permanent functional damage to an organ or a physiological system is to be determined by a physician.

Issue 7: Why Do Licensees Need To Notify the NRC By Telephone No Later Than the Next Calendar Day After Discovery of a Medical Event?

Comment. Two commenters questioned the need for licensees to notify the NRC no later than the next calendar day after discovery of a medical event because this requirement implies that these events are harmful or hazardous. There are some medical events with serious consequences that should be reported right away but there is no benefit in reporting events with no medical significance so promptly.

Response. According to the Statements of Consideration for the Quality Management Program and Misadministration final rule [56 FR 34104; July 25, 1991], misadministrations (medical events) warrant telephone notification of the NRC no later than the next calendar day because these events require that a threshold of either 0.05 Sv (5 rem) effective dose equivalent or 0.5 Sv (50 rem) dose equivalent be exceeded. The early telephone notification allows the NRC to promptly take any necessary actions based on the circumstances, e.g., dispatch an inspector or medical consultant or notify other licensees of potential generic problems. The NRC continues to believe that licensees should promptly notify the NRC of medical events that trigger these thresholds because the circumstances of the medical events need to be evaluated as soon as possible to determine if any

immediate follow-up or corrective actions are necessary.

All medical events may not be associated with serious consequences. However, we believe that a requirement that allows for different reporting periods, depending on the initial assessment of the event, would lead to differing interpretations and confusion as to whether the magnitude of the event requires notification of the NRC no later than the next calendar day. In addition, there may be a medical event where the seriousness of the consequences would not be immediately apparent and which, therefore, would not be reported.

Issue 8: Should Licensees Be Required To Notify the Individual (Affected By the Medical Event) About a Medical Event?

Comment. The NRC received a range of comments on the requirement in § 35.3045(e) to notify the individual affected by the medical event. These ranged from the licensee should always notify the patient or guardian to this requirement should be deleted.

Some commenters suggested modification of the requirement. For example, a licensee should be allowed not to notify an individual if the rationale for withholding the information is noted in the written report to the NRC. Other suggestions were that notification of the patient should not be required unless the medical event results in a detrimental effect to the patient, or it is necessary to ensure patient safety.

Other commenters said that the requirement should depend on the risk of the procedure. In cases of diagnostic and low-risk therapeutic procedures, notification should not be mandatory. For high-risk therapeutic applications, a patient should only be notified if an adverse outcome is probable and only if the patient's mental state would not be adversely affected.

Commenters provided a number of reasons why they felt that this requirement should be deleted: it overlaps with existing medical practice standards; it intrudes into the practice of medicine; it interferes with the physician-patient relationship; there are no data that patients are not being notified; it presents the appearance of much greater harm than there may actually be; there is no precedent in other areas of medicine; and it is in contradiction to NRC's Medical Policy Statement.

Response. The NRC retained the proposed requirements for notifying individuals following a medical event in the final rule. As stated in the proposed rule (63 FR 43516; August 13, 1998), this position reaffirms statements made by the Commission during the misadministration rulemaking, that patient notification " * * * recognizes the right of individuals to know information about themselves which is contained in records both inside and outside the Federal sector" ["Human Uses of Byproduct Material, Misadministration Reporting Requirements," (43 FR 2927; May 7, 1978)]. We continue to believe that patient notification enables patients, in consultation with their personal physicians, to make timely decisions regarding any remedial and prospective medical care. This approach also codifies existing medical ethical standards obligating physicians to provide complete and accurate information to their patients.

This approach is consistent with aspects of another Federal patient notification requirement specifically in "The Mammography Quality Standards Reauthorization Act of 1998," Pub. L. 105–248, under which notification of a patient may be required for certain events (e.g., when a patient has received mammography from a facility whose quality is found to be "so inconsistent with quality standards as to present a risk to individual or public health"). [42 U.S.C. 263b(h)(2)(1999)]. By statute, as well as FDA regulations, a summary of the written report of the patient's mammography results must be sent directly to the patient if the patient's physician is not available or if there is no such physician. [42 U.S.C. 263b(f)(1)(G)(ii)(III); 21 CFR 900.12(e)(1)(2)(ii)(a) and (iii) (1999).]

Issue 9: Should Licensees Be Required To Notify the Referring Physician About a Medical Event?

Comment. Several commenters disagreed with the need for a regulation requiring licensees to notify referring physicians about a medical event. Nuclear medicine physicians and referring physicians have a professional relationship that would be negatively impacted if the nuclear medicine physician provided inaccurate information or withheld information from the referring physician. Therefore, the NRC does not need to mandate notification of the referring physician.

Response. It is important that a referring physician is aware of medical events involving individuals. The referring physician knows the individual and his or her medical history and is likely to be in the best position to make a decision about whether informing the individual about the medical event would be harmful. That physician may also need to evaluate any follow-up actions relative to the individual's overall health history. Although notification of referring physicians may represent the "standard of care," that practice may not be uniformly followed. Therefore, the NRC retained the current requirement for a licensee to notify the referring physician about a medical event. The final rule includes a requirement that licensees annotate a copy of their report to the NRC about the medical event and provide it to the referring physician, if other than the licensee, within 15 days after discovery of the medical event. We believe that it is important for the referring physician to have all the available documentation about the medical event to support any decision about remedial or prospective health care. The 15-day time period to provide the referring physician with a copy of the record is based on paragraph (d) which requires a licensee to submit a report to the NRC within 15 days. Consistency, where possible, between the requirements in Subparts L and M will simplify compliance with the recordkeeping and reporting requirements.

The issue of notifying the referring physician was addressed in the Statements of Consideration for the 1995 rulemaking that amended the medical misadministration requirements ("Medical Misadministration of Radiation and Radioactive Material," 60 FR 48623; September 20, 1995). The Commission noted that "If a misadministration occurs because the material was administered to the wrong individual, there may be no referring physician. If there is no referring physician, the licensee is relieved of the responsibility of notifying the referring physician, but must comply with all other requirements of § 35.33."

Issue 10: Why Is There a Requirement for a Licensee To Provide a Written Report to the Individual Affected by a Medical Event?

Comment. The NRC received several comments on the need for a licensee to provide a written report to the individual affected by a medical event. Commenters were concerned that providing a written report to the individual may lead to a misunderstanding of the consequences for the patient (i.e., the individual may be unduly alarmed that a report had to be submitted to NRC) and jeopardize the individual's confidence in the ability of the physician providing medical care. Another commenter noted that there is no precedent for providing a written

report to a patient about a misadministration of other diagnostic agents.

Response. The NRC deleted the current requirement to furnish an individual affected by a medical event with a written report. Instead, in the final rule licensees are required to inform the individual, or responsible relative or guardian, that a written description of the event can be obtained from the licensee upon request. Licensees are required to provide such a written description to the individual, if requested. We believe that a written report would be especially useful to an individual who needs to make decisions about any follow-up medical care, and provides the individual a permanent record to refer to for information about the event.

Issue 11: What Other Changes Were Made as a Result of Comments?

Comment. It is not clear whether the thresholds in paragraph (a)(1) and either (a)(1)(i) or (ii) need to occur simultaneously for the event to be reported.

Response. The NRC made editorial changes in the text of paragraph (a) to make it clearer that an event is only classified as a reportable medical event if both the threshold in paragraph (a)(1) and the threshold for the difference between the total dose and prescribed dose in paragraph (a)(1)(i) or the difference between the total dosage and prescribed dosage in paragraph (a)(1)(ii) or the difference between the fractionated dose delivered and the prescribed dose in paragraph (a)(1)(iii) have been exceeded.

Comment. The word ''of'' is missing between ''20 percent'' (50 percent in the final rule) and ''the dose expected'' in paragraph (a)(3) of this section that addresses the threshold for determining when a dose to a ''wrong treatment site'' is a reportable medical event.

Response. The text of paragraph (a)(3) of this section has been corrected to read ''50 percent of the dose expected from the administration defined in a written directive.''

Comment. Paragraphs (c)(1)(vi) and (vii) could be combined into one paragraph because they both address actions or improvements that have been taken, or are planned, to prevent recurrence of a medical event.

Response. We combined the requirements in the proposed paragraphs into paragraph (d)(1)(vi) in the final rule.

Issue 12: Were There Any Other Changes Made in This Section Between the Proposed and Final Rule?

Response. Yes. The NRC amended the title of this section to state more correctly that this section includes both reporting and notification requirements for medical events.

The phrase ''results from intervention by a patient or human research subject'' in paragraph (a) of the proposed rule was deleted and replaced by ''an event that results from patient intervention'' in the final rule. We made this change because the definition of patient intervention in § 35.2 includes actions by either a patient or human research subject, so paragraph (a) of the proposed rule contained duplicative language.

We added the phrase ''administration of byproduct material or radiation from byproduct material'' in paragraph (a) of the final rule because the requirements in Part 35 are limited to the medical use of byproduct material.

Paragraph (a)(1) was clarified to add the phrase ''dose that would have resulted from the prescribed dosage.'' This change was needed to clarify that this provision applies to the medical use of sealed and unsealed byproduct material as evidenced by the reference to ''total dosage'' in paragraph (a)(1)(ii).

Paragraph (a)(1)(i) of the proposed rule that contained the threshold for the difference between the delivered dose or dosage and the prescribed dose or dosage was split into paragraphs (a)(1)(i) and (ii) in the final rule. We made this change to reflect the fact that physicians can prescribe a range of dosages, but not doses, in written directives.

We replaced the word ''pharmaceutical'' in paragraph (a)(2)(i) with ''radioactive drug containing byproduct material'' because the requirements in Part 35 are limited to the medical use of byproduct material.

We amended paragraph (a)(3) to read ''50 percent or more'' (20 percent in the proposed rule) to make it clearer that the dose to a wrong treatment site has to exceed 50 percent or more of the dose expected from the administration defined in the written directive before a licensee is required to report the event to NRC as a medical event.

Paragraphs (d)(1)(v)and (vi) [paragraphs (c)(1)(v) and (vii) of the proposed rule] require that information on the effects of the medical event on the individual who received the administration and on the actions to prevent recurrence be included in the written report to the NRC. We reworded these paragraphs in the final rule to read ''the effect, if any, on the individual;'' and ''what actions, if any, have been taken, or are planned, to prevent recurrence.'' The words ''if any'' and ''are planned'' were added because there might not be any effect or any actions taken at the time the event is reported.

We revised paragraph (d)(1)(vii) [paragraph (c)(1)(viii) in the proposed rule] to require that the written report include a certification that the licensee notified the individual (or the individual's responsible relative or guardian), and if not, why not. We made this revision because notifying these individuals is important enough to warrant documentation that the individual(s) was notified. In addition, we believe that it is important that the licensee notify the patient so that he or she can be actively involved in any decision about remedial or prospective health care following the event.

We deleted paragraph (c)(1)(ix) in the proposed rule because the referring physician, and not the licensee, may have notified the individual. Therefore, the licensee may not know what information the referring physician provided to the individual.

We amended paragraph (e) [paragraph (d) of the proposed rule] in the final rule. The words ''when appropriate'' were deleted from the last sentence in paragraph (d) of the proposed rule because the intent was covered by the phrase ''may be made'' in the same sentence.

We added paragraph (g) to the final rule to require that licensees annotate a copy of their report to the NRC about the medical event and provide it to the referring physician, if other than the licensee, within 15 days after discovery of the medical event. We believe that it is important for the referring physician to have all the available documentation about the medical event to support any decision about remedial or prospective health care.

Section 35.3047, Report and Notification of a Dose To An Embryo/Fetus or a Nursing Child

Issue 1: Should the Abnormal Occurrence Policy Statement Criteria for Reporting of Unintended Exposures to an Embryo/Fetus or Nursing Child Be Modified?

Comment. Numerous commenters recommended that § 35.3047 be deleted and the Abnormal Occurrence (AO) Criteria be revised to reflect the deletion of this section.

Response. The information required by this section is needed so that NRC can comply with Section 208 of the Energy Reorganization Act of 1974 (Pub. L. 93–438, 5848, 42 U.S.C.), as amended, to submit an annual report to

Congress of unscheduled incidents or events which the Commission considers significant from the standpoint of public health and safety, e.g., abnormal occurrences. (The ''Reports Elimination Act,'' Pub. L. 104–66, changed the Abnormal Occurrence (AO) report to a yearly publication.)

The NRC identifies an abnormal occurrence using the revised abnormal occurrence criteria that were published in the **Federal Register** (62 FR 18820; April 17, 1997). Section II of that policy statement defines unintended radiation exposure as ''any occupational exposure, exposure to the general public, or exposure as a result of a medical misadministration (as defined in § 35.2) involving the wrong individual that exceeds the reporting values established in the regulations.'' This section also states that ''All other reported medical misadministrations will be considered for reporting as an Abnormal Occurrence under the criteria for medical licensees. In addition, unintended radiation exposures include any exposure to a nursing child, fetus, or embryo as a result of an exposure (other than an occupational exposure to an undeclared pregnant woman) to a nursing mother or pregnant woman above specified values.'' Appendix A, Section I.A.2., ''Abnormal Occurrence Criteria,'' of the policy statement, states that NRC will provide information on ''any unintended radiation exposure to any minor (an individual less than 18 years of age) resulting in an annual total effective dose equivalent of 50 mSv (5 rem) or more, or to an embryo/fetus resulting in a dose equivalent of 50 mSv (5 rem) or more.''

At the present time, the NRC has no regulatory requirements that require licensees to report those types of events. Therefore, the Commission considered two alternatives: revise the current Abnormal Occurrence Criteria to delete the requirement to report this type of event to Congress; or develop a reporting requirement for licensees that would provide the information needed by the Commission to comply with Section 208.

After extensive discussion and consideration of the public comments, we have decided to pursue the second option. We are not convinced that it is inappropriate for the NRC to report this type of event to Congress and that the reporting requirement in § 35.3047 will be overly burdensome or unwarranted. We are also not inclined to further revise the AO criteria because they have recently been revised and limited comments were received on the proposed criteria.

The thresholds for reporting an unintended dose to an embryo/fetus or a nursing child have been raised in the final rule to the reporting levels in Appendix A, Section I.A.2, of the AO policy statement. Licensees are now required to report any unintended dose to an embryo/fetus that is greater than 50 mSv (5 rem) dose equivalent and any dose to a nursing child that is either greater than 50 mSv (5 rem) effective dose equivalent or results in unintended permanent functional damage to an organ or a physiological system, as determined by a physician. We believe that § 35.3047, as revised in the final rule, provides a balanced resolution of this issue. The regulatory burden on licensees will be substantially less than it would have been under the proposed § 35.3047 because of the higher reporting thresholds in the final rule; and the NRC will receive the information it needs to report to Congress. In addition, because of the more serious consequences associated with these higher thresholds, we believe that the NRC should receive reports of these unintended doses to an embryo/fetus or nursing child.

Issue 2: What Is the Impact of the Proposed Reporting Requirement on Licensee Procedures, Activities, or Medical Practices?

Comment. According to the comments, the biggest impact of the proposed reporting requirement on licensees is associated with the need to determine the pregnancy status of individuals. Commenters had many concerns about NRC's expectations of pregnancy testing, such as delays in emergency scans pending the completion of pregnancy tests; the sensitivity of pregnancy tests; false negative tests in early pregnancy; the age range for pregnancy testing; privacy of minors; patients refusing to pay for pregnancy tests; and the method for calculating conception dates.

Commenters were also concerned about the licensees' responsibilities when they find out later that there was an unintended exposure to a pregnant individual. This can happen if, for example, the patient may not be aware of, or opts to conceal, the fact that she is pregnant. Licensees should not be held responsible for what patients do against medical advice and reporting such incidents will not prevent a recurrence. Unintended exposures may also occur in cases where the AU is not required to examine the patient, consult with the referring physician, or see the patient's chart, e.g., non-iodine diagnostic studies.

Commenters said that the overwhelming majority of nuclear medicine procedures are safe to perform on pregnant women. In fact, they are often the tests of choice for pregnant women because other radiologic procedures frequently involve higher radiation doses. For the few cases in which administration of a pharmaceutical is not recommended (e.g., sodium iodide I–131), pregnancy information is ascertained. They believe that, by default, the proposed requirement will require pregnancy testing on every female of childbearing age. The inaccuracy, costs, etc. of the tests will lead patients to seek alternative, and often less effective, treatments.

Response. The Commission recognizes that the standard of practice for AUs is to assess the pregnancy or nursing status of their patients (reference ACR ''Standard for the Performance of Therapy with Unsealed Radionuclide Sources,'' 1996, and ''Society of Nuclear Medicine General Procedure Guidelines for Imaging with Radionuclides,'' 1997). As a result, we do not believe that it is necessary for the NRC to require a licensee to assess the pregnancy or nursing status of patients before a medical treatment involving byproduct material.

We do believe that it is appropriate to require the licensee to inform the NRC when the licensee learns of an unintended dose to an embryo/fetus or a nursing child that exceeds the thresholds in § 35.3047. The occurrence of such an unintended dose does not necessarily mean that the licensee is in violation of the requirements in Part 35 as long as the licensee reports it and it is not otherwise in violation of NRC regulatory requirements.

However, the NRC acknowledges that, in some cases, the licensee might not be able to prevent the dose to an embryo/fetus or nursing child. For example, there is no way for an AU to prevent administration of an unintended dose to an embryo/fetus if the pregnancy test was negative because it was given very early in the pregnancy.

Issue 3: What Should Be the Reporting Threshold for a Dose to an Embryo/Fetus or a Nursing Child?

Comment. Commenters said that the proposed reporting level of 5 mSv (500 millirem) to an embryo/fetus or a nursing child is not consistent with the Commission's intent of making Part 35 more risk-informed and performance based because it cannot be justified on the basis of risk. This reporting level is also not consistent with the NRC's need to submit an annual report to Congress

on unscheduled incidents or events which the Commission considers significant from the standpoint of public health and safety, i.e., abnormal occurrences. One commenter noted that significant biological effects would not be observable at this reporting level in either an embryo/fetus or a nursing child, as demonstrated by the healthy births of children who were exposed to radiopharmaceuticals in utero for the purpose of diagnosing the mothers of these children. The only radiation doses that truly present a significant health and safety issue are those which result in actual non-stochastic effects. Therefore, another commenter suggested that the NRC consider only those medical events which result in actual non-stochastic effects as abnormal occurrences. In addition, one commenter said that there is no similar requirement by agencies regulating diagnostic x-ray machines. Furthermore, the proposed reporting level is going to result in NRC receiving a number of reports of questionable accuracy and utility.

Commenters suggested a range of reporting levels from 1–25 rem dose equivalent. One commenter suggested that the reporting level should be the same as for medical events: 5 rem total effective dose equivalent or 50 rem to an organ or tissue. Another commenter noted that at his institution, genetic counselors do not consider radiation to be a risk until about 15–20 rem to the embryo/fetus. One commenter suggested that licensees report only radiation-induced injuries and deaths from radiopharmaceuticals and radiologic devices that were due to accidents and that were not reportable to the FDA.

A commenter noted that NCRP Report No. 54, ''Medical Radiation Exposure of Pregnant and Potentially Pregnant Women'' (1977), states that the risk to the embryo/fetus is negligible below 5 rad and is only significant when compared to other risks of pregnancy above 15 rad. This is consistent with the recommendations in AAPM Radiation Therapy Task Group No. 36—Fetal Dose from Radiotherapy with Photon Beams, 1995 (AAPM TG–36).

Commenters also noted that the lack of adequate data makes it virtually impossible to accurately calculate radiation doses to an embryo/fetus at various gestational periods from radiopharmaceuticals. They also questioned how the NRC suggests that patients be monitored to ensure that they are complying with instructions about breast feeding if the nursing child could receive a dose in excess of 100 millirem.

Response. Following an evaluation of the comments and further review of published recommendations and literature, the NRC changed the reporting thresholds in § 35.3047 in the final rule. Paragraph (a) requires that a licensee report to the NRC any administration of byproduct material or radiation from byproduct material to a pregnant woman that results in a dose to an embryo/fetus that is greater than 50 mSv (5 rem) dose equivalent unless the administration was specifically approved, in advance, by the AU. We emphasize that only unintended exposures must be reported to the NRC. If a licensee knows that an individual is pregnant and makes the decision that it is necessary to proceed with a test involving the administration of byproduct material or radiation from byproduct material, the licensee would not have to report the dose to the pregnant individual as a medical event. Paragraph (b) requires that a licensee report to NRC any administration of byproduct material to a breast-feeding woman that results in a dose to the nursing child that is greater than 50 mSv (5 rem) total effective dose equivalent or a dose that has resulted in unintended permanent functional damage to an organ or a physiological system, as determined by a physician. These reporting levels are consistent with the recommendations in NCRP Commentary No. 9, ''Considerations Regarding the Unintended Radiation Exposure of the Embryo, Fetus or Nursing Child'' (1994). At a reporting threshold of 50 mSv (5 rem), there are no detectable deterministic effects, and the risk of stochastic effects (e.g., cancer) is less than 1 percent. This report concluded that ''setting requirements for action after radiation exposure of the embryo, fetus, or nursing child at some level below an effective dose of 100 mSv (10 rem) to allow for a margin of safety should enable all such incidents with the potential for harm to be dealt with appropriately.''

We believe that the reporting threshold on the final rule is not overly burdensome on licensees. Unintended doses to an embryo/fetus or nursing child exceeding 50 mSv (5 rem) are rarely encountered in the practice of nuclear medicine (refer, for example, to Russell, J.R., et. al, Radiation Absorbed Dose to the Embryo/Fetus from Radiopharmaceuticals, Health Physics 73:756–769;1997).

Issue 4: Should § 35.3047 Include a Requirement for a Licensee To Notify a Pregnant Individual or Mother About an Event That Must Be Reported to the NRC in Accordance With This Section?

Comment. The physician should be able to determine whom to notify. The method and extent of notifying a pregnant individual or mother are solely a matter of the physician's judgment, within the context of the physician-patient relationship. In some cases, the best individual to notify may be the pediatrician (or future pediatrician), which is not an option in the rule. The pediatrician, not the mother's referring physician, will be caring for the infant. The notification requirements in this section are an intrusion into the practice of medicine.

Response. The NRC retained the requirement for notification of the pregnant individual or mother in the final rule. Although notification of the pregnant individual or mother may represent the ''standard of care,'' that practice may not be uniformly followed. We believe that the pregnant individual or mother should be notified so that she can participate in any decisions on follow-up medical care, if necessary.

Issue 5: Is there a Better Term Than ''Responsible Relative or Guardian'' That Could be Applied to Those Situations Where the Mother is Not Notified, e.g., in the Referring Physician's Medical Judgment Telling the Mother Would Be Harmful; the Mother Is a Minor; or the Mother Is Not Competent To Make Decisions Regarding Medical Care?

Comment. Several comments were received in response to this question, which was published in the proposed rule. Some commenters said that the term ''responsible relative or guardian'' itself was sufficient, and recommended no alternative wording. The term ''guardian'' appears to be very clear because the only comment on guardian said that it does not need to be fixed.

The NRC also received several comments on the interpretation of ''responsible relative.'' Several commenters hoped that ''responsible'' is not used as a substitute for ''legal.'' The term ''responsible'' should allow for notification of someone who cares for the minor but who is neither a blood relative nor a legal guardian. Not telling the mother only because she is a minor is not a responsible rule and is inappropriate. The medical community and the laws of each state determine if a mother is allowed information that may affect her child if she is a minor. The other two situations, it would be

harmful to the mother or the mother is not competent, should cover when notification of the responsible relative or guardian is necessary. Another commenter said that for an adult, what is really meant by notifying the ''responsible relative'' is notifying the relative or individual who has medical power of attorney.

Response. The final rule retains the current phrase ''responsible relative or guardian'' because the NRC did not receive any suggested term that better captures the intent of this requirement, which is that someone be told in those situations where the mother is not notified. We believe this terminology could include an individual who has medical power of attorney. However, it would be unduly restrictive to limit the individual to be notified, in lieu of the patient, to an individual with medical power of attorney. A physician's decision on whom to notify is based on many factors, including the Code of Medical Ethics of the American Medical Association and state laws that govern the release of a patient's medical information to another individual.

To assist with the interpretation of the current notification requirements in the misadministration rule, the Commission had previously provided the examples used in the question of when it expects that a ''responsible relative or guardian,'' rather than the patient, would be notified about a misadministration. These were provided only as examples, and are not part of the actual regulatory text, e.g., we did not intend by the examples that a mother should not necessarily be notified if she is a minor. We believe that the referring physician should have the discretion to either inform the mother or to determine that, based on medical judgment, telling her would be harmful, in which case the mother's or child's responsible relative should be notified.

Issue 6: Why Do Licensees Need To Notify the NRC, by Telephone, Within 5 Days and in Writing no Later Than 15 Days After Discovery of a Dose to an Embryo/Fetus or Nursing Child that Requires a Report Under This Section?

Comment. Commenters questioned the need to notify NRC by telephone within 5 days and in writing no later than 15 days after discovery of a dose to an embryo/fetus or nursing child that requires a report under this section. These reporting requirements give the perception that there is much greater harm than there actually is. One commenter said that the licensee should only have to report in writing to the Regional Office within 30 days after discovery of the dose. The other commenter said that notification of the NRC should be changed from 5 days to 15 days after discovery of the event, or at least changed to 5 working days so there is ample time over a holiday period. The additional time is needed for the licensee to assure the validity of the information in the report.

Response. The final rule contains a significantly higher reporting threshold than the proposed rule for reporting an unintended dose to a nursing child or an embryo/fetus as a result of the unintentional administration of byproduct material or radiation from byproduct material. Licensees are now required to report any dose to an embryo/fetus that is greater than 50 mSv (5 rem) dose equivalent and any dose to a nursing child that is either greater than 50 mSv (5 rem) effective dose equivalent or results in unintended permanent functional damage to an organ or a physiological system, as determined by a physician. More serious consequences are associated with these higher thresholds. Therefore, the reporting requirement in the proposed rule to notify the NRC within 5 days after discovery of the unintended dose has been revised to require notification of the NRC no later than the next calendar day. Early telephone notification will allow the NRC to promptly take any necessary actions based on the circumstances, e.g., dispatch a medical consultant. Prompt notification of events that trigger these thresholds is important because the circumstances of the medical event may need to be reviewed as soon as possible to determine if any follow-up actions are necessary.

The reporting requirement in the proposed rule to submit a written report to the NRC Regional Office no later than 15 days after discovery of the dose has also been retained in the final rule. We believe that the 15 day reporting period is justified by the more serious consequences associated with the higher reporting thresholds. It is important that the NRC has all of the information in the written report as soon as possible to evaluate the event and to determine if any follow-up actions are available. The rule language recognizes that the licensee may not have all of the final information on the event at the time the report is submitted to NRC.

Issue 7: Were There any Other Changes Made in This Section Between The Proposed and Final Rules?

Response. Yes. The NRC amended the title of this section to state more correctly that this section includes both reporting and notification requirements following a dose to an embryo/fetus or nursing child that exceeds the thresholds in § 35.3047.

We amended paragraph (b)(2) to read '' * * * permanent functional damage to an organ or a physiological system of the child * * *'' to make it clear that this reporting criterion applies to the nursing child.

We combined paragraphs (d)(1)(vi) and (vii) in the proposed rule into one paragraph [(d)(1)(vi)] in the final rule because they both address actions or improvements that have been taken, or are planned, to prevent recurrence of a medical event.

We reworded paragraphs (d)(1)(v)and (vi) in the final rule to read ''the effect, if any, on the embryo/fetus or the nursing child;'' and ''what actions, if any, have been taken, or are planned, to prevent recurrence.'' We added the words ''if any'' and ''are planned'' because there might not be any effect or any actions taken at the time the event is reported. We deleted paragraph (d)(1)(vi) in the proposed rule because it was duplicative of paragraph (d)(1)(vii).

We added a new paragraph (d)(1)(vii) to require that the written report include a certification that the licensee notified the pregnant individual or mother (or the mother's or child's responsible relative or guardian), and if not, why not. This provides NRC with documentation that the pregnant individual or mother was notified. We made this revision because notifying these individuals is important enough to warrant documentation that the individual(s) was notified. In addition, we believe that it is important that the licensee notify the pregnant individual or mother so that she can be actively involved in any decision about remedial or prospective health care following the event.

We amended paragraph (e) [paragraph (d) of the proposed rule] in the final rule. The words ''when appropriate'' were deleted from the last sentence in paragraph (d) of the proposed rule because the intent was covered by the phrase ''may be made'' in the same sentence.

We combined proposed paragraphs (e), (f), and (g) into one paragraph so the format of this section is similar to the section on reporting medical events.

Paragraph (h) of the proposed rule that required the licensee to furnish the mother, or responsible relative or guardian, with a written report was deleted in the final rule. Instead, paragraph (e) in the final rule requires licensees to inform the mother, or the mother's or child's responsible relative or guardian, that a written description of the event can be obtained from the licensee upon request. Licensees are

required to provide such a written description to the individual, if requested. We believe that a written description would be especially useful to an individual who needs to make decisions about any follow-up medical care, and provides the individual a permanent record to refer to for information about the event.

We added paragraph (f) to the final rule to require that licensees annotate a copy of their report to the NRC about the event and provide it to the referring physician, if other than the licensee, within 15 days after discovery of the event. We believe that it is important for the referring physician to have all the available documentation about the event to support any decision about remedial or prospective health care. The 15-day time period to provide the referring physician with a copy of the record was based on paragraph (d) which requires a licensee to submit a report to the NRC within 15 days. We have attempted to have consistency in the requirements in Subparts L and M, where possible, to simplify compliance with the recordkeeping and reporting requirements.

Section 35.3067, Report of a leaking source

Issue: Where There any Changes Made in This Section Between the Proposed and Final Rules?

Response. Yes. The NRC changed the title of this section so that it refers to a single report. This change makes the title of this section consistent with the titles of the other sections in Subpart M.

We made this section more performance based by using ''the results of the test'' instead of the more detailed requirements of ''the measured activity of each test sample expressed in microcuries'' and ''a description of the method used to measure each test sample.'' These changes are consistent with changes made in response to comments on § 35.2067, Records of leaking sources.

IV. Summary of Comments on Agreement State Compatibility and Responses to Comments

Part 1: General Questions

Issue 1: How does NRC Determine if a Requirement Should Be Given a Health and Safety (H&S) Classification?

Comment. Several commenters expressed a concern regarding the compatibility categories, especially those designated as ''D (H&S)''. Commenters stated that the (H&S) classification has nothing to do with compatibility but does apply to adequacy of a State's radiation control program. They further stated that, if the NRC finds it necessary to use this classification, then it should define the ''significant safety issues'' that led to the (H&S) designation. Other commenters stated that H&S designations for Agreement State requirements is a ''back door'' to compatibility requirements and may be unevenly and/or inappropriately enforced. Commenters recommended that if a requirement must be adopted by an Agreement State in order for that State's program to be found ''adequate,'' the requirement should be assigned a ''compatibility'' designation. H&S designations should be assigned only when a requirement has a direct Part 20 connection.

Response. On September 3, 1997, the Commission approved an Adequacy and Compatibility Policy for Agreement State Programs. This policy was developed in an open environment, with early and substantive involvement by Agreement State representatives. Management Directive 5.9, ''Adequacy and Compatibility of Agreement State Programs'' (Adequacy and Compatibility Policy) provides guidance on applying the Adequacy and Compatibility Policy to Agreement State program elements including regulations.

The assignment of compatibility categories to each requirement in the revised rule has been made in accordance with the Adequacy and Compatibility Policy. The compatibility category assignments are needed to assure that byproduct material is used with a minimum level of safety nationwide. Those program elements (including regulations) which are not required for compatibility, as noted in the Adequacy and Compatibility Policy, may be required because of their health and safety (H&S) significance. The NRC has reviewed and revised, where appropriate, the chart detailing the compatibility categories for each requirement in the final rule. Each requirement in the rule, identified for compatibility or adequacy, has an accompanying rationale explaining its health and safety significance or its need based on consistency between NRC and Agreement State programs.

NRC conducts performance based reviews of Agreement State programs in accordance with the Integrated Materials Performance Evaluation Program (IMPEP). Findings of Adequacy and Compatibility for each Agreement State program are made by a management review board (MRB) consisting of senior NRC managers along with a manager from an Agreement State. These findings are made based on a number of factors, including regulations.

Under the Adequacy and Compatibility Policy, and the review of Agreement State programs under IMPEP, the Agreement States are provided flexibility in administering their programs. Regulations and other program elements identified as having adequacy or health and safety significance may be addressed through the promulgation of compatible regulations or the adoption of other legally binding documents. Final findings of Agreement State program adequacy and compatibility are made by the MRB based on their assessment of the entire program, not just its regulations. This process assures a level of consistency in the review of Agreement State programs. Each Agreement State program director is afforded an opportunity to appear before the board to explain his or her State's performance and answer questions from the MRB.

Issue 2: What Flexibility Should Be Given to Agreement States?

Comment. A commenter stated that Part 35 should not be a matter of compatibility for the Agreement States beyond requiring that states have a system for authorizing the medical use of byproduct material. Another commenter stated that the Agreement States should be allowed to regulate medical users as appropriate and as needed. They believed that the rule should be a low compatibility issue. Another commenter stated that the proposed Part 35 will deal a death blow to the Agreement State Program by demanding that every Agreement State adopt the essential portions of NRC's new Part 35 under threat of being incompatible and inadequate. The commenter stated that the Agreement States want flexibility. A commenter also expressed that this may cause Agreement States to give back their programs.

On this same topic, a commenter stated that nearly all of NRC's policy on Agreement State adequacy and compatibility should be rejected. The practices of medicine and pharmacy have no ''transboundary implications'' and should be changed from compatibility Category ''B'' to ''D'' because they are State functions. All compatibility category ''C'' items should be changed to ''D'' because they are too restrictive. All ''Health and Safety'' (H&S) requirements for adequacy should be removed because they are not necessary for ''Health and Safety.'' The commenter further stated that, ''Health and Safety'' is accomplished by starting

with qualified professionals who follow professional standards.

In contrast, commenters stated that a uniform or relatively uniform approach nationwide between Agreement State regulations and NRC regulations can be worked out and can be adopted. In particular, the American Association for Nuclear Cardiology requested that the NRC require the new Part 35 requirements to be at least a level C compatibility for the Agreement States.

Response. The Adequacy and Compatibility Policy for Agreement States Programs is explained in response to Issue 1. The assignment of the specific compatibility categories to the requirements in the revised rule is necessary to assure that byproduct material is used with a uniform level of radiation safety nationwide. This is different from the State regulation of medicine and pharmacy, which addresses global safety and competency issues.

Issue 3: Was the Comment Period on the Proposed Rule and on Compatibility Assignments Extended?

Comment. Agreement State representatives commented that the comment period was too brief to allow a comprehensive review of the rule, the licensing guide, and the compatibility listing. They also asked that we provide a listing of essential objectives for each section and why particular designations were assigned. In addition, Agreement State representatives asked that the comment period for the rationale for compatibility assignments should be extended up to 90-days after publication of the listing. They further stated that the degree of flexibility allowed the Agreement States is an important issue and should not be omitted from the discussion because information was not available in a timely manner.

Response. Supplement III of this document contains more detailed discussion of the comments that we received on the length of the comment period. As a result of public comment, we extended the comment period on the proposed rule from November 12, 1999 to December 16, 1999.

The proposed rule contained a brief explanation of the compatibility assignments that were made for the proposed rule. Subsequent to that publication, we received requests from Agreement State representatives to provide supporting documentation for how the assignments were made and to provide the essential objectives for each section. This information has been made available to the Agreement States in an All Agreement States letter, dated January 4, 1999. We asked that the States provide comments and suggestions on the compatibility designations by February 12, 1999.

The NRC considered all comments received on the compatibility designations and, where appropriate, made changes to either the assignment or to the rationale for the assignment. Section X of this document contains a summary of the compatibility designations. A more detailed compatibility chart which provides the essential objectives for each section and why particular designations were assigned is posted on the NRC Website at *http://www.hsrd.ornl.gov/nrc/home.html.* Click on [NRC-State Letters] and then select Part 35 Compatibility Chart.

Issue 4: How has NRC Incorporated Comments From the Agreement States on Agreement State issues?

Comment. A commenter questioned how the Agreement States comments were considered during the rulemaking.

Response. In the early stages of the rulemaking process, the NRC established a working group and a steering committee comprised of State personnel and NRC staff. One member of the NRC working group was also a member of the Conference of Radiation Control Program Director's, Inc., SR–6 Committee. This Committee is responsible for revising Part G, ''Medical Use of Radionuclides,'' of the Suggested State Regulations. As such, there was a considerable amount of information exchanged between the States and the NRC staff during the development of the proposed and final rule. We also discussed the revision of Part 35 with representatives of the Agreement States at the 1997, 1998, and 1999 annual meetings of the Organization of Agreement States. In addition, we received numerous comment letters from the States, all of which were considered in developing the final rule.

Technical comments and our response to the comments are discussed under the specific section headings. More general comments or comments that pertain exclusively to the compatibility level assigned to the requirement are discussed in this section.

Part 2—Comments on Compatibility Designations

The NRC received numerous comments on the compatibility designations assigned to specific sections. The following part provides the comments and our response to the comments. In many cases, but not all, we made changes to the compatibility designation based on the comment.

Part 20—Standards for Protection Against Radiation

Section 20.1301, Dose Limits for Individual Members of the Public

Comment. A commenter stated that this requirement should not be a compatibility category A. The compatibility category for this requirement should be D.

Response. This section meets the criteria for compatibility category A because it is an NRC program element which is generally applicable and is a dose limit. No change is required.

Part 35—Medical Use of Byproduct Material

Section 35.6, Provision for Research Involving Human Subjects

Comment. A commenter stated that compelling Agreement States to adopt this requirement does not reflect that there may be other criteria affecting human research subjects.

Response. A further review of this section indicates that Agreement States should adopt this requirement in order to avoid a gap in the consistent nationwide application of this Federal policy. The compatibility category was changed from ''D'' to ''C.'' The NRC also added a requirement to the section indicating that nothing in this section relieved licensees from complying with the other requirements in Part 35.

Section 35.24, Authority and Responsibilities for the Radiation Protection Program

Comment. A commenter stated that this requirement should be classified compatibility category D, not D Health and Safety (H&S). The commenter indicated that, while management should be responsible for the areas identified here, there may be other ways to ensure radiation safety. Further, in the opinion of the commenter, the intent of this requirement will be defeated for small facilities where the AU/RSO is management's designee.

Response. Section 35.24 in the final rule is assigned a compatibility category D, with the exception of paragraphs (b) and (f). These two paragraphs are assigned to compatibility category H&S. The H&S compatibility category provides the Agreement States with the flexibility needed to use other methods such as legally binding requirements to achieve the essential objective of this rule. In addition, § 35.24(b) and (f) meet the two failure test criteria for the assignment of compatibility category H&S. This designation provides a

minimum level of safety in the implementation of a radiation protection program.

Section 35.40, Written Directives

Comment. A commenter stated that the requirement for a written directive may not be contained in the State's radiation regulations. Another commenter stated that written directives do not meet the definition for a compatibility category C in Subpart A, because it does not create a gap or a duplication. It was also noted that written directives are a compatibility category ''D (H&S)'' in Subpart B. Another commenter stated that written directives should not be designated compatibility category H&S and that there are other methods to ensure the right dose is delivered to the right patient (e.g., requiring the physician to be present during a therapy treatment).

Response. In the final rule, paragraphs (a) and (b) of § 35.40, ''Written Directives,'' are assigned a compatibility category H&S. The NRC believes that it may be possible to ensure the right dose is delivered to the right patient if a legally binding requirement is in effect and there is some documentation by the physician in the routine radionuclide use log. In accordance with the Policy on Adequacy and Compatibility for Agreement State Programs, legally binding requirements may be acceptable in lieu of a specific regulation on written directives if the essential objectives of this rule are achieved. Section 35.40 meets the two failure test criteria for the assignment of compatibility category H&S. This designation provides a minimum level of safety for the medical use of agreement materials by reducing the likelihood of a medical event.

Section 35.61, Calibration of Survey Instruments

Comment. A commenter stated that the requirement in § 35.61 to note the date of the calibration on an instrument should not be a compatibility category H&S. The length of time for record retention is not a compatibility category H&S and should be designated a compatibility category C in all areas of the regulations.

Response. The NRC agrees with the commenter that the requirement to note the calibration date on a survey instrument and the record retention requirement should not be a compatibility category H&S. Therefore, these requirements have been revised from H&S to a compatibility category D. All of the other requirements in § 35.61 remain compatibility category H&S.

Section 35.63, Determination of Dosages of Unsealed Byproduct Material for Medical Use

Comment. A commenter stated that there may be some confusion regarding the compatibility category assigned to the requirement covering radiopharmaceutical dosages prepared by the medical use licensee under 10 CFR 35.63 versus those prepared by a commercial pharmacy/manufacturer under 10 CFR 32.72.

Response. Both medical licensees and the commercial preparer of radiopharmaceuticals must determine and record the activity of each dosage intended for medical use. Therefore, this requirement is a compatibility category H&S.

Section 35.67, Requirements for Possession of Sealed Sources and Brachytherapy Sources

Comment. A commenter stated that paragraph (a) should be a compatibility category C. The commenter believed that licensees can develop better procedures and should have the opportunity to submit them for review and approval by the licensing agency.

Response. Section 35.67(a) meets the two failure test criteria for the assignment of compatibility category H&S. This designation assists in establishing a minimum level of safety for the medical use of agreement materials by reducing the likelihood of a medical event and worker overexposure.

Comment. A commenter stated that paragraph (f) rather than (e) should be a compatibility category D and paragraph (e) should be a compatibility category ''D (H&S)''. Another commenter stated that paragraph (f) which provides a waiver of leak test requirements does not meet the criteria for compatibility category H&S.

Response. Paragraph (e) is a compatibility category H&S because the technical requirements are already addressed in Part 20 and Part 30 and the actual reporting requirement for leaking sources is contained in § 35.3067 which is a compatibility category C. We agree with the commenters. The compatibility category for paragraph (f) was revised from H&S to D.

Section 35.70, Surveys of Ambient Radiation Exposure Rate

Comment. A commenter questioned the need for a compatibility category H&S for paragraph (b).

Response. The NRC agrees with the commenters and have revised this section to indicate that § 35.70(b) is assigned a compatibility category D.

Section 35.75, Release of Individuals Containing Radioactive Drugs or Implants Containing Byproduct Material

Comment. A commenter stated that 10 CFR 35.75, which has been assigned a compatibility category C, should be changed to category B due to significant transboundary implications.

Response. The assignment of a compatibility category C to this requirement is appropriate because the term transboundary applies to the use of byproduct material by licensees which operate in multiple locations. The compatibility category C designation provides a minimum level of safety, while providing some flexibility to Agreement States to be more restrictive.

Section 35.80, Provisions of Mobile Medical Service

Comment. A commenter did not agree with the original basis for designating this section as D compatibility. They disagreed with the following statement: ''since there is no potential for medical use of byproduct material in other regulatory jurisdictions under reciprocity'' the section is designated a D compatibility.''

Other commenters commented on specific paragraph designations. A commenter stated that paragraph (a)(1) should not be a compatibility category H&S issue. Another commenter stated that paragraph (a)(4) should be a compatibility category H&S issue, but that the designation is inconsistent with the requirements for fixed facilities. (Note: Fixed facilities have to conduct surveys only for procedures requiring a written directive (§ 35.70)).

Response. The Agreement State representatives informed the NRC staff that not all Agreement States authorize mobile services and that there are a number of additional State professional and technical licensing issues which complicate this activity. The medical use of byproduct material (diagnostic or therapeutic) as a mobile service has been designated a compatibility category D for all Agreement States (not required for compatibility) and category H&S for those Agreement States which authorize mobile services. This designation H&S assists in establishing a minimum level of safety for the medical use of agreement materials by reducing the likelihood of a medical event and worker overexposure.

The NRC agrees with the specific comments on paragraphs (a)(1) and (a)(4). The compatibility categories were revised from H&S to D in these sections.

Section 35.92, Decay-In-Storage

Comment. A commenter stated that this section should not be a

compatibility category H&S issue. The failure scenario is in error in that it assumes waste would be placed in ordinary trash if storage of isotopes with longer or shorter half-lives were permitted. Permitting decay-in-storage does not mean material that has not decayed would be placed in ordinary trash.

Response. This section is a compatibility category D for those States that choose not to allow the decay-in-storage option. For States allowing this option, the compatibility category is H&S. The two or fewer failure test scenario was reworded to better reflect the importance of the H&S assignment for this requirement.

Sections 35.100, Use of Unsealed Byproduct Material for Uptake, Dilution, and Excretion Studies for Which a Written Directive Is Not Required and 35.200, Use of Unsealed Byproduct Material for Imaging and Localization Studies for Which a Written Directive Is Not Required

Comment. A commenter questioned the assignment of a compatibility category H&S to §§ 35.100 and 35.200 because they are very low risk procedures.

Response. Both requirements meet the two or fewer failure test scenario detailed in Management Directive 5.9 for the assignment of compatibility category H&S. These provisions assist in establishing a minimum level of safety in the medical use of agreement materials by reducing the likelihood of a medical event.

Section 35.390, Training for Use of Unsealed Byproduct Material for Which a Written Directive Is Required

Comment. A commenter believed that Agreement States should have the option of adopting higher standards for training even if it means the state would become ''incompatible.''

Response. A compatibility category B was assigned to this requirement, as well as all of the other training and experience requirements in Part 35. This ensures that the training and experience requirements for the medical use of byproduct material are consistent between NRC and the Agreement States.

Section 35.432, Calibration Measurements of Brachytherapy Sealed Sources

Comment. A commenter stated that this requirement should not be a compatibility category C.

Response. This requirement was assigned a compatibility category H&S which provides a minimum level of safety for the medical use of agreement materials by reducing the likelihood of a medical event.

Section 35.604, Surveys of Patients and Human Research Subjects Treated With a Remote Afterloader Unit

Comment. A commenter stated that the requirement for after implant surveys is not appropriate for a compatibility category C, since it is a Part 20 requirement.

Response. The NRC agrees with this comment and has changed the requirement to a compatibility category H&S.

Sections 35.610, Safety Procedures and Instructions for Remote Afterloader Units, Teletherapy Units, and Gamma Stereotactic Radiosurgery Units

*Comment.*A commenter stated that § 35.610 should be compatibility category C, as there can be other ways of meeting the essential objectives.

Response. Section 35.610 meets the two or fewer failure test criteria for the assignment of compatibility category H&S. This designation assists in establishing a minimum level of safety for the medical use of agreement materials by reducing the likelihood of a medical event and worker overexposure.

Section 35.615, Safety Precautions for Remote Afterloader Units, Teletherapy Units, and Gamma Stereotactic Radiosurgery Units

Comment. A commenter stated that § 35.615 should be compatibility category C, as there can be other ways of meeting the essential objectives.

Response. Section 35.615 meets the two or fewer failure test criteria for the assignment of compatibility category H&S. This designation assists in establishing a minimum level of safety for the medical use of agreement materials by reducing the likelihood of a medical event and worker overexposure.

General Comments on Training

Comment. A commenter stated that when the Part 35 rulemaking becomes effective, Agreement States that have more strict training and experience requirements for non-board certified physicians will not be able to accept individuals who have met the less restrictive requirements needed to become AUs on NRC licenses as authorized.

Response. When the final Part 35 becomes effective, the Agreement States will have up to 3 years to adopt compatible regulations. The training and experience criteria for physicians is a compatibility category B which means that the requirement has significant direct transboundary implications. Agreement States' requirements should be essentially identical to those of the NRC so that there are consistent training and experience requirements for the medical use of byproduct material. Non-board certified physicians will continue to be afforded the opportunity to present alternate credentials on a case-by-case basis.

V. Summary of Changes Made Between the Current Part 35 and the Revised Part 35

Subpart A, General Information, contains general information regarding medical use of byproduct material.

Section 35.1, Purpose and scope, was amended to specify that Part 35 provides for the radiation safety of workers, the general public, patients, and human research subjects. The NRC included the phrase ''patients, and human research subjects'' to make it clear that the provisions of this rule apply to the radiation safety of those individuals. This addition is consistent with the revision of the Medical Use Policy Statement that was published in the **Federal Register** on August 3, 2000 (65 FR 47654). We also added a reference to Part 171, ''Annual Fees for Reactor Operating Licenses, and Fuel Cycle Licenses and Materials Licenses, Including Holders of Certificates of Compliance, Registrations, and Quality Assurance Program Approvals and Government Agencies Licensed By NRC.'' This change makes it clear that the provisions in Part 171 apply to medical licensees.

Section 35.2, Definitions, was amended. The NRC either deleted, revised, or added specific definitions based on the use of the terms within Part 35. Each category of action is discussed separately.

Deleted Definitions

The NRC deleted the following terms because they do not appear in the final rule: as low as is reasonably achievable (ALARA), dental use, diagnostic clinical procedures manual, ministerial change, misadministration, podiatric use, recordable event, and teletherapy physicist.

Revised Definitions

The NRC revised the definitions of *address of use* and *area of use* to clarify that they also include the building where byproduct material is prepared for use. This recognizes that licensees not only receive, use, and store byproduct material, but, in the case of medical licensees, they may also prepare the material for use.

The NRC revised the definition for *authorized nuclear pharmacist* (ANP) to eliminate the specific board certifications by name and to refer to the specific section(s) in Part 35 containing the requirements the individual must meet to be considered an ANP. We deleted the reference to the specific board certifications because the regulatory text in Part 35 no longer incorporates a listing of specialty boards whose diplomates automatically fulfill the training and experience requirements. In place of listing the boards, the final rule provides for NRC recognition of the boards. We revised the definition of ANP to include individuals identified as ANPs on a specific license issued by the Commission or Agreement State that authorizes medical use or the practice of nuclear pharmacy; a permit issued by a Commission master material licensee that authorizes medical use or the practice of nuclear pharmacy; a permit issued by a Commission or Agreement State broad scope medical use licensee that authorizes medical use or the practice of nuclear pharmacy; or a permit issued by a Commission master material license broad scope medical use permittee that authorizes medical use or the practice of nuclear pharmacy. In addition, an ANP can be an individual identified as an authorized nuclear pharmacist by a commercial nuclear pharmacy which has been given authorization to identify authorized nuclear pharmacists or an individual designated as an authorized nuclear pharmacist in accordance with § 32.72(b)(4).

The NRC revised the definition for an *authorized user* (AU) to eliminate the specific board certifications by name and to refer to the specific section(s) in Part 35 containing the requirements the individual must meet to be considered or an AU. We deleted the reference to the specific board certifications because the regulatory text in Part 35 no longer incorporates a listing of specialty boards whose diplomates automatically fulfill the training and experience requirements. In place of listing the boards, the final rule provides for NRC recognition of the boards. We revised the definition of AU to include individuals identified as AUs on a Commission or Agreement State license that authorizes the medical use of byproduct material; a permit issued by a Commission master material licensee that is authorized to permit the medical use of byproduct material; a permit issued by a Commission or Agreement State specific licensee of broad scope that is authorized to permit the medical use of byproduct material; or a permit issued by a Commission master material license broad scope permittee that is authorized to permit the medical use of byproduct material.

The NRC revised the definition for a *brachytherapy source* to acknowledge current practices within the radiation oncology field. In addition, we deleted the word ''sealed'' from the definition to include sources that do not meet the definition of ''sealed source,'' i.e., radioactive plated, embedded, and activated sources.

The NRC revised the definition of *management* to recognize an individual having the authority to manage, direct, or administer the licensee's activities who may not have the title of Chief Executive Officer.

The NRC amended the definition of *medical use* to replace the word ''therefrom'' with the phrase ''from byproduct material'' because the regulations in Part 35 apply only to the medical use of byproduct material.

The NRC replaced the definition of *mobile nuclear medicine service* with a definition for *mobile medical service* because it is a broader term that encompasses all modalities that could be performed by a mobile medical service.

The NRC revised the definition of *output* to refer to the exposure rate or dose rate coming from a brachytherapy source, remote afterloader, or gamma stereotactic radiosurgery unit. The current rule only addresses the output from a teletherapy unit.

The NRC revised the definitions of *prescribed dosage* and *prescribed dose*. As modified, the definition of prescribed dosage allows the AU to prescribe a range of activity, without reference to the diagnostic clinical procedures manual. The term unsealed byproduct material in this definition replaces the term radiopharmaceutical. We added a reference to remote afterloaders to the definition of prescribed dose.

The NRC revised the definition of *Radiation Safety Officer* (RSO) to include a reference to the specific requirements an individual must meet in order to be authorized as an RSO. This change makes the definition of RSO consistent with the definitions of ANP, AU, and authorized medical physicist (AMP). We also amended the definition to state that an RSO could also be an individual identified on a specific medical use license issued by the Commission or Agreement State license or a permit issued by a Commission master material licensee.

The NRC revised the definition of *written directive* to delete the provisions for the date the directive was signed, the signature of the AU before administration of any byproduct material or radiation from byproduct material to a specific patient or human research subject, and the specific information that must be included in written directives. These provisions were considered to be substantive requirements and were moved to § 35.40, Written directives.

New Definitions

The NRC added the following definitions either because they are used in the final Part 35 or the stakeholders asked that definitions of the terms be added to help clarify regulatory text. Definitions were added for the following terms: authorized medical physicist, brachytherapy, client's address, high dose-rate remote afterloader, low dose-rate remote afterloader, manual brachytherapy, medical event, medium dose-rate remote afterloader, patient intervention, preceptor, pulsed dose-rate remote afterloader, Sealed Source and Device Registry, stereotactic radiosurgery, structured educational program, teletherapy, temporary job site, therapeutic dosage, therapeutic dose, treatment site, type of use, and unit dosage.

The NRC amended § 35.5, Maintenance of records, to insert ''and'' in the current phrase ''drawings and specifications.''

The NRC amended the title of § 35.6 to read Provisions for the protection of human research subjects. We also restructured this section to make it easier to read. We added an introductory paragraph to make it clear that research permitted under § 35.6 may only be performed using byproduct material that is already authorized for medical use by the license. For example, if a licensee is authorized to use byproduct material for medical use under §§ 35.100, 35.200, and 35.300 and Cs-137 for calibration of survey instruments, it cannot conduct medical research using the Cs-137 source. However, the same licensee can conduct research using materials authorized under §§ 35.100, 35.200, or 35.300.

We added paragraph (d) to codify the Commission's intent that § 35.6 does not relieve licensees from complying with other provisions in Part 35 and that all relevant radiation safety provisions of Part 35 are applicable to research involving human subjects. This position is further discussed in the regulatory history of § 35.6. For further information on this issue, see the **Federal Register** of December 2, 1994 (59 FR 61767).

The NRC made no changes in § 35.7, FDA, other Federal, and State requirements.

The NRC amended § 35.8, Information collection requirements; OMB approval, to reflect the renumbering of some sections within the rule and the additional recordkeeping and reporting sections which are in separate subparts in the new rule.

Section 35.10, Implementation, is a new section that discusses the provisions for implementing the final rule. A detailed discussion of the implementation provisions can be found in Section IX of the **SUPPLEMENTARY INFORMATION.** This section replaces the current § 35.999, Resolution of conflicting requirements during transition period.

The NRC revised § 35.11, License required. Paragraph (a) was revised to state more clearly that a person may manufacture, produce, acquire, receive, possess, prepare, use, or transfer byproduct material for medical use only in accordance with a specific license issued by the Commission or an Agreement State or as allowed in paragraphs (b)(1) and (b)(2) of this section. We added ''prepare'' to recognize that medical use licensees may also prepare the byproduct material for use and need a license to do so. We amended paragraphs (b)(1) and (b)(2) to reflect that the requirements for supervision in the current § 35.25 were replaced by the requirements in the final § 35.27.

The NRC revised § 35.12, Application for license, amendment, or renewal.

We revised paragraph (a) to state that any application for a license, amendment, or renewal must be signed by the applicant's or licensee's management. The current rule indicates that any person may apply if the application is for medical use not sited in a medical institution and that only management may apply for a license if the application is for use in a medical institution. We believe it is important that management apply for a license, regardless of where the byproduct material is used, because NRC holds the licensee responsible for any actions of its employees.

We revised paragraph (b) to address license applications for uses authorized under §§ 35.600 and 35.1000. Therefore, the current paragraph (c) was no longer needed and was deleted. We no longer require licensees to have separate licenses for teletherapy or gamma stereotactic radiosurgery units. In addition, paragraph (b) lists the items that must be submitted to NRC in support of a license application. The new paragraph (c) provides a list of the items that must be submitted to NRC in support of a license amendment. The lists in paragraphs (b) and (c) codify existing licensing practices. Finally, we amended paragraphs (b) and (c) to delete the reference to the regulatory guides. Guidance for completing an application is in NUREG–1556, Vol. 9 (draft), ''Consolidated Guidance About Materials Licenses: Program-Specific Guidance About Medical Use Licenses.'' NUREG–1556, Vol 9 (draft), is available for inspection at the NRC Public Document Room, 2120 L Street NW. (Lower Level), Washington, DC.

We deleted the statement in the current paragraph (d) that referenced where to find copies of regulatory guides, application forms, or where to submit an application or an amendment request. This information is not needed in the regulation. The new paragraph (d) addresses applications for medical use of byproduct material as described in § 35.1000, i.e. applications that are not specifically included in Subparts D through H of the final rule and are referred to as ''emerging technologies.'' The current rule does not address emerging technologies. Therefore, it does not provide for efficient licensing of emerging technologies. Paragraph (d)(1) provides a list of the additional information needed by NRC to approve a license or license amendment for a use not specifically addressed in Subparts D through H of the new rule. This additional submittal will provide NRC with information on the radiation safety aspects of the specific medical use of the material. Applicants for uses under § 35.1000 must also submit the information required by paragraph (b) and (c) of this section.

The NRC revised § 35.13, License amendments. We revised paragraph (a) to clarify that a licensee must apply for a license amendment before it ''prepares'' byproduct material for a type of use that is not authorized on the licensee's current license. Paragraph (a) was also changed to reference ''type of use'' rather than ''clinical procedure.'' In addition, paragraph (a) was expanded to include AUs, AMPs, and ANPs identified on a permit issued by a Commission master material licensee that is authorized to permit the use of byproduct material in medical use or in the practice of nuclear pharmacy or by a commercial nuclear pharmacy that has been given authorization to identify authorized nuclear pharmacists. The term ''type of use'' is defined in Part 35 and is more appropriate for use in this requirement. We added the reference to an AMP to paragraph (b). A medical use licensee is no longer required to amend its license before allowing anyone to work as an AMP if that individual meets the training and experience requirements in § 35.51(a), and the training and experience requirements were met within the 7 years preceding the date of the application in accordance with § 35.59. In addition, paragraphs (a) and (b) were reworded to indicate clearly the subject of each paragraph.

In paragraph (c), we deleted the requirement for a licensee to apply for a license amendment if the teletherapy physicist changes, provided the individual meets the requirements in §§ 35.51(a) and 35.59. This change is consistent with licensing requirements for AUs and ANPs. Additionally, in the revised § 35.24(c), the Commission recognizes that unusual conditions may arise when the RSO leaves a licensee with little to no advance warning. In this event, the licensee may want to consider using an AU or other individual qualified to be an RSO to fill the position, pending appointment of a new RSO. Under these conditions, the licensee must move expeditiously to permanently fill the position of RSO and should contact the appropriate NRC regional office and explain the situation.

We revised paragraph (d) to require the licensee to apply for and receive a license amendment before it receives byproduct material in excess of the amount or in a different form or it receives a different radionuclide than is authorized on the license. This change clarifies that the requirement is tied to a licensee's authorization to possess, not order, byproduct material and to clarify when an amendment is needed. For example, if a license authorizes possession of any byproduct material identified in §§ 35.100, 35.200, and 35.300, in any chemical and/or physical form, a licensee would be required to obtain a license amendment if it wanted to possess sealed sources for manual brachytherapy (§ 35.400). This same licensee would not need to amend its license if it wanted to use sodium iodide I–131 for thyroid carcinoma because that use is authorized by § 35.300. Further, an amendment would not be required if the licensee wanted to use Tc-99m labeled methylene diphosphonate (MDP) rather than Tc-99m labeled sestamibi because the use is authorized by § 35.200.

To reduce regulatory burden, we deleted the requirement in paragraph (e) for a licensee to apply for a license amendment if there is a change in the areas where byproduct material is used under either § 35.100 or § 35.200. In addition, the requirement in the current paragraph (e) for a licensee to apply for an amendment before it changes the

address(es) of use identified in the application or on the license was moved to the final paragraph (f).

We added a new paragraph (g) that requires a licensee to apply for a license amendment if it revises the procedures that must be submitted in accordance with § 35.12(b)(2), where the revision reduces radiation safety. This applies to procedures required by §§ 35.610, 35.642, 35.643, and 35.645, as applicable.

The NRC revised § 35.14, Notifications. Paragraph (a) was revised to include a requirement for the licensee to notify NRC no later than 30 days after the date the licensee permits an individual to work as an AMP under § 35.13(b), which is comparable to the notification requirements for AUs or ANPs. This change was needed because we would like to be notified when an AMP who has been approved by the licensee begins work. (Reference change made to § 35.13(b)). We revised paragraph (b) to require that the licensee notify NRC when an AMP permanently discontinues performance of duties under the license and to require that a licensee notify NRC when the licensee changes its name. This provision applies only if there is no change in ownership, as described in § 30.34 of this chapter. If there is a change in ownership, the licensee must take appropriate action to have its license amended before the transfer occurs. We also added a requirement to paragraph (b) for a licensee to notify NRC of any changes in areas where byproduct material is used in accordance with either § 35.100 or § 35.200. These revisions to the requirements for notifications were warranted because of the associated revisions to the requirements for license amendments in § 35.13.

The NRC amended § 35.15, Exemptions regarding Type A specific licenses of broad scope, to add the term ''authorized medical physicist'' to paragraph (e). This change is needed because, under the revised requirements in § 35.13, broad scope licensees have the authority to appoint AUs, ANPs, or AMPs without applying for a license amendment if the individuals meet the approved criteria in Subparts B and D through H.

We added a new paragraph (f) to exempt broad scope licensees from § 35.14(b)(4), which requires licensees to notify NRC if there have been any changes in the areas where byproduct material is used in accordance with either § 35.100 or § 35.200. This provision for exemptions is consistent with the current exemption these licensees have from applying for a license amendment before they add to or change the areas of use identified in the application or on the license.

We added a new paragraph (g) to also exempt these broad scope licensees from § 35.49(a). This change codifies an exemption currently provided to these licensees through a standard license condition. NRC's medical use licensees with a Type A specific license of broad scope currently receive a standard license condition that exempts the licensee from only receiving sealed sources or devices manufactured from licensees with medical distribution licenses issued in accordance with § 32.74. This change replaces the license condition.

The NRC revised § 35.18, License issuance. Paragraph (a) lists the conditions that must be met in order for the Commission to issue a license. We added requirements for a mobile medical service license as paragraph (b). The NRC will issue a license for mobile medical service if the applicant meets the requirements specified in paragraph (a) of the section and if the individual or human research subject to whom the applicant administers byproduct material, or radiation from byproduct material, may be released following treatment in accordance with § 35.75. The later provision is necessary because mobile medical service licensees do not have the capability of controlling individuals who cannot be released under § 35.75.

The NRC amended § 35.19, Specific exemptions, to delete the statement that the Commission will review requests for exemptions from training and experience requirements with the assistance of its Advisory Committee on the Medical Uses of Isotopes (ACMUI). This statement is a matter of Commission policy rather than a regulatory requirement.

Subpart B, General Administrative Requirements, contains the general administrative requirements regarding medical use of byproduct material.

The NRC deleted the current § 35.20, ALARA program. ALARA is discussed in § 20.1101, Radiation protection programs, and medical licensees must comply with the requirements of that section. That section requires, in part, that a licensee develop, document, and implement a radiation protection program and use, to the extent practicable, procedures and engineering controls to achieve occupational doses and doses to members of the public ALARA. Therefore, we do not believe that the current § 35.20 is needed in light of the requirements in § 20.1101. A medical use licensee should have flexibility in developing, maintaining, and implementing a radiation protection program that meets the requirements of Part 20.

The NRC deleted the current § 35.21, Radiation Safety Officer. The requirements in paragraph (a) were moved to § 35.24. The list of the RSO's duties in paragraph (b) was deleted because it is overly prescriptive and in some cases overlaps with the requirements in § 20.1101. We believe that the licensee should have flexibility in developing, maintaining, and implementing its radiation protection program, including establishing the RSO's duties.

The NRC deleted the current § 35.22, Radiation Safety Committee. The issue of whether the NRC should require a Radiation Safety Committee (RSC) was identified as a cross-cutting issue. Therefore, this issue was discussed at public meetings throughout the rulemaking process. Comments received on this topic are discussed in Section III of the **SUPPLEMENTARY INFORMATION.** The basic requirement for certain medical licensees to have an RSC to oversee all uses of byproduct material permitted by the license was moved to § 35.24. However, the requirement was modified so that only licensees that are authorized for two or more different types of uses of byproduct material under Subparts E, F and H, or two or more types of units under Subpart H, are required to establish an RSC. Several other requirements that are currently in § 35.22 were also moved to § 35.24 and are discussed under that section. However, most of the requirements that are currently in § 35.22 have been deleted to provide licensees with more flexibility in how they use the Committee to oversee the radiation safety aspects of the medical use of byproduct material.

The NRC deleted the current § 35.23, Statements of authority and responsibilities. The requirements in this section, with some modifications, were moved to § 35.24.

The NRC added a new § 35.24, Authority and responsibilities for the radiation protection program. A number of the current, prescriptive requirements associated with the radiation protection program have been deleted to provide licensees more flexibility in achieving the objective of radiation safety.

Paragraph (a) requires licensee management to approve, in writing, licensing actions; individuals before allowing them to work as an AU, ANP, or AMP; and radiation protection program changes that do not require a license amendment and are permitted under § 35.26. We believe that licensee

management should be responsible for these approvals as part of their overall responsibility for the radiation protection program. This is a change from the current § 35.22, which gives the RSC the responsibility for two of these approvals: approval of individuals before allowing them to work as an RSO, AU, ANP, or AMP; and approval of radiation protection program changes that do not require a license amendment.

The requirement in paragraph (b) to appoint an RSO is currently in § 35.21. Paragraph (b) also includes a new requirement that the RSO agree, in writing, to be responsible for implementing the radiation protection program. The requirements in paragraphs (e) and (g), associated with the authorities, duties, and responsibilities of the RSO, are similar to the requirements in the current § 35.23.

Paragraph (c) includes a new provision that allows a licensee to have a temporary RSO for up to 60 days a year if the individual is qualified to be an RSO under §§ 35.50 and 35.59 and if the licensee meets the requirements for RSOs in paragraphs (b), (e), (g), and (h) of this section. We added this new provision so that licensees can appoint someone to fulfill the duties and responsibilities of the RSO in a timely manner, following the sudden departure of the permanent RSO named on the license. Licensees are required by § 35.14(b) to notify the Commission in writing no later than 30 days after an RSO permanently discontinues performance of duties under the license.

Paragraph (d) allows a licensee to simultaneously appoint more than one temporary RSO, if needed, to ensure that the licensee has an individual that is qualified to be an RSO for each of the different types and uses of byproduct material permitted by the license.

Paragraph (f) contains a requirement for certain medical licensees to have an RSC to oversee all the uses of byproduct material permitted by the license. We modified the current requirement in § 35.22 so that only licensees that are authorized for two or more different types of uses of byproduct material under Subparts E, F, and H, or two or more types of units under Subpart H, are required to establish an RSC. For example, licensees that are permitted on their license to use therapeutic quantities of unsealed byproduct material (§ 35.300) and manual brachytherapy (§ 35.400), or manual brachytherapy (§ 35.400) and low dose-rate remote afterloaders (§ 35.600), or teletherapy (§ 34.600) and gamma stereotactic radiosurgery (§ 35.600) would be required to have an RSC. However, we believe that many other medical licensees will also continue to use an RSC to oversee the use of byproduct material. Licensees should note that the requirement for an RSC is no longer limited to medical institutions, which means that it now also applies to free-standing clinics.

The new requirement for an RSC is much less prescriptive than the requirements in the current § 35.22. For example, paragraph (f) does not include the list of administrative requirements and committee tasks that are specified in the current rule. However, based on public comment, we have specified that the membership of the committee should include an AU of each type of use permitted by the license, the RSO, a representative of the nursing service, a representative of management who is neither an AU nor an RSO, and other members the licensee considers appropriate.

Paragraph (h) requires that the licensee retain a record of management's approval of actions in paragraph (a); written acceptance of RSO duties as specified in paragraph (b); and the duties, responsibilities, and authority of the RSO specified in paragraph (e) in accordance with § 35.2024, Records of authority and responsibilities for radiation protection programs.

The NRC deleted the current § 35.25, Supervision. The requirements in this section, with some modifications, were moved to § 35.27. The requirements in paragraphs (a)(3) and (b)(3) for periodic reviews of the work of supervised individuals were deleted because we believe that these requirements are too prescriptive. Licensees should have flexibility in how they evaluate supervised individuals because they are held responsible for their acts and omissions.

Section 35.26, Radiation protection program changes, is a new section. The requirements in this section are similar to the requirements in the current § 35.31, which was deleted. This section allows licensees to revise their radiation protection programs without Commission approval if the revision does not require an amendment in accordance with § 35.13; if the revision is in compliance with the regulations and license; if the change has been reviewed and approved by the RSO, and reviewed and approved in writing by licensee management; and if the affected individuals have been instructed on the revised program before the changes are implemented. This requirement provides licensees with flexibility to manage their radiation protection programs and clearly defines the situations that will not require Commission approval of an amendment to their license. The NRC believes that many licensees were reluctant to make changes to their current program because the term ''ministerial changes,'' as defined in the current § 35.2 and as used in the current § 35.31, was subject to misinterpretation. This change is intended to provide clear guidance to licensees on when they can revise their radiation protection programs without obtaining Commission approval.

We believe that it is important to instruct individuals in program changes, including those permitted under § 35.26, before they are implemented. This instruction may be provided in writing or orally and may be conducted on an informal or formal basis. It is not necessary to document that this instruction has been provided to affected parties, because these changes should not reduce radiation safety. At the time of inspection, NRC inspectors may question whether this instruction was provided.

Section 35.27, Supervision, is a new section. The requirements in this section are similar to the requirements in the current § 35.25, which was deleted. The NRC deleted the requirement to instruct individuals in the principles of radiation safety from paragraphs (a)(1) and (b)(1). This type of instruction is adequately addressed by § 19.12, Instructions to workers, of this chapter. We also amended paragraphs (a)(1) and (b)(1) to require that, in addition to the requirements in § 19.12, the licensee shall instruct supervised individuals in the written radiation protection procedures, written directive procedures, regulations of this chapter, and license conditions. We revised paragraph (a)(2) to clarify that the instructions, procedures, regulations, and license conditions that supervised individuals are required to follow are limited in this part to those involving the medical use of byproduct material. We deleted paragraphs (a)(3) and (b)(3) of the current § 35.25 because the licensee should have flexibility in evaluating employee performance. We amended paragraph (b)(2) to require supervised individuals to follow the instructions of the supervising AU or ANP regarding the preparation of byproduct material for medical use, written radiation protection procedures, regulations of this chapter, and license conditions. The statement in paragraph (c) that licensees are responsible for the acts and omissions of supervised individuals is similar to the statement in the current § 35.25(c).

The NRC deleted the current § 35.29, Administrative requirements that apply

to the provision of mobile service. The conditions for the Commission to issue a mobile medical service license were moved to § 35.18. The requirements in paragraphs (b) and (d) were moved to § 35.80. We deleted paragraph (c) because this requirement, which addressed the client's responsibilities, was viewed as being overly prescriptive. Mobile medical service licensees are required to comply with all the provisions of the license that authorize the use, possession, and transfer of material.

The NRC deleted the current § 35.31, Radiation safety program changes. The requirements, with some modifications, were moved to § 35.26 so that all the requirements pertaining to management of the licensee's radiation protection program appear in one area of Subpart B.

The NRC deleted the current § 35.32, Quality management program. The issue of whether the Commission should continue to require that a licensee develop, implement, and maintain a quality management program was identified as a cross-cutting issue and was discussed at public meetings throughout the rulemaking. Comments received on this topic are discussed in Section III of the **SUPPLEMENTARY INFORMATION.** Based on these comments, the Commission deleted the requirements for a quality management program. However, the Commission believes there are three elements of the current quality management program that should continue to be addressed in the rule for certain procedures: confirming patient identity, requiring written directives, and verifying dose. The requirements for these three elements are in §§ 35.40 and 35.41. However, we believe that licensees will continue to implement other elements of the current quality management program as part of the ''standard of care'' in medicine. In this regard, the Commission acknowledges that other factors, such as accreditation, have resulted in medical institutions adopting programs similar to those specified in the current rule.

The NRC deleted the current § 35.33, Notifications, reports, and records of misadministrations. The recordkeeping and reporting requirements were moved to Subparts L and M, respectively.

Section 35.40, Written directives, is a new section. This section contains requirements for the preparation of written directives that are similar to the requirements in the current §§ 35.2 and 35.32. Written directives are no longer required for administrations of sodium iodide I–125 because sodium iodide I–131 is primarily used now. Based on public comments and discussions with the ACMUI, changes were made in the information that must be included in written directives. For gamma stereotactic radiosurgery, the requirements for target coordinates, collimator size, plug pattern, and total dose have been deleted, and requirements for total dose, treatment site, and values for the target coordinate settings per treatment for each anatomically distinct treatment site have been added. For teletherapy, the requirement for overall treatment period has been deleted and a requirement for number of fractions has been added. For high dose-rate remote afterloading brachytherapy, requirements have been added for the dose per fraction and the number of fractions. For all other brachytherapy, before implantation, the requirements for number of sources and source strengths have been deleted and requirements for treatment site and dose have been added; and after implantation, but before completion of the procedure, a requirement for the number of sources has been added. Licensees should refer to § 35.41 for the requirements for procedures for administrations requiring written directives.

Section 35.41, Procedures for administrations requiring a written directive, is a new section. Paragraph (a) of this section requires licensees to develop, implement, and maintain written procedures to provide high confidence that, before each administration, the patient's or human research subject's identity is verified and that each administration is in accordance with the written directive. The specific details to be included in the written directives are in § 35.40. Paragraph (b) of this section specifies the items that must, at a minimum, be addressed in the procedures. The items identified in § 35.41 are viewed by the Commission as key elements of a program that will provide high confidence that byproduct material will be administered as directed by the AU. However, the regulations are not prescriptive about how these objectives are met, allowing licensees the flexibility to develop procedures to meet their needs. This section includes no requirement for submittal or approval of the procedures, as was previously required by the quality management rule. The recordkeeping requirements for this section are in § 35.2041, Records for procedures for administrations requiring a written directive.

The NRC retained § 35.49, Suppliers for sealed sources or devices for medical use with one modification. We added a new paragraph (b) to this section to permit noncommercial transfer of sealed sources or devices for medical use between Part 35 licensees that have a license to possess the source or device. Currently, licensees must obtain an amendment exempting them from the requirements in this section following initial distribution of the sealed source or device.

Section 35.50, Training for Radiation Safety Officer, is a new section. The training and experience requirements for an RSO were moved, with some modifications, from the current § 35.900, Radiation Safety Officer. Two changes made in the new section should be noted. First, the listing of specialty boards by name was deleted because the regulatory text in Part 35 will no longer incorporate a listing of specialty boards whose diplomates automatically fulfill the training and experience requirements for RSOs. In place of listing the boards, the final rule provides for NRC recognition of the boards. Second, an individual must obtain written certification from a preceptor indicating that the individual has satisfactorily completed the requirements in this section and has achieved a level of competency sufficient to function independently as an RSO. Section III of the **SUPPLEMENTARY INFORMATION** contains a detailed discussion of the Commission's changes to the training and experience requirements in Part 35. Note, 2 years after the effective date of the final rule, § 35.50 will replace the current requirements in § 35.900, Radiation Safety Officer.

The NRC deleted the current § 35.50, Possession, use, calibration and check of dose calibrators. The requirements in this section, with some modifications, were moved to § 35.60.

Section 35.51, Training for an authorized medical physicist, is a new section. The training and experience requirements for an AMP were moved, with some modifications, from the current § 35.961, Training for teletherapy physicist. Three changes made in the new section should be noted. First, the title of this section was revised because the training and experience requirements in this section now apply to AMPs, rather than just teletherapy physicists, because requirements for gamma stereotactic radiosurgery units and remote afterloader units have been codified in the revised Part 35. Second, the listing of specialty boards by name was deleted because the regulatory text in Part 35 will no longer incorporate a listing of specialty boards whose diplomates automatically fulfill the training and experience requirements for AMPs. In

place of listing the boards, the final rule provides for NRC recognition of the boards. Third, an individual must obtain written certification from a preceptor indicating that the individual has satisfactorily completed the requirements in this section and has achieved a level of competency sufficient to function independently as an AMP. Section III of the **SUPPLEMENTARY INFORMATION** contains a detailed discussion of the Commission's changes to the training and experience requirements in Part 35. Note, 2 years after the effective date of the final rule, § 35.51 will replace the requirements in § 35.961, Training for authorized medical physicist.

The NRC deleted the current § 35.51, Calibration and check of survey instruments. The requirements in this section, with some modifications, were moved to § 35.61.

The NRC deleted the current § 35.52, Possession, use, calibration, and check of instruments to measure dosages of alpha- or beta-emitting radionuclides. The requirements in this section, with some modifications, were moved to § 35.60.

The NRC deleted the current § 35.53, Measurements of dosages of unsealed byproduct material for medical use. The requirements in this section, with some modifications, were moved to § 35.63.

Section 35.55, Training for an authorized nuclear pharmacist, is a new section. The training and experience requirements for an ANP were moved, with some modifications, from the current § 35.980, Training for an authorized nuclear pharmacist. One change made in the new section should be noted. The listing of specialty boards by name was deleted because the regulatory text in Part 35 will no longer incorporate a listing of specialty boards whose diplomates automatically fulfill the training and experience requirements for ANPs. In place of listing the boards, the final rule provides for NRC recognition of the boards. Section III of the **SUPPLEMENTARY INFORMATION** contains a detailed discussion of the new training and experience requirements in Part 35. Note, 2 years after the effective date of the final rule, § 35.55 will replace the current requirements in § 35.980, Training for an authorized nuclear pharmacist.

Section 35.57, Training for an experienced Radiation Safety Officer, teletherapy or medical physicist, authorized user, and nuclear pharmacist, is a new section that replaces the current requirements in §§ 35.901, 35.970, and 35.981, which will be retained for 2 years after the effective date of the final rule. All individuals who are identified as RSOs, teletherapy or medical physicists, AUs, and nuclear pharmacists on an NRC or Agreement State license or an equivalent permit issued before the effective date of the final rule will have ''deemed'' status after the rule becomes effective. These individuals do not need to comply with the new training and experience requirements unless they want to be named on a license for other types of uses.

The NRC deleted the current § 35.57, Authorization for calibration and reference sources. The requirements in this section, with some modifications, were moved to § 35.65.

Section 35.59, Recentness of training, is a new section that replaces the current requirements in § 35.972. Although this is not a new requirement, questions have recently been raised regarding whether all elements of the requirements must have been obtained in the last 7 years. The NRC expects that (1) either the individual has been board certified or has completed the training specified in the alternative pathway within the 7 years preceding the date of the application; or that (2) the individual has had related continuing education and experience since completing the required training and experience requirements. Continuing education and experience requirements are reviewed on a case-by-case basis, with input from the ACMUI, as necessary. We amended the text in the current § 35.972 to reference Subparts B, D, E, F, G, and H because the revised training and experience requirements appear in the subparts with their associated modality.

The NRC deleted the current § 35.59, Requirements for possession of sealed sources and brachytherapy sources. The requirements in this section, with some modifications, were moved to § 35.67.

Subpart C, General Technical Requirements, contains general technical requirements regarding medical use of byproduct material.

Section 35.60, Possession, use, and calibration of instruments used to measure the activity of unsealed byproduct material, is a new section that replaces the current §§ 35.50 and 35.52. This section addresses calibration of all instruments used to measure the activity of all unsealed byproduct materials, rather than only dose calibrators used to measure the activity of dosages of photon-emitting radionuclides (§ 35.50) or instruments used to measure dosages of alpha- or beta-emitting radionuclides (§ 35.52). The change recognizes that there are various types of instruments that can be used to measure the activity of unsealed byproduct materials. This change also gives licensees flexibility in developing a calibration program which meets their program needs.

The NRC deleted prescriptive calibration requirements in the current §§ 35.50 and 35.52. Paragraph (b) in the final rule requires that licensees calibrate the instrumentation in accordance with nationally recognized standards (e.g., voluntary consensus standards, such as ANSI N42.13–1986 (R 1993), ''Calibration and Usage of Dose Calibrator Ionization Chambers for the Assay of Radionuclides'') or with the manufacturer's instructions. This change makes the regulation more flexible, more adaptable to new technology, and more performance-based.

Licensees should note that they are required by § 35.63 to determine the activity of each dosage before medical use. If they use only unit dosages of radioactive drugs that meet the definition in § 35.2, then § 35.63 allows the licensee to determine the dosage by direct measurement of radioactivity; or by a decay correction based on the activity or activity concentration determined by either a manufacturer or preparer licensed under § 32.72 or equivalent Agreement State requirements or an NRC or Agreement State licensee for use in research in accordance with a Radioactive Drug Research Committee (RDRC)-approved protocol or an Investigational New Drug (IND) protocol accepted by the Food and Drug Administration (FDA). If a licensee chooses to determine the dosage using this method, a licensee would not be required to possess instrumentation to measure the activity of the dosage, i.e., the licensee would not be required to comply with § 35.60. However, if a licensee chooses to reassay a unit dosage for the purpose of adjusting the activity, it would no longer be considered a unit dosage once it was altered, and the licensee must comply with § 35.60. This requirement is appropriate because confirmation of a dosage, or adjustment of dosages, must be based on properly-calibrated equipment.

The recordkeeping requirements for this section are in § 35.2060, Records of calibrations of instruments used to measure the activity of unsealed byproduct material.

The requirements in the current § 35.60, with minor modifications, were moved to the final § 35.69.

Section 35.61, Calibration of survey instruments, is a new section that replaces the current § 35.51. The requirements in the current § 35.51 to

note the apparent exposure rate from a dedicated check source, as determined at the time of calibration; to attach a correction chart or graph to the instrument; and to check each survey instrument for proper operation with a dedicated check source each day of use were deleted. These changes give the licensee greater flexibility in calibrating instruments.

Paragraph (a) in the new § 35.61 now requires the licensee to calibrate survey instruments used to show compliance with this part and with Part 20 before first use, annually, and following a repair that affects the calibration. Paragraph (b) requires that survey instruments be removed from use if the indicated exposure rate differs from the calculated exposure rate by more than 20 percent. Previously, there was no threshold for removing instruments from use. The requirements in this section are generally consistent with ANSI N323–1978 (R 1993), ''Radiation Protection Instrumentation Test and Calibration.''

The recordkeeping requirements for this section are in § 35.2061, Records of radiation survey instrument calibrations.

The requirements in the current § 35.61, with minor modifications, were moved to the final § 35.69.

Section 35.63, Determination of dosages of unsealed byproduct material for medical use, is a new section that replaces the current § 35.53. This section requires licensees to determine and record the activity of each dosage before medical use. For unit dosages as defined in § 35.2, paragraph (b) allows the licensee to determine the dosage by direct measurement of radioactivity; or by a decay correction based on the activity or activity concentration determined by either a manufacturer or preparer licensed under § 32.72 or equivalent Agreement State requirements or an NRC or Agreement State licensee for use in research in accordance with a RDRC-approved protocol or an IND protocol accepted by the FDA. Because the unit dosages have been assayed by the Part 32 licensee or by a licensee for use in research in accordance with an RDRC-approved protocol or an IND protocol accepted by FDA, the NRC does not believe the Part 35 licensee should be required to reassay the dosage. Licensees should note that if a unit dosage is changed or manipulated in any way it is no longer considered to be a unit dosage and will need to be reassayed before it is administered.

For other than unit doses, paragraph (c) allows the licensee to determine the dosage by direct measurement of radioactivity; by combination of direct measurement of radioactivity and mathematical calculations; or by combination of volumetric measurements and mathematical calculations based on the measurement made by a manufacturer or preparer licensed under § 32.72 or an equivalent Agreement State requirement. The current rule limits the licensee to using direct measurement for determining the activity of a photon-emitting radionuclide, but allows alpha-or beta-emitting radionuclides to be measured either by direct measurement or by combination of measurements and calculations. This change allows licensees flexibility in determining dosages and does not distinguish between the type of the radiation (e.g., alpha, beta, or photon) and the way the determination is made.

Paragraph (d) permits a licensee to use a dosage if the dosage does not differ from the prescribed dosage by more than 20 percent or if the dosage falls within the prescribed dosage range. We believe that the rule should allow for some deviation from the prescribed dosage if the licensee chooses to prescribe a dosage rather than a dosage range. Without this allowed deviation, the administered dosage would need to match the prescribed dosage. We have not allowed a deviation outside of the prescribed range because we believe that allowing the AU to establish a dosage range provides the AU with the needed flexibility. The final paragraph (d) codifies requirements that are currently imposed on licensees by license conditions and provides guidance regarding allowed deviations for a dosage range. This does not prevent an AU from revising the prescribed dosage at any time prior to the administration.

The recordkeeping requirements for this section would appear in § 35.2063, Records of dosages of unsealed byproduct material for medical use.

Section 35.65, Authorization for calibration, transmission, and reference sources, is a new section that replaces the current § 35.57. Paragraph (a) was revised to allow the receipt, possession, and use of sealed sources for the purposes of this section if they do not exceed 1.11 GBq (30 mCi) each and they are manufactured and distributed by a person licensed under § 32.74 or equivalent Agreement State regulations. Paragraph (b) was revised to allow the receipt, possession, and use of sealed sources for the purposes of this section if they do not exceed 1.11 GBq (30 mCi) each and they are redistributed by a licensee authorized to redistribute the sealed sources manufactured and distributed by a person licensed under § 32.74 of this chapter, providing the redistributed sealed sources are in the original packaging and shielding and are accompanied by the manufacturer's approved instructions. In paragraphs (b) and (c) of the final rule, the references in the current § 35.57 to §§ 35.100 and 35.200 were deleted because specific radionuclides were not listed in these sections. Paragraph (c) was revised to allow possession of calibration and reference sources with half-lives not longer than 120 days. The current section only allows possession of sources with half-lives not longer than 100 days. This change has been made so that the section would be consistent with the financial assurance regulations in Part 30. Paragraph (d) was revised to allow possession of any byproduct material with a half-life longer than 120 days in individual amounts that do not exceed the smaller of the following two values: 7.4 Megabecquerels (MBq) (200 μCi) or 1000 times the quantities in Appendix B of Part 30. This change has been made to limit the possession activity below the level where financial assurance is required. In paragraph (e), the possession limit for Tc-99m was deleted. The Commission believes that it is not necessary to limit the possession of Tc-99m for calibration and reference sources because there are no possession limits for Tc-99m associated with the use of Tc-99m under § 35.100 or § 35.200.

Section 35.67, Requirements for possession of sealed sources and brachytherapy sources, is a new section that replaces the current § 35.59. Paragraph (a) continues to require that the licensee follow the radiation safety and handling instructions supplied by the manufacturer, but the requirement to maintain the instructions for the duration of source use has been deleted. Paragraph (b) requires that a source be tested for leakage before its first use, unless the licensee has a certificate from the supplier indicating that the source was tested within 6 months, and the source is tested for leakage at intervals not to exceed 6 months or at other intervals approved in the Sealed Source and Device Registry (SSDR).[1] The SSDR certificates, in most cases, will include a requirement for leak-testing. Approved intervals for testing are based on information regarding source design

[1] A national registry that contains all the registration certificates generated by both NRC and the Agreement States. Registration certificates summarize the radiation safety information submitted by the applicant, and describe the licensing and use conditions approved for the product.

construction that is provided by the manufacturer.

Paragraph (c) retains the detection level for leakage at 185 Becquerels (Bq) (0.005 microcuries (μCi). The NRC deleted the prescriptive requirements on how to satisfy the leak test requirements in the current § 35.59(c) to reflect the more risk-informed, performance-based nature of this final rule. Paragraph (d) requires that leak test records be maintained in accordance with § 35.2067, Records of leak tests and inventory of sealed sources and brachytherapy sources. We revised paragraph (e) to give the licensee two additional alternatives for action after a leaking source has been identified. The final rule gives the licensee the added flexibility of repairing or disposing of the source in accordance with Parts 20 and 30 if the leakage test reveals the presence of 185 Bq (0.005 μCi) or more of removable contamination. The current rule only allows the licensee to withdraw the sealed source from use and store it in accordance with the requirements in Parts 20 and 30. The licensee is still required to report to the NRC if a leakage test reveals the presence of 185 Bq (0.005 μCi) or more of removable contamination. Reporting requirements for this section are in § 35.3067, Report of a leaking source.

We amended paragraph (g) to change the frequency for source inventories from quarterly to semi-annually to reduce the regulatory burden on licensees and to exempt gamma stereotactic radiosurgery sources from the requirement for physical inventories. However, the final rule does not preclude the licensee from conducting an inventory on a more frequent basis. The recordkeeping requirements for this section were moved to § 35.2067, Records of leak tests and inventory of sealed sources and brachytherapy sources.

We deleted paragraphs (h) and (i) in the current § 35.59 because radiation surveys are addressed under Part 20.

Section 35.69, Labeling of vials and syringes, is a new section that replaces the current §§ 35.60 and 35.61. It requires that syringes and vials containing unsealed byproduct material be labeled to identify the radioactive drug. It also requires that syringe shields and vial shields be labeled unless the label on the syringe or vial is visible when shielded. These requirements are needed because the Commission does not believe that the labeling requirements in Part 20 are sufficient to ensure that syringes, vials, syringe shields, or vial shields are properly labeled to identify the radioactive drug. In addition, the Commission believes that labeling helps to reduce administration errors.

The NRC does not address shielding of vials and syringes in this section. Licensees are required to show compliance with the public and occupational dose limits specified in Part 20 of this chapter. We believe that the licensee should have flexibility in complying with these limits.

The NRC revised § 35.70, Surveys of ambient radiation exposure rate, was revised. The term ''contamination'' was deleted from the title because this section no longer addresses contamination surveys. The final rule requires that licensees survey, at the end of each day of use, all areas where unsealed byproduct material requiring written directives were prepared for use or administered, except areas where patients or human research subjects are confined when they cannot be released under § 35.75. Maintaining the requirement for surveys in areas where unsealed byproduct material requiring a written directive is used is consistent with the Commission's direction for a more risk-informed rule.

Licensees are required to show compliance with the public and occupational dose limits specified in Part 20 of this chapter and specifically to develop, document, and implement a radiation protection program commensurate with the scope and extent of licensed activities (§ 20.1101). In situations where radioactive material is used at levels that would not require a survey under this section, the licensee should be aware that a survey may be required by § 20.1501. The Commission believes that licensees will continue to perform radiation surveys as dictated by ''good health physics'' practices.

The recordkeeping requirements for this section are in § 35.2070, Records of surveys for ambient radiation exposure rate. All other requirements in the current § 35.70 were deleted.

The NRC revised § 35.75, Release of individuals containing unsealed byproduct material or implants containing byproduct material. We amended the title of the section and paragraph (a) to delete the term ''permanent.'' This clarifies that this section applies to all individuals released from licensee control. Paragraph (b) was revised to specify that licensees may provide instructions to either the released individual or to the individual's parent or guardian and to replace the term ''dose'' with the term ''total effective dose equivalent.'' The first change acknowledges that, in some cases, it is not appropriate to provide the individual being released with instructions (e.g., the individual is a minor or incapable of understanding the instructions). The later change has been made to clarify what is meant by ''dose'' in this section.

We modified paragraph (b)(2) to state ''potential consequences, if any,'' of failure to follow the guidance. The Commission recognizes that, at low doses, there may be no consequences to continued breast-feeding. A patient may be unnecessarily alarmed if he/she is provided with information on consequences. Therefore, if consequences are not anticipated, the licensee would not be required to provide information to the individual.

We amended the footnote to reference NUREG–1556, Volume 9 (draft), ''Consolidated Guidance About Materials Licenses, Program-Specific Guidance About Medical Licenses,'' that superseded Regulatory Guide 8.39.

We revised paragraphs (c) and (d) to indicate that the recordkeeping requirements for this section are in § 35.2075, Records of the release of individuals containing radioactive drugs or implants containing byproduct material.

The NRC revised § 35.80, Provision of mobile medical service. We changed the title to make it clear that the provisions in this part apply to all mobile medical services and not just to mobile nuclear medicine services. We deleted the current paragraphs (a), (b), and (c) because the use of unsealed byproduct material is limited by the requirements in §§ 35.100 and 35.200, and control and security of material are addressed in Part 20. The remainder of the current requirements were incorporated into paragraphs (a) or (c) of the final rule.

Paragraph (a) requires the mobile medical service provider to obtain a letter from its client that permits the use of byproduct material at the client's address. This letter should clearly delineate the authority and responsibility of the licensee and the client. This paragraph also requires that the mobile medical service provider checks the instruments used to measure the activity of unsealed byproduct materials for constancy before medical use at each address of use or on each day of use, whichever is more frequent. For example, if a mobile medical service licensee provides service to more than one client in a day, the instruments would need to be checked at each client's address. The Commission recognizes that the standard of practice is to check other types of equipment, such as gamma cameras, for proper operation at each place of use. Therefore, the Commission has not included any requirements to check this type of equipment in the final rule.

Paragraph (a) also requires that the licensee check survey instruments for proper operation with a dedicated check source, before use, at each client's address. We believe this is appropriate because extensive movement in a transport vehicle may cause the instruments to become damaged or uncalibrated. Finally, paragraph (a) requires the licensee to survey all areas of use to ensure compliance with the dose limits in Part 20 before leaving each client's address. This is necessary to ensure that all radioactive material is removed from a client's facility.

Paragraph (b) addresses the delivery of byproduct material. It does not allow byproduct material to be delivered from the manufacturer or the distributor to the client's address, unless the client has a license allowing possession of the byproduct material. This requirement is similar to the requirement in the current § 35.29 (which was deleted by this rulemaking).

The recordkeeping requirements for this section are in § 35.2080, Records of mobile medical services.

The NRC deleted the current § 35.90, Storage of volatiles and gases. Licensees are required to comply with the public and occupational dose limits in Part 20 and to maintain exposures ALARA. We believe that licensees should have flexibility in complying with Part 20, and, therefore, a prescriptive requirement in Part 35 is not needed.

We revised § 35.92, Decay-in-storage, to allow decay-in-storage for byproduct material with a physical half-life of less than 120 days. Under the current rule, decay-in-storage was only authorized for material with a half-life of less than 65 days. This change provides licensees with greater flexibility in handling radioactive waste and codifies current licensing practice. Licensees that would like to decay material with a physical half life greater than 120 days would have to apply for and receive an amendment that would permit the decay-in-storage.

Paragraph (a) was revised to indicate clearly that the provisions in this section pertain only to disposal of material without regard to its radioactivity. The requirement in the current paragraph (a)(1) to hold byproduct material for 10 half-lives was deleted. This requirement was not needed in light of the requirement in paragraph (a) of the final rule that precludes disposal of radioactive material until radiation levels adjacent to the material do not exceed background levels. Paragraph (a)(2) requires the licensee to remove or obliterate all radiation labels, except for radiation labels on materials that are within containers and that will be managed as biomedical waste after they have been released from the licensee.

The requirement in the current paragraph (a)(4) to separate and monitor each generator column was deleted. This change recognized that the current level of prescriptiveness is not needed because of the requirements in paragraph (a)(1).

The recordkeeping requirements for this section are in § 35.2092, Records of decay-in-storage.

The NRC retitled Subpart D Unsealed Byproduct Material—Written Directive Not Required. This subpart combines the requirements in the current Subpart D, Uptake, dilution, and excretion and Subpart E, Imaging and localization. This change has been made to consolidate specific requirements for the use of unsealed byproduct material where a written directive is not required into one subpart. These changes are consistent with the Commission's intent to make Part 35 modality specific where appropriate. We believe that administrations of unsealed byproduct material not requiring a written directive are in a lower risk category than those administrations requiring a written directive. Therefore, we are using the requirement for a written directive as the threshold to distinguish between the two levels of risk associated with administrations of unsealed byproduct material.

The NRC revised § 35.100, Use of unsealed byproduct material for uptake, dilution, and excretion studies for which a written directive is not required. The title and introductory paragraph were changed to state clearly that the provisions in this subpart do not apply to the medical use of byproduct material that would require a written directive.

Paragraph (a) was amended to change the format for citing Title 10 of the Code of Federal Regulations (CFR). The reference to Title 10 is now stated as ''of this chapter'' instead of using the format ''10 CFR.''

We amended paragraph (b) to reflect changes to the section numbers in the final rule (i.e., requirements in §§ 35.25 and 35.920 were moved, with some modification, to §§ 35.27 and 35.290, respectively). We also added a reference to § 35.390 because physicians meeting these training and experience criteria can now elute generators and prepare radioactive drugs. This paragraph permits medical use licensees to prepare radioactive drugs from any unsealed byproduct material (e.g., radiochemicals), provided the drug is prepared by an ANP or AU.

We added paragraph (c) to allow specific licensees to obtain unsealed byproduct material prepared by an NRC or Agreement State licensee for use in research in accordance with a RDRC-approved protocol or an IND protocol accepted by the FDA. This change has been made because the current rule did not allow a licensee to use material from a supplier, who was not a § 32.72 licensee, unless the supplier had obtained a license exemption from the NRC. The final rule allows a medical use licensee to receive radioactive drugs that are for use in an RDRC-approved protocol or an IND protocol and are prepared and distributed by NRC or Agreement State licensees who are not § 32.72 licensees.

We added paragraph (d) to allow any individual to prepare a radioactive drug from any unsealed byproduct material (e.g., radiochemicals) for use in research in accordance with either an RDRC-approved protocol or an IND protocol accepted by FDA. This change has been made because an AU meeting the qualifications in § 35.910 of the current rule could not prepare radioactive drugs under an RDRC-approved protocol or an IND protocol. Therefore, if a licensee was only authorized to use byproduct material under § 35.100, it could not prepare byproduct material for use under an RDRC-approved protocol or an IND protocol unless the material had been prepared by an ANP or AU who was qualified to prepare radioactive drugs. The final rule resolves the issue by allowing any individual to prepare a radioactive drug in accordance with either an RDRC-approved protocol or an IND protocol.

The NRC deleted the current § 35.120, Possession of survey instruments, because these specific requirements are not needed in Part 35. Section 20.1501 of this chapter requires that the licensee make, or cause to be made, surveys to demonstrate compliance with Part 20, and requires the licensee to ensure that instruments and equipment used to show compliance with Part 20 are periodically calibrated. In addition, § 30.33(a)(2) of this chapter requires the licensee to have adequate instrumentation. Guidance on the types of instruments medical licensees could consider using is in NUREG–1556, Vol. 9 (draft), ''Program-Specific Guidance about Medical Use Licenses.''

Section 35.190, Training for uptake, dilution, and excretion studies, is a new section. The training and experience requirements for an AU for unsealed byproduct material for uptake, dilution, and excretion studies for which a written directive is not required were moved, with some modifications, from

the current § 35.910, Training for uptake, dilution, and excretion studies. Three changes made in the new section should be noted. First, the listing of specialty boards by name was deleted because the regulatory text in Part 35 will no longer incorporate a listing of specialty boards whose diplomates automatically fulfill the training and experience requirements for AUs. In place of listing the boards, the final rule provides for NRC recognition of the boards. Second, the new requirements require a total of 60 hours of training and experience that must include classroom, laboratory, and supervised work experience. Third, an individual must obtain written certification from a preceptor indicating that the individual has satisfactorily completed the requirements in this section and has achieved a level of competency sufficient to function independently as an AU. Section III of the **SUPPLEMENTARY INFORMATION** a detailed discussion of the Commission's changes to the training and experience requirements in Part 35. Note, 2 years after the effective date of the final rule, § 35.190 will replace the current requirements in § 35.910, Training for uptake, dilution, and excretion studies.

The NRC revised § 35.200, Use of unsealed byproduct material for imaging and localization studies for which a written directive is not required. The title and introductory paragraph were changed to state clearly that the provisions in this subpart do not apply to the medical use of byproduct material that would require a written directive.

We amended paragraph (a) to change the format for citing Title 10 of the Code of Federal Regulations (CFR). The reference to Title 10 is now stated as ''of this chapter'' instead of using the format ''10 CFR.''

We amended paragraph (b) to reflect changes to the section numbers in the final rule (i.e., requirements in §§ 35.25 and 35.920 were moved, with some modification, to §§ 35.27 and 35.290, respectively). We also added a reference to § 35.390 because physicians meeting these training and experience criteria can now elute generators and prepare radioactive drugs. This paragraph permits medical use licensees to prepare radioactive drugs from any unsealed byproduct material (e.g., radiochemicals), provided the drug is prepared by an ANP or AU.

We added paragraph (c) to allow specific licensees to obtain unsealed byproduct material prepared by an NRC or Agreement State licensee for use in research in accordance with an RDRC-approved protocol or an IND protocol accepted by the FDA. This change has been made because the current rule did not allow a licensee to use material from a supplier, who was not a § 32.72 licensee, unless the supplier had obtained a license exemption from the NRC. The final rule allows a medical use licensee to receive radioactive drugs that are for use in an RDRC-approved protocol or an IND research protocol and are prepared and distributed by NRC or Agreement State licensees who are not § 32.72 licensees.

We added paragraph (d) to allow any individual to prepare a radioactive drug from any unsealed byproduct material (e.g., radiochemicals) for use in research in accordance with either an RDRC-approved protocol or an IND protocol accepted by FDA. This change has been made because an AU meeting the qualifications in § 35.920 of the current rule could not prepare radioactive drugs under an RDRC-approved protocol or an IND protocol. Therefore, if a licensee was only authorized to use byproduct material under § 35.200, it could not prepare byproduct material for use under an RDRC-approved protocol or an IND protocol unless the material had been prepared by an ANP or AU who was qualified to prepare radioactive drugs. The final rule resolves the issue by allowing any individual to prepare a radioactive drug in accordance with either an RDRC-approved protocol or an IND protocol.

The NRC revised § 35.204, Permissible molybdenum-99 concentration. Paragraph (a) was revised to express the permissible concentration level as 0.15 kilobecquerel of molybdenum-99 per megabecquerel of technetium-99m (0.15 microcurie of molybdenum-99 per millicurie of technetium-99m). This level is identical to that used in the U.S. Pharmacopea (USP) 24 U.S. Pharmacopial Convention, Inc., 2000, pages 1598–1599. Paragraph (b) was revised to require that a licensee measure the molybdenum-99 concentration of the first eluate from a generator. We believe that the licensee should measure the molybdenum-99 concentration in the first elution of a generator after the generator is received at the licensee's facility. Although the frequency of molybdenum breakthrough is exceedingly rare, an initial check may detect generators that have been damaged in transport. The term ''extract'' was deleted because the term is no longer needed. NRC is not aware of any licensees that prepare technetium-99m by the solvent extraction method.

The recordkeeping requirements for this section were moved to § 35.2204, Records of molybdenum-99 concentration.

The NRC deleted the current § 35.205, Control of aerosols and gases. Part 35 licensees must comply with the occupational and public dose limits of Part 20. Additional prescriptive requirements for limiting airborne concentrations of radioactive material are not needed in Part 35.

The NRC deleted the current § 35.220, Possession of survey instruments because these specific requirements are not needed in Part 35. Section 20.1501 of this chapter requires that the licensee make, or cause to be made, surveys to demonstrate compliance with Part 20, and requires the licensee to ensure that instruments and equipment used to show compliance with Part 20 are periodically calibrated. In addition, § 30.33(a)(2) of this chapter requires licensees to have adequate equipment. Guidance on the types of instruments medical licensees could consider using is in NUREG–1556, Vol. 9 (draft).

Section 35.290, Training for imaging and localization studies, is a new section. The training and experience requirements for an AU for unsealed byproduct material for imaging and localization studies for which a written directive is not required were moved, with some modifications, from the current § 35.920, Training for imaging and localization studies. Three changes made in the new section should be noted. First, the listing of specialty boards by name was deleted because the regulatory text in Part 35 will no longer incorporate a listing of specialty boards whose diplomates automatically fulfill the training and experience requirements for AUs. In place of listing the boards, the final rule provides for NRC recognition of the boards. Second, the new requirements require a total of 700 hours of training and experience that must include classroom, laboratory, and supervised work experience. Third, an individual must obtain written certification from a preceptor indicating that the individual has satisfactorily completed the requirements in this section and has achieved a level of competency sufficient to function independently as an AU. Section III of the **SUPPLEMENTARY INFORMATION** contains a detailed discussion of the Commission's changes to the training and experience requirements in Part 35. Note, 2 years after the effective date of the final rule, § 35.290 will replace the current requirements in § 35.920, Training for imaging and localization studies.

Subpart E was retitled, Unsealed byproduct material—written directive required. The subpart contains the

requirements for any medical use of unsealed byproduct material for which a written directive is required. This subpart would replace the requirements in the current Subpart F, Radiopharmaceuticals for therapy.

The NRC revised § 35.300, Use of unsealed byproduct material for which a written directive is required. The title and introductory paragraph were changed to clearly state that the provisions in this subpart apply to the medical use of unsealed byproduct material that would require a written directive. The first paragraph in this section was revised to state clearly that medical uses under this section require a written direction. Also, the phrase ''therapeutic administration'', used in the current rule, was deleted because some medical uses in this modality will require a written directive, but they are not ''therapeutic administrations'' (e.g., diagnostic whole body imaging with sodium iodide I–131).

We amended paragraph (a) to change the format for citing Title 10 of the Code of Federal Regulations (CFR). The reference to Title 10 is now stated as ''of this chapter'' instead of using the format ''10 CFR.''

We amended paragraph (b) to reflect changes to the section numbers in the final rule (i.e., requirements in §§ 35.25 and 35.920 were moved, with some modification, to §§ 35.27 and 35.290, respectively). We also added a reference to § 35.390 because physicians meeting these training and experience criteria can now elute generators and prepare radioactive drugs. This paragraph permits medical use licensees to prepare radioactive drugs from any unsealed byproduct material (e.g., radiochemicals), provided the drug is prepared by an ANP or AU.

We added paragraph (c) to allow specific licensees to obtain unsealed byproduct material prepared by other NRC or Agreement State licensees for use in medical research in accordance with an IND protocol accepted by the FDA. This change has been made because the current rule did not allow a licensee to use material from a supplier, who was not a § 32.72 licensee, unless the supplier had obtained a license exemption from the NRC. The final rule allows a medical use licensee to receive radioactive drugs, for use in IND research protocols, that are prepared and distributed by NRC or Agreement State licensees who are not § 32.72 licensees. This paragraph is similar to the regulatory text added to §§ 35.100 and 35.200. However, we have not included a reference to RDRC-approved protocols because RDRCs are authorized to approve radioactive drugs for certain types of research uses intended to obtain basic information regarding the metabolism of a radioactive drug, or regarding human physiology, pathophysiology, or biochemistry, but they are not intended for immediate diagnostic, therapeutic, or similar purposes. Additionally, the maximum radiation dose from a single administration of a radioactive drug in an RDRC-approved protocol must be less than 3 rem to the whole body, active blood forming organs, lens of the eye, and gonads, and less than 5 rem to other organs. We expect that doses from materials requiring a written directive would exceed these limits. Thus, research with such materials could not be conducted under the aegis of RDRC approval.

We added paragraph (d) to allow any individual to prepare a radioactive drug from any unsealed byproduct material (e.g., radiochemicals) for use in research in accordance with an IND protocol accepted by FDA. This change has been made because an AU meeting the qualifications in §§ 35.930, 35.932, or 35.934 of the current rule could not prepare radioactive drugs under an IND protocol. Therefore, if a licensee was only authorized to use byproduct material under § 35.300, it could not prepare byproduct material for use under an IND protocol unless the material had been prepared by an ANP or AU who was qualified to prepare radioactive drugs. The final rule resolves the issue by allowing any individual to prepare a radioactive drug in accordance with an IND protocol.

The NRC revised § 35.310, Safety instruction to state explicitly that the instruction requirements of this section are in addition to, and not in lieu of, the training requirements in § 19.12. We believe it is important that personnel caring for patients or human research subjects that have received a dosage requiring a written directive, and cannot be released in accordance with § 35.75, receive instruction in limiting radiation exposure to the public or occupational workers and the actions to be taken in the case of a death or medical emergency.

Paragraph (a) in the final rule requires that safety instruction be provided initially and at least annually. The current rule does not specify when instructions must be given. Typically, the frequency of training has been handled during the licensing process. We do not expect that the same level of training be provided to all individuals caring for the patient. The level of training should be commensurate with the potential radiation exposure the caregiver may receive, based on the level of contact the individual is expected to have with the patient or human research subject. For example, the instruction provided to the registered nurse will not necessarily be the same as the instruction provided to a nursing assistant. We have deleted the reference to ''procedures'' in paragraph (a) because we have chosen to focus this section on instruction rather than on procedures. The licensee should have flexibility in program management and recognize that licensees may develop alternative ways of addressing the issues in paragraphs (a)(1) through (a)(5). Paragraph (a)(2) was also revised to require that instruction on visitor control include instruction on routine visitation authorized under the provisions in § 20.1301(a)(1), as well as visitation that is authorized under the final provisions of § 20.1301(c). Paragraph (a)(5) was revised to state that personnel should notify the RSO, or his or her designee, and the AU if the patient or the human research subject has a medical emergency or dies. This change has been made to allow the RSO to designate an individual to act in his or her behalf, in such cases, to address radiation protection issues and to ensure that the AU is notified. The recordkeeping requirements for this section are in § 35.2310, Records of safety instruction.

We revised § 35.315, Safety precautions. Paragraph (a) was revised to clarify that the requirements in this section only apply if a patient or research subject cannot be released under § 35.75. Paragraph (a)(1) was revised to give the licensee flexibility in quartering patients. Option 1 is identical to the current rule, i.e., it allows the licensee to quarter the patient or human research subject in a private room with a private sanitary facility. Option 2 allows the licensee to quarter the individual in a room, with a private sanitary facility, with another individual who also has received therapy with a radioactive drug containing byproduct material and who also cannot be released under § 35.75. We included option 2 in the final rule because we believe that the dose that patients would receive from each other would be inconsequential in light of the dose that they receive from the medical treatment that they have undergone.

We revised paragraph (a)(2) to require that the patient's room, rather than the door, be visibly posted to give the licensee some flexibility in determining where to place the posting so it is visible. These requirements are in addition to the posting requirements in Part 20. We believe that the posting requirements in Part 20 are not adequate

to ensure that individuals entering the room would be aware of the presence of radioactive materials in the room. The current requirements in paragraphs (a)(3), (4), (6), (7), and (8) were deleted because they are radiation protection requirements that are covered under Part 20. We revised paragraph (b) to state that the licensee shall notify the RSO, or his or her designee, and the AU as soon as possible if the patient or human research subject has a medical emergency or dies. This change allows the RSO to designate an individual to act in his or her behalf, in such cases, to address radiation protection issues and to ensure that the AU is notified.

The NRC deleted the current § 35.320, Possession of survey instruments because these specific requirements are not needed in Part 35. Section 20.1501 of this chapter requires that the licensee make, or cause to be made, surveys to demonstrate compliance with Part 20, and requires the licensee to ensure that instruments and equipment used to show compliance with Part 20 are periodically calibrated. In addition, § 30.33(a)(2) of this chapter requires a licensee to have adequate equipment. Guidance on the types of instruments medical licensees could consider using is in NUREG–1556, Vol. 9 (draft).

Section 35.390, Training for use of unsealed byproduct material for which a written directive is required, is a new section. The training and experience requirements for an AU for unsealed byproduct material for which a written directive is required were moved, with some modifications, from the current § 35.930, Training for therapeutic use of unsealed byproduct material. Three changes made in the new section should be noted. First, the listing of specialty boards by name was deleted because the regulatory text in Part 35 will no longer incorporate a listing of specialty boards whose diplomates automatically fulfill the training and experience requirements for AUs. In place of listing the boards, the final rule provides for NRC recognition of the boards. Second, the new requirements require a total of 700 hours of training and experience that must include classroom, laboratory, and supervised work experience. Third, an individual must obtain written certification from a preceptor indicating that the individual has satisfactorily completed the requirements in this section and has achieved a level of competency sufficient to function independently as an AU. Section III of the **SUPPLEMENTARY INFORMATION** contains a detailed discussion of the Commission's changes to the training and experience requirements in Part 35. Note, 2 years after the effective date of the final rule, § 35.390 will replace the current requirements in § 35.930, Training for therapeutic use of unsealed byproduct material.

Section 35.392, Training for the oral administration of sodium iodide I-131 requiring a written directive in quantities less than or equal to 1.22 Gigabecquerels (33 millicuries), is a new section. The training and experience requirements for an AU for iodine-131 treatment of hyperthyroidism were moved, with some modifications, from the current 35.932, Training for treatment of hyperthyroidism. Three changes made in the new section should be noted. First, the section is no longer limited to use of iodine-131 for treatment of hyperthyroidism. Second, the final rule provides for NRC recognition of the boards. Third, an individual must obtain written certification from a preceptor indicating that the individual has satisfactorily completed the requirements in this section and has achieved a level of competency sufficient to function independently as an AU. Section III of the **SUPPLEMENTARY INFORMATION** contains a detailed discussion of the Commission's changes to the training and experience requirements in Part 35. Note, 2 years after the effective date of the final rule, § 35.392 will replace the current requirements in § 35.932, Training for treatment of hyperthyroidism.

Section 35.394, Training for the oral administration of sodium iodide I-131 requiring a written directive in quantities greater than 1.22 Gigabecquerels (33 millicuries), is a new section. The training and experience requirements for an AU for iodine-131 for treatment of thyroid carcinoma were moved, with some modifications, from the current 35.934, Training for treatment of thyroid carcinoma. Three changes made in the new section should be noted. First, the section is no longer limited to use of iodine-131 for treatment of thyroid carcinoma. Second, the final rule provides for NRC recognition of the boards. Third, an individual must obtain written certification from a preceptor indicating that the individual has satisfactorily completed the requirements in this section and has achieved a level of competency sufficient to function independently as an AU. Section III of the **SUPPLEMENTARY INFORMATION** contains a detailed discussion of the Commission's changes to the training and experience requirements in Part 35. Note, 2 years after the effective date of the final rule, § 35.394 will replace the current requirements in § 35.934, Training for treatment of thyroid carcinoma.

Subpart F was retitled Manual Brachytherapy. This subpart contains the requirements for medical use of sealed sources for manual brachytherapy and replaces the requirements in the current Subpart G, Sources for Brachytherapy.

The NRC retitled § 35.400, Use of sources for manual brachytherapy, and deleted the specific sources and uses listed in the current paragraphs (a) through (g). This conforms with the more risk-informed, performance-based nature of this final rule. The licensee has the flexibility to use brachytherapy sources for therapeutic medical uses as approved in the SSDR. In addition, we added a new paragraph (b) to allow the use of brachytherapy sources in medical research as long as the research is conducted in accordance with an active Investigational Device Exemption (IDE) application accepted by the FDA. With this revision, we allow previously registered sources to be used for uses other than those described in the original sealed source registration process if the research is conducted under an active IDE application accepted by the FDA.

The NRC retitled and revised § 35.404, Surveys after source implant and removal. The current paragraph (a) was redesignated paragraph (b) and was amended to delete the requirement that a licensee may not release a patient or a human research subject treated by temporary implant until all sources have been removed. The release of patients or human research subjects is addressed in § 35.75. The reference to radiation when referring to the survey was also removed because this was repetitive of the requirement to perform the survey with a radiation detection survey instrument. The new paragraph (a) contains the requirements, with minor modifications, that were previously required by § 35.406(c). The survey required by paragraph (a) is performed to locate and account for all sources that have not been implanted. However, this survey does not necessarily have to be a radiation survey. Depending on the area being surveyed and the ability to distinguish from the radiation background around the patient implanted with brachytherapy sources, the survey may be a visual or a radiation survey. Therefore, this section includes all of the survey requirements for this subpart. The recordkeeping requirements for this section are in § 35.2404, Records of surveys after source implant and removal.

The NRC retitled and revised § 35.406, Brachytherapy sources accountability. Paragraph (a) requires that the licensee maintain accountability for all brachytherapy sources in storage or use. We deleted the majority of the prescriptive requirements and associated recordkeeping requirements in the final section to give the licensee flexibility in program management. The requirements in the current paragraph (c) were moved to § 35.404. We believe that the requirements that were retained in this section are essential to the radiation safety program. The recordkeeping requirements for this section are in § 35.2406, Records of brachytherapy source accountability.

The NRC revised § 35.410, Safety instruction to state explicitly that the instruction requirements in this section are in addition to, and not in lieu of, the training requirements of § 19.12. We believe that it is important that personnel caring for patients or human research subjects that have received brachytherapy (and cannot be released under § 35.75), receive instruction in limiting radiation exposure to the public and workers and the actions to be taken in the case of a medical emergency or death.

Paragraph (a) in the final rule requires that safety instruction be provided initially and at least annually. The current rule does not specify when instructions must be given. Typically, the frequency of training has been handled during the licensing process. We do not expect that the same level of training be provided to all individuals caring for the patient. The level of training should be commensurate with the type of care that the personnel may render to the patient or human research subject. We have deleted the reference to ''procedures'' in paragraph (a) because we have chosen to focus this section on instruction rather than on procedures. We believe the licensee should have flexibility in program management and recognize that licensees may develop alternative ways of addressing the issues in paragraphs (a)(1) through (a)(5). We revised paragraph (a)(4) to require that instruction on visitor control include instruction on routine visitation authorized under the provisions in § 20.1301(a)(1), as well as visitation that is authorized under the final provisions of § 20.1301(c). We revised paragraph (a)(5) to state that personnel should notify the RSO, or his or her designee, and an AU, if the patient or human research subject has a medical emergency or dies. This change provides the RSO flexibility in designating who should be notified to address radiation protection issues and ensures that an AU is notified. The recordkeeping requirements for this section are in § 35.2310, Records of safety instruction.

The NRC revised § 35.415, Safety precautions. Paragraph (a) was amended to clarify that the requirements in this section only apply if a patient or human research subject is receiving brachytherapy and cannot be released in accordance with § 35.75. Paragraph (a)(1) was amended to clarify that a patient or human research subject who is receiving brachytherapy can only share a room with another brachytherapy patient.

We revised paragraph (a)(2) to require that the patient's room, rather than the door, be visibly posted to give the licensee flexibility in determining where to place the posting so it is visible. These posting requirements are in addition to the posting requirements in Part 20. We believe that the posting requirements in Part 20 are not adequate to ensure that individuals entering the room would be aware of the presence of radioactive materials in the room. The requirement to put a note on the door or in the patient's or human research subject's chart where and how long visitors may stay in the patient's or human research subject's room was moved from the current paragraph (a)(2) to the new paragraph (a)(3). We deleted the current requirements in paragraphs (a)(3) and (4) because they are radiation protection requirements that are covered under Part 20. We added a new requirement (paragraph b) that requires the licensee to have emergency response equipment available near each treatment room. This addition codifies requirements that are currently imposed on licensees by license conditions. The current paragraph (b) was redesignated as paragraph (c) and was revised to state that the licensee shall notify the RSO, or his or her designee, and an AU as soon as possible if the patient or human research subject has a medical emergency or dies. This change has been made: (1) To recognize that in a medical emergency, the licensee's primary responsibility is the care of the patient; (2) to provide the RSO flexibility in whom should be notified to address radiation protection issues; and (3) to ensure that the AU is notified.

The NRC deleted the current § 35.420, Possession of survey instruments because these specific requirements are not needed in Part 35. Section 20.1501 of this chapter requires that the licensee make, or cause to be made, surveys to demonstrate compliance with Part 20 and requires the licensee to ensure that instruments and equipment used to show compliance with Part 20 are periodically calibrated. In addition, § 30.33(a)(2) of this chapter requires the licensee to have adequate equipment. Guidance on the types of instruments medical licensees could consider using is in NUREG–1556, Vol. 9.

Section 35.432, Calibration measurements of brachytherapy sources, is a new section that requires a licensee authorized to use brachytherapy sources for medical use to perform calibration measurements on brachytherapy sources before the first medical use of the source(s) after the effective date of this rule. The requirements in this section are based on recommendations found in AAPM TG–40 and TG–56, and are consistent with the calibration requirements for sealed sources and devices for therapy. The final rule allows the licensee to rely on the output measurement provided by the source manufacturer or by a calibration laboratory accredited by the American Association of Physicists in Medicine, as long as the calibration was conducted in accordance with a published protocol accepted by a nationally recognized body and appropriately calibrated equipment was used. As discussed in the Regulatory Impact Statement, the NRC recognizes that licensees may need to procure additional equipment to meet this requirement. We believe that the additional expenditure is warranted in order for the licensee administering brachytherapy doses to ensure that the correct dose is delivered to patients. The recordkeeping requirements for this section are in § 35.2432, Records of calibration measurements of brachytherapy sources.

Section 35.433, Decay of strontium-90 sources for ophthalmic treatment, is a new section. This section requires that only an AMP may calculate the activity of a strontium-90 source that is used to determine the treatment times for ophthalmic treatments. It also requires that the decay must be based on the activity determined under § 35.432. This section was added because the NRC is aware of numerous misadministrations involving strontium-90 for ophthalmic use that were caused by individuals improperly decaying the sources. Given the risks associated with the use of strontium-90 and the numerous misadministrations in this area, more prescriptive requirements are warranted to ensure that the activities of strontium-90 sources are correctly determined. The recordkeeping requirements for this section are in § 35.2433, Records of decay of strontium-90 sources for ophthalmic treatments.

Section 35.457, Therapy-related computer systems, is a new section that requires acceptance testing on the treatment planning system of therapy-related computer systems in accordance with published protocols accepted by nationally recognized bodies. The requirements in this section are based on recommendations found in AAPM TG–56. The components of the acceptance testing are provided in this section. However, the licensee retains the flexibility in developing the acceptance testing program. The NRC believes that these new requirements are warranted in order for the licensee administering brachytherapy doses to ensure that the correct dose is delivered to patients.

Section 35.490, Training for use of manual brachytherapy sources, is a new section. The training and experience requirements for an AU of manual brachytherapy sources were moved, with some modifications, from the current § 35.940, Training for use of brachytherapy sources. Two changes made in the new section should be noted. First, the listing of specialty boards by name was deleted because the regulatory text in Part 35 will no longer incorporate a listing of specialty boards whose diplomates automatically fulfill the training and experience requirements for AUs. In place of listing the boards, the final rule provides for NRC recognition of the boards. Second, an individual must obtain written certification from a preceptor indicating that the individual has satisfactorily completed the requirements in this section and has achieved a level of competency sufficient to function independently as an AU. Section III of the **SUPPLEMENTARY INFORMATION** contains a detailed discussion of the Commission's changes to the training and experience requirements in Part 35. Note, 2 years after the effective date of the final rule, § 35.490 will replace the current requirements in § 35.940, Training for use of brachytherapy sources.

Section 35.491, Training for ophthalmic use of strontium-90, is a new section. The training and experience requirements for an AU of strontium-90 sources for ophthalmic treatment were moved, with some modifications, from the current § 35.941, Training for ophthalmic use of strontium-90. Two provisions in the new section should be noted. First, an individual must obtain written certification from a preceptor indicating that the individual has satisfactorily completed the requirements in this section and has achieved a level of competency sufficient to function independently as an AU. Second, the NRC added a provision that a physician who meets the requirements in § 35.490 would automatically meet the requirements to become an AU under § 35.491. Section III of the **SUPPLEMENTARY INFORMATION** contains a detailed discussion of the Commission's changes to the training and experience requirements in Part 35. Note, 2 years after the effective date of the final rule, § 35.491 will replace the current requirements in § 35.941, Training for ophthalmic use of strontium-90.

Subpart G was retitled Sealed Sources for Diagnosis. This subpart contains the requirements for diagnostic medical use of sealed sources and replaces the requirements in the current Subpart H, Sealed Sources for Diagnosis.

In § 35.500, Use of sealed sources for diagnosis, the NRC deleted the specific sources and uses listed in paragraphs (a) and (b). This conforms with the more risk-informed, performance-based nature of this final rule. The licensee has the flexibility to use sealed sources for diagnostic medical uses as approved in the SSDR.

The NRC deleted the current § 35.520, Availability of survey instrument because these specific requirements are not needed in Part 35. Section 20.1501 of this chapter requires that the licensee make, or cause to be made, surveys to demonstrate compliance with Part 20 and requires the licensee to ensure that instruments and equipment used to show compliance with Part 20 are periodically calibrated. In addition, § 30.33(a)(2) of this chapter requires the licensee to have adequate equipment. Guidance on the types of instruments medical licensees could consider using is in NUREG–1556, Vol. 9 (draft).

Section 35.590, Training for use of sealed sources for diagnosis, is a new section. The training and experience requirements for an AU of a diagnostic sealed source in a device were moved, with some modifications, from the current § 35.950, Training for use of sealed sources for diagnosis. One change made in the new section should be noted. The listing of specialty boards by name was deleted because the regulatory text in Part 35 will no longer incorporate a listing of specialty boards whose diplomates automatically fulfill the training and experience requirements for AUs. In place of listing the boards, the final rule provides for NRC recognition of the boards. Section III of the **SUPPLEMENTARY INFORMATION** contains a detailed discussion of the Commission's changes to the training and experience requirements in Part 35. Note, 2 years after the effective date of the final rule, § 35.590 will replace the current requirements in § 35.950, Training for use of sealed sources for diagnosis.

The NRC retitled Subpart H, Photon Emitting Remote Afterloader Units, Teletherapy Units, and Gamma Stereotactic Radiosurgery Units, and amended its provisions to address all medical uses of photon emitting sealed sources in devices for therapy. Devices such as teletherapy, remote afterloaders, and gamma stereotactic radiosurgery units are addressed in this subpart. This subpart does not contain requirements for manual brachytherapy, which are in Subpart F, nor does it include requirements for beta emitting devices, such as beta emitting intravascular brachytherapy devices. This subpart replaces the requirements in the current Subpart I, Teletherapy.

The NRC retitled § 35.600, Use of a sealed source in a remote afterloader unit, teletherapy unit, or gamma stereotactic radiosurgery unit, and deleted any references to specific radionuclides and devices in the codified text. The licensee has the flexibility to use sealed sources in photon emitting devices for therapeutic medical uses as approved in the SSDR. In addition, we added paragraph (b) to allow the use of therapy sealed sources in medical research as long as the research is conducted in accordance with an active IDE application accepted by the FDA. This change allows previously registered sources to be used for uses other than those described in the original sealed source registration process, if the research is conducted under an active IDE application accepted by the FDA.

Section 35.604, Surveys of patients and human research subjects treated with a remote afterloader unit, is a new section. This section requires that a licensee make a radiation survey of a patient or human research subject to confirm that the sources have been removed from the individual and returned to a shielded position before releasing the individual from licensee control. For fractionated low dose-rate or pulsed dose-rate treatments where the patient is not releasable under § 35.75, surveys need only be performed after the last time the source is returned to the shielded position. For example, a survey of the patient is not required every time that the source is retracted into the shielded safe when nursing personnel enter the patient treatment room to provide care to patients undergoing fractionated treatments using a low or pulsed dose-rate remote afterloader unit. This new requirement was previously imposed on remote afterloader licensees by license

condition. The recordkeeping requirements for this section are in § 35.2404, Records of radiation surveys of patients and human research subjects.

The NRC retitled § 35.605, Installation, maintenance, adjustment, and repair, and amended the codified text to clarify that only a person specifically licensed by the Commission or an Agreement State can install, maintain, adjust, or repair a unit that involves work on the source shielding, source driving unit, or other electronic or mechanical mechanism that could expose the source, reduce the shielding around the source, or compromise the radiation safety of the unit or the sources. The types of units referred to in this section were revised to include remote afterloader units and gamma stereotactic radiosurgery units, rather than just teletherapy units.

Paragraph (b) also specifies that, except for low dose-rate remote afterloader units, only a person specifically licensed by the Commission or an Agreement State shall install, replace, relocate, or remove a sealed source or source contained in a device. For low dose-rate remote afterloader units, installation, replacement, relocation, or removal of a sealed source must be done by a person specifically licensed by the Commission or an Agreement State or by an AMP. The exception to allow an AMP to perform these activities for low dose-rate remote afterloader units was included in the final rule because we believe that the radiation hazards associated with installation, replacement, relocation, or removal of a sealed source in these devices are similar to that of manipulation of manual brachytherapy sources. The recordkeeping requirements for this section are in § 35.2605, Records of installation, maintenance, adjustment, and repair.

The NRC deleted the current § 35.606, License amendments. The requirements in the current paragraphs (a), (b), and (d) are addressed in the final § 35.13(e). Paragraph (c) was deleted because the licensees must comply with the dose limit requirements in Part 20, and no further limitations are warranted. Paragraph (e) was deleted because the requirement to file an amendment before allowing an individual to perform the duties of the AMP is addressed in the final § 35.13(b). Paragraph (e) was deleted because the requirements in Subpart H require that the AMP perform specific duties. Any deviations from these requirements would necessitate an exemption from Part 35.

The NRC retitled § 35.610, Safety procedures and instructions for remote afterloader units, teletherapy units, and gamma stereotactic radiosurgery units, and amended the codified text to include remote afterloader units and gamma stereotactic radiosurgery units.

Paragraph (a) requires that a licensee secure the unit, console, console keys, and treatment room when not in use or unattended; permit only approved individuals into the treatment room during treatment; prevent dual operation of radiation producing devices; and develop, implement, and maintain written emergency response procedures.

Paragraphs (a)(1) and (a)(3) codify requirements that are currently imposed on licensees by license conditions related to use of remote afterloaders. Because of the applicability of the requirements to all therapy units, they were added to the rule with the intent of having the requirements apply to all such units. We expanded paragraph (a)(2) to recognize that there are certain design conditions that will necessitate an individual, other than the patient, being in the treatment room during the treatment. An example of this condition is use of a low energy gamma source in a therapeutic medical device where the AU may need to be in the room with the patient. This exception does not relieve the licensees from complying with the dose limits for occupationally-exposed individuals or the general public in Part 20. In paragraph (a)(4), we codified requirements that are currently imposed on licensees by license conditions related to emergency procedures.

We revised paragraph (b) to require that a copy of the licensee's procedures be physically located at the unit console. We revised paragraph (c) to require that the location of the procedures and emergency response telephone numbers be posted. Previously, all of these procedures were required to be posted. This was impractical with the addition of remote afterloaders because error conditions and responses are often several pages in length.

Paragraphs (d) and (e), previously paragraph (b), were revised to require that the licensee provide initial and at least annual instruction in specifically identified procedures to all individuals who operate the unit, and initial and at least annual practice drills in emergency procedures to unit operators, AMPs, and AUs. The level of instruction should be commensurate with the individual's assigned duties. For example, an individual need not be instructed in equipment inspection, unless it is expected that during the normal course of the day, the individual will be required to inspect the unit. We believe that due to the complexity of therapeutic treatment units, refresher training and practice drills on emergency response are warranted. The recordkeeping requirements for this section are in § 35.2310, Records of instruction and training.

Paragraph (g) was added to refer to the recordkeeping requirements in § 35.2610 for the procedures required by paragraphs (a)(4) and (d)(2).

The NRC retitled § 35.615, Safety precautions for remote afterloader units, teletherapy units, and gamma stereotactic radiosurgery units, and amended the codified text to include remote afterloader units and gamma stereotactic radiosurgery units. The current requirements in paragraphs (a) and (b) remain essentially the same, with minor changes to the language to support requirements for remote afterloader units and gamma stereotactic radiosurgery units. We deleted many of the prescriptive requirements [e.g., beam condition indicator light] [current paragraph (c)] and radiation monitor [current paragraph (d)] because they are addressed in Part 20.

We added new requirements in paragraph (d) for intercom systems, and in paragraphs (e), (f), and (g) to codify requirements that are currently imposed by license conditions. Current license conditions were modified when they were incorporated into the final rule. For example, the presence of an AU and an AMP during patient treatments was clarified for each type of unit. As used in this provision, physically present means to be within hearing distance of normal voice. Immediately available means that the individual is available on an on-call basis to respond to an emergency. At a minimum, this person must be available by telephone.

We believe that the inherent risk of these procedures justifies the prescriptiveness of this regulation and that it is important for a properly trained physician to be available at all times to respond to an emergency requiring source removal.

We deleted the current § 35.620, Possession of survey instruments, because these specific requirements are not needed in Part 35. Section 20.1501 of this chapter requires that the licensee make, or cause to be made, surveys to demonstrate compliance with Part 20, and that the licensee ensure that instruments and equipment used to show compliance with Part 20 are periodically calibrated. In addition, § 30.33(a)(2) of this chapter requires licensees to have adequate equipment. Guidance on the types of instruments medical licensees could consider using is in NUREG–1556, Vol. 9 (draft).

The NRC amended § 35.630, Dosimetry equipment, to provide calibration requirements for instruments used in this subpart and Subpart F. Paragraph (a)(1) requires that dosimetry systems be calibrated using a source or system traceable to the National Institute of Standards and Technology (NIST) and in accordance with published protocols accepted by a nationally recognized body; or by a calibration laboratory accredited by AAPM. This change gives licensees two alternatives for direct traceability of dosimetry equipment calibration, i.e., either a source or the measurement instrument (e.g., well chamber) can be calibrated against a national standard. We acknowledge that the industry standards for instrument calibration provide adequate assurance that equipment is properly calibrated. We amended paragraph (a)(2) to delete the reference to intercomparison meetings sanctioned by a calibration laboratory or radiologic physics centers accredited by the AAPM. This provision is no longer necessary because the AAPM does not sanction intercomparison meetings. References to cobalt-60 and cesium-137 contained within teletherapy units were deleted to make the section applicable to dosimetry equipment for all radionuclides and therapy units. In addition, licensees using only low dose-rate remote afterloader units are not required to possess dosimetry equipment if they rely on the source output or activity determined by the manufacturer, as long as the manufacturer uses appropriately calibrated equipment and performs the calibration in accordance with published protocols accepted by a nationally recognized body. This allowance has been made to be consistent with the requirements for manual brachytherapy sources. The recordkeeping requirements for this section are in § 35.2630, Records of dosimetry equipment.

The NRC retitled § 35.632, Full calibration measurements on teletherapy units, and amended the codified text to clarify that the requirements in this section apply to teletherapy units. In paragraph (d), we deleted the reference to the AAPM Task Group Reports and replaced it with a requirement that full calibration measurements be done in accordance with published protocols accepted by nationally recognized bodies. This allows the licensee more flexibility in choosing appropriate protocols. We acknowledge that the industry standards for teletherapy unit calibration provide adequate assurance that equipment is properly calibrated. Paragraph (e) was revised to include mathematical correction of output for sources other than cobalt-60 and cesium-137. In paragraph (f), we replaced the term ''teletherapy physicist'' with the term ''authorized medical physicist.'' The recordkeeping requirements for this section are in § 35.2632, Records of teletherapy, remote afterloader, and gamma stereotactic radiosurgery full calibrations.

Section 35.633, Full calibration measurements on remote afterloader units, is a new section that contains the requirements for the calibration of remote afterloader units. This section is similar in content to § 35.632. Requirements in this section were based on recommendations found in AAPM Task Group Report No. 56—Code of Practice for Brachytherapy Physics (1997) and AAPM Task Group Report No. 59. The recordkeeping requirements for this section are in § 35.2632, Records of teletherapy, remote afterloader, and gamma stereotactic radiosurgery full calibrations.

The NRC deleted the current § 35.634, Periodic spot-checks, and moved the requirements of this section, with minor modifications, to § 35.642.

Section 35.635, Full calibration measurements on gamma stereotactic radiosurgery units, is a new section that contains the requirements for the calibration of gamma stereotactic radiosurgery units. This section is similar in content to § 35.632. Requirements in this section are based on recommendations found in AAPM Report No. 54. The recordkeeping requirements for this section are in § 35.2632, Records of teletherapy, remote afterloader, and gamma stereotactic radiosurgery full calibrations.

The NRC deleted the current § 35.636, Safety checks for teletherapy facilities. The requirements in this section were extended to all therapy units and incorporated into the final §§ 35.642, 35.643, 35.645, and 35.647.

The NRC deleted the current § 35.641, Radiation surveys for teletherapy facilities. Radiation surveys at the surface of the main source safe of therapy units were addressed in the final § 35.652. The remaining requirements in the current § 35.641 were deleted to allow the licensee more flexibility in managing its radiation protection program.

Section 35.642, Periodic spot-checks for teletherapy units, is a new section that contains the requirements that were previously found in § 35.634, Periodic spot-checks. The NRC replaced the phrase ''teletherapy physicist'' with the term ''authorized medical physicist'' throughout the section. We deleted the requirement in paragraph (c) to maintain a copy of the physicist's notification of the results of spot-checks to the licensee to reduce the recordkeeping requirements for licensees. We modified paragraph (d) to require that the safety spot-checks be performed once in each calendar month and after each source installation. This change replaces the safety check requirements after each source replacement in the current § 35.636, which is deleted in the final rule. We modified paragraph (d)(3) to replace the term ''beam condition indicator'' with ''source exposure indicator'' to clarify that indicators were needed to note whether the source was exposed and note to what degree the source was exposed. We revised paragraph (d)(4) to include a requirement for an intercom system that was previously imposed by license condition. An intercom is needed to assure that the licensee's staff and the patients have the ability to communicate verbally in addition to the ability to communicate visually. We revised paragraph (e) to require that if a malfunction is identified during a safety spot-check the licensee lock the control console in the off position and not use the unit except as may be necessary to repair, replace, or check the malfunctioning system. This change makes § 35.642 consistent with the requirement in the current § 35.636 regarding immediate actions to be taken when a malfunctioning system is identified. The recordkeeping requirements for this section are in § 35.2642, Records of periodic spot-checks for teletherapy units.

Section 35.643, Periodic spot-checks for remote afterloader units, is a new section that replaces the current § 35.643, Modification of teletherapy unit or room before beginning a treatment program. The NRC deleted requirements in the current § 35.643 because they were considered overly prescriptive. This allows the licensee more flexibility in designing a radiation protection program that is specific to its facility and which assures that the dose limits in Part 20 are not exceeded.

The new § 35.643 contains the requirements for periodic spot-checks of remote afterloader units, and is similar in content to § 35.642. Requirements in this section are based on recommendations in AAPM TG–40 and TG–56. The recordkeeping requirements for this section are in § 35.2643, Records of periodic spot-checks for remote afterloader units.

Section 35.645, Periodic spot-checks for gamma stereotactic radiosurgery

units, is a new section that replaces the current § 35.645, Reports of teletherapy surveys, checks, tests, and measurements. The requirements in the current § 35.645 were deleted to reduce the reporting burden on medical use licensees. The NRC believes that there is no need to submit survey results to the appropriate Regional Office because the survey results are maintained by a licensee to show compliance with Part 20 and, therefore, are available for review.

The new § 35.645 contains requirements for periodic spot-checks of gamma stereotactic radiosurgery units, and is similar in content to § 35.642. Requirements in this section are based on recommendations found in AAPM Report No. 54. The recordkeeping requirements for this section are in § 35.2645, Records of periodic spot-checks for gamma stereotactic radiosurgery units.

Section 35.647, Additional technical requirements for mobile remote afterloader units, replaces the current § 35.647, 5-year inspection. Requirements in the current § 35.647 were moved to § 35.655. This section now contains the requirements for mobile remote afterloader units which were previously listed in an internal NRC document entitled, ''Supplement 1 to Policy and Guidance Directive FC 86–4; Revision 1, Mobile Remote Afterloading Brachytherapy Licensing Module.'' The recordkeeping requirements for this section are in § 35.2647, Records of additional technical requirements for mobile remote afterloader units.

Section 35.652, Radiation surveys, is a new section. This section replaces the current requirements in § 35.641. This section requires that, in addition to the surveys required by § 20.1501, the licensee make surveys to ensure that the maximum radiation levels and average radiation levels from the surface of the main source safe do not exceed the levels stated in the SSDR. These surveys provide added assurance that a device has been manufactured and that source(s) have been installed properly. The recordkeeping requirements for this section are in § 35.2652, Records of surveys of therapeutic treatment units.

Section 35.655, 5-year inspection for teletherapy and gamma stereotactic radiosurgery units, is a new Section and contains the requirements for inspections that were in the current § 35.647. Section 35.655 requires that teletherapy units and gamma stereotactic radiosurgery units be inspected and serviced during source replacement, or at intervals not to exceed 5 years, to assure proper functioning of the source exposure mechanism. Most gamma stereotactic radiosurgery licensees are required, by license condition, to inspect the units every 7 years. However, professionals in the medical community have indicated that the units are inspected on a more frequent basis. The NRC believes that the risk associated with using gamma stereotactic radiosurgery units justifies a change in the inspection frequency to a frequency consistent with teletherapy units, i.e., 5 years. The recordkeeping requirements for this section are in § 35.2655, Records of 5-year inspection for teletherapy and gamma stereotactic radiosurgery units.

Section 35.657, Therapy-related computer systems, is a new section that requires licensees to perform acceptance testing on the treatment planning system of therapy-related computer systems in accordance with published protocols accepted by nationally recognized bodies. These changes are consistent with recommendations found in AAPM TG–56. The components of the testing are provided in this section. However, the licensee retains flexibility in developing the acceptance testing program. The NRC believes that these new requirements are warranted for the licensee administering therapy doses to ensure that the correct dose is delivered to patients.

Section 35.690, Training for use of remote afterloader units, teletherapy units, and gamma stereotactic radiosurgery units, is a new section. This section contains the training and experience requirements for an AU of teletherapy, remote afterloader, and gamma stereotactic radiosurgery units. The current section, § 35.960, Training for teletherapy, was expanded to include the training for AUs of remote afterloaders and gamma stereotactic radiosurgery units because requirements for gamma stereotactic radiosurgery units and remote afterloader units have been codified in the revised Part 35. Two changes made in the new section should be noted. First, the listing of specialty boards by name was deleted because the regulatory text in Part 35 will no longer incorporate a listing of specialty boards whose diplomates automatically fulfill the training and experience requirements for AUs. In place of listing the boards, the final rule provides for NRC recognition of the boards. Second, an individual must obtain written certification from a preceptor indicating that the individual has satisfactorily completed the requirements in this section and has achieved a level of competency sufficient to function independently as an AU. Section III of the **SUPPLEMENTARY INFORMATION** contains a detailed discussion of the Commission's changes to the training and experience requirements in Part 35. Note, 2 years after the effective date of the final rule, § 35.690 will replace the current requirements in § 35.960, Training for use of therapeutic medical devices.

Subpart J, Training and Experience Requirements, is in the current Part 35 and will be retained for 2 years after the effective date of the final rule. Licensees will have the option to comply with the training and experience requirements in Subpart J or in Subparts B and D–H until 2 years after the effective date of the final rule. During this transition period, the NRC will continue working with the ACMUI and the medical community to resolve any concerns with the training and experience requirements. The Commission will consider changes to the training and experience requirements, as appropriate. A more detailed discussion of the Commission's changes to the training and experience requirements is in Section III of the **SUPPLEMENTARY INFORMATION** of this document. The schedule for implementation of the training and experience requirements is in Section IX of the **SUPPLEMENTARY INFORMATION** of this document.

Section 35.900, Radiation Safety Officer, is in the current Part 35. Two changes have been made in this section to correspond to the revised numbering system: § 35.57, Training for experienced Radiation Safety Officer, teletherapy or medical physicist, authorized user, and nuclear pharmacist; and § 35.24, Authority and responsibilities for the radiation protection program. This section will be retained for 2 years after the effective date of the final rule, at which time licensees will be required to comply with the training and experience requirements in the new § 35.50, Training for Radiation Safety Officer. Section IX of the **SUPPLEMENTARY INFORMATION** of this document contains a detailed discussion of the Commission's implementation of the training and experience requirements.

Section 35.901, Training for experienced Radiation Safety Officer, was deleted in its entirety, and the requirements of this section have been moved to the § 35.57.

Section 35.910, Training for uptake, dilution, and excretion studies, is in the current Part 35. One change has been made in this section to correspond to the revised numbering system: § 35.57, Training for experienced Radiation Safety Officer, teletherapy or medical physicist, authorized user, and nuclear pharmacist. This section will be

retained for 2 years after the effective date of the final rule, at which time licensees will be required to comply with the training and experience requirements in the new § 35.190, Training for uptake, dilution, and excretion studies. Section IX of the **SUPPLEMENTARY INFORMATION** of this document contains a detailed discussion of the Commission's implementation of the training and experience requirements.

Section 35.920, Training for imaging and localization studies, is in the current Part 35. One change has been made in this section to correspond to the revised numbering system: § 35.57, Training for experienced Radiation Safety Officer, teletherapy or medical physicist, authorized user, and nuclear pharmacist. This section will be retained for 2 years after the effective date of the final rule, at which time licensees will be required to comply with the training and experience requirements in the new § 35.290, Training for imaging and localization studies. Section IX of the **SUPPLEMENTARY INFORMATION** of this document contains a detailed discussion of the Commission's implementation of the training and experience requirements.

Section 35.930, Training for therapeutic use of unsealed byproduct material, is in the current Part 35. One change has been made in this section to correspond to the revised numbering system: § 35.57, Training for experienced Radiation Safety Officer, teletherapy or medical physicist, authorized user, and nuclear pharmacist. This section will be retained for 2 years after the effective date of the final rule, at which time licensees will be required to comply with the training and experience requirements in the new § 35.390, Training for use of unsealed byproduct material for which a written directive is required. Section IX of the **SUPPLEMENTARY INFORMATION** of this document contains a detailed discussion of the Commission's implementation of the training and experience requirements.

Section 35.932, Training for treatment of hyperthyroidism, is in the current Part 35. One change has been made in this section to correspond to the revised numbering system: § 35.57, Training for experienced Radiation Safety Officer, teletherapy or medical physicist, authorized user, and nuclear pharmacist. This section will be retained for 2 years after the effective date of the final rule, at which time licensees will be required to comply with the training and experience requirements in the new § 35.392, Training for the oral administration of sodium iodide I-131 requiring a written directive in quantities less than or equal to 1.22 Gigabecquerels (33 millicuries). Section IX of the **SUPPLEMENTARY INFORMATION** of this document contains a detailed discussion of the Commission's implementation of the training and experience requirements.

Section 35.934, Training for treatment of thyroid carcinoma, is in the current Part 35. One change has been made in this section to correspond to the revised numbering system: § 35.57, Training for experienced Radiation Safety Officer, teletherapy or medical physicist, authorized user, and nuclear pharmacist. This section will be retained for 2 years after the effective date of the final rule, at which time licensees will be required to comply with the training and experience requirements in the new § 35.394, Training for the oral administration of sodium iodide I-131 requiring a written directive in quantities greater than 1.22 Gigabecquerels (33 millicuries). Section IX of the **SUPPLEMENTARY INFORMATION** of this document contains a detailed discussion of the Commission's implementation of the training and experience requirements.

Section 35.940, Training for use of brachytherapy sources, is in the current Part 35. One change has been made in this section to correspond to the revised numbering system: § 35.57, Training for experienced Radiation Safety Officer, teletherapy or medical physicist, authorized user, and nuclear pharmacist. This section will be retained for 2 years after the effective date of the final rule, at which time licensees will be required to comply with the training and experience requirements in the new § 35.490, Training for use of manual brachytherapy sources. Section IX of the **SUPPLEMENTARY INFORMATION** of this document contains a detailed discussion of the Commission's implementation of the training and experience requirements.

Section 35.941, Training for ophthalmic use of strontium-90, is in the current Part 35. One change has been made in this section to correspond to the revised numbering system: § 35.57, Training for experienced Radiation Safety Officer, teletherapy or medical physicist, authorized user, and nuclear pharmacist. This section will be retained for 2 years after the effective date of the final rule, at which time licensees will be required to comply with the training and experience requirements in the new § 35.491, Training for ophthalmic use of strontium-90. Section IX of the **SUPPLEMENTARY INFORMATION** of this document contains a detailed discussion of the Commission's implementation of the training and experience requirements.

Section 35.950, Training for use of sealed sources for diagnosis, is in the current Part 35. One change has been made in this section to correspond to the revised numbering system: § 35.57, Training for experienced Radiation Safety Officer, teletherapy or medical physicist, authorized user, and nuclear pharmacist. This section will be retained for 2 years after the effective date of the final rule, at which time licensees will be required to comply with the training and experience requirements in the new § 35.590, Training for use of sealed sources for diagnosis. Section IX of the **SUPPLEMENTARY INFORMATION** of this document contains a detailed discussion of the Commission's implementation of the training and experience requirements.

Section 35.960, Training for use of therapeutic medical devices, is in the current Part 35. One change has been made in this section to correspond to the revised numbering system: § 35.57, Training for experienced Radiation Safety Officer, teletherapy or medical physicist, authorized user, and nuclear pharmacist. This section will be retained for 2 years after the effective date of the final rule, at which time licensees will be required to comply with the training and experience requirements in the new § 35.690, Training for use of remote afterloader units, teletherapy units, and gamma stereotactic radiosurgery units. Section IX of the **SUPPLEMENTARY INFORMATION** of this document contains a detailed discussion of the Commission's implementation of the training and experience requirements.

Section 35.961 has been retitled, Training for an authorized medical physicist, to reflect that the training and experience requirements in this section apply to authorized medical physicists rather than just teletherapy physicists. In addition, the list of tasks in paragraph (c) has been changed to reflect the new numbering system. This section will be retained for 2 years after the effective date of the final rule, at which time licensees will be required to comply with the training and experience requirements in the new § 35.51, Training for an authorized medical physicist. Section IX of the **SUPPLEMENTARY INFORMATION** of this document contains a detailed discussion of the Commission's

implementation of the training and experience requirements.

Section 35.970, Training for experienced authorized users, was deleted in its entirety and the requirements are moved to § 35.57.

Section 35.971, Physicians training in a three month program, was deleted in its entirety. Three-month nuclear medicine programs are no longer available. Criteria for authorized users are now specified in other areas of the rule.

Section 35.972, Recentness of training, was deleted in its entirety and the requirements are moved to § 35.59.

Section 35.980, Training for an authorized nuclear pharmacist, was not changed. This section will be retained for 2 years after the effective date of the final rule, at which time licensees will be required to comply with the training and experience requirements in the new § 35.55, Training for an authorized nuclear pharmacist. Section IX of the SUPPLEMENTARY INFORMATION of this document contains a detailed discussion of the Commission's implementation of the training and experience requirements.

Section 35.981, Training for experienced nuclear pharmacists, has not been changed. This section will be retained for 2 years after the effective date of the final rule, at which time licensees will be required to comply with the training and experience requirements in the new § 35.57, Training for experienced Radiation Safety Officer, teletherapy or medical physicist, authorized user, and nuclear pharmacist.

The NRC deleted the current § 35.990, Violations, and moved the requirements of this section, with minor modifications, to the new § 35.4001, Violations.

The NRC deleted the current § 35.991, Criminal penalties, and moved the requirements of this section, with minor modifications, to the new § 35.4002, Criminal penalties.

The NRC deleted the current § 35.999, Resolution of conflicting requirements during transition period, and moved the requirements of this section, with modifications, to the new § 35.10, Implementation.

Subpart K, Other Medical Uses of Byproduct Material or Radiation from Byproduct Material, is a new subpart. This subpart includes all new medical uses of byproduct material or radiation from byproduct material, i.e., types of uses that are not regulated under Subparts D through H.

Section 35.1000, Other medical uses of byproduct material or radiation from byproduct material, is a new section. It has been added so that there are codified regulatory requirements and a more clearly defined process to obtain a license, or an amendment to a license, for a new medical use of byproduct material or radiation from byproduct material, i.e., an emerging technology. The specific information that must be provided to the Commission in support of an application for use under § 35.1000 is provided in § 35.12(d). The Commission intends to evaluate each application on a case-by-case basis and to work with the ACMUI, the medical community, and the developers of the new technology, as appropriate, to determine the risks associated with the technology and the appropriate regulatory requirements, including the training and experience requirements, for use of the technology.

Subpart L, Records, is a new subpart. This subpart contains all the specific recordkeeping requirements necessary to implement the requirements in Part 35. The general requirements for record maintenance, such as electronic storage, are provided in § 35.5. The records are grouped in one subpart to facilitate use by the licensees. A licensee may refer to this subpart to determine whether something must be recorded, instead of having to review the entire regulation to find out if there is a particular recordkeeping requirement. Many of the recordkeeping requirements remain unchanged from the current Part 35. However, some new sections have been added as a result of new requirements, especially in Subpart H, that codify requirements for remote afterloaders and gamma stereotactic radiosurgery units that are currently imposed by license conditions.

Section 35.2024, Records of authority and responsibilities for radiation protection programs, requires the licensee to retain a record of actions taken by the licensee's management in accordance with § 35.24(a) for 5 years. The Commission believes that it is important to document the licensee's management review and approval of licensing actions and changes to the radiation protection program. The record of licensing actions and radiation protection program changes must include a summary of the actions taken and a signature of licensee management. The 5-year retention period is a reduction from the current requirements to maintain records of the approval of licensing actions, individuals, and radiation protection program changes. Similar records in the current §§ 35.23 and 35.31 are required to be maintained for the duration of the license. The 5-year retention period will decrease the recordkeeping burden on licensees and will also allow sufficient time for NRC to review records of licensee actions.

Paragraph (b) of this section requires the licensee to retain a copy of both the authorities, duties, and responsibilities of the RSO in accordance with § 35.24(e) and a signed copy of each RSO's agreement to be responsible for implementing the radiation safety program, in accordance with § 35.24(b), for the duration of the license. These records must include the signatures of both the RSO and licensee management. The current Part 35 requires that the signed copy of the authorities, duties, and responsibilities of the RSO be retained until the Commission terminates the license.

Section 35.2026, Records of radiation protection program changes, requires the licensee to retain a record of each radiation protection program change made in accordance with § 35.26(a) for 5 years. The record must include a copy of the old and new procedures, the effective date of the change, and the signature of the licensee management that reviewed and approved the change. The requirements in the current § 35.31 to include the reasons for the change, and a summary of radiation safety matters that were considered before making the change, have been deleted. The Commission recognizes that the requirement for management's signature is redundant with the requirement in § 35.2024. However, it believes this approach is warranted in light of the importance of these actions. This record is needed to document what radiation changes were made in the program to facilitate the Commission's evaluation of minor radiation safety program changes, and provides licensees with a record of the changes. Currently, licensees must retain a record of each ''radiation safety program'' change until the license has been renewed or terminated. Therefore, the 5-year retention period in the final rule represents a reduction in the licensee's recordkeeping burden.

Section 35.2040, Records of written directives, requires the licensee to retain a copy of written directives required by § 35.40 for 3 years. The final rule includes only minor changes to the specific items that must currently be recorded in written directives in accordance with § 35.32. These records will help to ensure that administrations are in accordance with the written directives. The 3-year recordkeeping retention period corresponds with the current retention period for written directives in § 35.32(d). These changes are discussed under § 35.40.

Section 35.2041, Records for procedures for administrations requiring

a written directive, is a new section. This section requires licensees to retain a copy of the procedures required by § 35.41(a) for the duration of the license.

Section 35.2060, Records of calibrations of instruments used to measure the activity of unsealed byproduct material, requires the licensee to maintain a record of instrument calibrations performed in accordance with § 35.60 for 3 years. These records are required to document that the instruments are calibrated properly. This section replaces the requirements in the current § 35.50 (e) and adds recordkeeping requirements for instruments used to measure the activity of dosages of nonphoton-emitting radionuclides. The prescriptive requirements for the record were deleted because licensees should have flexibility in determining how the results of the calibration are recorded. The final rule requires that the name of the individual who performed the calibration be documented in the record, rather than the initials of the individual who performed the constancy check and the identity of the individual for all other required tests. The NRC believes that this change is needed because recording the name of the individual will better ensure future identification of the individual who performed the calibration. The change is also needed because it gives the licensee the flexibility of using paper records or computer-generated records. This requirement does not prohibit licensees from continuing to have the individual who performed the calibration sign the record. The 3-year recordkeeping retention period is consistent with the current retention period for instrument calibrations.

The final rule requires that the record contain the model and serial number of the instrument; the date of the calibration, the results of the calibration; and the name of the individual who performed the calibration.

Section 35.2061, Records of radiation survey instrument calibrations, requires the licensee to maintain a record of radiation survey instrument calibrations required by § 35.61 for 3 years. This record is needed to provide adequate documentation of instrument calibration. This section replaces the requirements in the current § 35.51(d). The NRC deleted the requirement to include the descriptions of the calibration procedure and the source used; the certified exposure rates from the source and the rates indicated by the instrument being calibrated; and the correction factors deduced from the calibration data. This revision is consistent with the revisions made to § 35.61. The 3-year recordkeeping retention period is consistent with the current retention period for instrument calibrations.

The final rule requires that the licensee record the model and serial number of the instrument; the date of the calibration; the results of the calibration; and the name of the individual who performed the calibration.

Section 35.2063, Records of dosage of unsealed byproduct material for medical use, requires the licensee to maintain a record of dosage determinations required by § 35.63 for 3 years. This record is needed to show that material has been administered to a patient or human research subject. This section replaces the requirements in the current § 35.53(c). Changes have been made from the current recordkeeping requirements for dosage measurement. The NRC deleted the requirement to include the generic name, trade name, or abbreviation of the radiopharmaceutical; its lot number and expiration date; and the activity of the dosage at the time of measurement. With the exception of the expiration date, the requirements were deleted to make the rule less prescriptive. We deleted the expiration date because it is primarily related to drug stability and sterility. The term ''dosage measurement'' was replaced by the term ''dosage determination'' to be consistent with the changes made in § 35.63. Finally, a change has been made to require that the name of the individual who determined the dosage be documented rather than the initial of the individual who made the record. We believe that this change is needed because recording the name of the individual will better ensure future identification of the individual who determined the dosage. The 3-year recordkeeping retention period corresponds with the current retention period for dosage records.

The final rule requires that licensees record the radiopharmaceutical; the patient's or human research subject's name, or identification number if one has been assigned; the prescribed dosage, the determined dosage, or a notation that the total activity is less than 1.1 MBq (30 μCi); the date and time of the dosage determination; and the name of the individual who determined the dosage.

Section 35.2067, Records of leak tests and inventory of sealed sources and brachytherapy sources, requires the licensee to retain records of the leak tests and inventory required by § 35.67(b) and (g), respectively, for 3 years. Leak test records are required to show that the leak test was done at the appropriate time interval and that sealed sources are not leaking. Inventory records are necessary to show that the possession of sealed sources did not exceed the amount authorized by the license. This section replaces the requirements in the current § 35.59(d) and (g). The NRC deleted the requirement to record the measured activity of each leak test sample and a description of the method used to measure each test sample. These changes were done to make the rule less prescriptive. We also revised the rule to require that the name of the individual performing the leak test and inventory be recorded rather than the signature of the RSO. We believe this change is needed because recording the name of the individual will ensure future identification of the individual who performed the leak test or inventory. The record retention period was reduced from 5 years to 3 years to reduce regulatory burden. The Commission does not believe the longer record retention period is warranted.

The final rule requires that leak test records must contain the model number, and serial number if one has been assigned, of each source tested; the identity of each source radionuclide and its estimated activity; the results of the test; the date of the test; and the name of the individual who performed the test. Inventory records must contain the model number of each source, and serial number if one has been assigned; the identity of each source radionuclide and its nominal activity; the location of each source; and the name of the individual who performed the inventory.

Section 35.2070, Records of surveys for ambient radiation exposure rate, requires the licensee to maintain records of radiation surveys for 3 years. These records are needed to document that surveys were performed. This section replaces the requirements in the current § 35.70(h). The NRC revised the current requirements to delete the need to record a plan of each area surveyed; the trigger level established for each area; and the detected dose rate at several points in each area expressed in millirem per hour or the removable contamination in each area expressed in disintegrations per minute per 100 square centimeters. These deletions were done to make the rule less prescriptive and to delete reference to surveys for removable contamination. The final rule requires that the name of the individual performing the survey be recorded rather than the initials of the individual. We believe this change is needed because recording the name of the individual will ensure easier

identification of the individual who performed the survey. The 3-year recordkeeping retention period is consistent with the current retention period for radiation surveys.

The final rule requires that the record include the date of the survey; the results of the survey; the instrument used to make the survey; and the name of the individual who performed the survey.

Section 35.2075, Records of the release of individuals containing unsealed byproduct material or implants containing byproduct material, requires the licensee to maintain records of patient release required by § 35.75 for 3 years. This record is needed to show compliance with the requirements in § 35.75. No changes have been made from the recordkeeping requirements in the current § 35.75 (c) and (d).

Section 35.2080, Records of mobile medical services, requires the licensees to maintain a copy of each letter that permits the use of byproduct material at a client's address of use for 3 years after the last provision of service; and to retain the records of the surveys for 3 years. The records are needed to show compliance with the requirements in § 35.80. The NRC deleted the requirements to record a plan of each area that was surveyed and the measured dose rate at several points in each area of use expressed in millirem per hour. This change was done to make the rule less prescriptive. The final rule requires that the name of the individual performing the survey rather than the initials of the individual be recorded. We believe this change is needed because recording the name of the individual will ensure easier identification of the individual who performed the survey.

Paragraph (a) of the final rule requires that the record include a copy of each letter that permits the use of byproduct material at a client's address. Paragraph (b) requires that the record of each survey include the date of survey, the result of the survey, the instrument used to make the survey, and the name of the individual who performed the survey.

Section 35.2092, Records of decay-in-storage, requires the licensee to maintain records of the disposal of licensed materials made in accordance with § 35.92 for 3 years. This record is needed to document that radioactive material is not disposed of as ordinary waste. This section replaces the requirements in the current § 35.92 (b). The NRC deleted the requirement to record the date that the material was placed in storage and the radionuclides because the requirement to store material for 10 half-lives was deleted. We also revised the requirement so that the record includes the name of the individual who performed the survey, rather than the name of the individual who performed the disposal. We believe that it is important to have a record of the individual who actually surveyed the material and determined that it could be disposed without regard to its radioactivity. The 3-year recordkeeping retention period is consistent with the current retention period for waste disposal records.

The final rule requires that the record include the date of the disposal; the survey instrument used; the background radiation level; the radiation level measured at the surface of each waste container; and the name of the individual who performed the survey.

Section 35.2204, Records of molybdenum-99 concentrations, requires the licensee to maintain a record of the molybdenum-99 concentration tests required by § 35.204(b) for 3 years. This record is needed to document that the concentration measurement has been made and that the maximum molybdenum-99 concentration level was not exceeded. This section replaces the requirements in the current § 35.204 (c). The NRC deleted the requirements to record the measured activity of the technetium expressed in millicuries and the measured activity of the molybdenum expressed in microcuries. The 3-year recordkeeping retention period is consistent with the current retention period for records of molybdenum-99 concentration.

The final rule requires that the record include, for each measured elution of technetium-99m, the ratio for the measures expressed as kilobecquerel of molybdenum-99 per megabecquerel of technetium-99m (microcuries of molybdenum per millicurie of technetium); the time and date of the measure; and the name of the individual who made the measurement.

Section 35.2310, Records of safety instruction, requires the licensee to maintain a record of radiation safety instructions required by §§ 35.310, 35.410, and 35.610 for 3 years. This record is needed to document that the instruction was given. This section replaces the requirements in §§ 35.310, 35.410, and 35.610. The rule has been revised to require that the licensee record the topics covered rather than a description of the instruction. The NRC believes the term ''description of the instruction'' was too vague and could have been interpreted too broadly. For example, the licensee could question whether the rule required a listing of the topics or a general description, e.g., such as laboratory or classroom training. The change makes it clear that the record should contain the topics, e.g., patient, visitor, waste, or contamination control. The 3-year recordkeeping retention period is consistent with the current retention period for training records.

The final rule requires that the record include a list of the topics covered, the date of the instruction, the name(s) of the attendee(s), and the name(s) of the individual(s) who provided the instruction.

Section 35.2404, Records of surveys after source implant or removal, requires the licensee to maintain a record of the surveys required by §§ 35.404 and 35.604 for 3 years. The licensee is no longer specifically required to record the dose rate from the patient or the human research subject expressed as millirem per hour and measured at 1 meter from the patient or human research subject. Each record must include the date and results of the survey, the survey instrument used, and the name of the individual who made the survey. These records are used to show that sources have not been misplaced and that all sources have been removed from the patient. The 3-year recordkeeping retention period is consistent with the current retention period for surveys found in Part 20.

Section 35.2406, Records of brachytherapy source accountability, requires the licensee to maintain a record of brachytherapy source accountability required by § 35.406 for 3 years. Changes have been made in the recordkeeping requirements found in the current rule. The licensee is no longer required to record the following items because they were deleted from § 35.406: the names of the individuals permitted to handle the sources; name and room number of the patient or the human research subject receiving the implant; number and activity of the sources in storage after the removal; and the number and activity of sources in storage after the return.

The final rule requires that, for temporary implants, the record must include the number and activity of sources removed from and returned to storage; the time and date they were removed from and returned to storage; the name(s) of the individual(s) who removed them from and returned them to storage; and the location of use. For permanent implants, the record must include the number and activity of sources removed from storage; the number and activity of sources permanently implanted in the patient or human research subject; the number and activity of sources not implanted; the

date they were removed from and returned to storage; and the name(s) of the individual(s) who removed them from and returned them to storage. This record is required so that if a brachytherapy source is misplaced or missing the licensee is immediately alerted and can take appropriate action. The 3-year recordkeeping retention period is consistent with the current retention period for inventory records.

Section 35.2432, Records of calibration measurements of brachytherapy sources, requires the licensee to retain a record of the results of brachytherapy source calibrations required by § 35.432 for 3 years after the last use of the source. This is a new recordkeeping section. The record must contain the date of the calibration; the manufacturer's name, model number, and serial number for the source and instruments used to calibrate the source; the source output or activity; the source positioning accuracy within the applicators; and the signature of the AMP. These records are needed to document that the brachytherapy sources have been calibrated.

Section 35.2433, Records of decay of strontium-90 sources for ophthalmic treatments, requires the licensee to maintain a record of the activity of a strontium-90 source, as required by § 35.433, for the life of the source. This is a new recordkeeping section. The records for each strontium-90 source must include the date and initial activity of the source as determined under § 35.432; and, for each decay calculation, the date and the source activity as determined under § 35.433. These records are needed to document that the treatment times for ophthalmic uses of strontium-90 are based on properly decayed sources.

Section 35.2605, Records of installation, maintenance, adjustment, and repair of remote afterloader units, teletherapy units, and gamma stereotactic radiosurgery units, requires the licensee to retain a record of the installation, maintenance, adjustment, and repair of these units as required by § 35.605, for 3 years. This is a new recordkeeping section. Previously, licensees were not required to keep records of installation, maintenance, adjustment, and repair. For each installation, maintenance, adjustment, and repair, the record must include the date, description of the service, and name(s) of the individual(s) who performed the work. This record is necessary to document that the units are properly installed, maintained, adjusted, and repaired; to establish trends in unit performance; and to establish a service history that may be used in evaluation of generic equipment problems.

Section 35.2610, Records of safety procedures, is a new section. This section requires licensees to retain a copy of the procedures required by §§ 35.610(a)(4) and (d)(2) until the licensee no longer possesses the remote afterloader, teletherapy unit, or gamma stereotactic radiosurgery unit.

Section 35.2630, Records of dosimetry equipment used with remote afterloader units, teletherapy units, and gamma stereotactic radiosurgery units, requires the licensee to retain a record of the calibration, intercomparison, and comparisons of its dosimetry equipment done in accordance with § 35.630 for the duration of the license. Some changes have been made in the recordkeeping requirements from the current rule. For example, a requirement, similar to requirements for other instruments, has been added to record the manufacturer's name of the instruments that were calibrated. These records are needed to show that calibrations of medical units were made with properly calibrated instruments.

Section 35.2632, Records of teletherapy, remote afterloader, and gamma stereotactic radiosurgery full calibrations, requires the licensee to maintain a record of the full calibrations required by §§ 35.632, 35.633, and 35.635 for 3 years. The record retention period was decreased from the duration of the use of the unit's source to 3 years to reduce regulatory burden. The term ''teletherapy physicist'' was replaced with the term ''authorized medical physicist.'' In addition, the current recordkeeping requirements for this section were reduced to recording the date of the calibration; manufacturer's name, model number, and serial number for the unit, source and instruments used to calibrate the unit; the results and assessment of the calibration; the results of the autoradiograph required for low dose-rate remote afterloader units; and the signature of the AMP who performed the full calibration. These records are needed to document that calibrations were performed in accordance with §§ 35.632, 35.633, and 35.635.

Section 35.2642, Records of periodic spot-checks for teletherapy units, requires the licensee to retain a record of each periodic spot-check for teletherapy units required by § 35.642 for 3 years. Minor changes have been made in the recordkeeping requirements from the current rule. For instance, the licensee is no longer required to record the operability of the beam condition indicator light, but is required to record the operability of the source exposure indicator light. This change reflects corresponding changes made in § 35.642. These records are needed to document that spot-checks were performed in accordance with § 35.642. The 3-year recordkeeping retention period is consistent with the current retention period for periodic spot-checks.

Paragraph (c) requires that the licensee retain a copy of the procedures required by § 35.642(b) until the licensee no longer possesses the teletherapy unit.

Section 35.2643, Records of periodic spot-checks for remote afterloader units, requires the licensee to retain a record of each spot-check for remote afterloader units required by § 35.643 for 3 years. This is a new recordkeeping section. The record must include the date of the spot-check; the manufacturer's name, model number, and serial number for both the remote afterloader unit and source; an assessment of timer accuracy; notations indicating the operability of each entrance door electrical interlock, radiation monitors, source exposure indicator lights, viewing and intercom systems, clock and decayed source activity in the unit's computer; the name of the individual who performed the periodic spot-check; and the signature of the AMP who reviewed the record of the spot-check. These records are needed to document that spot-checks were performed in accordance with § 35.643.

Paragraph (c) requires that the licensee retain a copy of the procedures required by § 35.643(b) until the licensee no longer possesses the remote afterloader.

Section 35.2645, Records of periodic spot-checks for gamma stereotactic radiosurgery units, requires the licensee to retain a record of each spot-check for gamma stereotactic radiosurgery units required by § 35.645 for 3 years. This is a new recordkeeping section. The record must include the date of the spot-check; the manufacturer's name, model number, and serial number for the gamma stereotactic radiosurgery unit and the instrument used to measure the output of the unit; an assessment of timer linearity and accuracy; the calculated on-off error; a determination of trunnion centricity; the difference between the anticipated output and the measured output; an assessment of source output against computer calculations; notations indicating the operability of radiation monitors, helmet microswitches, emergency timing circuits, emergency off buttons, electrical interlocks, source exposure indicator lights, viewing and intercom

systems, timer termination, treatment table retraction mechanism, stereotactic frames and localizing devices (trunnions); the name of the individual who performed the periodic spot-check; and the signature of the AMP who reviewed the periodic spot-check. This record is needed to show that spot-checks were performed in accordance with § 35.645.

Paragraph (c) requires that the licensee retain a copy of the procedures required by § 35.645 (b) until the licensee no longer possesses the gamma stereotactic radiosurgery unit.

Section 35.2647, Records of additional technical requirements for mobile remote afterloader units, requires the licensee to retain a record of each check for mobile remote afterloader units required by § 35.647 for 3 years. This is a new recordkeeping section. The record must include the date of the check; the manufacturer's name, model number, and serial number for the remote afterloader unit; notations accounting for all sources before departing from a facility; notations indicating the operability of each entrance door electrical interlock, radiation monitors, source exposure indicator lights, viewing and intercom system, applicators, source transfer tubes, and transfer tube applicator interfaces, and source positioning accuracy; and the signature of the individual who performed the check. This record is needed to show that required spot-checks were performed in accordance with § 35.647 and that the unit is operable.

Section 35.2652, Records of surveys of therapeutic treatment units, requires the licensee to maintain a record of radiation surveys made in accordance with § 35.652 for the duration of use of the unit. This recordkeeping requirement has been changed to require that the records of radiation surveys of the treatment unit must be maintained for the duration of use of the unit, rather than for the duration of the license, to reduce regulatory burden. In addition, the licensee is no longer required by this section to maintain a plan of the areas surrounding the treatment room that were surveyed, the measured dose rate at several points in each area expressed in millirem per hour, and the calculated maximum quantity of radiation over a period of 1 week for each restricted and unrestricted area. This change reflects corresponding changes made in § 35.652. The record must include the date of the measurements; the manufacturer's name, model number and serial number of the treatment unit, source, and instrument used to measure radiation levels; each dose rate measured around the source while the unit is in the off position and the average of all measurements; and the signature of the individual who performed the surveys. This record is needed to document radiation levels in areas surrounding therapeutic devices in accordance with § 35.652.

Section 35.2655, Records of 5-year inspection for teletherapy and gamma stereotactic radiosurgery units, requires the licensee to maintain a record of the 5-year inspection for teletherapy and gamma stereotactic radiosurgery units required by § 35.655 for the duration of the unit. This recordkeeping requirement has been changed to require that the records of inspections of the treatment units must be maintained for the duration of use of the unit, rather than for the duration of the license, to reduce the regulatory burden. A minor change has been made to delete the requirement to maintain a record of the components replaced to also reduce the regulatory burden. The record must contain the inspector's radioactive materials license number; the date of inspection; the manufacturer's name, model number and serial number for both the treatment unit and source; a list of components inspected and serviced; the type of service; and the signature of the inspector. This record is needed to document the type of service that was performed in accordance with § 35.655.

Subpart M, Reports, is a new subpart in Part 35. This subpart contains all the reporting requirements necessary to implement the requirements in Part 35. Grouping of reporting requirements into one subpart was done to facilitate use by licensees. A licensee may refer to this section when determining whether something must be reported, rather than having to review the entire regulation to find out if there is a particular reporting requirement. Two of the reporting requirements appear in the current §§ 35.33 and 35.59. A third reporting requirement was added so that the NRC can comply with the requirement to submit an annual report to Congress of unscheduled incidents or events which the Commission considers significant from the standpoint of public health and safety.

Section 35.3045, Report and notification of a medical event, provides criteria for reporting and notifying individuals about a medical event. The requirements in the final rule are based on the current requirements in § 35.33, Notifications, reports, and records of misadministrations. Changes were made to make the reporting threshold dose-based where possible; to add a dose threshold of 0.5 Sievert (Sv) (50 rem) shallow dose equivalent to the skin; and to address two areas that have caused problems in implementing the current requirements for reporting misadministrations—patient intervention and wrong treatment site. In addition, several changes were made to the requirements associated with the report and record of the event.

Patient intervention is not specifically addressed in the current rule. However, a licensee is expected to act reasonably, in accordance with prevailing standards of care, to prevent patient intervention from causing a misadministration. This situation has resulted in numerous debates over whether or not a licensee had done everything it should to prevent patient intervention during treatment. In order to correct the current situation, the NRC defined patient intervention to mean intentional or unintentional actions taken by a patient or human research subject such as dislodging or removing treatment devices or prematurely terminating the administration. We have also added a specific requirement for reporting medical events that occur as a result of patient intervention. Licensees are required to report any event resulting from intervention of a patient or human research subject in which the administration of byproduct material or radiation from byproduct material results or will result in unintended permanent functional damage to an organ or a physiological system, as determined by a physician. This reporting requirement should result in minimal regulatory burden on licensees because in most situations where patients or human research subjects intervene, either voluntarily or involuntarily, in their treatment there is no resultant permanent medical damage. Even though there is a high threshold for reporting in the final rule, licensees are expected to continue to act reasonably, as required under the current rule, to prevent medical events caused by patient intervention.

The final rule includes specific criteria for determining when a dose to a wrong treatment site is a reportable medical event: a dose to the skin or an organ or tissue other than the treatment site that exceeds by 0.5 Sv (50 rem) to an organ or tissue and 50 percent or more of the dose expected from the administration defined in the written directive (excluding, for permanent implants, seeds that were implanted in the correct site but migrated outside the treatment site).

The final rule retains the current requirement in § 35.33 that licensees notify the NRC Operations Center, by telephone, no later than the next

calendar day after discovery of the medical event. The final rule also retains the current requirement for licensees to submit a written report to the appropriate NRC Regional Office listed in 10 CFR 30.6 within 15 days after discovery of the medical event. This reporting requirement is needed to ensure that NRC is aware of medical events. In addition, the licensee is required to notify the referring physician and the individual affected by the medical event, or the responsible relative or guardian, no later than 24 hours after its discovery, unless the referring physician personally informs the licensee either that he will inform the individual or that, based on medical judgment, telling the individual would be harmful. The written report to the NRC must include certification that the licensee notified the individual (or the individual's responsible relative or guardian), and, if not, why not. Since licensees are required to report information about the medical event to the NRC and to the referring physician, we believe that it is not necessary to require licensees to retain a record of the medical event.

A change was also made in the current requirement for a written report to be provided to the affected individual within 15 days of discovery of the medical event. In the current rule, licensees can provide the individual with a brief description of both the event and the consequences as they may affect the individual if they include a statement that the individual can also obtain a copy of the report that was submitted to the NRC from the licensee. In the final rule, the licensee is not required to include this statement because knowledge that a report had to be submitted to the NRC might unduly alarm an individual involved in a medical event with no added benefit. However, licensees are required to inform the individual, or a responsible relative or guardian, that a written description of the event can be obtained from the licensee upon request. Licensees are required to provide this written description to the individual, if requested. In addition, licensees are required to annotate a copy of their report to the NRC about the medical event and provide it to the referring physician, if other than the licensee, within 15 days after discovery of the medical event. The NRC believes that this is important so that the individual's referring physician has all the available documentation about the medical event to support any decisions about remedial or prospective health care. The 15-day time period to provide the referring physician with a copy of the record was based on paragraph (d), which requires a licensee to submit a report to the NRC within 15 days. We have attempted to have consistency in the requirements in Subparts L and M, where possible, to simplify compliance with the recordkeeping and reporting requirements. Refer to Section III of the **SUPPLEMENTARY INFORMATION** for additional information on the reporting and notification requirements in § 35.3045.

Section 35.3047, Report and notification of a dose to an embryo/fetus or a nursing child, is a new section. Paragraph (a) requires that a licensee report to NRC any administration of byproduct material, or radiation from byproduct material, to a pregnant female that results in a dose to an embryo/fetus that is greater than 50 mSv (5 rem) dose equivalent unless the administration was specifically approved, in advance, by the AU. It should be emphasized that only unintended exposures are required to be reported to NRC.

Paragraph (b) requires that a licensee report to NRC any administration of byproduct material to a breast feeding woman that results in a dose to a nursing child that is greater than 50 mSv (5 rem) total effective dose equivalent or a dose that has resulted in unintended permanent functional damage to an organ or a physiological system of the child, as determined by a physician.

The reporting requirements in this section are similar to the reporting requirements for medical events. Paragraph (c) in the final rule requires that licensees notify the NRC Operations Center, by telephone, no later than the next calendar day after discovery of a dose to an embryo/fetus or a nursing child that requires a report. In paragraph (d), the licensee is required to submit a written report to the appropriate NRC Regional Office listed in 10 CFR 30.6 no later than 15 days after discovery of a dose to an embryo/fetus or a nursing child.

Paragraph (e) requires the licensee to notify the referring physician and the pregnant individual or mother no later than 24 hours after discovery of the event, unless the referring physician personally informs the licensee either that he/she will inform the mother or that, based on medical judgment, telling the mother would be harmful. If verbal notification is made, licensees are required to inform the mother, or the mother's or child's responsible relative or guardian, that a written description of the event can be obtained from the licensee upon request. Licensees are required to provide such a written description, if requested.

Licensees are required in paragraph (f) annotate a copy of their report to the NRC about the event and provide it to the referring physician, if other than the licensee, within 15 days after discovery of the event. The NRC believes that this is important so that the referring physician has all the available documentation about the event to support any decisions about remedial or prospective health care. The 15-day time period to provide the referring physician with a copy of the record was based on paragraph (d) which requires a licensee to submit a report to the NRC within 15 days. We have attempted to have consistency in the requirements in Subparts L and M, where possible, to simplify compliance with the recordkeeping and reporting requirements. Refer to Section III of the **SUPPLEMENTARY INFORMATION** for additional information on the notification requirements in § 35.3047.

Information required by this section is needed so that the NRC can comply with Section 208 of the Energy Reorganization Act of 1974 (Pub. L. 93–438), as amended, to submit an annual report to Congress of unscheduled incidents or events which the Commission considers significant from the standpoint of public health and safety, e.g., abnormal occurrences.

The NRC identifies an abnormal occurrence using the revised abnormal occurrence criteria that were published in the **Federal Register** on April 17, 1997 (62 FR 18820). Section II of the policy statement defines unintended radiation exposure as ''any occupational exposure, exposure to the general public or exposure as a result of a medical misadministration (as defined in § 35.2) involving the wrong individual that exceeds the reporting values established in the regulations.'' This section also states that ''All other reported medical misadministrations will be considered for reporting as an Abnormal Occurrence under the criteria for medical licensees. In addition, unintended radiation exposures include any exposure to a nursing child, fetus, or embryo as a result of an exposure (other than an occupational exposure to an undeclared pregnant woman) to a nursing mother or pregnant woman above specified values.'' Appendix A, Section I. A, of the policy statement, states that NRC will provide information on ''any unintended radiation exposure to any minor (an individual less than 18 years of age) resulting in an annual total effective dose equivalent of 50 mSv (5 rem) or more, or to an embryo/fetus

resulting in a dose equivalent of 50 mSv (5 rem) or more.''

At the present time, the NRC has no regulatory requirements that require reporting of those types of events. The Commission considered two alternatives that could be pursued: revise the current Abnormal Occurrence Criteria to delete the requirement to inform Congress of this type of event; or develop a reporting requirement that would provide the information needed by the Commission to comply with Section 208. The Commission did not pursue the first option because the Abnormal Occurrence reporting criteria were recently reviewed and revised.

The Commission recognizes that the standard of practice for AUs is to assess the pregnancy or nursing status of their patients (reference American College of Radiology ''Standard for the Performance of Therapy with Unsealed Radionuclide Sources,'' 1996, and ''Society of Nuclear Medicine General Procedure Guidelines for Imaging with Radionuclides,'' 1997). As a result, the NRC does not believe that it is appropriate to have a rule that requires a licensee to assess the pregnancy or nursing status of patients prior to a medical treatment involving byproduct material. However, we do believe it is appropriate to require the licensee to inform the NRC when the licensee learns of an unintended dose to an embryo/fetus or a nursing child that exceeds the thresholds in § 35.3047. For example, a licensee must report an unintended dose resulting from an individual not disclosing her pregnancy or nursing status at the time of administration of the byproduct material or radiation from byproduct material. In this situation, the unintended dose could have been prevented if the AU had followed the standard of practice, noted above, to assess the pregnancy status of the patient. The occurrence of such an incident does not necessarily mean that the licensee is in violation of the requirements in Part 35, as long as the licensee reports it and it is not otherwise in violation of NRC regulatory requirements. For example, a reportable dose to a nursing child under § 35.3047 is not necessarily subject to enforcement action if the licensee has complied with § 35.75.

However, the NRC acknowledges that, in some cases, the licensee might not be able to prevent the dose to an embryo/fetus or nursing child. This type of case is not reportable under § 35.3047. For example, there is no way for an AU to prevent administration of an unintended dose to an embryo/fetus if the pregnancy test was negative because it was given very early in the pregnancy.

Section 35.3067, Report of a leaking source, requires the licensee to file a report with the appropriate NRC Office listed in § 30.6 of this chapter, with a copy to the Director, Office of Nuclear Material Safety and Safeguards, U.S. Nuclear Regulatory Commission, Washington, DC 20555–0001, within 5 days if a leak test required by § 35.67 reveals the presence of 185 Bq (0.005 microcurie) or more of removable contamination. This reporting requirement is similar to the reporting requirements for leaking sources in the current § 35.59, but the final rule does not require that as much prescriptive information be included in the report. The report must contain the model number and serial number, if assigned, of the leaking source; the radionuclide and its estimated activity; the results of the test; the date of the test; and the action taken.

Subpart N, Enforcement, contains statements regarding enforcement. This subpart contains the statements in the current Subpart K, Enforcement.

Section 35.4001, Violations, is a new section that replaces the current § 35.990 which was deleted. Other than changing the number of this section to reflect the new numbering system, no changes were made in the current statements regarding violations.

Section 35.4002, Criminal penalties, is a new section that replaces the current § 35.991 which was deleted. Other than changing the numbers of this section and the sections referenced under paragraph (b) to reflect the new numbering system, no changes were made in the current statements regarding criminal penalties.

VI. Coordination With the Advisory Committee on the Medical Uses of Isotopes

The Advisory Committee on the Medical Uses of Isotopes (ACMUI) is an advisory body established to advise the NRC staff on matters that involve the administration of radioactive material and radiation from radioactive material. The proposed rule (63 FR 43516; August 13, 1998) for Part 35 summarized the ACMUI positions on the major crosscutting issues that were considered during development of the proposed rule.

During the development of the final rule, the NRC held public meetings of the ACMUI subcommittees for diagnostic and therapeutic medical uses on February 23–24, 1999, and February 25–26, 1999, respectively. The subcommittees reviewed the comments received by NRC during the public comment period and during the three facilitated public meetings held during that period. They also reviewed a first draft of the final rule that addressed the public comments. The subcommittees' comments are summarized in ''Summary of Discussion: Public Meeting of the Advisory Committee on the Medical Uses of Isotopes (ACMUI) Diagnostic Subcommittee Held in Rockville, Maryland on February 23–24, 1999'' (April 22, 1999) and ''Summary of Discussion: Public Meeting of the Advisory Committee on the Medical Uses of Isotopes (ACMUI) Therapeutic Subcommittee Held in Rockville, Maryland on February 25–26, 1999'' (April 22, 1999). The summary documents are available for inspection at the NRC Public Document Room, 2120 L Street NW. (Lower Level), Washington, DC. Single copies of the summary documents are available as indicated in the For Further Information Contact section of this document.

The full ACMUI held a public meeting on March 24–25, 1999, to discuss specific issues that the Part 35 Working Group wanted the ACMUI to review and comment on before it forwarded a draft final rule for Commission consideration. The issues included training and experience; Radiation Safety Committee; temporary Radiation Safety Officer; information that must be included in a written directive; determination of dosages of unsealed byproduct material; reports of medical events; and report of an unintended dose to an embryo/fetus or nursing child. The ACMUI presented their position on these and other issues at their annual briefing of the Commission on March 25, 1999. The ACMUI meeting was transcribed and the minutes are available for inspection at the NRC Public Document Room. Single copies of the minutes are available as indicated in the For Further Information Contact section of this document. The Commission briefing was also transcribed, and the transcript is available for inspection at the NRC Public Document Room.

On October 20, 1999, the ACMUI met to prepare for a Commission briefing, the next day, on the draft final rule for Part 35. Because the briefings are public opportunities for the Commission to hear from ACMUI, the Committee identified specific issues that they wanted to bring to the Commission's attention. The ACMUI meeting was transcribed and the minutes are available for inspection at the NRC Public Document Room. Single copies of the minutes are available as indicated in the For Further Information Contact section of this document.

At the October 21, 1999, briefing of the Commission, the ACMUI reaffirmed that stakeholders were involved throughout the rulemaking process, including extensive involvement of the ACMUI and its subcommittees and the regulated community. In addition, the Committee believed that the draft final rule forwarded to the Commission in August 1999 (SECY–99–201) was more risk-informed and more performance-based, while maintaining occupational, public, and patient safety. ACMUI endorsed the provisions in the draft final rule for the Radiation Safety Committee, the dose thresholds for reporting medical events, and the reporting threshold for unintended exposure of an embryo/fetus or nursing child. In addition, the ACMUI endorsed the training and experience requirements for authorized users, authorized medical physicists, authorized nuclear pharmacists, and radiation safety officers, and, in particular, encouraged uniform national standards for training and experience. The ACMUI noted that it does not support any regulation requiring notification of physicians and patients, as this is redundant of existing standards of care. However, if notification requirements for medical events continue to be in Part 35, the ACMUI said that it would prefer the alternative rule language provided by the NRC staff over the existing requirements (refer to SECY–99–201, Attachment 4, for further discussion of the alternative text). (Note: A modification of the alternative rule language was approved by the Commission and is in § 35.3045 of the final rule.) In addition, the Committee encouraged early recognition of the medical specialty boards and use of the guidance document, as well as focusing NRC license reviewers and inspectors on licensee performance and high risk procedures. The Commission briefing was transcribed and is available for inspection at the NRC Public Document Room or via the Commission's web site at *http://www.nrc.gov/NRC/COMMISSION/TRANSCRIPTS/19991021b.html.*

The issue of recognition of medical and other specialty boards was again discussed during an ACMUI briefing of the Commission on February 19, 2002. The ACMUI meeting was transcribed and the transcript is available for inspection at the NRC Public Document Room. Single copies of the transcript are available as indicated in the For Further Information Contact section of this document. In that meeting, two committee members expressed concern that some boards did not qualify for recognition and might not be ready to apply for recognition within 6 months after publication of the final rule. Therefore, implementation of the new Part 35, without Subpart J, could disrupt the current license authorization process for new medical personnel because many license authorizations are granted based on recognition of board certification. The Commission has considered this matter, and decided to retain the current training requirements in Subpart J for a 2-year period after the effective date of the final rule. As discussed, under Section IX, Implementation, licensees will have the option of complying with either Subpart J or Subparts B and D–H for 2 years. During this transition period, the NRC will continue working with the ACMUI and the medical community to resolve any concerns with the training and experience requirements. The Commission will consider changes to the training and experience requirements, as appropriate.

VII. Coordination With NRC Agreement States

The NRC staff discussed the revision of Part 35 with representatives of the Agreement States at the 1997, 1998, and 1999 annual meetings of the Organization of Agreement States. In addition, a draft compatibility chart for the proposed revision was developed in accordance with the compatibility categorization criteria detailed in NRC Management Directive 5.9, ''Adequacy and Compatibility of Agreement State Programs'' (dated February 27, 1998), and was published for comment with the proposed rule (63 FR 43516; August 13, 1998). The compatibility chart was later updated and provided to the Agreement States for comment on January 4, 1999. A summary of the comments received on the Agreement State compatibility designations and NRC's responses to the comments, and the compatibility designations for the final rule are found in Sections IV and X, respectively, of the **SUPPLEMENTARY INFORMATION.**

Both the Working Group and Steering Group that developed the revision of Part 35 included Agreement State representatives. The Agreement State representative on the Working Group is also a member of the Conference of Radiation Control Directors' Suggested State Regulation Committee on Medical Regulation, which has been working toward parallel development of suggested state medical regulations. State participation in the process provided an early and continuous opportunity for State input and enhanced the development of corresponding rules in State regulations.

VIII. Consistency With Medical Policy Statement

The Commission has revised its General Policy on the Regulation of the Medical Uses of Radioisotopes that was issued on February 9, 1979 (44 FR 8424), as part of the Commission's overall program for revising its regulatory framework for medical use. The proposed revision and detailed discussion on the need for the revision was published for comment in the **Federal Register** (63 FR 43580; August 13, 1998), concurrently with publication of the proposed revision to Part 35 (63 FR 43516; August 13, 1998). The revised MPS was published on August 3, 2000; 65 FR 47654. That document addressed the comments received on the proposed revision to the MPS.

The revision of Part 35 is consistent with the Commission's revision of the Medical Use Policy Statement. The consistency of the final rule with each policy statement is discussed below.

The first statement of the revised policy reads ''NRC will continue to regulate the uses of radionuclides in medicine as necessary to provide for the radiation safety of workers and the general public.'' The final rule is consistent with the statement because one of its purposes is to provide for the radiation safety of workers and individual members of the public, which is central to fulfillment of the Commission's statutory mandate in the Atomic Energy Act of 1954, as amended, to ''protect health and minimize danger to life.''

The second statement of the revised policy reads ''NRC will not intrude into medical judgments affecting patients, except as necessary to provide for the radiation safety of workers and the general public.'' The final rule is consistent with this statement because its focus is on protecting the public and workers from patients who have been administered byproduct material or radiation from byproduct material for medical use.

The third statement of the revised policy reads ''NRC will, when justified by the risk to patients, regulate the radiation safety of patients primarily to assure the use of radionuclides is in accordance with the physician's directions.'' The final rule is consistent with this statement because it includes provisions, where warranted by the risk, to provide high confidence that the authorized user's directions for the administration of byproduct material are followed.

The fourth statement of the revised policy reads ''NRC, in developing a specific regulatory approach, will consider industry and professional standards that define acceptable approaches of achieving radiation safety.'' The final rule is consistent with this statement because the rulemaking process included NRC examining relevant industry and professional standards to determine if specific areas of concern to NRC were included in the standards, or whether regulatory requirements needed to be included in Part 35.

IX. Implementation

Except as discussed below, the revised regulations in 10 CFR Parts 20, 32, and 35 become effective October 24, 2002, 6 months after publication of this final rule. Because the draft consolidated guidance document for medical use licensees has been developed in parallel with the revised regulatory requirements in Part 35, the Commission believes that a longer implementation period is not necessary. The 6-month implementation period allows the NRC time to train licensing and inspection staff so that the revised Part 35 will be uniformly implemented; and provides licensees the time to understand the specific features of the revised Part 35, and to develop and implement any changes in their radiation safety programs or procedures that are required to comply with the revised requirements. The NRC is evaluating what type of workshops might need to be offered for the benefit of licensees, Regional Offices, States, and others who are affected by the revision.

The Commission provides that licensees will have up to 2 years after the effective date of the final rule to comply with the training requirements for authorized users, authorized medical physicists, authorized nuclear pharmacists, and Radiation Safety Officers. During this 2-year period, licensees will have the option of complying with either requirements of Subpart J or the requirements in Subparts B and D–H.

The 2-year transition period will allow additional time for medical and other specialty boards to seek NRC recognition as a ''specialty board'' in accordance with §§ 35.50(a), 35.51(a), 35.55(a), 35.190(a), 35.290(a), 35.390(a), 35.392(a), 35.394(a), 35.490(a), 35.590(a), and 35.690(a). The 2-year time period will also allow individuals from Agreement States time to satisfy the training requirements in order to work in NRC jurisdictions.

Section 35.10 of the rule addresses how a licensee can determine if it must comply with the requirements of the revised Part 35 when it becomes effective or if it must continue to comply with the requirements of its license conditions. If a license condition exempts a licensee from a provision of the current Part 35 on the effective date of the final rule, paragraph (d) of this section states that the license condition will continue to exempt the licensee from the requirements in the corresponding provision in the revised Part 35. Paragraph (e) states that if a requirement in the revised Part 35 differs from the requirements in an existing license requirement that addresses the same issue, the requirement in Part 35 governs. Under most circumstances, medical use licensees will not be required to have their licenses amended in this situation, even if the revised requirement is less restrictive than their current license condition. The exceptions to paragraph (e) are listed in paragraph (f), which requires a licensee to continue to comply with any licensee condition to have procedures for responding to emergency situations (§ 35.610) and spot checks involving teletherapy units (§ 35.642), photon emitting remote afterloader units (§ 35.643), or gamma stereotactic radiosurgery units (§ 35.645).

X. Issues of Compatibility for Agreement States

Under the ''Policy Statement on Adequacy and Compatibility of Agreement State Programs'' approved by the Commission on June 30, 1997 (62 FR 46517), specific requirements within this rule should be adopted by Agreement States for purposes of compatibility or because of their health and safety significance. Implementing procedures for the Policy Statement establish specific categories which have been applied to categorize the requirements in Parts 20, 32, and 35. A Compatibility Category ''A'' designation means the requirement is a basic radiation protection standard or deals with related definitions, signs, labels, or terms necessary for a common understanding of radiation protection principles. Compatibility Category ''A'' designated Agreement State requirements should be essentially identical to those of the NRC. A Compatibility Category ''B'' designation means the requirement has significant direct transboundary implications. Compatibility Category ''B'' designated Agreement State requirements should be essentially identical to those of the NRC. A Compatibility Category ''C'' designation means the essential objectives of the requirement should be adopted by the State to avoid conflicts, duplications, or gaps. The manner in which the essential objectives are addressed in the Agreement State requirement need not be the same as NRC provided the essential objectives are met. A Compatibility Category ''D'' designation means the requirement does not need to be adopted by an Agreement State for purposes of compatibility. The Compatibility Category Health and Safety (H&S) identifies requirements that are not required for compatibility, but which have particular health and safety significance. Agreement States should adopt the essential objectives of such requirements in order to maintain an adequate program.

Summary of NRC Rules With Compatibility or Health and Safety Designations Under the Revision of 10 CFR Parts 20, 32 & 35

All Sections not listed here are Compatibility Category D

Section and paragraph	Section title
CATEGORY A	
20.1003, Occupational dose. Public Dose	Definitions.
20.1301(a) & (c)	Dose limits to individual members of the public.
CATEGORY B	
32.72(b)(1) & (b)(2)(ii)	Manufacture, preparation, or transfer for commercial distribution of radioactive drugs containing byproduct material for medical use under Part 35.
32.74(a) & (a)(3)	Manufacture and distribution of sources or devices containing byproduct material for medical use.
35.2, Agreement State. Authorized medical physicist. Authorized nuclear pharmacist. Authorized user. Radiation safety officer. Sealed source.	Definitions.
35.50	Training for Radiation Safety Officer.

Section and paragraph	Section title
35.51	Training for an authorized medical physicist.
35.55	Training for an authorized nuclear pharmacist.
35.57	Training for experienced Radiation Safety Officer, teletherapy or medical physicist, authorized user, and nuclear pharmacist.
35.59	Recentness of training.
35.190	Training for uptake, dilution and excretion studies.
35.290	Training for imaging and localization studies.
35.390	Training for use of unsealed byproduct material for which a written directive is required.
35.392	Training for the oral administration of sodium iodide I–131 requiring a written directive in quantities less than or equal to 1.22 Gigabecquerels (33 millicuries).
35.394	Training for the oral administration of sodium iodide I–131 requiring a written directive in quantities greater than 1.22 Gigabecquerels (33 millicuries).
35.490	Training for use of manual brachytherapy sources.
35.491	Training for ophthalmic use of strontium-90.
35.590	Training for use of sealed sources for diagnosis.
35.690	Training for use of remote afterloader units, teletherapy units, and gamma stereotactic radiosurgery units.
	CATEGORY C
35.2, Medical use. Prescribed dosage. Prescribed dose. Treatment site.	Definitions.
35.6	Provisions for the protection of human research subjects.
35.11	License required.
35.49	Suppliers for sealed sources or devices for medical use.
35.75(a) & (b)	Release of individuals containing unsealed byproduct material or implants containing byproduct material.
35.400	Use of sealed sources for manual brachytherapy.
35.500	Use of sealed sources for diagnosis.
35.600	Use of a sealed source in a remote afterloader unit, teletherapy unit, or gamma stereotactic radiosurgery unit.
35.3045	Report and notification of a medical event.
35.3047	Report and notification of a dose to an embryo/fetus or a nursing child.
35.3067	Report of a leaking source.
	CATEGORY H&S
35.24(b) & (f)	Authority and responsibilities for the radiation protection program.
35.27	Supervision.
35.40(a) & (b)	Written directives.
35.41(a)	Procedures for administrations requiring a written directive.
35.60(a) & (b)	Possession, use and calibration of instruments used to measure the activity of unsealed byproduct material.
35.61(a)(1), (a)(2), (b), & (c)	Calibration of survey instruments.
35.63(a)–(d)	Determination of dosages of unsealed byproduct material for medical use.
35.67(a)–(e) & (g)	Requirements for possession of sealed sources and brachytherapy sources.
35.69	Labeling of vials and syringes.
35.70(a)	Surveys of ambient radiation exposure rate
35.80(a)(2), (a)(3), & (b)	Provision of mobile medical service.
35.92	Decay-in-storage.
35.100	Use of unsealed byproduct material for uptake, dilution, and excretion studies for which a written directive is not required.
35.200	Use of unsealed byproduct material for imaging and localization studies for which a written directive is not required.
35.204(a) & (b)	Permissible molybdenum-99 concentration.
35.300	Use of unsealed byproduct material for which a written directive is required.
35.310(a)	Safety instruction.
35.315	Safety precautions.
35.404(a) & (b)	Surveys after source implant and removal.
35.406(a) & (b)	Brachytherapy sources accountability.
35.410(a)	Safety instruction
35.415 Safety precautions.	
35.432(a)–(c)	Calibration measurements of brachytherapy sealed sources.
35.433(a)	Decay of strontium-90 sources for ophthalmic treatments.
35.457	Therapy-related computer systems.
35.604(a)	Surveys of patients and human research subjects treated with a remote afterloader unit.
35.605(a)–(c)	Installation, maintenance, adjustment and repair.
35.610(a)–(e)	Safety procedures and instructions for remote afterloader units, teletherapy units, and gamma stereotactic radiosurgery units.
35.615	Safety precautions for remote afterloader units, teletherapy units, and gamma stereotactic radiosurgery units.
35.630(a) & (b)	Dosimetry equipment.
35.632(a)–(f)	Full calibration measurements on teletherapy units.
35.633(a)–(h)	Full calibration measurements on remote afterloader units.
35.635(a)–(f)	Full calibration measurements on gamma stereotactic radiosurgery units.
35.642(a)–(e)	Periodic spot-checks for teletherapy units.
35.643(a)–(e)	Periodic spot-checks for remote afterloader units.
35.645(a)–(f)	Periodic spot-checks for gamma stereotactic radiosurgery units.

Section and paragraph	Section title
35.647(a)–(d)	Additional technical requirements for mobile remote afterloader units.
35.652(a) & (b)	Radiation surveys.
35.655(a) & (b)	Five-year inspection for teletherapy and gamma stereotactic radiosurgery units.
35.657	Therapy-related computer systems.

XI. Assessment of Federal Regulations and Policies on Families

In accordance with Section 654 of the Treasury and General Government Appropriation Act of 1999, Public Law No. 105–277, 112 Stat. 2681, 528–29 (1998), to be codified at 5 USC 601 note, the NRC has assessed this action against the seven factors set forth in the Act. The NRC has determined that this action will not negatively affect family well-being.

XII. Finding of No Significant Environmental Impact Availability

The Commission has determined under the National Environmental Policy Act of 1969, as amended, and the Commission's regulations in Subpart A of 10 CFR Part 51, that this rule is a major Federal action but will not significantly affect the quality of the human environment, and, therefore, an environmental impact statement is not required. The amendments relax some requirements, eliminate certain procedural restrictions, focus on those requirements that are essential for patient safety, reduce or eliminate duplications or overlaps between Part 35 and the other parts of 10 CFR, and provide greater flexibility for licensees in how they meet the objectives in the requirements. The Commission believes that the more risk-informed, performance-based amendments will provide greater flexibility in the medical use of byproduct material while continuing to adequately protect public health and safety. With the exception of the amendment to 10 CFR 20.1301, the rulemaking action will not lead to an increase in radiation exposure to the public or health care workers, or radiation releases to the environment beyond the exposures or releases currently resulting from the medical use of byproduct material or radiation from byproduct material. The amendment to 10 CFR 20.1301 is expected to result in an increase in radiation exposure to the public. However, this alternative is consistent with generally accepted radiation protection principles, such as those expressed by the International Commission on Radiation Protection (ICRP), the National Council on Radiation Protection and Measurements (NCRP), and the International Atomic Energy Agency (IAEA).

The NRC requested public comments on any environmental justice considerations that may be related to this rule. Because there were no comments specific to those considerations, the environmental assessment has not changed in this regard as a result of public comment.

The NRC requested the views of the States on the environmental assessment for this rule. Because there were no comments specific to the environmental assessment, the environmental assessment has not changed as a result of the views of the States.

The environmental assessment is available for inspection as indicated in the **ADDRESSES** section of this document. Single copies of the environmental assessment are available as indicated in the **FOR INFORMATION CONTACT** section of this document.

XIII. Paperwork Reduction Act Statement

This final rule amends information collection requirements that are subject to the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 *et seq.*). These requirements were approved by the Office of Management and Budget, approval numbers 3150–0010 and 3150–0120.

Because the rule will reduce existing information collection requirements, the annual burden to the public for these information collections is expected to be decreased by 65 hours per licensee. This reduction includes the time required for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the information collection. The final rule has been revised to allow licensees, as an alternative to the revised training and experience requirements in Subparts B and D–H, to continue to use the current Subpart J training and experience requirements for a period of 2 years after the effective date of the final rule. This will allow NRC licensees and individuals in Agreement States sufficient time to meet the revised training requirements. This final rule adds an information collection burden for individuals to request certification for training and experience. The burden for this information collection is estimated to average .5 hours per request. Because the burden for this information collection is insignificant, Office of Management and Budget (OMB) clearance is not required.

Public Protection Notification

The NRC may not conduct or sponsor, and a person is not required to respond to, a request for information or an information collection requirement unless the requesting document displays a currently valid OMB control number.

XIV. Regulatory Analysis

The Commission has prepared a regulatory analysis on this final regulation. The analysis examines the costs and benefits of the alternatives considered by the Commission. The analysis is available for inspection as indicated in the **ADDRESSES** section of this document. Single copies of the analysis are available as indicated in the **FOR INFORMATION CONTACT** section of this document.

XV. Regulatory Flexibility Analysis

The NRC has prepared a final regulatory flexibility analysis of the impact of this rule on small entities as required by Section 604 of the Regulatory Flexibility Act. The analysis indicates that 40 percent of the medical licensees are small entities. Although the final rule has an economic impact of an estimated $8,000 annually on the smallest of these licensees, the selected alternative is the least costly alternative that provides adequate protection from radiation exposure to the public, patients and workers. The analysis is available for inspection as indicated in the **ADDRESSES** section of this document. Single copies of the analysis are available as indicated in the **FOR INFORMATION CONTACT** section of this document.

XVI. Backfit Analysis

The NRC has determined that the backfit rule does not apply to this final rule; and therefore, a backfit analysis is not required for this final rule because these amendments do not involve any provisions that would impose backfits as defined in 10 CFR Chapter I.

XVII. Small Business Regulatory Enforcement Fairness Act

In accordance with the Small Business Regulatory Enforcement

Fairness Act of 1996, the NRC has determined that this action is not a major rulemaking and has verified this determination with the Office of Information and Regulatory Affairs of OMB.

List of Subjects

10 CFR Part 20

Byproduct material, Criminal penalties, Licensed material, Nuclear materials, Nuclear power plants and reactors, Occupational safety and health, Packaging and containers, Radiation protection, Reporting and recordkeeping requirements, Special nuclear material, Source material, Waste treatment and disposal.

10 CFR Part 32

Byproduct material, Criminal penalties, Labeling, Nuclear materials, Radiation protection, Reporting and recordkeeping requirements.

10 CFR Part 35

Biologics, Byproduct material, Criminal penalties, Drugs, Health facilities, Health professions, Medical devices, Nuclear materials, Occupational safety and health, Radiation protection, Reporting and recordkeeping requirements.

For the reasons set out in the preamble and under the authority of the Atomic Energy Act of 1954, as amended, the Energy Reorganization Act of 1974, as amended, and 5 U.S.C. 552 and 553, the NRC is adopting the following amendments to 10 CFR parts 20, 32 and 35.

PART 20—STANDARDS FOR PROTECTION AGAINST RADIATION

1. The authority citation for Part 20 continues to read as follows:

Authority: Secs. 53, 63, 65, 81, 103, 104, 161, 182, 186, 68 Stat. 930, 933, 935, 936, 937, 948, 953, 955, as amended, sec. 1701, 106 Stat. 2951, 2952, 2953 (42 U.S.C. 2073, 2093, 2095, 2111, 2133, 2134, 2201, 2232, 2236, 2297f), secs. 201, as amended, 202, 206, 88 Stat. 1242, as amended, 1244, 1246 (42 U.S.C. 5841, 5842, 5846).

2. Section 20.1002 is revised to read as follows:

§ 20.1002 Scope.

The regulations in this part apply to persons licensed by the Commission to receive, possess, use, transfer, or dispose of byproduct, source, or special nuclear material or to operate a production or utilization facility under Parts 30 through 36, 39, 40, 50, 60, 61, 70, or 72 of this chapter, and in accordance with 10 CFR 76.60 to persons required to obtain a certificate of compliance or an approved compliance plan under part 76 of this chapter. The limits in this part do not apply to doses due to background radiation, to exposure of patients to radiation for the purpose of medical diagnosis or therapy, to exposure from individuals administered radioactive material and released, under § 35.75, or to exposure from voluntary participation in medical research programs.

3. In § 20.1003, the definitions for occupational dose and public dose are revised to read as follows:

§ 20.1003 Definitions

* * * * *

Occupational dose means the dose received by an individual in the course of employment in which the individual's assigned duties involve exposure to radiation or to radioactive material from licensed and unlicensed sources of radiation, whether in the possession of the licensee or other person. Occupational dose does not include doses received from background radiation, from any medical administration the individual has received, from exposure to individuals administered radioactive material and released, under § 35.75, from voluntary participation in medical research programs, or as a member of the public.

* * * * *

Public dose means the dose received by a member of the public from exposure to radiation or to radioactive material released by a licensee, or to any other source of radiation under the control of a licensee. Public dose does not include occupational dose or doses received from background radiation, from any medical administration the individual has received, from exposure to individuals administered radioactive material and released, under § 35.75, or from voluntary participation in medical research programs.

* * * * *

4. In § 20.1301, the introductory text of paragraph (a) and paragraph (a)(1) are revised, paragraphs (c), (d), and (e) are redesignated as paragraphs (d), (e), and (f), and a new paragraph (c) is added to read as follows:

§ 20.1301 Dose limits for individual members of the public.

(a) Each licensee shall conduct operations so that —

(1) The total effective dose equivalent to individual members of the public from the licensed operation does not exceed 0.1 rem (1 mSv) in a year, exclusive of the dose contributions from background radiation, from any medical administration the individual has received, from exposure to individuals administered radioactive material and released, under § 35.75, from voluntary participation in medical research programs, and from the licensee's disposal of radioactive material into sanitary sewerage in accordance with § 20.2003, and

* * * * *

(c) Notwithstanding paragraph (a)(1) of this section, a licensee may permit visitors to an individual who cannot be released, under § 35.75, to receive a radiation dose greater than 0.1 rem (1 mSv) if—

(1) The radiation dose received does not exceed 0.5 rem (5 mSv); and

(2) The authorized user, as defined in 10 CFR Part 35, has determined before the visit that it is appropriate.

* * * * *

PART 32—SPECIFIC DOMESTIC LICENSES TO MANUFACTURE OR TRANSFER CERTAIN ITEMS CONTAINING BYPRODUCT MATERIAL

5. The authority citation for Part 32 continues to read as follows:

Authority: Secs. 81, 82, 161, 182, 183, 68 Stat. 935, 948, 953, 954, as amended (42 U.S.C. 2111, 2201, 2232, 2233); sec. 201, 88 Stat. 1242, as amended (42 U.S.C. 5841).

§ 32.72 [Amended]

6. In § 32.72, in paragraph (b)(1), the reference to ''paragraph (b)(2) and (b)(3)'' is revised to read ''paragraphs (b)(2) and (b)(4)'' and the reference to ''10 CFR 35.25'' is revised to read ''10 CFR 35.27'' and in paragraph (b)(2)(ii), the reference to ''10 CFR 35.980(b) and 35.972'' is revised to read ''10 CFR 35.55(b) and 35.59.''

§ 32.74 [Amended]

7. In § 32.74, in the introductory text of paragraph (a), the reference to ''§§ 35.400 and 35.500'' is revised to read ''§§ 35.400, 35.500, and 35.600'' and in paragraph (a)(3), the reference to ''§§ 35.57, 35.400, or 35.500'' is revised to read ''§§ 35.65, 35.400, 35.500, and 35.600.''

8. 10 CFR Part 35 is revised to read as follows:

PART 35—MEDICAL USE OF BYPRODUCT MATERIAL

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Authority: Secs. 81, 161, 182, 183, 68 Stat. 935, 948, 953, 954, as amended (42 U.S.C. 2111, 2201, 2232, 2233); sec. 201, 88 Stat. 1242, as amended (42 U.S.C. 5841).

Subpart A—General Information

§ 35.1 Purpose and scope.

This part contains the requirements and provisions for the medical use of byproduct material and for issuance of specific licenses authorizing the medical use of this material. These requirements and provisions provide for the radiation safety of workers, the general public, patients, and human research subjects. The requirements and provisions of this part are in addition to, and not in substitution for, others in this chapter. The requirements and provisions of parts 19, 20, 21, 30, 71, 170, and 171 of this chapter apply to applicants and licensees subject to this part unless specifically exempted.

§ 35.2 Definitions.

Address of use means the building or buildings that are identified on the license and where byproduct material may be received, prepared, used, or stored.

Agreement State means any State with which the Commission or the Atomic Energy Commission has entered into an effective agreement under subsection 274b of the Atomic Energy Act of 1954, as amended.

Area of use means a portion of an address of use that has been set aside for the purpose of receiving, preparing, using, or storing byproduct material.

Authorized medical physicist means an individual who—

(1) Meets the requirements in §§ 35.51(a) and 35.59; or

(2) Is identified as an authorized medical physicist or teletherapy physicist on—

(i) A specific medical use license issued by the Commission or Agreement State;

(ii) A medical use permit issued by a Commission master material licensee;

(iii) A permit issued by a Commission or Agreement State broad scope medical use licensee; or

(iv) A permit issued by a Commission master material license broad scope medical use permittee.

Authorized nuclear pharmacist means a pharmacist who—

(1) Meets the requirements in §§ 35.55(a) and 35.59; or

(2) Is identified as an authorized nuclear pharmacist on—

(i) A specific license issued by the Commission or Agreement State that authorizes medical use or the practice of nuclear pharmacy;

(ii) A permit issued by a Commission master material licensee that authorizes medical use or the practice of nuclear pharmacy;

(iii) A permit issued by a Commission or Agreement State broad scope medical use licensee that authorizes medical use or the practice of nuclear pharmacy; or

(iv) A permit issued by a Commission master material license broad scope medical use permittee that authorizes medical use or the practice of nuclear pharmacy; or

(3) Is identified as an authorized nuclear pharmacist by a commercial nuclear pharmacy that has been authorized to identify authorized nuclear pharmacists; or

(4) Is designated as an authorized nuclear pharmacist in accordance with § 32.72(b)(4).

Authorized user means a physician, dentist, or podiatrist who—

(1) Meets the requirements in §§ 35.59 and 35.190(a), 35.290(a), 35.390(a), 35.392(a), 35.394(a), 35.490(a), 35.590(a), or 35.690(a); or

(2) Is identified as an authorized user on—

(i) A Commission or Agreement State license that authorizes the medical use of byproduct material;

(ii) A permit issued by a Commission master material licensee that is authorized to permit the medical use of byproduct material;

(iii) A permit issued by a Commission or Agreement State specific licensee of broad scope that is authorized to permit the medical use of byproduct material; or

(iv) A permit issued by a Commission master material license broad scope permittee that is authorized to permit the medical use of byproduct material.

Brachytherapy means a method of radiation therapy in which sources are used to deliver a radiation dose at a distance of up to a few centimeters by surface, intracavitary, intraluminal, or interstitial application.

Brachytherapy source means a radioactive source or a manufacturer-assembled source train or a combination of these sources that is designed to deliver a therapeutic dose within a distance of a few centimeters.

Client's address means the area of use or a temporary job site for the purpose of providing mobile medical service in accordance with § 35.80.

Dedicated check source means a radioactive source that is used to assure the constant operation of a radiation detection or measurement device over several months or years.

Dentist means an individual licensed by a State or Territory of the United States, the District of Columbia, or the Commonwealth of Puerto Rico to practice dentistry.

High dose-rate remote afterloader, as used in this part, means a brachytherapy device that remotely delivers a dose rate in excess of 12 gray (1200 rads) per hour at the point or surface where the dose is prescribed.

Low dose-rate remote afterloader, as used in this part, means a brachytherapy device that remotely delivers a dose rate of less than or equal to 2 gray (200 rads) per hour at the point or surface where the dose is prescribed.

Management means the chief executive officer or other individual having the authority to manage, direct, or administer the licensee's activities, or those persons' delegate or delegates.

Manual brachytherapy, as used in this part, means a type of brachytherapy in which the brachytherapy sources (e.g., seeds, ribbons) are manually placed topically on or inserted either into the body cavities that are in close proximity to a treatment site or directly into the tissue volume.

Medical event means an event that meets the criteria in § 35.3045(a).

Medical institution means an organization in which more than one medical discipline is practiced.

Medical use means the intentional internal or external administration of byproduct material or the radiation from byproduct material to patients or human research subjects under the supervision of an authorized user.

Medium dose-rate remote afterloader, as used in this part, means a brachytherapy device that remotely delivers a dose rate of greater than 2 gray (200 rads), but less than 12 gray (1200 rads) per hour at the point or surface where the dose is prescribed.

Mobile medical service means the transportation of byproduct material to and its medical use at the client's address.

Output means the exposure rate, dose rate, or a quantity related in a known manner to these rates from a brachytherapy source or a teletherapy, remote afterloader, or gamma stereotactic radiosurgery unit for a specified set of exposure conditions.

Patient intervention means actions by the patient or human research subject, whether intentional or unintentional, such as dislodging or removing treatment devices or prematurely terminating the administration.

Pharmacist means an individual licensed by a State or Territory of the United States, the District of Columbia, or the Commonwealth of Puerto Rico to practice pharmacy.

Physician means a medical doctor or doctor of osteopathy licensed by a State or Territory of the United States, the District of Columbia, or the Commonwealth of Puerto Rico to prescribe drugs in the practice of medicine.

Podiatrist means an individual licensed by a State or Territory of the United States, the District of Columbia, or the Commonwealth of Puerto Rico to practice podiatry.

Preceptor means an individual who provides or directs the training and experience required for an individual to become an authorized user, an authorized medical physicist, an authorized nuclear pharmacist, or a Radiation Safety Officer.

Prescribed dosage means the specified activity or range of activity of unsealed byproduct material as documented—

(1) In a written directive; or

(2) In accordance with the directions of the authorized user for procedures performed pursuant to §§ 35.100 and 35.200.

Prescribed dose means—

(1) For gamma stereotactic radiosurgery, the total dose as documented in the written directive;

(2) For teletherapy, the total dose and dose per fraction as documented in the written directive;

(3) For manual brachytherapy, either the total source strength and exposure time or the total dose, as documented in the written directive; or

(4) For remote brachytherapy afterloaders, the total dose and dose per fraction as documented in the written directive.

Pulsed dose-rate remote afterloader, as used in this part, means a special type of remote afterloading brachytherapy device that uses a single source capable of delivering dose rates in the ''high dose-rate'' range, but—

(1) Is approximately one-tenth of the activity of typical high dose-rate remote afterloader sources; and

(2) Is used to simulate the radiobiology of a low dose-rate treatment by inserting the source for a given fraction of each hour.

Radiation Safety Officer means an individual who—

(1) Meets the requirements in §§ 35.50(a) and 35.59; or

(2) Is identified as a Radiation Safety Officer on—

(i) A specific medical use license issued by the Commission or Agreement State; or

(ii) A medical use permit issued by a Commission master material licensee.

Sealed source means any byproduct material that is encased in a capsule designed to prevent leakage or escape of the byproduct material.

Sealed Source and *Device Registry* means the national registry that contains all the registration certificates, generated by both NRC and the Agreement States, that summarize the radiation safety information for the sealed sources and devices and describe the licensing and use conditions approved for the product.

Stereotactic radiosurgery means the use of external radiation in conjunction with a stereotactic guidance device to very precisely deliver a therapeutic dose to a tissue volume.

Structured educational program means an educational program designed to impart particular knowledge and practical education through interrelated studies and supervised training.

Teletherapy, as used in this part, means a method of radiation therapy in which collimated gamma rays are delivered at a distance from the patient or human research subject.

Temporary job site means a location where mobile medical services are conducted other than those location(s) of use authorized on the license.

Therapeutic dosage means a dosage of unsealed byproduct material that is intended to deliver a radiation dose to a patient or human research subject for palliative or curative treatment.

Therapeutic dose means a radiation dose delivered from a source containing byproduct material to a patient or human research subject for palliative or curative treatment.

Treatment site means the anatomical description of the tissue intended to receive a radiation dose, as described in a written directive.

Type of use means use of byproduct material under §§ 35.100, 35.200, 35.300, 35.400, 35.500, 35.600, or 35.1000.

Unit dosage means a dosage prepared for medical use for administration as a single dosage to a patient or human research subject without any further manipulation of the dosage after it is initially prepared.

Written directive means an authorized user's written order for the administration of byproduct material or radiation from byproduct material to a specific patient or human research subject, as specified in § 35.40.

§ 35.5 Maintenance of records.

Each record required by this part must be legible throughout the specified retention period. The record may be the original, a reproduced copy, or a microform if the copy or microform is authenticated by authorized personnel and the microform is capable of producing a clear copy throughout the required retention period. The record may also be stored in electronic media with the capability for producing legible, accurate, and complete records during the required retention period. Records such as letters, drawings, and specifications must include all pertinent information such as stamps, initials, and signatures. The licensee shall maintain adequate safeguards against tampering with and loss of records.

§ 35.6 Provisions for the protection of human research subjects.

(a) A licensee may conduct research involving human research subjects only if it uses the byproduct materials specified on its license for the uses authorized on its license.

(b) If the research is conducted, funded, supported, or regulated by another Federal agency that has implemented the Federal Policy for the Protection of Human Subjects (Federal Policy), the licensee shall, before conducting research—

(1) Obtain review and approval of the research from an ''Institutional Review Board,'' as defined and described in the Federal Policy; and

(2) Obtain ''informed consent,'' as defined and described in the Federal

Policy, from the human research subject.

(c) If the research will not be conducted, funded, supported, or regulated by another Federal agency that has implemented the Federal Policy, the license shall, before conducting research, apply for and receive a specific amendment to its NRC medical use license. The amendment request must include a written commitment that the licensee will, before conducting research—

(1) Obtain review and approval of the research from an ''Institutional Review Board,'' as defined and described in the Federal Policy; and

(2) Obtain ''informed consent'', as defined and described in the Federal Policy, from the human research subject.

(d) Nothing in this section relieves licensees from complying with the other requirements in this part.

§ 35.7 FDA, other Federal, and State requirements.

Nothing in this part relieves the licensee from complying with applicable FDA, other Federal, and State requirements governing radioactive drugs or devices.

§ 35.8 Information collection requirements: OMB approval.

(a) The Commission has submitted the information collection requirements contained in this part to the Office of Management and Budget (OMB) for approval as required by the Paperwork Reduction Act (44 U.S.C. 3501 et seq.). The NRC may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number. OMB has approved the information collection requirements in this part under control number 3150–0010.

(b) The approved information collection requirements contained in this part appear in §§ 35.6, 35.12, 35.13, 35.14, 35.19, 35.24, 35.26, 35.27, 35.40, 35.41, 35.50, 35.51, 35.55, 35.60, 35.61, 35.63, 35.67, 35.69, 35.70, 35.75, 35.80, 35.92, 35.190, 35.204, 35.290, 35.310, 35.315, 35.390, 35.392, 35.394, 35.404, 35.406, 35.410, 35.415, 35.432, 35.433, 35.490, 35.491, 35.590, 35.604, 35.605, 35.610, 35.615, 35.630, 35.632, 35.633, 35.635, 35.642, 35.643, 35.645, 35.647, 35.652, 35.655, 35.690, 35.900, 35.910, 35.920, 35.930, 35.940, 35.950, 35.960, 35.961, 35.980, 35.981, 35.1000, 35.2024, 35.2026, 35.2040, 35.2041, 35.2060, 35.2061, 35.2063, 35.2067, 35.2070, 35.2075, 35.2080, 35.2092, 35.2204, 35.2310, 35.2404, 35.2406, 35.2432, 35.2433, 35.2605, 35.2610, 35.2630, 35.2632, 35.2642, 35.2643, 35.2645, 35.2647, 35.2652, 35.2655, 35.3045, 35.3047, and 35.3067.

(c) This part contains information collection requirements in addition to those approved under the control number specified in paragraph (a) of this section. These information collection requirements and the control numbers under which they are approved are as follows:

(1) In § 35.12, NRC Form 313, including NRC Form 313A, which licensees may use to provide supplemental information, is approved under control number 3150–0120.

(2) [Reserved]

§ 35.10 Implementation.

(a) A licensee shall implement the provisions in this part on or before October 24, 2002, with the exception of the requirements listed in paragraph (b) of this section.

(b) A licensee shall implement the training requirements in §§ 35.50(a), 35.51(a), 35.55(a), 35.59, 35.190(a), 35.290(a), 35.390(a), 35.392(a), 35.394(a), 35.490(a), 35.590(a), and 35.690(a) on or before October 25, 2004.

(c) Prior to October 25, 2004, a licensee shall satisfy the training requirements of this part for a Radiation Safety Officer, an authorized medical physicist, an authorized nuclear pharmacist, or an authorized user by complying with either:

(1) The appropriate training requirements in subpart J; or

(2) The appropriate training requirements in subpart B or subparts D through H.

(d) If a license condition exempted a licensee from a provision of Part 35 on October 24, 2002, then the license condition continues to exempt the licensee from the requirements in the corresponding provision of §§ 35.1–35.4002.

(e) When a requirement in this part differs from the requirement in an existing license condition, the requirement in this part shall govern.

(f) A licensee shall continue to comply with any license condition that requires it to implement procedures required by §§ 35.610, 35.642, 35.643, and 35.645 until there is a license amendment or renewal that modifies the license condition.

§ 35.11 License required.

(a) A person may manufacture, produce, acquire, receive, possess, prepare, use, or transfer byproduct material for medical use only in accordance with a specific license issued by the Commission or an Agreement State, or as allowed in paragraphs (b)(1) or (b)(2) of this section.

(b) A specific license is not needed for an individual who—

(1) Receives, possesses, uses, or transfers byproduct material in accordance with the regulations in this chapter under the supervision of an authorized user as provided in § 35.27, unless prohibited by license condition; or

(2) Prepares unsealed byproduct material for medical use in accordance with the regulations in this chapter under the supervision of an authorized nuclear pharmacist or authorized user as provided in § 35.27, unless prohibited by license condition.

§ 35.12 Application for license, amendment, or renewal.

(a) An application must be signed by the applicant's or licensee's management.

(b) An application for a license for medical use of byproduct material as described in §§ 35.100, 35.200, 35.300, 35.400, 35.500, 35.600, and 35.1000 must be made by—

(1) Filing an original and one copy of NRC Form 313, ''Application for Material License,'' that includes the facility diagram, equipment, and training and experience qualifications of the Radiation Safety Officer, authorized user(s), authorized medical physicist(s), and authorized nuclear pharmacist(s); and

(2) Submitting procedures required by §§ 35.610, 35.642, 35.643, and 35.645, as applicable.

(c) A request for a license amendment or renewal must be made by—

(1) Submitting an original and one copy of either—

(i) NRC Form 313, ''Application for Material Licens''; or

(ii) A letter requesting the amendment or renewal; and

(2) Submitting procedures required by §§ 35.610, 35.642, 35.643, and 35.645, as applicable.

(d) In addition to the requirements in paragraphs (b) and (c) of this section, an application for a license or amendment for medical use of byproduct material as described in § 35.1000 must also include information regarding any radiation safety aspects of the medical use of the material that is not addressed in Subparts A through C of this part.

(1) The applicant shall also provide specific information on—

(i) Radiation safety precautions and instructions;

(ii) Methodology for measurement of dosages or doses to be administered to patients or human research subjects; and

(iii) Calibration, maintenance, and repair of instruments and equipment necessary for radiation safety.

(2) The applicant or licensee shall also provide any other information requested by the Commission in its review of the application.

(e) An applicant that satisfies the requirements specified in § 33.13 of this chapter may apply for a Type A specific license of broad scope.

§ 35.13 License amendments.

A licensee shall apply for and must receive a license amendment—

(a) Before it receives, prepares, or uses byproduct material for a type of use that is permitted under this part, but that is not authorized on the licensee's current license issued under this part;

(b) Before it permits anyone to work as an authorized user, authorized nuclear pharmacist, or authorized medical physicist under the license, except—

(1) For an authorized user, an individual who meets the requirements in §§ 35.190(a), 35.290(a), 35.390(a), 35.392(a), 35.394(a), 35.490(a), 35.590(a), 35.690(a), 35.910, 35.920, 35.930, 35.932, 35.934, 35.940, 35.941, 35.950, or 35.960 and 35.59;

(2) For an authorized nuclear pharmacist, an individual who meets the requirements in §§ 35.55(a) or 35.980 and 35.59;

(3) For an authorized medical physicist, an individual who meets the requirements in §§ 35.51(a) or 35.961 and 35.59;

(4) An individual who is identified as an authorized user, an authorized nuclear pharmacist, or authorized medical physicist—

(i) On a Commission or Agreement State license or other equivalent permit or license recognized by NRC that authorizes the use of byproduct material in medical use or in the practice of nuclear pharmacy;

(ii) On a permit issued by a Commission or Agreement State specific license of broad scope that is authorized to permit the use of byproduct material in medical use or in the practice of nuclear pharmacy;

(iii) On a permit issued by a Commission master material licensee that is authorized to permit the use of byproduct material in medical use or in the practice of nuclear pharmacy; or

(iv) By a commercial nuclear pharmacy that has been authorized to identify authorized nuclear pharmacists.

(c) Before it changes Radiation Safety Officers, except as provided in § 35.24(c);

(d) Before it receives byproduct material in excess of the amount or in a different form, or receives a different radionuclide than is authorized on the license;

(e) Before it adds to or changes the areas of use identified in the application or on the license, except for areas of use where byproduct material is used only in accordance with either § 35.100 or § 35.200;

(f) Before it changes the address(es) of use identified in the application or on the license; and

(g) Before it revises procedures required by §§ 35.610, 35.642, 35.643, and 35.645, as applicable, where such revision reduces radiation safety.

§ 35.14 Notifications.

(a) A licensee shall provide the Commission a copy of the board certification, the Commission or Agreement State license, the permit issued by a Commission master material licensee, the permit issued by a Commission or Agreement State licensee of broad scope, or the permit issued by a Commission master material license broad scope permittee for each individual no later than 30 days after the date that the licensee permits the individual to work as an authorized user, an authorized nuclear pharmacist, or an authorized medical physicist, under § 35.13 (b)(1) through (b)(4).

(b) A licensee shall notify the Commission by letter no later than 30 days after:

(1) An authorized user, an authorized nuclear pharmacist, a Radiation Safety Officer, or an authorized medical physicist permanently discontinues performance of duties under the license or has a name change;

(2) The licensee's mailing address changes;

(3) The licensee's name changes, but the name change does not constitute a transfer of control of the license as described in § 30.34(b) of this chapter; or

(4) The licensee has added to or changed the areas of use identified in the application or on the license where byproduct material is used in accordance with either § 35.100 or § 35.200.

(c) The licensee shall mail the documents required in this section to the appropriate address identified in § 30.6 of this chapter.

§ 35.15 Exemptions regarding Type A specific licenses of broad scope.

A licensee possessing a Type A specific license of broad scope for medical use, issued under Part 33 of this chapter, is exempt from—

(a) The provisions of § 35.12(d) regarding the need to file an amendment to the license for medical use of byproduct material, as described in § 35.1000;

(b) The provisions of § 35.13(b);

(c) The provisions of § 35.13(e) regarding additions to or changes in the areas of use at the addresses identified in the application or on the license;

(d) The provisions of § 35.14(a);

(e) The provisions of § 35.14(b)(1) for an authorized user, an authorized nuclear pharmacist, or an authorized medical physicist;

(f) The provisions of § 35.14(b)(4) regarding additions to or changes in the areas of use identified in the application or on the license where byproduct material is used in accordance with either § 35.100 or § 35.200.

(g) The provisions of § 35.49(a).

§ 35.18 License issuance.

(a) The Commission shall issue a license for the medical use of byproduct material if—

(1) The applicant has filed NRC Form 313 ''Application for Material License'' in accordance with the instructions in § 35.12;

(2) The applicant has paid any applicable fee as provided in Part 170 of this chapter;

(3) The Commission finds the applicant equipped and committed to observe the safety standards established by the Commission in this Chapter for the protection of the public health and safety; and

(4) The applicant meets the requirements of Part 30 of this chapter.

(b) The Commission shall issue a license for mobile medical service if the applicant:

(1) Meets the requirements in paragraph (a) of this section; and

(2) Assures that individuals or human research subjects to whom unsealed byproduct material or radiation from implants containing byproduct material will be administered may be released following treatment in accordance with § 35.75.

§ 35.19 Specific exemptions.

The Commission may, upon application of any interested person or upon its own initiative, grant exemptions from the regulations in this part that it determines are authorized by law and will not endanger life or property or the common defense and security and are otherwise in the public interest.

Subpart B—General Administrative Requirements

§ 35.24 Authority and responsibilities for the radiation protection program.

(a) In addition to the radiation protection program requirements of § 20.1101 of this chapter, a licensee's management shall approve in writing—

(1) Requests for a license application, renewal, or amendment before submittal to the Commission;

(2) Any individual before allowing that individual to work as an authorized user, authorized nuclear pharmacist, or authorized medical physicist; and

(3) Radiation protection program changes that do not require a license amendment and are permitted under § 35.26;

(b) A licensee's management shall appoint a Radiation Safety Officer, who agrees, in writing, to be responsible for implementing the radiation protection program. The licensee, through the Radiation Safety Officer, shall ensure that radiation safety activities are being performed in accordance with licensee-approved procedures and regulatory requirements.

(c) For up to 60 days each year, a licensee may permit an authorized user or an individual qualified to be a Radiation Safety Officer, under §§ 35.50 and 35.59, to function as a temporary Radiation Safety Officer and to perform the functions of a Radiation Safety Officer, as provided in paragraph (g) of this section, if the licensee takes the actions required in paragraphs (b), (e), (g), and (h) of this section and notifies the Commission in accordance with § 35.14(b).

(d) A licensee may simultaneously appoint more than one temporary Radiation Safety Officer in accordance with paragraph (c) of this section, if needed to ensure that the licensee has a temporary Radiation Safety Officer that satisfies the requirements to be a Radiation Safety Officer for each of the different types of uses of byproduct material permitted by the license.

(e) A licensee shall establish the authority, duties, and responsibilities of the Radiation Safety Officer in writing.

(f) Licensees that are authorized for two or more different types of uses of byproduct material under Subparts E, F, and H of this part, or two or more types of units under Subpart H of this part, shall establish a Radiation Safety Committee to oversee all uses of byproduct material permitted by the license. The Committee must include an authorized user of each type of use permitted by the license, the Radiation Safety Officer, a representative of the nursing service, and a representative of management who is neither an authorized user nor a Radiation Safety Officer. The Committee may include other members the licensee considers appropriate.

(g) A licensee shall provide the Radiation Safety Officer sufficient authority, organizational freedom, time, resources, and management prerogative, to—

(1) Identify radiation safety problems;

(2) Initiate, recommend, or provide corrective actions;

(3) Stop unsafe operations; and,

(4) Verify implementation of corrective actions.

(h) A licensee shall retain a record of actions taken under paragraphs (a), (b), and (e) of this section in accordance with § 35.2024.

§ 35.26 Radiation protection program changes.

(a) A licensee may revise its radiation protection program without Commission approval if—

(1) The revision does not require a license amendment under § 35.13;

(2) The revision is in compliance with the regulations and the license ;

(3) The revision has been reviewed and approved by the Radiation Safety Officer and licensee management; and

(4) The affected individuals are instructed on the revised program before the changes are implemented.

(b) A licensee shall retain a record of each change in accordance with § 35.2026.

§ 35.27 Supervision.

(a) A licensee that permits the receipt, possession, use, or transfer of byproduct material by an individual under the supervision of an authorized user, as allowed by § 35.11(b)(1), shall—

(1) In addition to the requirements in § 19.12 of this chapter, instruct the supervised individual in the licensee's written radiation protection procedures, written directive procedures, regulations of this chapter, and license conditions with respect to the use of byproduct material; and

(2) Require the supervised individual to follow the instructions of the supervising authorized user for medical uses of byproduct material, written radiation protection procedures established by the licensee, written directive procedures, regulations of this chapter, and license conditions with respect to the medical use of byproduct material.

(b) A licensee that permits the preparation of byproduct material for medical use by an individual under the supervision of an authorized nuclear pharmacist or physician who is an authorized user, as allowed by § 35.11(b)(2), shall—

(1) In addition to the requirements in § 19.12 of this chapter, instruct the supervised individual in the preparation of byproduct material for medical use, as appropriate to that individual's involvement with byproduct material; and

(2) Require the supervised individual to follow the instructions of the supervising authorized user or authorized nuclear pharmacist regarding the preparation of byproduct material for medical use, written radiation protection procedures established by the licensee, the regulations of this chapter, and license conditions.

(c) A licensee that permits supervised activities under paragraphs (a) and (b) of this section is responsible for the acts and omissions of the supervised individual.

§ 35.40 Written directives.

(a) A written directive must be dated and signed by an authorized user before the administration of I-131 sodium iodide greater than 1.11 Megabequerels (MBq) (30 microcuries (μCi)), any therapeutic dosage of unsealed byproduct material or any therapeutic dose of radiation from byproduct material.

(1) If, because of the emergent nature of the patient's condition, a delay in order to provide a written directive would jeopardize the patient's health, an oral directive is acceptable. The information contained in the oral directive must be documented as soon as possible in writing in the patient's record. A written directive must be prepared within 48 hours of the oral directive.

(b) The written directive must contain the patient or human research subject's name and the following information—

(1) For any administration of quantities greater than 1.11 MBq (30 μCi) of sodium iodide I-131: the dosage;

(2) For an administration of a therapeutic dosage of unsealed byproduct material other than sodium iodide I-131: the radioactive drug, dosage, and route of administration;

(3) For gamma stereotactic radiosurgery: the total dose, treatment site, and values for the target coordinate settings per treatment for each anatomically distinct treatment site;

(4) For teletherapy: the total dose, dose per fraction, number of fractions, and treatment site;

(5) For high dose-rate remote afterloading brachytherapy: the radionuclide, treatment site, dose per fraction, number of fractions, and total dose; or

(6) For all other brachytherapy, including low, medium, and pulsed dose rate remote afterloaders:

(i) Before implantation: treatment site, the radionuclide, and dose; and

(ii) After implantation but before completion of the procedure: the radionuclide, treatment site, number of sources, and total source strength and exposure time (or the total dose).

(c) A written revision to an existing written directive may be made if the revision is dated and signed by an authorized user before the administration of the dosage of unsealed byproduct material, the brachytherapy dose, the gamma stereotactic radiosurgery dose, the teletherapy dose, or the next fractional dose.

(1) If, because of the patient's condition, a delay in order to provide a written revision to an existing written directive would jeopardize the patient's health, an oral revision to an existing written directive is acceptable. The oral revision must be documented as soon as possible in the patient's record. A revised written directive must be signed by the authorized user within 48 hours of the oral revision.

(d) The licensee shall retain a copy of the written directive in accordance with § 35.2040.

§ 35.41 Procedures for administrations requiring a written directive.

(a) For any administration requiring a written directive, the licensee shall develop, implement, and maintain written procedures to provide high confidence that:

(1) The patient's or human research subject's identity is verified before each administration; and

(2) Each administration is in accordance with the written directive.

(b) At a minimum, the procedures required by paragraph (a) of this section must address the following items that are applicable to the licensee's use of byproduct material—

(1) Verifying the identity of the patient or human research subject;

(2) Verifying that the administration is in accordance with the treatment plan, if applicable, and the written directive;

(3) Checking both manual and computer-generated dose calculations; and

(4) Verifying that any computer-generated dose calculations are correctly transferred into the consoles of therapeutic medical units authorized by § 35.600.

(c) A licensee shall retain a copy of the procedures required under paragraph (a) in accordance with § 35.2041.

§ 35.49 Suppliers for sealed sources or devices for medical use.

For medical use, a licensee may only use—

(a) Sealed sources or devices manufactured, labeled, packaged, and distributed in accordance with a license issued under 10 CFR Part 30 and 10 CFR 32.74 of this chapter or equivalent requirements of an Agreement State;

(b) Sealed sources or devices noncommercially transferred from a Part 35 licensee; or

(c) Teletherapy sources manufactured and distributed in accordance with a license issued under 10 CFR Part 30 or the equivalent requirements of an Agreement State.

§ 35.50 Training for Radiation Safety Officer.

Except as provided in § 35.57, the licensee shall require an individual fulfilling the responsibilities of the Radiation Safety Officer as provided in § 35.24 to be an individual who—

(a) Is certified by a specialty board whose certification process includes all of the requirements in paragraph (b) of this section and whose certification has been recognized by the Commission or an Agreement State; or

(b)(1) Has completed a structured educational program consisting of both:

(i) 200 hours of didactic training in the following areas—

(A) Radiation physics and instrumentation;

(B) Radiation protection;

(C) Mathematics pertaining to the use and measurement of radioactivity;

(D) Radiation biology; and

(E) Radiation dosimetry; and

(ii) One year of full-time radiation safety experience under the supervision of the individual identified as the Radiation Safety Officer on a Commission or Agreement State license or permit issued by a Commission master material licensee that authorizes similar type(s) of use(s) of byproduct material involving the following—

(A) Shipping, receiving, and performing related radiation surveys;

(B) Using and performing checks for proper operation of instruments used to determine the activity of dosages, survey meters, and instruments used to measure radionuclides;

(C) Securing and controlling byproduct material;

(D) Using administrative controls to avoid mistakes in the administration of byproduct material;

(E) Using procedures to prevent or minimize radioactive contamination and using proper decontamination procedures;

(F) Using emergency procedures to control byproduct material; and

(G) Disposing of byproduct material; and

(2) Has obtained written certification, signed by a preceptor Radiation Safety Officer, that the individual has satisfactorily completed the requirements in paragraph (b)(1) of this section and has achieved a level of radiation safety knowledge sufficient to function independently as a Radiation Safety Officer for a medical use licensee; or

(c) Is an authorized user, authorized medical physicist, or authorized nuclear pharmacist identified on the licensee's license and has experience with the radiation safety aspects of similar types of use of byproduct material for which the individual has Radiation Safety Officer responsibilities.

§ 35.51 Training for an authorized medical physicist.

Except as provided in § 35.57, the licensee shall require the authorized medical physicist to be an individual who—

(a) Is certified by a specialty board whose certification process includes all of the training and experience requirements in paragraph (b) of this section and whose certification has been recognized by the Commission or an Agreement State; or

(b)(1) Holds a master's or doctor's degree in physics, biophysics, radiological physics, medical physics, or health physics and has completed 1 year of full-time training in therapeutic radiological physics and an additional year of full-time work experience under the supervision of an individual who meets the requirements for an authorized medical physicist at a medical institution that includes the tasks listed in §§ 35.67, 35.433, 35.632, 35.633, 35.635, 35.642, 35.643, 35.645, and 35.652, as applicable; and

(2) Has obtained written certification that the individual has satisfactorily completed the requirements in paragraph (b)(1) of this section and has achieved a level of competency sufficient to function independently as an authorized medical physicist for each type of therapeutic medical unit for which the individual is requesting authorized medical physicist status. The written certification must be signed by a preceptor authorized medical physicist who meets the requirements in § 35.51 or equivalent Agreement State requirements for an authorized medical physicist for each type of therapeutic medical unit for which the individual is requesting authorized medical physicist status.

§ 35.55 Training for an authorized nuclear pharmacist.

Except as provided in § 35.57, the licensee shall require the authorized nuclear pharmacist to be a pharmacist who—

(a) Is certified as a nuclear pharmacist by a specialty board whose certification process includes all of the requirements in paragraph (b) of this section and whose certification has been recognized by the Commission or an Agreement State; or

(b)(1) Has completed 700 hours in a structured educational program consisting of both:

(i) Didactic training in the following areas—

(A) Radiation physics and instrumentation;

(B) Radiation protection;

(C) Mathematics pertaining to the use and measurement of radioactivity;

(D) Chemistry of byproduct material for medical use; and

(E) Radiation biology; and

(ii) Supervised practical experience in a nuclear pharmacy involving—

(A) Shipping, receiving, and performing related radiation surveys;

(B) Using and performing checks for proper operation of instruments used to determine the activity of dosages, survey meters, and, if appropriate, instruments used to measure alpha- or beta-emitting radionuclides;

(C) Calculating, assaying, and safely preparing dosages for patients or human research subjects;

(D) Using administrative controls to avoid medical events in the administration of byproduct material; and

(E) Using procedures to prevent or minimize radioactive contamination and using proper decontamination procedures; and

(2) Has obtained written certification, signed by a preceptor authorized nuclear pharmacist, that the individual has satisfactorily completed the requirements in paragraph (b)(1) of this section and has achieved a level of competency sufficient to function independently as an authorized nuclear pharmacist.

§ 35.57 Training for experienced Radiation Safety Officer, teletherapy or medical physicist, authorized user, and nuclear pharmacist.

(a) An individual identified as a Radiation Safety Officer, a teletherapy or medical physicist, or a nuclear pharmacist on a Commission or Agreement State license or a permit issued by a Commission or Agreement State broad scope licensee or master material license permit or by a master material license permittee of broad scope before October 24, 2002 need not comply with the training requirements of §§ 35.50, 35.51, or 35.55, respectively.

(b) Physicians, dentists, or podiatrists identified as authorized users for the medical use of byproduct material on a license issued by the Commission or Agreement State, a permit issued by a Commission master material licensee, a permit issued by a Commission or Agreement State broad scope licensee, or a permit issued by a Commission master material license broad scope permittee before October 24, 2002 who perform only those medical uses for which they were authorized on that date need not comply with the training requirements of Subparts D–H of this part.

§ 35.59 Recentness of training.

The training and experience specified in Subparts B, D, E, F, G, H, and J of this part must have been obtained within the 7 years preceding the date of application or the individual must have had related continuing education and experience since the required training and experience was completed.

Subpart C—General Technical Requirements

§ 35.60 Possession, use, and calibration of instruments used to measure the activity of unsealed byproduct material.

(a) For direct measurements performed in accordance with § 35.63, a licensee shall possess and use instrumentation to measure the activity of unsealed byproduct material before it is administered to each patient or human research subject.

(b) A licensee shall calibrate the instrumentation required in paragraph (a) of this section in accordance with nationally recognized standards or the manufacturer's instructions.

(c) A licensee shall retain a record of each instrument calibration required by this section in accordance with § 35.2060.

§ 35.61 Calibration of survey instruments.

(a) A licensee shall calibrate the survey instruments used to show compliance with this part and 10 CFR Part 20 before first use, annually, and following a repair that affects the calibration. A licensee shall—

(1) Calibrate all scales with readings up to 10 mSv (1000 mrem) per hour with a radiation source;

(2) Calibrate two separated readings on each scale or decade that will be used to show compliance; and

(3) Conspicuously note on the instrument the date of calibration.

(b) A licensee may not use survey instruments if the difference between the indicated exposure rate and the calculated exposure rate is more than 20 percent.

(c) A licensee shall retain a record of each survey instrument calibration in accordance with § 35.2061.

§ 35.63 Determination of dosages of unsealed byproduct material for medical use.

(a) A licensee shall determine and record the activity of each dosage before medical use.

(b) For a unit dosage, this determination must be made by—

(1) Direct measurement of radioactivity; or

(2) A decay correction, based on the activity or activity concentration determined by—

(i) A manufacturer or preparer licensed under § 32.72 of this chapter or equivalent Agreement State requirements; or

(ii) An NRC or Agreement State licensee for use in research in accordance with a Radioactive Drug Research Committee-approved protocol or an Investigational New Drug (IND) protocol accepted by FDA.

(c) For other than unit dosages, this determination must be made by—

(1) Direct measurement of radioactivity;

(2) Combination of measurement of radioactivity and mathematical calculations; or

(3) Combination of volumetric measurements and mathematical calculations, based on the measurement made by a manufacturer or preparer licensed under § 32.72 of this chapter or equivalent Agreement State requirements.

(d) Unless otherwise directed by the authorized user, a licensee may not use a dosage if the dosage does not fall within the prescribed dosage range or if the dosage differs from the prescribed dosage by more than 20 percent.

(e) A licensee shall retain a record of the dosage determination required by this section in accordance with § 35.2063.

§ 35.65 Authorization for calibration, transmission, and reference sources.

Any person authorized by § 35.11 for medical use of byproduct material may receive, possess, and use any of the following byproduct material for check, calibration, transmission, and reference use.

(a) Sealed sources, not exceeding 1.11 GBq (30 mCi) each, manufactured and distributed by a person licensed under § 32.74 of this chapter or equivalent Agreement State regulations.

(b) Sealed sources, not exceeding 1.11 GBq (30 mCi) each, redistributed by a licensee authorized to redistribute the sealed sources manufactured and distributed by a person licensed under § 32.74 of this chapter, providing the redistributed sealed sources are in the original packaging and shielding and are accompanied by the manufacturer's approved instructions.

(c) Any byproduct material with a half-life not longer than 120 days in individual amounts not to exceed 0.56 GBq (15 mCi).

(d) Any byproduct material with a half-life longer than 120 days in individual amounts not to exceed the smaller of 7.4 MBq (200 μCi) or 1000 times the quantities in Appendix B of Part 30 of this chapter.

(e) Technetium-99m in amounts as needed.

§ 35.67 Requirements for possession of sealed sources and brachytherapy sources.

(a) A licensee in possession of any sealed source or brachytherapy source shall follow the radiation safety and handling instructions supplied by the manufacturer.

(b) A licensee in possession of a sealed source shall—

(1) Test the source for leakage before its first use unless the licensee has a certificate from the supplier indicating that the source was tested within 6 months before transfer to the licensee; and

(2) Test the source for leakage at intervals not to exceed 6 months or at other intervals approved by the Commission or an Agreement State in the Sealed Source and Device Registry.

(c) To satisfy the leak test requirements of this section, the licensee shall measure the sample so that the leak test can detect the presence of 185 Bq (0.005 μCi) of radioactive material in the sample.

(d) A licensee shall retain leak test records in accordance with § 35.2067(a).

(e) If the leak test reveals the presence of 185 Bq (0.005 μCi) or more of removable contamination, the licensee shall—

(1) Immediately withdraw the sealed source from use and store, dispose, or cause it to be repaired in accordance with the requirements in parts 20 and 30 of this chapter; and

(2) File a report within 5 days of the leak test in accordance with § 35.3067.

(f) A licensee need not perform a leak test on the following sources:

(1) Sources containing only byproduct material with a half-life of less than 30 days;

(2) Sources containing only byproduct material as a gas;

(3) Sources containing 3.7 MBq (100 μCi) or less of beta or gamma-emitting material or 0.37 MBq (10 μCi) or less of alpha-emitting material;

(4) Seeds of iridium-192 encased in nylon ribbon; and

(5) Sources stored and not being used. However, the licensee shall test each such source for leakage before any use or transfer unless it has been leak tested within 6 months before the date of use or transfer.

(g) A licensee in possession of sealed sources or brachytherapy sources, except for gamma stereotactic radiosurgery sources, shall conduct a semi-annual physical inventory of all such sources in its possession. The licensee shall retain each inventory record in accordance with § 35.2067(b).

§ 35.69 Labeling of vials and syringes.

Each syringe and vial that contains unsealed byproduct material must be labeled to identify the radioactive drug. Each syringe shield and vial shield must also be labeled unless the label on the syringe or vial is visible when shielded.

§ 35.70 Surveys of ambient radiation exposure rate.

(a) In addition to the surveys required by Part 20 of this chapter, a licensee shall survey with a radiation detection survey instrument at the end of each day of use. A licensee shall survey all areas where unsealed byproduct material requiring a written directive was prepared for use or administered.

(b) A licensee does not need to perform the surveys required by paragraph (a) of this section in an area(s) where patients or human research subjects are confined when they cannot be released under § 35.75.

(c) A licensee shall retain a record of each survey in accordance with § 35.2070.

§ 35.75 Release of individuals containing unsealed byproduct material or implants containing byproduct material.

(a) A licensee may authorize the release from its control of any individual who has been administered unsealed byproduct material or implants containing byproduct material if the total effective dose equivalent to any other individual from exposure to the released individual is not likely to exceed 5 mSv (0.5 rem). [1]

(b) A licensee shall provide the released individual, or the individual's parent or guardian, with instructions, including written instructions, on actions recommended to maintain doses to other individuals as low as is reasonably achievable if the total effective dose equivalent to any other individual is likely to exceed 1 mSv (0.1 rem). If the total effective dose equivalent to a nursing infant or child could exceed 1 mSv (0.1 rem) assuming there were no interruption of breast-feeding, the instructions must also include—

(1) Guidance on the interruption or discontinuation of breast-feeding; and

(2) Information on the potential consequences, if any, of failure to follow the guidance.

(c) A licensee shall maintain a record of the basis for authorizing the release of an individual in accordance with § 35.2075(a).

(d) The licensee shall maintain a record of instructions provided to a breast-feeding female in accordance with § 35.2075(b).

§ 35.80 Provision of mobile medical service.

(a) A licensee providing mobile medical service shall—

(1) Obtain a letter signed by the management of each client for which services are rendered that permits the use of byproduct material at the client's address and clearly delineates the authority and responsibility of the licensee and the client;

(2) Check instruments used to measure the activity of unsealed byproduct material for proper function before medical use at each client's address or on each day of use, whichever is more frequent. At a minimum, the check for proper function required by this paragraph must include a constancy check;

(3) Check survey instruments for proper operation with a dedicated check source before use at each client's address; and

(4) Before leaving a client's address, survey all areas of use to ensure compliance with the requirements in Part 20 of this chapter.

(b) A mobile medical service may not have byproduct material delivered from the manufacturer or the distributor to the client unless the client has a license allowing possession of the byproduct material. Byproduct material delivered to the client must be received and handled in conformance with the client's license.

(c) A licensee providing mobile medical services shall retain the letter required in paragraph (a)(1) and the record of each survey required in paragraph (a)(4) of this section in

[1] NUREG–1556, Vol. 9 (draft), ''Consolidated Guidance About Materials Licenses: Program-Specific Guidance About Medical Licenses,'' describes methods for calculating doses to other individuals and contains tables of activities not likely to cause doses exceeding 5 mSv (0.5 rem).

accordance with § 35.2080(a) and (b), respectively.

§ 35.92 Decay-in-storage.

(a) A licensee may hold byproduct material with a physical half-life of less than 120 days for decay-in-storage before disposal without regard to its radioactivity if it—

(1) Monitors byproduct material at the surface before disposal and determines that its radioactivity cannot be distinguished from the background radiation level with an appropriate radiation detection survey meter set on its most sensitive scale and with no interposed shielding; and

(2) Removes or obliterates all radiation labels, except for radiation labels on materials that are within containers and that will be managed as biomedical waste after they have been released from the licensee.

(b) A licensee shall retain a record of each disposal permitted under paragraph (a) of this section in accordance with § 35.2092.

Subpart D—Unsealed Byproduct Material—Written Directive Not Required

§ 35.100 Use of unsealed byproduct material for uptake, dilution, and excretion studies for which a written directive is not required.

Except for quantities that require a written directive under § 35.40(b), a licensee may use any unsealed byproduct material prepared for medical use for uptake, dilution, or excretion studies that is—

(a) Obtained from a manufacturer or preparer licensed under § 32.72 of this chapter or equivalent Agreement State requirements; or

(b) Prepared by an authorized nuclear pharmacist, a physician who is an authorized user and who meets the requirements specified in §§ 35.290 or 35.390, or an individual under the supervision of either as specified in § 35.27; or

(c) Obtained from and prepared by an NRC or Agreement State licensee for use in research in accordance with a Radioactive Drug Research Committee-approved protocol or an Investigational New Drug (IND) protocol accepted by FDA; or

(d) Prepared by the licensee for use in research in accordance with a Radioactive Drug Research Committee-approved application or an Investigational New Drug (IND) protocol accepted by FDA.

§ 35.190 Training for uptake, dilution, and excretion studies.

Except as provided in § 35.57, the licensee shall require an authorized user of unsealed byproduct material for the uses authorized under § 35.100 to be a physician who—

(a) Is certified by a medical specialty board whose certification process includes all of the requirements in paragraph (c) of this section and whose certification has been recognized by the Commission or an Agreement State; or

(b) Is an authorized user under §§ 35.290 or 35.390 or equivalent Agreement State requirements; or

(c)(1) Has completed 60 hours of training and experience in basic radionuclide handling techniques applicable to the medical use of unsealed byproduct material for uptake, dilution, and excretion studies. The training and experience must include—

(i) Classroom and laboratory training in the following areas—

(A) Radiation physics and instrumentation;

(B) Radiation protection;

(C) Mathematics pertaining to the use and measurement of radioactivity;

(D) Chemistry of byproduct material for medical use; and

(E) Radiation biology; and

(ii) Work experience, under the supervision of an authorized user who meets the requirements in § 35.190, § 35.290, or § 35.390 or equivalent Agreement State requirements, involving—

(A) Ordering, receiving, and unpacking radioactive materials safely and performing the related radiation surveys;

(B) Calibrating instruments used to determine the activity of dosages and performing checks for proper operation of survey meters;

(C) Calculating, measuring, and safely preparing patient or human research subject dosages;

(D) Using administrative controls to prevent a medical event involving the use of unsealed byproduct material;

(E) Using procedures to contain spilled byproduct material safely and using proper decontamination procedures; and

(F) Administering dosages of radioactive drugs to patients or human research subjects; and

(2) Has obtained written certification, signed by a preceptor authorized user who meets the requirements in §§ 35.190, 35.290, or 35.390 or equivalent Agreement State requirements, that the individual has satisfactorily completed the requirements in paragraph (c)(1) of this section and has achieved a level of competency sufficient to function independently as an authorized user for the medical uses authorized under § 35.100.

§ 35.200 Use of unsealed byproduct material for imaging and localization studies for which a written directive is not required.

Except for quantities that require a written directive under § 35.40(b), a licensee may use any unsealed byproduct material prepared for medical use for imaging and localization studies that is—

(a) Obtained from a manufacturer or preparer licensed under § 32.72 of this chapter or equivalent Agreement State requirements; or

(b) Prepared by an authorized nuclear pharmacist, a physician who is an authorized user and who meets the requirements specified in §§ 35.290 or 35.390, or an individual under the supervision of either as specified in § 35.27;

(c) Obtained from and prepared by an NRC or Agreement State licensee for use in research in accordance with a Radioactive Drug Research Committee-approved protocol or an Investigational New Drug (IND) protocol accepted by FDA; or

(d) Prepared by the licensee for use in research in accordance with a Radioactive Drug Research Committee-approved application or an Investigational New Drug (IND) protocol accepted by FDA.

§ 35.204 Permissible molybdenum-99 concentration.

(a) A licensee may not administer to humans a radiopharmaceutical that contains more than 0.15 kilobecquerel of molybdenum-99 per megabecquerel of technetium-99m (0.15 microcurie of molybdenum-99 per millicurie of technetium-99m).

(b) A licensee that uses molybdenum-99/technetium-99m generators for preparing a technetium-99m radiopharmaceutical shall measure the molybdenum-99 concentration of the first eluate after receipt of a generator to demonstrate compliance with paragraph (a) of this section.

(c) If a licensee is required to measure the molybdenum-99 concentration, the licensee shall retain a record of each measurement in accordance with § 35.2204.

§ 35.290 Training for imaging and localization studies.

Except as provided in § 35.57, the licensee shall require an authorized user of unsealed byproduct material for the uses authorized under § 35.200 to be a physician who—

(a) Is certified by a medical specialty board whose certification process includes all of the requirements in paragraph (c) of this section and whose certification has been recognized by the Commission or an Agreement State; or

(b) Is an authorized user under § 35.390 or equivalent Agreement State requirements; or

(c)(1) Has completed 700 hours of training and experience in basic radionuclide handling techniques applicable to the medical use of unsealed byproduct material for imaging and localization studies. The training and experience must include, at a minimum,—

(i) Classroom and laboratory training in the following areas—

(A) Radiation physics and instrumentation;

(B) Radiation protection;

(C) Mathematics pertaining to the use and measurement of radioactivity;

(D) Chemistry of byproduct material for medical use;

(E) Radiation biology; and

(ii) Work experience, under the supervision of an authorized user, who meets the requirements in §§ 35.290 or 35.390 or equivalent Agreement State requirements, involving—

(A) Ordering, receiving, and unpacking radioactive materials safely and performing the related radiation surveys;

(B) Calibrating instruments used to determine the activity of dosages and performing checks for proper operation of survey meters;

(C) Calculating, measuring, and safely preparing patient or human research subject dosages;

(D) Using administrative controls to prevent a medical event involving the use of unsealed byproduct material;

(E) Using procedures to safely contain spilled radioactive material and using proper decontamination procedures;

(F) Administering dosages of radioactive drugs to patients or human research subjects; and

(G) Eluting generator systems appropriate for preparation of radioactive drugs for imaging and localization studies, measuring and testing the eluate for radionuclidic purity, and processing the eluate with reagent kits to prepare labeled radioactive drugs; and

(2) Has obtained written certification, signed by a preceptor authorized user who meets the requirements in §§ 35.290 or 35.390 or equivalent Agreement State requirements, that the individual has satisfactorily completed the requirements in paragraph (c)(1) of this section and has achieved a level of competency sufficient to function independently as an authorized user for the medical uses authorized under §§ 35.100 and 35.200.

Subpart E—Unsealed Byproduct Material—Written Directive Required

§ 35.300 Use of unsealed byproduct material for which a written directive is required.

A licensee may use any unsealed byproduct material prepared for medical use and for which a written directive is required that is—

(a) Obtained from a manufacturer or preparer licensed under § 32.72 of this chapter or equivalent Agreement State requirements; or

(b) Prepared by an authorized nuclear pharmacist, a physician who is an authorized user and who meets the requirements specified in §§ 35.290 or 35.390, or an individual under the supervision of either as specified in § 35.27; or

(c) Obtained from and prepared by an NRC or Agreement State licensee for use in research in accordance with an Investigational New Drug (IND) protocol accepted by FDA; or

(d) Prepared by the licensee for use in research in accordance with an Investigational New Drug (IND) protocol accepted by FDA.

§ 35.310 Safety instruction.

In addition to the requirements of § 19.12 of this chapter,

(a) A licensee shall provide radiation safety instruction, initially and at least annually, to personnel caring for patients or human research subjects who cannot be released under § 35.75. To satisfy this requirement, the instruction must be commensurate with the duties of the personnel and include—

(1) Patient or human research subject control;

(2) Visitor control, including—

(i) Routine visitation to hospitalized individuals in accordance with § 20.1301(a)(1) of this chapter; and

(ii) Visitation authorized in accordance with § 20.1301(c) of this chapter;

(3) Contamination control;

(4) Waste control; and

(5) Notification of the Radiation Safety Officer, or his or her designee, and the authorized user if the patient or the human research subject has a medical emergency or dies.

(b) A licensee shall retain a record of individuals receiving instruction in accordance with § 35.2310.

§ 35.315 Safety precautions.

(a) For each patient or human research subject who cannot be released under § 35.75, a licensee shall—

(1) Quarter the patient or the human research subject either in—

(i) A private room with a private sanitary facility; or

(ii) A room, with a private sanitary facility, with another individual who also has received therapy with unsealed byproduct material and who also cannot be released under § 35.75;

(2) Visibly post the patient's or the human research subject's room with a ''Radioactive Materials'' sign.

(3) Note on the door or in the patient's or human research subject's chart where and how long visitors may stay in the patient's or the human research subject's room; and

(4) Either monitor material and items removed from the patient's or the human research subject's room to determine that their radioactivity cannot be distinguished from the natural background radiation level with a radiation detection survey instrument set on its most sensitive scale and with no interposed shielding, or handle the material and items as radioactive waste.

(b) A licensee shall notify the Radiation Safety Officer, or his or her designee, and the authorized user as soon as possible if the patient or human research subject has a medical emergency or dies.

§ 35.390 Training for use of unsealed byproduct material for which a written directive is required.

Except as provided in § 35.57, the licensee shall require an authorized user of unsealed byproduct material for the uses authorized under § 35.300 to be a physician who—

(a) Is certified by a medical specialty board whose certification process includes all of the requirements in paragraph (b) of this section and whose certification has been recognized by the Commission or an Agreement State; or

(b)(1) Has completed 700 hours of training and experience in basic radionuclide handling techniques applicable to the medical use of unsealed byproduct material requiring a written directive. The training and experience must include—

(i) Classroom and laboratory training in the following areas—

(A) Radiation physics and instrumentation;

(B) Radiation protection;

(C) Mathematics pertaining to the use and measurement of radioactivity;

(D) Chemistry of byproduct material for medical use; and

(E) Radiation biology; and

(ii) Work experience, under the supervision of an authorized user who meets the requirements in § 35.390(a), § 35.390(b), or equivalent Agreement State requirements. A supervising authorized user, who meets the requirements in § 35.390(b), must have experience in administering dosages in the same dosage category or categories (i.e., § 35.390(b)(1)(ii)(G)(*1*), (*2*), (*3*), or (*4*)) as the individual requesting authorized user status. The work experience must involve—

(A) Ordering, receiving, and unpacking radioactive materials safely and performing the related radiation surveys;

(B) Calibrating instruments used to determine the activity of dosages, and performing checks for proper operation of survey meters;

(C) Calculating, measuring, and safely preparing patient or human research subject dosages;

(D) Using administrative controls to prevent a medical event involving the use of unsealed byproduct material;

(E) Using procedures to contain spilled byproduct material safely and using proper decontamination procedures;

(F) Eluting generator systems, measuring and testing the eluate for radionuclidic purity, and processing the eluate with reagent kits to prepare labeled radioactive drugs; and

(G) Administering dosages of radioactive drugs to patients or human research subjects involving a minimum of three cases in each of the following categories for which the individual is requesting authorized user status—

(*1*) Oral administration of less than or equal to 1.22 Gigabecquerels (33 millicuries) of sodium iodide I–131;

(*2*) Oral administration of greater than 1.22 Gigabecquerels (33 millicuries) of sodium iodide I-131 [2];

(*3*) Parenteral administration of any beta emitter or a photon-emitting radionuclide with a photon energy less than 150 keV; and/or

(*4*) Parenteral administration of any other radionuclide; and

(2) Has obtained written certification that the individual has satisfactorily completed the requirements in paragraph (b)(1) of this section and has achieved a level of competency sufficient to function independently as an authorized user for the medical uses authorized under § 35.300. The written certification must be signed by a preceptor authorized user who meets the requirements in § 35.390(a), § 35.390(b), or equivalent Agreement State requirements. The preceptor authorized user, who meets the requirements in § 35.390(b), must have experience in administering dosages in the same dosage category or categories (i.e., § 35.390(b)(1)(ii)(G)(*1*), (*2*), (*3*), or (*4*)) as the individual requesting authorized user status.

[2] Experience with at least 3 cases in Category (G)(*2*) also satisfies the requirement in Category (G)(*1*).

§ 35.392 Training for the oral administration of sodium iodide I-131 requiring a written directive in quantities less than or equal to 1.22 Gigabecquerels (33 millicuries).

Except as provided in § 35.57, the licensee shall require an authorized user for the oral administration of sodium iodide I-131 requiring a written directive in quantities less than or equal to 1.22 Gigabecquerels (33 millicuries), to be a physician who—

(a) Is certified by a medical specialty board whose certification process includes all of the requirements in paragraph (c) of this section and whose certification has been recognized by the Commission or an Agreement State; or

(b) Is an authorized user under § 35.390(a), § 35.390(b), for uses listed in § 35.390(b)(1)(ii)(G)(*1*) or (*2*), § 35.394, or equivalent Agreement State requirements; or

(c)(1) Has successfully completed 80 hours of classroom and laboratory training, applicable to the medical use of sodium iodide I-131 for procedures requiring a written directive. The training must include—

(i) Radiation physics and instrumentation;

(ii) Radiation protection;

(iii) Mathematics pertaining to the use and measurement of radioactivity;

(iv) Chemistry of byproduct material for medical use; and

(v) Radiation biology; and

(2) Has work experience, under the supervision of an authorized user who meets the requirements in § 35.390(a), § 35.390(b), § 35.392, § 35.394, or equivalent Agreement State requirements. A supervising authorized user who meets the requirements in § 35.390(b), must have experience in administering dosages as specified in § 35.390(b)(1)(ii)(G)(*1*) or (*2*). The work experience must involve—

(i) Ordering, receiving, and unpacking radioactive materials safely and performing the related radiation surveys;

(ii) Calibrating instruments used to determine the activity of dosages and performing checks for proper operation for survey meters;

(iii) Calculating, measuring, and safely preparing patient or human research subject dosages;

(iv) Using administrative controls to prevent a medical event involving the use of byproduct material;

(v) Using procedures to contain spilled byproduct material safely and using proper decontamination procedures; and

(vi) Administering dosages to patients or human research subjects, that includes at least 3 cases involving the oral administration of less than or equal to 1.22 Gigabecquerels (33 millicuries) of sodium iodide I-131; and

(3) Has obtained written certification that the individual has satisfactorily completed the requirements in paragraphs (c)(1) and (c)(2) of this section and has achieved a level of competency sufficient to function independently as an authorized user for medical uses authorized under § 35.300. The written certification must be signed by a preceptor authorized user who meets the requirements in § 35.390(a), § 35.390(b), § 35.392, § 35.394, or equivalent Agreement State requirements. A preceptor authorized user, who meets the requirement in § 35.390(b), must have experience in administering dosages as specified in § 35.390(b)(1)(ii)(G)(*1*) or (*2*).

§ 35.394 Training for the oral administration of sodium iodide I–131 requiring a written directive in quantities greater than 1.22 Gigabecquerels (33 millicuries).

Except as provided in § 35.57, the licensee shall require an authorized user for the oral administration of sodium iodide I-131 requiring a written directive in quantities greater than 1.22 Gigabecquerels (33 millicuries), to be a physician who—

(a) Is certified by a medical specialty board whose certification process includes all of the requirements in paragraph (c) of this section and whose certification has been recognized by the Commission or an Agreement State; or

(b) Is an authorized user under § 35.390(a), § 35.390(b) for uses listed in § 35.390(b)(1)(ii)(G)(*2*), or equivalent Agreement State requirements; or

(c)(1) Has successfully completed 80 hours of classroom and laboratory training, applicable to the medical use of sodium iodide I–131 for procedures requiring a written directive. The training must include—

(i) Radiation physics and instrumentation;

(ii) Radiation protection;

(iii) Mathematics pertaining to the use and measurement of radioactivity;

(iv) Chemistry of byproduct material for medical use; and

(v) Radiation biology; and

(2) Has work experience, under the supervision of an authorized user who

meets the requirements in § 35.390(a), § 35.390(b), § 35.394, or equivalent Agreement State requirements. A supervising authorized user, who meets the requirements in § 35.390(b), must have experience in administering dosages as specified in § 35.390(b)(1)(ii)(G)(*2*). The work experience must involve—

(i) Ordering, receiving, and unpacking radioactive materials safely and performing the related radiation surveys;

(ii) Calibrating instruments used to determine the activity of dosages and performing checks for proper operation for survey meters;

(iii) Calculating, measuring, and safely preparing patient or human research subject dosages;

(iv) Using administrative controls to prevent a medical event involving the use of byproduct material;

(v) Using procedures to contain spilled byproduct material safely and using proper decontamination procedures; and

(vi) Administering dosages to patients or human research subjects, that includes at least 3 cases involving the oral administration of greater than 1.22 Gigabecquerels (33 millicuries) of sodium iodide I-131; and

(3) Has obtained written certification that the individual has satisfactorily completed the requirements in paragraphs (c)(1) and (c)(2) of this section and has achieved a level of competency sufficient to function independently as an authorized user for medical uses authorized under § 35.300. The written certification must be signed by a preceptor authorized user who meets the requirements in § 35.390(a), § 35.390(b), § 35.394, or equivalent Agreement State requirements. A preceptor authorized user, who meets the requirements in § 35.390(b), must have experience in administering dosages as specified in § 35.390(b)(1)(ii)(G)(*2*).

Subpart F— Manual Brachytherapy

§ 35.400 Use of sources for manual brachytherapy.

A licensee shall use only brachytherapy sources for therapeutic medical uses:

(a) As approved in the Sealed Source and Device Registry; or

(b) In research in accordance with an active Investigational Device Exemption (IDE) application accepted by the FDA provided the requirements of § 35.49(a) are met.

§ 35.404 Surveys after source implant and removal.

(a) Immediately after implanting sources in a patient or a human research subject, the licensee shall make a survey to locate and account for all sources that have not been implanted.

(b) Immediately after removing the last temporary implant source from a patient or a human research subject, the licensee shall make a survey of the patient or the human research subject with a radiation detection survey instrument to confirm that all sources have been removed.

(c) A licensee shall retain a record of the surveys required by paragraphs (a) and (b) of this section in accordance with § 35.2404.

§ 35.406 Brachytherapy sources accountability.

(a) A licensee shall maintain accountability at all times for all brachytherapy sources in storage or use.

(b) As soon as possible after removing sources from a patient or a human research subject, a licensee shall return brachytherapy sources to a secure storage area.

(c) A licensee shall maintain a record of the brachytherapy source accountability in accordance with § 35.2406.

§ 35.410 Safety instruction.

In addition to the requirements of § 19.12 of this chapter,

(a) The licensee shall provide radiation safety instruction, initially and at least annually, to personnel caring for patients or human research subjects who are receiving brachytherapy and cannot be released under § 35.75. To satisfy this requirement, the instruction must be commensurate with the duties of the personnel and include the—

(1) Size and appearance of the brachytherapy sources;

(2) Safe handling and shielding instructions;

(3) Patient or human research subject control;

(4) Visitor control, including both:

(i) Routine visitation of hospitalized individuals in accordance with § 20.1301(a)(1) of this chapter; and

(ii) Visitation authorized in accordance with § 20.1301(c) of this chapter; and

(5) Notification of the Radiation Safety Officer, or his or her designee, and an authorized user if the patient or the human research subject has a medical emergency or dies.

(b) A licensee shall retain a record of individuals receiving instruction in accordance with § 35.2310.

§ 35.415 Safety precautions.

(a) For each patient or human research subject who is receiving brachytherapy and cannot be released under § 35.75, a licensee shall—

(1) Not quarter the patient or the human research subject in the same room as an individual who is not receiving brachytherapy;

(2) Visibly post the patient's or human research subject's room with a ''Radioactive Materials'' sign; and

(3) Note on the door or in the patient's or human research subject's chart where and how long visitors may stay in the patient's or human research subject's room.

(b) A licensee shall have applicable emergency response equipment available near each treatment room to respond to a source—

(1) Dislodged from the patient; and

(2) Lodged within the patient following removal of the source applicators.

(c) A licensee shall notify the Radiation Safety Officer, or his or her designee, and an authorized user as soon as possible if the patient or human research subject has a medical emergency or dies.

§ 35.432 Calibration measurements of brachytherapy sources.

(a) Before the first medical use of a brachytherapy source on or after October 24, 2002, a licensee shall have—

(1) Determined the source output or activity using a dosimetry system that meets the requirements of § 35.630(a);

(2) Determined source positioning accuracy within applicators; and

(3) Used published protocols currently accepted by nationally recognized bodies to meet the requirements of paragraphs (a)(1) and (a)(2) of this section.

(b) A licensee may use measurements provided by the source manufacturer or by a calibration laboratory accredited by the American Association of Physicists in Medicine that are made in accordance with paragraph (a) of this section.

(c) A licensee shall mathematically correct the outputs or activities determined in paragraph (a) of this section for physical decay at intervals consistent with 1 percent physical decay.

(d) A licensee shall retain a record of each calibration in accordance with § 35.2432.

§ 35.433 Decay of strontium-90 sources for ophthalmic treatments.

(a) Only an authorized medical physicist shall calculate the activity of

each strontium-90 source that is used to determine the treatment times for ophthalmic treatments. The decay must be based on the activity determined under § 35.432.

(b) A licensee shall retain a record of the activity of each strontium-90 source in accordance with § 35.2433.

§ 35.457 Therapy-related computer systems.

The licensee shall perform acceptance testing on the treatment planning system of therapy-related computer systems in accordance with published protocols accepted by nationally recognized bodies. At a minimum, the acceptance testing must include, as applicable, verification of:

(a) The source-specific input parameters required by the dose calculation algorithm;

(b) The accuracy of dose, dwell time, and treatment time calculations at representative points;

(c) The accuracy of isodose plots and graphic displays; and

(d) The accuracy of the software used to determine sealed source positions from radiographic images.

§ 35.490 Training for use of manual brachytherapy sources.

Except as provided in § 35.57, the licensee shall require an authorized user of a manual brachytherapy source for the uses authorized under § 35.400 to be a physician who—

(a) Is certified by a medical specialty board whose certification process includes all of the requirements in paragraph (b) of this section and whose certification has been recognized by the Commission or an Agreement State; or

(b)(1) Has completed a structured educational program in basic radionuclide handling techniques applicable to the use of manual brachytherapy sources that includes—

(i) 200 hours of classroom and laboratory training in the following areas—

(A) Radiation physics and instrumentation;

(B) Radiation protection;

(C) Mathematics pertaining to the use and measurement of radioactivity; and

(D) Radiation biology; and

(ii) 500 hours of work experience, under the supervision of an authorized user who meets the requirements in § 35.490 or equivalent Agreement State requirements at a medical institution, involving—

(A) Ordering, receiving, and unpacking radioactive materials safely and performing the related radiation surveys;

(B) Checking survey meters for proper operation;

(C) Preparing, implanting, and removing brachytherapy sources;

(D) Maintaining running inventories of material on hand;

(E) Using administrative controls to prevent a medical event involving the use of byproduct material;

(F) Using emergency procedures to control byproduct material; and

(2) Has obtained 3 years of supervised clinical experience in radiation oncology, under an authorized user who meets the requirements in § 35.490 or equivalent Agreement State requirements, as part of a formal training program approved by the Residency Review Committee for Radiation Oncology of the Accreditation Council for Graduate Medical Education or the Committee on Postdoctoral Training of the American Osteopathic Association. This experience may be obtained concurrently with the supervised work experience required by paragraph (b)(1)(ii) of this section; and

(3) Has obtained written certification, signed by a preceptor authorized user who meets the requirements in § 35.490 or equivalent Agreement State requirements, that the individual has satisfactorily completed the requirements in paragraphs (b)(1) and (b)(2) of this section and has achieved a level of competency sufficient to function independently as an authorized user of manual brachytherapy sources for the medical uses authorized under § 35.400.

§ 35.491 Training for ophthalmic use of strontium-90.

Except as provided in § 35.57, the licensee shall require the authorized user of strontium-90 for ophthalmic radiotherapy to be a physician who—

(a) Is an authorized user under § 35.490 or equivalent Agreement State requirements; or

(b)(1) Has completed 24 hours of classroom and laboratory training applicable to the medical use of strontium-90 for ophthalmic radiotherapy. The training must include—

(i) Radiation physics and instrumentation;

(ii) Radiation protection;

(iii) Mathematics pertaining to the use and measurement of radioactivity; and

(iv) Radiation biology; and

(2) Supervised clinical training in ophthalmic radiotherapy under the supervision of an authorized user at a medical institution that includes the use of strontium-90 for the ophthalmic treatment of five individuals. This supervised clinical training must involve—

(i) Examination of each individual to be treated;

(ii) Calculation of the dose to be administered;

(iii) Administration of the dose; and

(iv) Follow up and review of each individual's case history; and

(3) Has obtained written certification, signed by a preceptor authorized user who meets the requirements in § 35.490, § 35.491, or equivalent Agreement State requirements, that the individual has satisfactorily completed the requirements in paragraphs (a) and (b) of this section and has achieved a level of competency sufficient to function independently as an authorized user of strontium-90 for ophthalmic use.

Subpart G—Sealed Sources for Diagnosis

§ 35.500 Use of sealed sources for diagnosis.

A licensee shall use only sealed sources for diagnostic medical uses as approved in the Sealed Source and Device Registry.

§ 35.590 Training for use of sealed sources for diagnosis.

Except as provided in § 35.57, the licensee shall require the authorized user of a diagnostic sealed source for use in a device authorized under § 35.500 to be a physician, dentist, or podiatrist who—

(a) Is certified by a specialty board whose certification process includes all of the requirements in paragraph (b) of this section and whose certification has been recognized by the Commission or an Agreement State; or

(b) Has had 8 hours of classroom and laboratory training in basic radionuclide handling techniques specifically applicable to the use of the device. The training must include—

(1) Radiation physics and instrumentation;

(2) Radiation protection;

(3) Mathematics pertaining to the use and measurement of radioactivity;

(4) Radiation biology; and

(5) Training in the use of the device for the uses requested.

Subpart H—Photon Emitting Remote Afterloader Units, Teletherapy Units, and Gamma Stereotactic Radiosurgery Units

§ 35.600 Use of a sealed source in a remote afterloader unit, teletherapy unit, or gamma stereotactic radiosurgery unit.

A licensee shall use sealed sources in photon emitting remote afterloader units, teletherapy units, or gamma stereotactic radiosurgery units for therapeutic medical uses:

(a) As approved in the Sealed Source and Device Registry; or

(b) In research in accordance with an active Investigational Device Exemption (IDE) application accepted by the FDA provided the requirements of § 35.49(a) are met.

§ 35.604 Surveys of patients and human research subjects treated with a remote afterloader unit.

(a) Before releasing a patient or a human research subject from licensee control, a licensee shall survey the patient or the human research subject and the remote afterloader unit with a portable radiation detection survey instrument to confirm that the source(s) has been removed from the patient or human research subject and returned to the safe shielded position.

(b) A licensee shall retain a record of these surveys in accordance with § 35.2404.

§ 35.605 Installation, maintenance, adjustment, and repair.

(a) Only a person specifically licensed by the Commission or an Agreement State shall install, maintain, adjust, or repair a remote afterloader unit, teletherapy unit, or gamma stereotactic radiosurgery unit that involves work on the source(s) shielding, the source(s) driving unit, or other electronic or mechanical component that could expose the source(s), reduce the shielding around the source(s), or compromise the radiation safety of the unit or the source(s).

(b) Except for low dose-rate remote afterloader units, only a person specifically licensed by the Commission or an Agreement State shall install, replace, relocate, or remove a sealed source or source contained in other remote afterloader units, teletherapy units, or gamma stereotactic radiosurgery units.

(c) For a low dose-rate remote afterloader unit, only a person specifically licensed by the Commission or an Agreement State or an authorized medical physicist shall install, replace, relocate, or remove a sealed source(s) contained in the unit.

(d) A licensee shall retain a record of the installation, maintenance, adjustment, and repair of remote afterloader units, teletherapy units, and gamma stereotactic radiosurgery units in accordance with § 35.2605.

§ 35.610 Safety procedures and instructions for remote afterloader units, teletherapy units, and gamma stereotactic radiosurgery units.

(a) A licensee shall—

(1) Secure the unit, the console, the console keys, and the treatment room when not in use or unattended;

(2) Permit only individuals approved by the authorized user, Radiation Safety Officer, or authorized medical physicist to be present in the treatment room during treatment with the source(s);

(3) Prevent dual operation of more than one radiation producing device in a treatment room if applicable; and

(4) Develop, implement, and maintain written procedures for responding to an abnormal situation when the operator is unable to place the source(s) in the shielded position, or remove the patient or human research subject from the radiation field with controls from outside the treatment room. These procedures must include—

(i) Instructions for responding to equipment failures and the names of the individuals responsible for implementing corrective actions;

(ii) The process for restricting access to and posting of the treatment area to minimize the risk of inadvertent exposure; and

(iii) The names and telephone numbers of the authorized users, the authorized medical physicist, and the Radiation Safety Officer to be contacted if the unit or console operates abnormally.

(b) A copy of the procedures required by paragraph (a)(4) of this section must be physically located at the unit console.

(c) A licensee shall post instructions at the unit console to inform the operator of—

(1) The location of the procedures required by paragraph (a)(4) of this section; and

(2) The names and telephone numbers of the authorized users, the authorized medical physicist, and the Radiation Safety Officer to be contacted if the unit or console operates abnormally.

(d) A licensee shall provide instruction, initially and at least annually, to all individuals who operate the unit, as appropriate to the individual's assigned duties, in—

(1) The procedures identified in paragraph (a)(4) of this section; and

(2) The operating procedures for the unit.

(e) A licensee shall ensure that operators, authorized medical physicists, and authorized users participate in drills of the emergency procedures, initially and at least annually.

(f) A licensee shall retain a record of individuals receiving instruction required by paragraph (d) of this section, in accordance with § 35.2310.

(g) A licensee shall retain a copy of the procedures required by §§ 35.610(a)(4) and (d)(2) in accordance with § 35.2610.

§ 35.615 Safety precautions for remote afterloader units, teletherapy units, and gamma stereotactic radiosurgery units.

(a) A licensee shall control access to the treatment room by a door at each entrance.

(b) A licensee shall equip each entrance to the treatment room with an electrical interlock system that will—

(1) Prevent the operator from initiating the treatment cycle unless each treatment room entrance door is closed;

(2) Cause the source(s) to be shielded when an entrance door is opened; and

(3) Prevent the source(s) from being exposed following an interlock interruption until all treatment room entrance doors are closed and the source(s) on-off control is reset at the console.

(c) A licensee shall require any individual entering the treatment room to assure, through the use of appropriate radiation monitors, that radiation levels have returned to ambient levels.

(d) Except for low-dose remote afterloader units, a licensee shall construct or equip each treatment room with viewing and intercom systems to permit continuous observation of the patient or the human research subject from the treatment console during irradiation.

(e) For licensed activities where sources are placed within the patient's or human research subject's body, a licensee shall only conduct treatments which allow for expeditious removal of a decoupled or jammed source.

(f) In addition to the requirements specified in paragraphs (a) through (e) of this section, a licensee shall—

(1) For medium dose-rate and pulsed dose-rate remote afterloader units, require—

(i) An authorized medical physicist and either an authorized user or a physician, under the supervision of an authorized user, who has been trained in the operation and emergency response for the unit to be physically present during the initiation of all patient treatments involving the unit; and

(ii) An authorized medical physicist and either an authorized user or an individual, under the supervision of an authorized user, who has been trained to remove the source applicator(s) in the event of an emergency involving the unit, to be immediately available during continuation of all patient treatments involving the unit.

(2) For high dose-rate remote afterloader units, require—

(i) An authorized user and an authorized medical physicist to be physically present during the initiation

of all patient treatments involving the unit; and

(ii) An authorized medical physicist and either an authorized user or a physician, under the supervision of an authorized user, who has been trained in the operation and emergency response for the unit, to be physically present during continuation of all patient treatments involving the unit.

(3) For gamma stereotactic radiosurgery units, require an authorized user and an authorized medical physicist to be physically present throughout all patient treatments involving the unit.

(4) Notify the Radiation Safety Officer, or his/her designee, and an authorized user as soon as possible if the patient or human research subject has a medical emergency or dies.

(g) A licensee shall have applicable emergency response equipment available near each treatment room to respond to a source—

(1) Remaining in the unshielded position; or

(2) Lodged within the patient following completion of the treatment.

§ 35.630 Dosimetry equipment.

(a) Except for low dose-rate remote afterloader sources where the source output or activity is determined by the manufacturer, a licensee shall have a calibrated dosimetry system available for use. To satisfy this requirement, one of the following two conditions must be met.

(1) The system must have been calibrated using a system or source traceable to the National Institute of Science and Technology (NIST) and published protocols accepted by nationally recognized bodies; or by a calibration laboratory accredited by the American Association of Physicists in Medicine (AAPM). The calibration must have been performed within the previous 2 years and after any servicing that may have affected system calibration; or

(2) The system must have been calibrated within the previous 4 years. Eighteen to thirty months after that calibration, the system must have been intercompared with another dosimetry system that was calibrated within the past 24 months by NIST or by a calibration laboratory accredited by the AAPM. The results of the intercomparison must indicate that the calibration factor of the licensee's system had not changed by more than 2 percent. The licensee may not use the intercomparison result to change the calibration factor. When intercomparing dosimetry systems to be used for calibrating sealed sources for therapeutic units, the licensee shall use a comparable unit with beam attenuators or collimators, as applicable, and sources of the same radionuclide as the source used at the licensee's facility.

(b) The licensee shall have a dosimetry system available for use for spot-check output measurements, if applicable. To satisfy this requirement, the system may be compared with a system that has been calibrated in accordance with paragraph (a) of this section. This comparison must have been performed within the previous year and after each servicing that may have affected system calibration. The spot-check system may be the same system used to meet the requirement in paragraph (a) of this section.

(c) The licensee shall retain a record of each calibration, intercomparison, and comparison in accordance with § 35.2630.

§ 35.632 Full calibration measurements on teletherapy units.

(a) A licensee authorized to use a teletherapy unit for medical use shall perform full calibration measurements on each teletherapy unit—

(1) Before the first medical use of the unit; and

(2) Before medical use under the following conditions:

(i) Whenever spot-check measurements indicate that the output differs by more than 5 percent from the output obtained at the last full calibration corrected mathematically for radioactive decay;

(ii) Following replacement of the source or following reinstallation of the teletherapy unit in a new location;

(iii) Following any repair of the teletherapy unit that includes removal of the source or major repair of the components associated with the source exposure assembly; and

(3) At intervals not exceeding 1 year.

(b) To satisfy the requirement of paragraph (a) of this section, full calibration measurements must include determination of—

(1) The output within +/−3 percent for the range of field sizes and for the distance or range of distances used for medical use;

(2) The coincidence of the radiation field and the field indicated by the light beam localizing device;

(3) The uniformity of the radiation field and its dependence on the orientation of the useful beam;

(4) Timer accuracy and linearity over the range of use;

(5) On-off error; and

(6) The accuracy of all distance measuring and localization devices in medical use.

(c) A licensee shall use the dosimetry system described in § 35.630(a) to measure the output for one set of exposure conditions. The remaining radiation measurements required in paragraph (b)(1) of this section may be made using a dosimetry system that indicates relative dose rates.

(d) A licensee shall make full calibration measurements required by paragraph (a) of this section in accordance with published protocols accepted by nationally recognized bodies.

(e) A licensee shall mathematically correct the outputs determined in paragraph (b)(1) of this section for physical decay for intervals not exceeding 1 month for cobalt-60, 6 months for cesium-137, or at intervals consistent with 1 percent decay for all other nuclides.

(f) Full calibration measurements required by paragraph (a) of this section and physical decay corrections required by paragraph (e) of this section must be performed by the authorized medical physicist.

(g) A licensee shall retain a record of each calibration in accordance with § 35.2632.

§ 35.633 Full calibration measurements on remote afterloader units.

(a) A licensee authorized to use a remote afterloader unit for medical use shall perform full calibration measurements on each unit—

(1) Before the first medical use of the unit;

(2) Before medical use under the following conditions:

(i) Following replacement of the source or following reinstallation of the unit in a new location outside the facility; and

(ii) Following any repair of the unit that includes removal of the source or major repair of the components associated with the source exposure assembly; and

(3) At intervals not exceeding 1 quarter for high dose-rate, medium dose-rate, and pulsed dose-rate remote afterloader units with sources whose half-life exceeds 75 days; and

(4) At intervals not exceeding 1 year for low dose-rate remote afterloader units.

(b) To satisfy the requirement of paragraph (a) of this section, full calibration measurements must include, as applicable, determination of:

(1) The output within ± 5 percent;

(2) Source positioning accuracy to within ±1 millimeter;

(3) Source retraction with backup battery upon power failure;

(4) Length of the source transfer tubes;

(5) Timer accuracy and linearity over the typical range of use;

(6) Length of the applicators; and

(7) Function of the source transfer tubes, applicators, and transfer tube-applicator interfaces.

(c) A licensee shall use the dosimetry system described in § 35.630(a) to measure the output.

(d) A licensee shall make full calibration measurements required by paragraph (a) of this section in accordance with published protocols accepted by nationally recognized bodies.

(e) In addition to the requirements for full calibrations for low dose-rate remote afterloader units in paragraph (b) of this section, a licensee shall perform an autoradiograph of the source(s) to verify inventory and source(s) arrangement at intervals not exceeding 1 quarter.

(f) For low dose-rate remote afterloader units, a licensee may use measurements provided by the source manufacturer that are made in accordance with paragraphs (a) through (e) of this section.

(g) A licensee shall mathematically correct the outputs determined in paragraph (b)(1) of this section for physical decay at intervals consistent with 1 percent physical decay.

(h) Full calibration measurements required by paragraph (a) of this section and physical decay corrections required by paragraph (g) of this section must be performed by the authorized medical physicist.

(i) A licensee shall retain a record of each calibration in accordance with § 35.2632.

§ 35.635 Full calibration measurements on gamma stereotactic radiosurgery units.

(a) A licensee authorized to use a gamma stereotactic radiosurgery unit for medical use shall perform full calibration measurements on each unit—

(1) Before the first medical use of the unit;

(2) Before medical use under the following conditions—

(i) Whenever spot-check measurements indicate that the output differs by more than 5 percent from the output obtained at the last full calibration corrected mathematically for radioactive decay;

(ii) Following replacement of the sources or following reinstallation of the gamma stereotactic radiosurgery unit in a new location; and

(iii) Following any repair of the gamma stereotactic radiosurgery unit that includes removal of the sources or major repair of the components associated with the source assembly; and

(3) At intervals not exceeding 1 year, with the exception that relative helmet factors need only be determined before the first medical use of a helmet and following any damage to a helmet.

(b) To satisfy the requirement of paragraph (a) of this section, full calibration measurements must include determination of—

(1) The output within ±3 percent;

(2) Relative helmet factors;

(3) Isocenter coincidence;

(4) Timer accuracy and linearity over the range of use;

(5) On-off error;

(6) Trunnion centricity;

(7) Treatment table retraction mechanism, using backup battery power or hydraulic backups with the unit off;

(8) Helmet microswitches;

(9) Emergency timing circuits; and

(10) Stereotactic frames and localizing devices (trunnions).

(c) A licensee shall use the dosimetry system described in § 35.630(a) to measure the output for one set of exposure conditions. The remaining radiation measurements required in paragraph (b)(1) of this section may be made using a dosimetry system that indicates relative dose rates.

(d) A licensee shall make full calibration measurements required by paragraph (a) of this section in accordance with published protocols accepted by nationally recognized bodies.

(e) A licensee shall mathematically correct the outputs determined in paragraph (b)(1) of this section at intervals not exceeding 1 month for cobalt-60 and at intervals consistent with 1 percent physical decay for all other radionuclides.

(f) Full calibration measurements required by paragraph (a) of this section and physical decay corrections required by paragraph (e) of this section must be performed by the authorized medical physicist.

(g) A licensee shall retain a record of each calibration in accordance with § 35.2632.

§ 35.642 Periodic spot-checks for teletherapy units.

(a) A licensee authorized to use teletherapy units for medical use shall perform output spot-checks on each teletherapy unit once in each calendar month that include determination of—

(1) Timer accuracy, and timer linearity over the range of use;

(2) On-off error;

(3) The coincidence of the radiation field and the field indicated by the light beam localizing device;

(4) The accuracy of all distance measuring and localization devices used for medical use;

(5) The output for one typical set of operating conditions measured with the dosimetry system described in § 35.630(b); and

(6) The difference between the measurement made in paragraph (a)(5) of this section and the anticipated output, expressed as a percentage of the anticipated output (i.e., the value obtained at last full calibration corrected mathematically for physical decay).

(b) A licensee shall perform measurements required by paragraph (a) of this section in accordance with written procedures established by the authorized medical physicist. That individual need not actually perform the spot-check measurements.

(c) A licensee shall have the authorized medical physicist review the results of each spot-check within 15 days. The authorized medical physicist shall notify the licensee as soon as possible in writing of the results of each spot-check.

(d) A licensee authorized to use a teletherapy unit for medical use shall perform safety spot-checks of each teletherapy facility once in each calendar month and after each source installation to assure proper operation of—

(1) Electrical interlocks at each teletherapy room entrance;

(2) Electrical or mechanical stops installed for the purpose of limiting use of the primary beam of radiation (restriction of source housing angulation or elevation, carriage or stand travel and operation of the beam on-off mechanism);

(3) Source exposure indicator lights on the teletherapy unit, on the control console, and in the facility;

(4) Viewing and intercom systems;

(5) Treatment room doors from inside and outside the treatment room; and

(6) Electrically assisted treatment room doors with the teletherapy unit electrical power turned off.

(e) If the results of the checks required in paragraph (d) of this section indicate the malfunction of any system, a licensee shall lock the control console in the off position and not use the unit except as may be necessary to repair, replace, or check the malfunctioning system.

(f) A licensee shall retain a record of each spot-check required by paragraphs (a) and (d) of this section, and a copy of the procedures required by paragraph (b), in accordance with § 35.2642.

§ 35.643 Periodic spot-checks for remote afterloader units.

(a) A licensee authorized to use a remote afterloader unit for medical use shall perform spot-checks of each remote afterloader facility and on each unit—

(1) Before the first use of a high dose-rate, medium dose-rate, or pulsed dose-rate remote afterloader unit on a given day;

(2) Before each patient treatment with a low dose-rate remote afterloader unit; and

(3) After each source installation.

(b) A licensee shall perform the measurements required by paragraph (a) of this section in accordance with written procedures established by the authorized medical physicist. That individual need not actually perform the spot check measurements.

(c) A licensee shall have the authorized medical physicist review the results of each spot-check within 15 days. The authorized medical physicist shall notify the licensee as soon as possible in writing of the results of each spot-check.

(d) To satisfy the requirements of paragraph (a) of this section, spot-checks must, at a minimum, assure proper operation of—

(1) Electrical interlocks at each remote afterloader unit room entrance;

(2) Source exposure indicator lights on the remote afterloader unit, on the control console, and in the facility;

(3) Viewing and intercom systems in each high dose-rate, medium dose-rate, and pulsed dose-rate remote afterloader facility;

(4) Emergency response equipment;

(5) Radiation monitors used to indicate the source position;

(6) Timer accuracy;

(7) Clock (date and time) in the unit's computer; and

(8) Decayed source(s) activity in the unit's computer.

(e) If the results of the checks required in paragraph (d) of this section indicate the malfunction of any system, a licensee shall lock the control console in the off position and not use the unit except as may be necessary to repair, replace, or check the malfunctioning system.

(f) A licensee shall retain a record of each check required by paragraph (d) of this section and a copy of the procedures required by paragraph (b) of this section in accordance with § 35.2643.

§ 35.645 Periodic spot-checks for gamma stereotactic radiosurgery units.

(a) A licensee authorized to use a gamma stereotactic radiosurgery unit for medical use shall perform spot-checks of each gamma stereotactic radiosurgery facility and on each unit—

(1) Monthly;

(2) Before the first use of the unit on a given day; and

(3) After each source installation.

(b) A licensee shall—

(1) Perform the measurements required by paragraph (a) of this section in accordance with written procedures established by the authorized medical physicist. That individual need not actually perform the spot check measurements.

(2) Have the authorized medical physicist review the results of each spot-check within 15 days. The authorized medical physicist shall notify the licensee as soon as possible in writing of the results of each spot-check.

(c) To satisfy the requirements of paragraph (a)(1) of this section, spot-checks must, at a minimum—

(1) Assure proper operation of—

(i) Treatment table retraction mechanism, using backup battery power or hydraulic backups with the unit off;

(ii) Helmet microswitches;

(iii) Emergency timing circuits; and

(iv) Stereotactic frames and localizing devices (trunnions).

(2) Determine—

(i) The output for one typical set of operating conditions measured with the dosimetry system described in § 35.630(b);

(ii) The difference between the measurement made in paragraph (c)(2)(i) of this section and the anticipated output, expressed as a percentage of the anticipated output (i.e., the value obtained at last full calibration corrected mathematically for physical decay);

(iii) Source output against computer calculation;

(iv) Timer accuracy and linearity over the range of use;

(v) On-off error; and

(vi) Trunnion centricity.

(d) To satisfy the requirements of paragraphs (a)(2) and (a)(3) of this section, spot-checks must assure proper operation of—

(1) Electrical interlocks at each gamma stereotactic radiosurgery room entrance;

(2) Source exposure indicator lights on the gamma stereotactic radiosurgery unit, on the control console, and in the facility;

(3) Viewing and intercom systems;

(4) Timer termination;

(5) Radiation monitors used to indicate room exposures; and

(6) Emergency off buttons.

(e) A licensee shall arrange for the repair of any system identified in paragraph (c) of this section that is not operating properly as soon as possible.

(f) If the results of the checks required in paragraph (d) of this section indicate the malfunction of any system, a licensee shall lock the control console in the off position and not use the unit except as may be necessary to repair, replace, or check the malfunctioning system.

(g) A licensee shall retain a record of each check required by paragraphs (c) and (d) and a copy of the procedures required by paragraph (b) of this section in accordance with § 35.2645.

§ 35.647 Additional technical requirements for mobile remote afterloader units.

(a) A licensee providing mobile remote afterloader service shall—

(1) Check survey instruments before medical use at each address of use or on each day of use, whichever is more frequent; and

(2) Account for all sources before departure from a client's address of use.

(b) In addition to the periodic spot-checks required by § 35.643, a licensee authorized to use mobile afterloaders for medical use shall perform checks on each remote afterloader unit before use at each address of use. At a minimum, checks must be made to verify the operation of—

(1) Electrical interlocks on treatment area access points;

(2) Source exposure indicator lights on the remote afterloader unit, on the control console, and in the facility;

(3) Viewing and intercom systems;

(4) Applicators, source transfer tubes, and transfer tube-applicator interfaces;

(5) Radiation monitors used to indicate room exposures;

(6) Source positioning (accuracy); and

(7) Radiation monitors used to indicate whether the source has returned to a safe shielded position.

(c) In addition to the requirements for checks in paragraph (b) of this section, a licensee shall ensure overall proper operation of the remote afterloader unit by conducting a simulated cycle of treatment before use at each address of use.

(d) If the results of the checks required in paragraph (b) of this section indicate the malfunction of any system, a licensee shall lock the control console in the off position and not use the unit except as may be necessary to repair, replace, or check the malfunctioning system.

(e) A licensee shall retain a record of each check required by paragraph (b) of this section in accordance with § 35.2647.

§ 35.652 Radiation surveys.

(a) In addition to the survey requirement in § 20.1501 of this chapter, a person licensed under this subpart shall make surveys to ensure that the maximum radiation levels and average radiation levels from the surface of the main source safe with the source(s) in the shielded position do not exceed the levels stated in the Sealed Source and Device Registry.

(b) The licensee shall make the survey required by paragraph (a) of this section at installation of a new source and following repairs to the source(s) shielding, the source(s) driving unit, or other electronic or mechanical component that could expose the source, reduce the shielding around the source(s), or compromise the radiation safety of the unit or the source(s).

(c) A licensee shall retain a record of the radiation surveys required by paragraph (a) of this section in accordance with § 35.2652.

§ 35.655 Five-year inspection for teletherapy and gamma stereotactic radiosurgery units.

(a) A licensee shall have each teletherapy unit and gamma stereotactic radiosurgery unit fully inspected and serviced during source replacement or at intervals not to exceed 5 years, whichever comes first, to assure proper functioning of the source exposure mechanism.

(b) This inspection and servicing may only be performed by persons specifically licensed to do so by the Commission or an Agreement State.

(c) A licensee shall keep a record of the inspection and servicing in accordance with § 35.2655.

§ 35.657 Therapy-related computer systems.

The licensee shall perform acceptance testing on the treatment planning system of therapy-related computer systems in accordance with published protocols accepted by nationally recognized bodies. At a minimum, the acceptance testing must include, as applicable, verification of:

(a) The source-specific input parameters required by the dose calculation algorithm;

(b) The accuracy of dose, dwell time, and treatment time calculations at representative points;

(c) The accuracy of isodose plots and graphic displays;

(d) The accuracy of the software used to determine sealed source positions from radiographic images; and

(e) The accuracy of electronic transfer of the treatment delivery parameters to the treatment delivery unit from the treatment planning system.

§ 35.690 Training for use of remote afterloader units, teletherapy units, and gamma stereotactic radiosurgery units.

Except as provided in § 35.57, the licensee shall require an authorized user of a sealed source for a use authorized under § 35.600 to be a physician who—

(a) Is certified by a medical specialty board whose certification process includes all of the requirements in paragraph (b) of this section and whose certification has been recognized by the Commission or an Agreement State; or

(b)(1) Has completed a structured educational program in basic radionuclide techniques applicable to the use of a sealed source in a therapeutic medical unit that includes—

(i) 200 hours of classroom and laboratory training in the following areas—

(A) Radiation physics and instrumentation;

(B) Radiation protection;

(C) Mathematics pertaining to the use and measurement of radioactivity; and

(D) Radiation biology; and

(ii) 500 hours of work experience, under the supervision of an authorized user who meets the requirements in § 35.690 or equivalent Agreement State requirements at a medical institution, involving—

(A) Reviewing full calibration measurements and periodic spot-checks;

(B) Preparing treatment plans and calculating treatment doses and times;

(C) Using administrative controls to prevent a medical event involving the use of byproduct material;

(D) Implementing emergency procedures to be followed in the event of the abnormal operation of the medical unit or console;

(E) Checking and using survey meters; and

(F) Selecting the proper dose and how it is to be administered; and

(2) Has completed 3 years of supervised clinical experience in radiation oncology, under an authorized user who meets the requirements in § 35.690 or equivalent Agreement State requirements, as part of a formal training program approved by the Residency Review Committee for Radiation Oncology of the Accreditation Council for Graduate Medical Education or the Committee on Postdoctoral Training of the American Osteopathic Association. This experience may be obtained concurrently with the supervised work experience required by paragraph (b)(1)(ii) of this section; and

(3) Has obtained written certification that the individual has satisfactorily completed the requirements in paragraphs (b)(1) and (b)(2) of this section and has achieved a level of competency sufficient to function independently as an authorized user of each type of therapeutic medical unit for which the individual is requesting authorized user status. The written certification must be signed by a preceptor authorized user who meets the requirements in § 35.690 or equivalent Agreement State requirements for an authorized user for each type of therapeutic medical unit for which the individual is requesting authorized user status.

Subpart I—[Reserved]

Subpart J—Training and Experience Requirements

§ 35.900 Radiation Safety Officer.

Except as provided in § 35.57, the licensee shall require an individual fulfilling the responsibilities of the Radiation Safety Officer as provided in § 35.24 to be an individual who—

(a) Is certified by the—

(1) American Board of Health Physics in Comprehensive Health Physics;

(2) American Board of Radiology;

(3) American Board of Nuclear Medicine;

(4) American Board of Science in Nuclear Medicine;

(5) Board of Pharmaceutical Specialties in Nuclear Pharmacy;

(6) American Board of Medical Physics in radiation oncology physics;

(7) Royal College of Physicians and Surgeons of Canada in nuclear medicine;

(8) American Osteopathic Board of Radiology; or

(9) American Osteopathic Board of Nuclear Medicine; or

(b) Has had classroom and laboratory training and experience as follows—

(1) 200 hours of classroom and laboratory training that includes—

(i) Radiation physics and instrumentation;

(ii) Radiation protection;

(iii) Mathematics pertaining to the use and measurement of radioactivity;

(iv) Radiation biology; and

(v) Radiopharmaceutical chemistry; and

(2) One year of full time experience as a radiation safety technologist at a medical institution under the supervision of the individual identified as the Radiation Safety Officer on a Commission or Agreement State license that authorizes the medical use of byproduct material; or

(c) Is an authorized user identified on the licensee's license.

§ 35.910 Training for uptake, dilution, and excretion studies.

Except as provided in § 35.57, the licensee shall require the authorized

user of a radiopharmaceutical in § 35.100(a) to be a physician who—

(a) Is certified in—

(1) Nuclear medicine by the American Board of Nuclear Medicine;

(2) Diagnostic radiology by the American Board of Radiology;

(3) Diagnostic radiology or radiology by the American Osteopathic Board of Radiology;

(4) Nuclear medicine by the Royal College of Physicians and Surgeons of Canada; or

(5) American Osteopathic Board of Nuclear Medicine in nuclear medicine; or

(b) Has had classroom and laboratory training in basic radioisotope handling techniques applicable to the use of prepared radiopharmaceuticals, and supervised clinical experience as follows—

(1) 40 hours of classroom and laboratory training that includes—

(i) Radiation physics and instrumentation;

(ii) Radiation protection;

(iii) Mathematics pertaining to the use and measurement of radioactivity;

(iv) Radiation biology; and

(v) Radiopharmaceutical chemistry; and

(2) 20 hours of supervised clinical experience under the supervision of an authorized user and that includes—

(i) Examining patients or human research subjects and reviewing their case histories to determine their suitability for radioisotope diagnosis, limitations, or contraindications;

(ii) Selecting the suitable radiopharmaceuticals and calculating and measuring the dosages;

(iii) Administering dosages to patients or human research subjects and using syringe radiation shields;

(iv) Collaborating with the authorized user in the interpretation of radioisotope test results; and

(v) Patient or human research subject follow up; or

(c) Has successfully completed a 6-month training program in nuclear medicine as part of a training program that has been approved by the Accreditation Council for Graduate Medical Education and that included classroom and laboratory training, work experience, and supervised clinical experience in all the topics identified in paragraph (b) of this section.

§ 35.920 Training for imaging and localization studies.

Except as provided in § 35.57, the licensee shall require the authorized user of a radiopharmaceutical, generator, or reagent kit in § 35.200(a) to be a physician who—

(a) Is certified in—

(1) Nuclear medicine by the American Board of Nuclear Medicine;

(2) Diagnostic radiology by the American Board of Radiology;

(3) Diagnostic radiology or radiology by the American Osteopathic Board of Radiology;

(4) Nuclear medicine by the Royal College of Physicians and Surgeons of Canada; or

(5) American Osteopathic Board of Nuclear Medicine in nuclear medicine; or

(b) Has had classroom and laboratory training in basic radioisotope handling techniques applicable to the use of prepared radiopharmaceuticals, generators, and reagent kits, supervised work experience, and supervised clinical experience as follows—

(1) 200 hours of classroom and laboratory training that includes—

(i) Radiation physics and instrumentation;

(ii) Radiation protection;

(iii) Mathematics pertaining to the use and measurement of radioactivity;

(iv) Radiopharmaceutical chemistry; and

(v) Radiation biology; and

(2) 500 hours of supervised work experience under the supervision of an authorized user that includes—

(i) Ordering, receiving, and unpacking radioactive materials safely and performing the related radiation surveys;

(ii) Calibrating dose calibrators and diagnostic instruments and performing checks for proper operation of survey meters;

(iii) Calculating and safely preparing patient or human research subject dosages;

(iv) Using administrative controls to prevent the medical event of byproduct material;

(v) Using procedures to contain spilled byproduct material safely and using proper decontamination procedures; and

(vi) Eluting technetium-99m from generator systems, measuring and testing the eluate for molybdenum-99 and alumina contamination, and processing the eluate with reagent kits to prepare technetium-99m labeled radiopharmaceuticals; and

(3) 500 hours of supervised clinical experience under the supervision of an authorized user that includes—

(i) Examining patients or human research subjects and reviewing their case histories to determine their suitability for radioisotope diagnosis, limitations, or contraindications;

(ii) Selecting the suitable radiopharmaceuticals and calculating and measuring the dosages;

(iii) Administering dosages to patients or human research subjects and using syringe radiation shields;

(iv) Collaborating with the authorized user in the interpretation of radioisotope test results; and

(v) Patient or human research subject follow up; or

(c) Has successfully completed a 6-month training program in nuclear medicine that has been approved by the Accreditation Council for Graduate Medical Education and that included classroom and laboratory training, work experience, and supervised clinical experience in all the topics identified in paragraph (b) of this section.

§ 35.930 Training for therapeutic use of unsealed byproduct material.

Except as provided in § 35.57, the licensee shall require the authorized user of radiopharmaceuticals in § 35.300 to be a physician who—

(a) Is certified by—

(1) The American Board of Nuclear Medicine;

(2) The American Board of Radiology in radiology, therapeutic radiology, or radiation oncology;

(3) The Royal College of Physicians and Surgeons of Canada in nuclear medicine; or

(4) The American Osteopathic Board of Radiology after 1984; or

(b) Has had classroom and laboratory training in basic radioisotope handling techniques applicable to the use of therapeutic radiopharmaceuticals, and supervised clinical experience as follows—

(1) 80 hours of classroom and laboratory training that includes—

(i) Radiation physics and instrumentation;

(ii) Radiation protection;

(iii) Mathematics pertaining to the use and measurement of radioactivity; and

(iv) Radiation biology; and

(2) Supervised clinical experience under the supervision of an authorized user at a medical institution that includes—

(i) Use of iodine-131 for diagnosis of thyroid function and the treatment of hyperthyroidism or cardiac dysfunction in 10 individuals; and

(ii) Use of iodine-131 for treatment of thyroid carcinoma in 3 individuals.

§ 35.932 Training for treatment of hyperthyroidism.

Except as provided in § 35.57, the licensee shall require the authorized user of only iodine-131 for the treatment of hyperthyroidism to be a physician with special experience in thyroid disease who has had classroom and laboratory training in basic radioisotope

handling techniques applicable to the use of iodine-131 for treating hyperthyroidism, and supervised clinical experience as follows—

(a) 80 hours of classroom and laboratory training that includes—

(1) Radiation physics and instrumentation;

(2) Radiation protection,

(3) Mathematics pertaining to the use and measurement of radioactivity; and

(4) Radiation biology; and

(b) Supervised clinical experience under the supervision of an authorized user that includes the use of iodine-131 for diagnosis of thyroid function, and the treatment of hyperthyroidism in 10 individuals.

§ 35.934 Training for treatment of thyroid carcinoma.

Except as provided in § 35.57, the licensee shall require the authorized user of only iodine-131 for the treatment of thyroid carcinoma to be a physician with special experience in thyroid disease who has had classroom and laboratory training in basic radioisotope handling techniques applicable to the use of iodine-131 for treating thyroid carcinoma, and supervised clinical experience as follows—

(a) 80 hours of classroom and laboratory training that includes—

(1) Radiation physics and instrumentation;

(2) Radiation protection;

(3) Mathematics pertaining to the use and measurement of radioactivity; and

(4) Radiation biology; and

(b) Supervised clinical experience under the supervision of an authorized user that includes the use of iodine-131 for the treatment of thyroid carcinoma in 3 individuals.

§ 35.940 Training for use of brachytherapy sources.

Except as provided in § 35.57, the licensee shall require the authorized user of a brachytherapy source listed in § 35.400 for therapy to be a physician who—

(a) Is certified in—

(1) Radiology, therapeutic radiology, or radiation oncology by the American Board of Radiology;

(2) Radiation oncology by the American Osteopathic Board of Radiology;

(3) Radiology, with specialization in radiotherapy, as a British ''Fellow of the Faculty of Radiology'' or ''Fellow of the Royal College of Radiology''; or

(4) Therapeutic radiology by the Canadian Royal College of Physicians and Surgeons; or

(b) Is in the active practice of therapeutic radiology, has had classroom and laboratory training in radioisotope handling techniques applicable to the therapeutic use of brachytherapy sources, supervised work experience, and supervised clinical experience as follows—

(1) 200 hours of classroom and laboratory training that includes—

(i) Radiation physics and instrumentation;

(ii) Radiation protection;

(iii) Mathematics pertaining to the use and measurement of radioactivity; and

(iv) Radiation biology;

(2) 500 hours of supervised work experience under the supervision of an authorized user at a medical institution that includes—

(i) Ordering, receiving, and unpacking radioactive materials safely and performing the related radiation surveys;

(ii) Checking survey meters for proper operation;

(iii) Preparing, implanting, and removing sealed sources;

(iv) Maintaining running inventories of material on hand;

(v) Using administrative controls to prevent a medical event involving byproduct material; and

(vi) Using emergency procedures to control byproduct material; and

(3) Three years of supervised clinical experience that includes one year in a formal training program approved by the Residency Review Committee for Radiology of the Accreditation Council for Graduate Medical Education or the Committee on Postdoctoral Training of the American Osteopathic Association, and an additional two years of clinical experience in therapeutic radiology under the supervision of an authorized user at a medical institution that includes—

(i) Examining individuals and reviewing their case histories to determine their suitability for brachytherapy treatment, and any limitations or contraindications;

(ii) Selecting the proper brachytherapy sources and dose and method of administration;

(iii) Calculating the dose; and

(iv) Post-administration follow up and review of case histories in collaboration with the authorized user.

§ 35.941 Training for ophthalmic use of strontium-90.

Except as provided in § 35.57, the licensee shall require the authorized user of only strontium-90 for ophthalmic radiotherapy to be a physician who is in the active practice of therapeutic radiology or ophthalmology, and has had classroom and laboratory training in basic radioisotope handling techniques applicable to the use of strontium-90 for ophthalmic radiotherapy, and a period of supervised clinical training in ophthalmic radiotherapy as follows—

(a) 24 hours of classroom and laboratory training that includes—

(1) Radiation physics and instrumentation;

(2) Radiation protection;

(3) Mathematics pertaining to the use and measurement of radioactivity; and

(4) Radiation biology;

(b) Supervised clinical training in ophthalmic radiotherapy under the supervision of an authorized user at a medical institution that includes the use of strontium-90 for the ophthalmic treatment of five individuals that includes—

(1) Examination of each individual to be treated;

(2) Calculation of the dose to be administered;

(3) Administration of the dose; and

(4) Follow up and review of each individual's case history.

§ 35.950 Training for use of sealed sources for diagnosis.

Except as provided in § 35.57, the licensee shall require the authorized user of a sealed source in a device listed in § 35.500 to be a physician, dentist, or podiatrist who—

(a) Is certified in—

(1) Radiology, diagnostic radiology, therapeutic radiology, or radiation oncology by the American Board of Radiology;

(2) Nuclear medicine by the American Board of Nuclear Medicine;

(3) Diagnostic radiology or radiology by the American Osteopathic Board of Radiology; or

(4) Nuclear medicine by the Royal College of Physicians and Surgeons of Canada; or

(b) Has had 8 hours of classroom and laboratory training in basic radioisotope handling techniques specifically applicable to the use of the device that includes—

(1) Radiation physics, mathematics pertaining to the use and measurement of radioactivity, and instrumentation;

(2) Radiation biology;

(3) Radiation protection; and

(4) Training in the use of the device for the uses requested.

§ 35.960 Training for use of therapeutic medical devices.

Except as provided in § 35.57, the licensee shall require the authorized user of a sealed source listed in § 35.600 to be a physician who—

(a) Is certified in—

(1) Radiology, therapeutic radiology, or radiation oncology by the American Board of Radiology;

(2) Radiation oncology by the American Osteopathic Board of Radiology;

(3) Radiology, with specialization in radiotherapy, as a British ''Fellow of the Faculty of Radiology'' or ''Fellow of the Royal College of Radiology''; or

(4) Therapeutic radiology by the Canadian Royal College of Physicians and Surgeons; or

(b) Is in the active practice of therapeutic radiology, and has had classroom and laboratory training in basic radioisotope techniques applicable to the use of a sealed source in a therapeutic medical device, supervised work experience, and supervised clinical experience as follows—

(1) 200 hours of classroom and laboratory training that includes—

(i) Radiation physics and instrumentation;

(ii) Radiation protection;

(iii) Mathematics pertaining to the use and measurement of radioactivity; and

(iv) Radiation biology;

(2) 500 hours of supervised work experience under the supervision of an authorized user at a medical institution that includes—

(i) Review of the full calibration measurements and periodic spot-checks;

(ii) Preparing treatment plans and calculating treatment times;

(iii) Using administrative controls to prevent medical events;

(iv) Implementing emergency procedures to be followed in the event of the abnormal operation of the medical device or console; and

(v) Checking and using survey meters; and

(3) Three years of supervised clinical experience that includes one year in a formal training program approved by the Residency Review Committee for Radiology of the Accreditation Council for Graduate Medical Education or the Committee on Postdoctoral Training of the American Osteopathic Association and an additional two years of clinical experience in therapeutic radiology under the supervision of an authorized user at a medical institution that includes—

(i) Examining individuals and reviewing their case histories to determine their suitability for teletherapy, remote afterloader, or gamma stereotactic radiosurgery treatment, and any limitations or contraindications;

(ii) Selecting the proper dose and how it is to be administered;

(iii) Calculating the doses and collaborating with the authorized user in the review of patients' or human research subjects' progress and consideration of the need to modify originally prescribed doses as warranted by patients' or human research subjects' reaction to radiation; and

(iv) Post-administration follow up and review of case histories.

§ 35.961 Training for authorized medical physicist.

The licensee shall require the authorized medical physicist to be an individual who—

(a) Is certified by the American Board of Radiology in—

(1) Therapeutic radiological physics;

(2) Roentgen ray and gamma ray physics;

(3) X-ray and radium physics; or

(4) Radiological physics; or

(b) Is certified by the American Board of Medical Physics in radiation oncology physics; or

(c) Holds a master's or doctor's degree in physics, biophysics, radiological physics, or health physics, and has completed 1 year of full time training in therapeutic radiological physics and an additional year of full time work experience under the supervision of a medical physicist at a medical institution that includes the tasks listed in §§ 35.67, 35.632, 35.633, 35.635, 35.642, 35.643, 35.644, 35.645 and 35.652, as applicable.

§ 35.980 Training for an authorized nuclear pharmacist.

The licensee shall require the authorized nuclear pharmacist to be a pharmacist who—

(a) Has current board certification as a nuclear pharmacist by the Board of Pharmaceutical Specialties; or

(b)(1) Has completed 700 hours in a structured educational program consisting of both—

(i) Didactic training in the following areas:

(A) Radiation physics and instrumentation;

(B) Radiation protection;

(C) Mathematics pertaining to the use and measurement of radioactivity;

(D) Chemistry of byproduct material for medical use; and

(E) Radiation biology; and

(ii) Supervised experience in a nuclear pharmacy involving the following—

(A) Shipping, receiving, and performing related radiation surveys;

(B) Using and performing checks for proper operation of dose calibrators, survey meters, and, if appropriate, instruments used to measure alpha- or beta-emitting radionuclides;

(C) Calculating, assaying, and safely preparing dosages for patients or human research subjects;

(D) Using administrative controls to avoid mistakes in the administration of byproduct material;

(E) Using procedures to prevent or minimize contamination and using proper decontamination procedures; and

(2) Has obtained written certification, signed by a preceptor authorized nuclear pharmacist, that the above training has been satisfactorily completed and that the individual has achieved a level of competency sufficient to independently operate a nuclear pharmacy.

§ 35.981 Training for experienced nuclear pharmacists.

A licensee may apply for and must receive a license amendment identifying an experienced nuclear pharmacist as an authorized nuclear pharmacist before it allows this individual to work as an authorized nuclear pharmacist. A pharmacist who has completed a structured educational program as specified in § 35.980(b)(1) before December 2, 1994, and who is working in a nuclear pharmacy would qualify as an experienced nuclear pharmacist. An experienced nuclear pharmacist need not comply with the requirements for a preceptor statement (§ 35.980(b)(2)) and recentness of training (§ 35.59) to qualify as an authorized nuclear pharmacist.

Subpart K—Other Medical Uses of Byproduct Material or Radiation From Byproduct Material

§ 35.1000 Other medical uses of byproduct material or radiation from byproduct material.

A licensee may use byproduct material or a radiation source approved for medical use which is not specifically addressed in subparts D through H of this part if—

(a) The applicant or licensee has submitted the information required by § 35.12(b) through (d); and

(b) The applicant or licensee has received written approval from the Commission in a license or license amendment and uses the material in accordance with the regulations and specific conditions the Commission considers necessary for the medical use of the material.

Subpart L—Records

§ 35.2024 Records of authority and responsibilities for radiation protection programs.

(a) A licensee shall retain a record of actions taken by the licensee's management in accordance with § 35.24(a) for 5 years. The record must include a summary of the actions taken and a signature of licensee management.

(b) The licensee shall retain a copy of both authority, duties, and responsibilities of the Radiation Safety Officer as required by § 35.24(e), and a signed copy of each Radiation Safety Officer's agreement to be responsible for implementing the radiation safety program, as required by § 35.24(b), for the duration of the license. The records must include the signature of the Radiation Safety Officer and licensee management.

§ 35.2026 Records of radiation protection program changes.

A licensee shall retain a record of each radiation protection program change made in accordance with § 35.26(a) for 5 years. The record must include a copy of the old and new procedures; the effective date of the change; and the signature of the licensee management that reviewed and approved the change.

§ 35.2040 Records of written directives.

A licensee shall retain a copy of each written directive as required by § 35.40 for 3 years.

§ 35.2041 Records for procedures for administrations requiring a written directive

A licensee shall retain a copy of the procedures required by § 35.41(a) for the duration of the license.

§ 35.2060 Records of calibrations of instruments used to measure the activity of unsealed byproduct material.

A licensee shall maintain a record of instrument calibrations required by § 35.60 for 3 years. The records must include the model and serial number of the instrument, the date of the calibration, the results of the calibration, and the name of the individual who performed the calibration.

§ 35.2061 Records of radiation survey instrument calibrations.

A licensee shall maintain a record of radiation survey instrument calibrations required by § 35.61 for 3 years. The record must include the model and serial number of the instrument, the date of the calibration, the results of the calibration, and the name of the individual who performed the calibration.

§ 35.2063 Records of dosages of unsealed byproduct material for medical use.

(a) A licensee shall maintain a record of dosage determinations required by § 35.63 for 3 years.

(b) The record must contain—

(1) The radiopharmaceutical;

(2) The patient's or human research subject's name, or identification number if one has been assigned;

(3) The prescribed dosage, the determined dosage, or a notation that the total activity is less than 1.1 MBq (30 μCi);

(4) The date and time of the dosage determination; and

(5) The name of the individual who determined the dosage.

§ 35.2067 Records of leaks tests and inventory of sealed sources and brachytherapy sources.

(a) A licensee shall retain records of leak tests required by § 35.67(b) for 3 years. The records must include the model number, and serial number if one has been assigned, of each source tested; the identity of each source by radionuclide and its estimated activity; the results of the test; the date of the test; and the name of the individual who performed the test.

(b) A licensee shall retain records of the semi-annual physical inventory of sealed sources and brachytherapy sources required by § 35.67(g) for 3 years. The inventory records must contain the model number of each source, and serial number if one has been assigned, the identity of each source by radionuclide and its nominal activity, the location of each source, and the name of the individual who performed the inventory.

§ 35.2070 Records of surveys for ambient radiation exposure rate.

A licensee shall retain a record of each survey required by § 35.70 for 3 years. The record must include the date of the survey, the results of the survey, the instrument used to make the survey, and the name of the individual who performed the survey.

§ 35.2075 Records of the release of individuals containing unsealed byproduct material or implants containing byproduct material.

(a) A licensee shall retain a record of the basis for authorizing the release of an individual in accordance with § 35.75, if the total effective dose equivalent is calculated by—

(1) Using the retained activity rather than the activity administered;

(2) Using an occupancy factor less than 0.25 at 1 meter;

(3) Using the biological or effective half-life; or

(4) Considering the shielding by tissue.

(b) A licensee shall retain a record that the instructions required by § 35.75(b) were provided to a breast-feeding female if the radiation dose to the infant or child from continued breast-feeding could result in a total effective dose equivalent exceeding 5 mSv (0.5 rem).

(c) The records required by paragraphs (a) and (b) of this section must be retained for 3 years after the date of release of the individual.

§ 35.2080 Records of mobile medical services.

(a) A licensee shall retain a copy of each letter that permits the use of byproduct material at a client's address, as required by § 35.80(a)(1). Each letter must clearly delineate the authority and responsibility of the licensee and the client and must be retained for 3 years after the last provision of service.

(b) A licensee shall retain the record of each survey required by § 35.80(a)(4) for 3 years. The record must include the date of the survey, the results of the survey, the instrument used to make the survey, and the name of the individual who performed the survey.

§ 35.2092 Records of decay-in-storage.

A licensee shall maintain records of the disposal of licensed materials, as required by § 35.92, for 3 years. The record must include the date of the disposal, the survey instrument used, the background radiation level, the radiation level measured at the surface of each waste container, and the name of the individual who performed the survey.

§ 35.2204 Records of molybdenum-99 concentrations.

A licensee shall maintain a record of the molybdenum-99 concentration tests required by § 35.204(b) for 3 years. The record must include, for each measured elution of technetium-99m, the ratio of the measures expressed as kilobecquerel of molybdenum-99 per megabecquerel of technetium-99m (or microcuries of molybdenum per millicurie of technetium), the time and date of the measurement, and the name of the individual who made the measurement.

§ 35.2310 Records of safety instruction.

A licensee shall maintain a record of safety instructions required by §§ 35.310, 35.410, and 35.610 for 3 years. The record must include a list of the topics covered, the date of the instruction, the name(s) of the attendee(s), and the name(s) of the individual(s) who provided the instruction.

§ 35.2404 Records of surveys after source implant and removal.

A licensee shall maintain a record of the surveys required by §§ 35.404 and 35.604 for 3 years. Each record must include the date and results of the survey, the survey instrument used, and the name of the individual who made the survey.

§ 35.2406 Records of brachytherapy source accountability.

(a) A licensee shall maintain a record of brachytherapy source accountability required by § 35.406 for 3 years.

(b) For temporary implants, the record must include—

(1) The number and activity of sources removed from storage, the time and date they were removed from storage, the name of the individual who removed them from storage, and the location of use; and

(2) The number and activity of sources returned to storage, the time and date they were returned to storage, and the name of the individual who returned them to storage.

(c) For permanent implants, the record must include—

(1) The number and activity of sources removed from storage, the date they were removed from storage, and the name of the individual who removed them from storage;

(2) The number and activity of sources not implanted, the date they were returned to storage, and the name of the individual who returned them to storage; and

(3) The number and activity of sources permanently implanted in the patient or human research subject.

§ 35.2432 Records of calibration measurements of brachytherapy sources.

(a) A licensee shall maintain a record of the calibrations of brachytherapy sources required by § 35.432 for 3 years after the last use of the source.

(b) The record must include—

(1) The date of the calibration;

(2) The manufacturer's name, model number, and serial number for the source and the instruments used to calibrate the source;

(3) The source output or activity;

(4) The source positioning accuracy within the applicators; and

(5) The signature of the authorized medical physicist.

§ 35.2433 Records of decay of strontium-90 sources for ophthalmic treatments.

(a) A licensee shall maintain a record of the activity of a strontium-90 source required by § 35.433 for the life of the source.

(b) The record must include—

(1) The date and initial activity of the source as determined under § 35.432; and

(2) For each decay calculation, the date and the source activity as determined under § 35.433.

§ 35.2605 Records of installation, maintenance, adjustment, and repair of remote afterloader units, teletherapy units, and gamma stereotactic radiosurgery units.

A licensee shall retain a record of the installation, maintenance, adjustment, and repair of remote afterloader units, teletherapy units, and gamma stereotactic radiosurgery units as required by § 35.605 for 3 years. For each installation, maintenance, adjustment and repair, the record must include the date, description of the service, and name(s) of the individual(s) who performed the work.

§ 35.2610 Records of safety procedures.

A licensee shall retain a copy of the procedures required by §§ 35.610(a)(4) and (d)(2) until the licensee no longer possesses the remote afterloader, teletherapy unit, or gamma stereotactic radiosurgery unit.

§ 35.2630 Records of dosimetry equipment used with remote afterloader units, teletherapy units, and gamma stereotactic radiosurgery units.

(a) A licensee shall retain a record of the calibration, intercomparison, and comparisons of its dosimetry equipment done in accordance with § 35.630 for the duration of the license.

(b) For each calibration, intercomparison, or comparison, the record must include—

(1) The date;

(2) The manufacturer's name, model numbers and serial numbers of the instruments that were calibrated, intercompared, or compared as required by paragraphs (a) and (b) of § 35.630;

(3) The correction factor that was determined from the calibration or comparison or the apparent correction factor that was determined from an intercomparison; and

(4) The names of the individuals who performed the calibration, intercomparison, or comparison.

§ 35.2632 Records of teletherapy, remote afterloader, and gamma stereotactic radiosurgery full calibrations.

(a) A licensee shall maintain a record of the teletherapy unit, remote afterloader unit, and gamma stereotactic radiosurgery unit full calibrations required by §§ 35.632, 35.633, and 35.635 for 3 years.

(b) The record must include—

(1) The date of the calibration;

(2) The manufacturer's name, model number, and serial number of the teletherapy, remote afterloader, and gamma stereotactic radiosurgery unit(s), the source(s), and the instruments used to calibrate the unit(s);

(3) The results and an assessment of the full calibrations;

(4) The results of the autoradiograph required for low dose-rate remote afterloader units; and

(5) The signature of the authorized medical physicist who performed the full calibration.

§ 35.2642 Records of periodic spot-checks for teletherapy units.

(a) A licensee shall retain a record of each periodic spot-check for teletherapy units required by § 35.642 for 3 years.

(b) The record must include—

(1) The date of the spot-check;

(2) The manufacturer's name, model number, and serial number of the teletherapy unit, source and instrument used to measure the output of the teletherapy unit;

(3) An assessment of timer linearity and constancy;

(4) The calculated on-off error;

(5) A determination of the coincidence of the radiation field and the field indicated by the light beam localizing device;

(6) The determined accuracy of each distance measuring and localization device;

(7) The difference between the anticipated output and the measured output;

(8) Notations indicating the operability of each entrance door electrical interlock, each electrical or mechanical stop, each source exposure indicator light, and the viewing and intercom system and doors; and

(9) The name of the individual who performed the periodic spot-check and the signature of the authorized medical physicist who reviewed the record of the spot-check.

(c) A licensee shall retain a copy of the procedures required by § 35.642(b) until the licensee no longer possesses the teletherapy unit.

§ 35.2643 Records of periodic spot-checks for remote afterloader units.

(a) A licensee shall retain a record of each spot-check for remote afterloader units required by § 35.643 for 3 years.

(b) The record must include, as applicable—

(1) The date of the spot-check;

(2) The manufacturer's name, model number, and serial number for the remote afterloader unit and source;

(3) An assessment of timer accuracy;

(4) Notations indicating the operability of each entrance door electrical interlock, radiation monitors, source exposure indicator lights, viewing and intercom systems, and clock and decayed source activity in the unit's computer; and

(5) The name of the individual who performed the periodic spot-check and

the signature of the authorized medical physicist who reviewed the record of the spot-check.

(c) A licensee shall retain a copy of the procedures required by § 35.643(b) until the licensee no longer possesses the remote afterloader unit.

§ 35.2645 Records of periodic spot-checks for gamma stereotactic radiosurgery units.

(a) A licensee shall retain a record of each spot-check for gamma stereotactic radiosurgery units required by § 35.645 for 3 years.

(b) The record must include—

(1) The date of the spot-check;

(2) The manufacturer's name, model number, and serial number for the gamma stereotactic radiosurgery unit and the instrument used to measure the output of the unit;

(3) An assessment of timer linearity and accuracy;

(4) The calculated on-off error;

(5) A determination of trunnion centricity;

(6) The difference between the anticipated output and the measured output;

(7) An assessment of source output against computer calculations;

(8) Notations indicating the operability of radiation monitors, helmet microswitches, emergency timing circuits, emergency off buttons, electrical interlocks, source exposure indicator lights, viewing and intercom systems, timer termination, treatment table retraction mechanism, and stereotactic frames and localizing devices (trunnions); and

(9) The name of the individual who performed the periodic spot-check and the signature of the authorized medical physicist who reviewed the record of the spot-check.

(c) A licensee shall retain a copy of the procedures required by § 35.645(b) until the licensee no longer possesses the gamma stereotactic radiosurgery unit.

§ 35.2647 Records of additional technical requirements for mobile remote afterloader units.

(a) A licensee shall retain a record of each check for mobile remote afterloader units required by § 35.647 for 3 years.

(b) The record must include—

(1) The date of the check;

(2) The manufacturer's name, model number, and serial number of the remote afterloader unit;

(3) Notations accounting for all sources before the licensee departs from a facility;

(4) Notations indicating the operability of each entrance door electrical interlock, radiation monitors, source exposure indicator lights, viewing and intercom system, applicators, source transfer tubes, and transfer tube applicator interfaces, and source positioning accuracy; and

(5) The signature of the individual who performed the check.

§ 35.2652 Records of surveys of therapeutic treatment units.

(a) A licensee shall maintain a record of radiation surveys of treatment units made in accordance with § 35.652 for the duration of use of the unit.

(b) The record must include—

(1) The date of the measurements;

(2) The manufacturer's name, model number and serial number of the treatment unit, source, and instrument used to measure radiation levels;

(3) Each dose rate measured around the source while the unit is in the off position and the average of all measurements; and

(4) The signature of the individual who performed the test.

§ 35.2655 Records of 5-year inspection for teletherapy and gamma stereotactic radiosurgery units.

(a) A licensee shall maintain a record of the 5-year inspections for teletherapy and gamma stereotactic radiosurgery units required by § 35.655 for the duration of use of the unit.

(b) The record must contain—

(1) The inspector's radioactive materials license number;

(2) The date of inspection;

(3) The manufacturer's name and model number and serial number of both the treatment unit and source;

(4) A list of components inspected and serviced, and the type of service; and

(5) The signature of the inspector.

Subpart M—Reports

§ 35.3045 Report and notification of a medical event.

(a) A licensee shall report any event, except for an event that results from patient intervention, in which the administration of byproduct material or radiation from byproduct material results in—

(1) A dose that differs from the prescribed dose or dose that would have resulted from the prescribed dosage by more than 0.05 Sv (5 rem) effective dose equivalent, 0.5 Sv (50 rem) to an organ or tissue, or 0.5 Sv (50 rem) shallow dose equivalent to the skin; and

(i) The total dose delivered differs from the prescribed dose by 20 percent or more;

(ii) The total dosage delivered differs from the prescribed dosage by 20 percent or more or falls outside the prescribed dosage range; or

(iii) The fractionated dose delivered differs from the prescribed dose, for a single fraction, by 50 percent or more.

(2) A dose that exceeds 0.05 Sv (5 rem) effective dose equivalent, 0.5 Sv (50 rem) to an organ or tissue, or 0.5 Sv (50 rem) shallow dose equivalent to the skin from any of the following—

(i) An administration of a wrong radioactive drug containing byproduct material;

(ii) An administration of a radioactive drug containing byproduct material by the wrong route of administration;

(iii) An administration of a dose or dosage to the wrong individual or human research subject;

(iv) An administration of a dose or dosage delivered by the wrong mode of treatment; or

(v) A leaking sealed source.

(3) A dose to the skin or an organ or tissue other than the treatment site that exceeds by 0.5 Sv (50 rem) to an organ or tissue and 50 percent or more of the dose expected from the administration defined in the written directive (excluding, for permanent implants, seeds that were implanted in the correct site but migrated outside the treatment site).

(b) A licensee shall report any event resulting from intervention of a patient or human research subject in which the administration of byproduct material or radiation from byproduct material results or will result in unintended permanent functional damage to an organ or a physiological system, as determined by a physician.

(c) The licensee shall notify by telephone the NRC Operations Center [3] no later than the next calendar day after discovery of the medical event.

(d) The licensee shall submit a written report to the appropriate NRC Regional Office listed in § 30.6 of this chapter within 15 days after discovery of the medical event.

(1) The written report must include—

(i) The licensee's name;

(ii) The name of the prescribing physician;

(iii) A brief description of the event;

(iv) Why the event occurred;

(v) The effect, if any, on the individual(s) who received the administration;

(vi) What actions, if any, have been taken or are planned to prevent recurrence; and

(vii) Certification that the licensee notified the individual (or the individual's responsible relative or guardian), and if not, why not.

[3] The commercial telephone number of the NRC Operations Center is (301) 951–0550.

(2) The report may not contain the individual's name or any other information that could lead to identification of the individual.

(e) The licensee shall provide notification of the event to the referring physician and also notify the individual who is the subject of the medical event no later than 24 hours after its discovery, unless the referring physician personally informs the licensee either that he or she will inform the individual or that, based on medical judgment, telling the individual would be harmful. The licensee is not required to notify the individual without first consulting the referring physician. If the referring physician or the affected individual cannot be reached within 24 hours, the licensee shall notify the individual as soon as possible thereafter. The licensee may not delay any appropriate medical care for the individual, including any necessary remedial care as a result of the medical event, because of any delay in notification. To meet the requirements of this paragraph, the notification of the individual who is the subject of the medical event may be made instead to that individual's responsible relative or guardian. If a verbal notification is made, the licensee shall inform the individual, or appropriate responsible relative or guardian, that a written description of the event can be obtained from the licensee upon request. The licensee shall provide such a written description if requested.

(f) Aside from the notification requirement, nothing in this section affects any rights or duties of licensees and physicians in relation to each other, to individuals affected by the medical event, or to that individual's responsible relatives or guardians.

(g) A licensee shall:

(1) Annotate a copy of the report provided to the NRC with the:

(i) Name of the individual who is the subject of the event; and

(ii) Social security number or other identification number, if one has been assigned, of the individual who is the subject of the event; and

(2) Provide a copy of the annotated report to the referring physician, if other than the licensee, no later than 15 days after the discovery of the event.

§ 35.3047 Report and notification of a dose to an embryo/fetus or a nursing child.

(a) A licensee shall report any dose to an embryo/fetus that is greater than 50 mSv (5 rem) dose equivalent that is a result of an administration of byproduct material or radiation from byproduct material to a pregnant individual unless the dose to the embryo/fetus was specifically approved, in advance, by the authorized user.

(b) A licensee shall report any dose to a nursing child that is a result of an administration of byproduct material to a breast-feeding individual that—

(1) Is greater than 50 mSv (5 rem) total effective dose equivalent; or

(2) Has resulted in unintended permanent functional damage to an organ or a physiological system of the child, as determined by a physician.

(c) The licensee shall notify by telephone the NRC Operations Center no later than the next calendar day after discovery of a dose to the embryo/fetus or nursing child that requires a report in paragraphs (a) or (b) in this section.

(d) The licensee shall submit a written report to the appropriate NRC Regional Office listed in § 30.6 of this chapter within 15 days after discovery of a dose to the embryo/fetus or nursing child that requires a report in paragraphs (a) or (b) in this section.

(1) The written report must include—

(i) The licensee's name;

(ii) The name of the prescribing physician;

(iii) A brief description of the event;

(iv) Why the event occurred;

(v) The effect, if any, on the embryo/fetus or the nursing child;

(vi) What actions, if any, have been taken or are planned to prevent recurrence; and

(vii) Certification that the licensee notified the pregnant individual or mother (or the mother's or child's responsible relative or guardian), and if not, why not.

(2) The report must not contain the individual's or child's name or any other information that could lead to identification of the individual or child.

(e) The licensee shall provide notification of the event to the referring physician and also notify the pregnant individual or mother, both hereafter referred to as the mother, no later than 24 hours after discovery of an event that would require reporting under paragraph (a) or (b) of this section, unless the referring physician personally informs the licensee either that he or she will inform the mother or that, based on medical judgment, telling the mother would be harmful. The licensee is not required to notify the mother without first consulting with the referring physician. If the referring physician or mother cannot be reached within 24 hours, the licensee shall make the appropriate notifications as soon as possible thereafter. The licensee may not delay any appropriate medical care for the embryo/fetus or for the nursing child, including any necessary remedial care as a result of the event, because of any delay in notification. To meet the requirements of this paragraph, the notification may be made to the mother's or child's responsible relative or guardian instead of the mother. If a verbal notification is made, the licensee shall inform the mother, or the mother's or child's responsible relative or guardian, that a written description of the event can be obtained from the licensee upon request. The licensee shall provide such a written description if requested.

(f) A licensee shall:

(1) Annotate a copy of the report provided to the NRC with the:

(i) Name of the pregnant individual or the nursing child who is the subject of the event; and

(ii) Social security number or other identification number, if one has been assigned, of the pregnant individual or the nursing child who is the subject of the event; and

(2) Provide a copy of the annotated report to the referring physician, if other than the licensee, no later than 15 days after the discovery of the event.

§ 35.3067 Report of a leaking source.

A licensee shall file a report within 5 days if a leak test required by § 35.67 reveals the presence of 185 Bq (0.005 μCi) or more of removable contamination. The report must be filed with the appropriate NRC Regional Office listed in § 30.6 of this chapter, with a copy to the Director, Office of Nuclear Material Safety and Safeguards, U.S. Nuclear Regulatory Commission, Washington, DC 20555–0001. The written report must include the model number and serial number if assigned, of the leaking source; the radionuclide and its estimated activity; the results of the test; the date of the test; and the action taken.

Subpart N—Enforcement

§ 35.4001 Violations.

(a) The Commission may obtain an injunction or other court order to prevent a violation of the provisions of—

(1) The Atomic Energy Act of 1954, as amended;

(2) Title II of the Energy Reorganization Act of 1974, as amended; or

(3) A regulation or order issued under those Acts.

(b) The Commission may obtain a court order for the payment of a civil penalty imposed under Section 234 of the Atomic Energy Act:

(1) For violations of—

(i) Sections 53, 57, 62, 63, 81, 82, 101, 103, 104, 107, or 109 of the Atomic Energy Act of 1954, as amended;

(ii) Section 206 of the Energy Reorganization Act;

(iii) Any rule, regulation, or order issued under the sections specified in paragraph (b)(1)(i) of this section;

(iv) Any term, condition, or limitation of any license issued under the sections specified in paragraph (b)(1)(i) of this section.

(2) For any violation for which a license may be revoked under Section 186 of the Atomic Energy Act of 1954, as amended.

§ 35.4002 Criminal penalties.

(a) Section 223 of the Atomic Energy Act of 1954, as amended, provides for criminal sanctions for willful violation of, attempted violation of, or conspiracy to violate, any regulation issued under sections 161b, 161i, or 161o of the Act. For purposes of Section 223, all the regulations in 10 CFR part 35 are issued under one or more of sections 161b, 161i, or 161o, except for the sections listed in paragraph (b) of this section.

(b) The regulations in 10 CFR part 35 that are not issued under subsections 161b, 161i, or 161o for the purposes of Section 223 are as follows: §§ 35.1, 35.2, 35.7, 35.8, 35.12, 35.15, 35.18, 35.19, 35.65, 35.100, 35.200, 35.300, 35.4001, and 35.4002.

Dated at Rockville, Maryland, this 16th day of April, 2002.

For the Nuclear Regulatory Commission.

Annette L. Vietti-Cook,

Secretary of the Commission.

[FR Doc. 02–9663 Filed 4–23–02; 8:45 am]

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Federal Register

Wednesday,
April 24, 2002

Part IV

Housing and Urban Development Department

24 CFR Part 3280

Condensation Control for Exterior Walls of Manufactured Homes Sited in Humid and Fringe Climates; Waiver; Final Rule

DEPARTMENT OF HOUSING AND URBAN DEVELOPMENT

24 CFR Part 3280

[Docket No. FR–4578–F–02]

Condensation Control for Exterior Walls of Manufactured Homes Sited in Humid and Fringe Climates; Waiver

AGENCY: Office of the Assistant Secretary for Housing—Federal Housing Commissioner, HUD.

ACTION: Final waiver.

SUMMARY: This document advises the public that HUD is issuing a waiver of its regulations regarding the condensation control provisions for exterior walls of the manufactured home construction and safety standards. By this action, HUD is waiving certain provisions of these regulations to permit manufacturers, at their option, to utilize the alternatives provided in this notice to reduce the problems currently being experienced in humid and fringe climate areas. Presently, there are no provisions in HUD's regulations that separately address condensation control and vapor retarder requirements for manufactured homes sited in warm, moist climates of the South Atlantic and Gulf Regions. Based on information provided by the States and the public, HUD has concluded there is an immediate need to recognize alternate requirements for exterior walls in these humid and fringe climate areas that help prevent moisture damage due to condensation. By this action, HUD is finalizing its previously announced proposed waiver. This waiver will be in place while HUD considers a more permanent change to the standards.

EFFECTIVE DATE: April 24, 2002.

FOR FURTHER INFORMATION CONTACT: Elizabeth A. Cocke, Director, Manufactured Housing and Standards Division, Office of Consumer and Regulatory Affairs, Room 9156, Department of Housing and Urban Development, 451 Seventh Street SW, Washington, DC 20410–8000; telephone (202) 708–6409 (this is not a toll-free telephone number). Hearing and speech-impaired individuals may access this telephone number via TTY by calling the toll-free Federal Information Relay Service at 1–800–877–8339.

SUPPLEMENTARY INFORMATION:

I. Background

The Department published a proposed waiver to 24 CFR 3280.504 of the Manufactured Home Construction and Safety Standards on March 30, 2000 (65 FR 17110). The proposed waiver was issued in response to information received from manufacturers and certain State Administrative Agencies (SAAs) in southeastern States concerning a recent increase in the number and severity of consumer complaints caused primarily by moisture build-up and condensation in homes located in the south. They suggest this increase in complaints coincides with the Department's implementing more stringent energy efficiency requirements in its regulations regarding manufactured home construction and safety standards located at 24 CFR part 3280 (referred to as the ''Standards'').

At present, § 3280.504 of the Standards does not distinguish among climates for requirements for condensation control and installation of vapor barriers. [The term ''vapor barrier'' is now commonly referred to as a ''vapor retarder''. Accordingly, the term ''vapor retarder'' will be used in all subsequent references throughout the text of this waiver.] Thus, for example, the Standards do not separately address homes placed in humid and fringe environments or climates, which are predominantly located in the southeastern part of the United States. In these climates, it may be beneficial to prevent the outside, moisture-laden air from entering through the warm (exterior) side of the home's exterior wall and condensing and collecting on the cold (living space or interior) side of the wall assembly. One means of preventing moisture from entering the exterior wall cavity from the outside, would be to install a vapor retarder on the warm or exterior side of the wall instead of on the interior or living space side of the exterior wall.

The interior surface of the exterior wall should also then be constructed of a permeable material. This would permit any moisture-laden air that may have entered the wall cavity through a discontinuity in the exterior vapor retarder to be dissipated through the interior permeable material. In such cases, use of vapor retarder paints, vinyl-covered gypsum wallboard, or other impermeable materials or finishes on the interior side of exterior walls could be detrimental, because they would trap moisture within the wall.

II. This Waiver

To address these concerns, HUD is issuing a waiver that applies to the first of the alternatives available under § 3280.504(b), the current condensation control and vapor barrier installation requirements for exterior walls in humid and fringe climates. Specifically, this waiver allows manufacturers of homes for humid and fringe climates to install the vapor retarder on the exterior side, rather than the interior or living space side, of the exterior wall, provided: (1) The exterior side of the exterior wall is constructed with a vapor retarder or exterior covering and sheathing that has a permeance not greater than 1.0 perm; and (2) the interior finish and interior wall panels are designed with a 5 perm or higher rating. The waiver also requires manufacturers to add a statement and a map to the data plate indicating that the home is only suitable for installation in humid and fringe climates (the map designates the acceptable locations for which the waiver is applicable).

III. The National Fire Protection Association (NFPA) Recommendations

Previously, HUD designated NFPA as the organization to undertake a voluntary consensus process to assist the Department in developing recommendations for new manufactured housing standards. Participants in the NFPA process met in December 1999 to discuss comments received on recommended standards changes. One such recommendation involved changes to HUD's regulation in § 3280.504(b)(1) for homes sited in ''humid climates'' or ''fringe climates'' as set forth in figure 16, in Chapter 21 of the 1989 American Society of Heating, Refrigerating, and Air-Conditioning Engineers (ASHRAE) Handbook of Fundamentals. (The Humid and Fringe Climate Map being utilized in this waiver is based on ASHRAE's figure 16.) HUD received the preliminary results of the consensus process deliberations, and the NFPA recommendations have been considered in preparing this final waiver.

The Department expects that recommendations received from the NFPA, research, field data obtained from the use of this waiver, and other information will be available for considering whether to effectuate changes to the standards of a more permanent nature. Any such change would first be reviewed by the Department and the new consensus committee to be established pursuant to section 604 of the Manufactured Housing Improvement Act of 2000(Pub. L.106–569, 114 Stat. 2944, approved December 27, 2000). A proposed rule would then be published for public comment.

IV. Analysis of Public Comments and Other Information Received

The public comments received in response to the proposed waiver ranged from support for the proposal, to suggestions for revising the proposal, to out-right rejection of its provisions. In

general, those who did not favor the proposal indicated that the waiver did not go far enough since it did not address the larger issues of air leakage and transport of moisture-laden or humid air into exterior wall cavities. Two commenters, referencing or quoting the 1993 ASHRAE Handbook of Fundamentals, suggested that while the amount of water deposited in wall or roof spaces by air currents or pressure diffusion cannot be calculated with certainty, under some conditions that amount of water can result in several times the amount of moisture that would be caused by other means, such as vapor diffusion.

While the Department agrees with the concerns raised in the comments, it also believes the waiver provides a partial solution for reducing the extent and number of moisture problems being experienced in Southern climates. Manufacturers who chose to take advantage of the waiver are reminded that it does not consider the larger transport of moisture by air leakage, and that their designs and construction in hot-humid climates also need to address those concerns. Among the strategies manufacturers should consider are: use of exterior air barriers; prevention of air leakage from supply duct systems and other penetrations causing negative pressurization of the home; avoiding use of oversized cooling equipment; and use of balanced mechanical ventilation systems. Complying with the provisions of the waiver does not relieve manufacturers of their responsibilities to use construction methods that result in ''durable, livable, and safe housing'' as required by 24 CFR 3280.303(b) of the Standards.

Several commenters agreed that an effectively located, good quality vapor retarder could eliminate condensation caused by vapor diffusion (differences in vapor pressure). However, the waiver also requires the interior wall surface to be permeable so that any moisture that does become deposited within the space is not trapped by having an impermeable surface, such as vinyl-covered gypsum panels, on the living space side of the wall.

The NFPA and another commenter recommended that a combined 5-perm rating be used instead of the 3 perm rating suggested in the proposed waiver. HUD agreed with this recommendation since there was no technical basis to support the lower perm rating in recognized engineering manuals, and the final waiver has been revised to require interior finish and wall panel materials to have a combined vapor permeance greater than 5.0 perms. Also, the Manufactured Housing Institute (MHI) collaborated with the Manufactured Home Research Alliance (MHRA) to test commonly used generic interior finish and wall panel designs to determine if they complied with the combined interior perm rating criteria in the proposed waiver. The results of the testing indicate that compliance with the higher perm rating would easily be achieved. Further, based on the Department's review of the MHI test results (submitted to amend MHI's original comments), the Department will not require testing of gypsum panels (textured or non-textured) that are finished or laminated with acrylic or latex paint or non-vinyl decorative wall paper to demonstrate the panels comply with the 5-perm minimum rating; these combinations of interior finish will be deemed to provide an acceptable level of performance.

One State Agency expressed concern about enforcing different provisions for condensation control for the limited geographic area of the State subject to the Waiver. Two commenters were concerned about potential hardships in relocating homes built under the waiver to cold climate areas for which the homes were not suited. However, those concerns are no different than for other geographic-based requirements in the Standards, such as those for thermal, wind, or roof-load protection. Therefore, the Department has not made any changes based on these comments.

Some commenters also suggested there is authority under the current Standards to permit the vapor retarder to be located on the exterior side of the wall. These commenters assert the 1989 ASHRAE Handbook of Fundamentals recognizes this practice and is incorporated by reference into the Standards. The Department does not agree that all provisions of the 1989 ASHRAE have been incorporated by reference, but to the extent they have been incorporated, the requirements of the Standards govern whenever the provisions of the 1989 ASHRAE Handbook are inconsistent with the requirements of the Standards. In addition, Interpretative Bulletin F–1–76 is not appropriate for these circumstances as it was intended to clarify requirements for cold climates, where vapor diffusion would occur from the interior to the exterior of the home and not vice-versa. As such, IB F–1–76 is applicable to the requirements in § 3280.504(b)(2), rather than § 3280.504(b)(1), the provision to which this waiver is applicable.

The Department did not accept a further recommendation of MHI and another commenter to exempt certain construction (kitchen back splash materials, bathroom tub and shower compartments, cabinetry and built-in furniture, and hardwood plywood paneling under chair rail areas) from the combined interior perm requirement, because the Department does not have technical data to support their proposal.

The Department also did not accept the commenters' recommendation to combine and simplify the ''humid'' and ''fringe'' designations on the map into one area, as both the ASHRAE Handbook of Fundamentals and the NFPA 501 Standard on Manufactured Housing refer to them as two distinct areas in their maps.

In view of all of the above, HUD is issuing this final waiver, but reminds manufacturers that additional measures are likely needed in the design and construction of their homes to sufficiently abate the moisture problems in hot, humid climates and, therefore, comply with other requirements in the Standards.

V. Alternative Methods

This waiver is not intended to limit alternate approaches by manufactured home producers in assuring that homes built and sited in humid and fringe climates are durable and free of moisture-related problems. Other methods of moisture control that do not meet the Standards or the conditions of this waiver may be submitted for review and consideration in accordance with 24 CFR 3282.14 (entitled ''Alternate Construction of Manufactured Homes'').

VI. Final Waiver

In accordance with 24 CFR 3280.8 and 42 U.S.C. 3535(q), the Secretary hereby waives, subject to certain conditions, the specific requirements of 24 CFR 3280.504(b)(1) for homes to be sited in humid or fringe climate areas as identified in section V.F of this waiver. Manufacturers who elect to utilize the alternative permitted under this waiver, rather than to follow the existing requirements in 24 CFR 3280.504(b)(1), must produce homes in accordance with the following requirements (all other requirements of the Standards also continue to apply):

A. Exterior walls must be constructed with one of the following installed on the exterior side of the wall assembly: (1) A vapor retarder of not greater than 1.0 perm when measured and tested in accordance with ASTM E–96–93, Standard Test Methods for Water Vapor Transmission of Materials (dry cup method); or (2) an external covering and sheathing with a combined permeance of not greater than 1.0 perm.

B. The interior finish and interior wall panel materials must have a combined

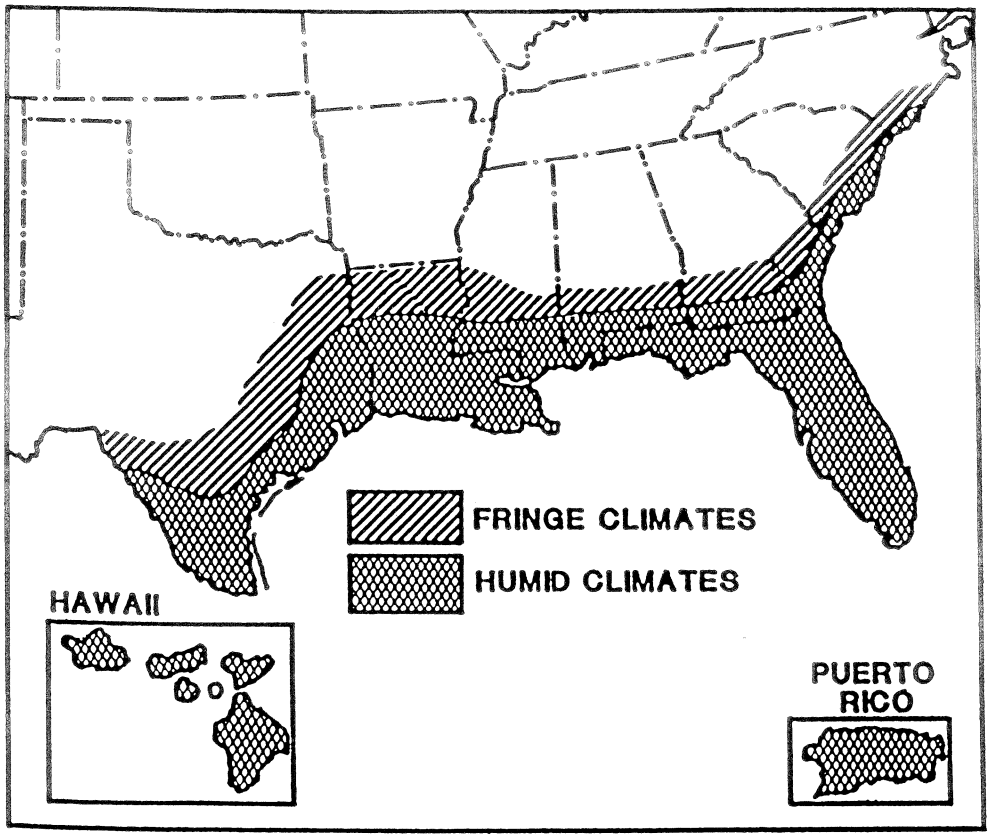
vapor permeance greater than 5.0 perm (dry cup method). Gypsum wall panels (textured or non-textured) that are finished or laminated with acrylic or latex paint or non-vinyl decorative wallpaper need not be tested to establish their compliance with the 5.0 perm combined vapor permeance requirement. Other interior finish and wall panel materials, such as vapor retarder paint, vinyl-covered gypsum wall panels, and other impermeable interior surfaces and finishes, must be demonstrated to have a combined rating greater than 5.0 perm (dry cup method) or they are prohibited.

C. Exterior wall cavities shall not be ventilated to the outdoors.

D. An additional statement shall be provided on the data plate required by 24 CFR 3280.5, to read as follows: ''As designed and constructed, this home is suitable for installation only in humid and fringe climates as shown on the Humid and Fringe Climate Map provided with this data plate.'' The statement is to be typed in bold face using letters at least ¼ inch in size.

E. A reproduction of the following Humid and Fringe Climate Map is to be provided on the data plate. The map shall not be less than 3½ in. by 2¼ in. in size.

Humid and Fringe Climate Map



F. The following areas of local governments (counties or similar areas, unless otherwise specified), listed by State, are deemed to be within the humid and fringe climate areas shown on the Humid and Fringe Climate Map, and this waiver may be applied to homes built to be sited within these jurisdictions:

Alabama

Baldwin, Barbour, Bullock, Butler, Chootaw, Clarke, Cofee, Conecuh, Covington, Crenshaw, Dale, Escambia, Geneva, Henry, Houston, Lowndes, Marengo, Mobile, Monroe, Montgomery, Pike, Washington, Wilcox

Florida

All counties and locations within the State of Florida.

Georgia

Appling, Atkinson, Bacon, Baker, Ben Hill, Berrien, Brantley, Brooks, Bryan, Calhoun, Camden, Charlton, Chatham, Clay, Clinch, Coffee, Colquitt, Cook, Crisp, Decatur, Dougherty, Early, Echols, Effingham, Evans, Glynn, Wayne, Grady, Irwin, Jeff Davis, Lanier, Lee, Liberty, Long, Lowndes, McIntosh, Miller, Mitchell, Pierce, Quitman, Randolph, Seminole, Tattnall, Terrell, Thomas, Tift, Turner, Ware, Worth

Louisiana

All counties and locations within the State of Louisiana.

Mississippi

Adams, Amite, Clairborne, Clarke, Copiah, Covington, Forrest, Franklin, George, Greene, Hancock, Harrison, Hinds, Issaquena, Jackson, Jasper, Jefferson, Jefferson Davis, Jones, Lamar, Lawrence, Lincoln, Pearl River, Perry, Pike, Rankin, Simpson, Smith, Stone, Walthall, Warren, Wayne, Wilkinson

North Carolina

Brunswick, Carteret, Columbus, New Hanover, Onslow, Pender

South Carolina

Jasper, Beaufort, Colleton, Dorchester, Charleston, Berkeley, Georgetown, Horry

Texas

Anderson, Angelina, Aransas, Atascosa, Austin, Bastrop, Bee, Bexar, Brazoria, Brazos, Brooks, Burleson, Caldwell, Calhoun, Cameron, Camp, Cass, Chambers, Cherokee, Colorado, Comal, De Witt, Dimmit, Duval, Falls, Fayette, Fort Bend, Franklin, Freestone, Frio, Gavelston, Goliad, Gonzales, Gregg, Grimes, Guadalupe, Hardin, Harris, Harrison, Hays, Henderson, Hidalgo, Hopkins, Houston, Jackson, Jasper, Jefferson, Jim Hogg, Jim Wells, Karnes, Kaufman, Kennedy, Kinney, Kleberg, La Salle, Lavaca, Lee, Leon, Liberty, Limestone, Live Oak, Madison, Marion, Matagorda, Maverick, McMullen, Medina, Milam, Montgomery, Morris, Nacogdoches, Navarro, Newton, Nueces, Orange, Panola, Polk, Rains, Refugio, Robertson, Rusk, Sabine, San Augistine, San Jacinto, San Patricio, Shelby, Smith, Starr, Titus, Travis, Trinity, Tyler, Upshur, Uvalde, Val Verde, Van Zandt, Victoria, Walker, Waller, Washington, Webb, Wharton, Willacy, Williamson, Wilson, Wood, Zapata, Zavala

Dated: April 16, 2002.

John C. Weicher,

Assistant Secretary for Housing-Federal Housing Commissioner.

[FR Doc. 02–9860 Filed 4–23–02; 8:45 am]

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Federal Register

Wednesday,
April 24, 2002

Part V

Environmental Protection Agency

Federal Interagency Working Group on Environmental Justice: Environmental Justice Revitalization Projects; Notice

ENVIRONMENTAL PROTECTION AGENCY

[FRL–7175–4]

Federal Interagency Working Group on Environmental Justice: Environmental Justice Revitalization Projects

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice.

SUMMARY: The Interagency Working Group on Environmental Justice (IWG) is soliciting a second round of nominations for collaborative partnerships working to address local environmental justice concerns. The following information outlines the goals, guidelines, and nomination procedures for IWG Environmental Justice/Revitalization Demonstration Projects.

DATES: Nominations must be submitted to the U.S. Environmental Protection Agency and postmarked no later than midnight Thursday, August 16, 2002.

ADDRESSES: For Regional questions:

Region 1: Connecticut, Maine, Massachusetts, New Hampshire, Rhode Island, Vermont.

Name: Kathy Castagna
Address: U.S. Environmental Protection Agency, One Congress Street, 11th Floor, Boston, MA 02203–0001
Phone: 617–918–1429 F: 617–918–1029
e-Mail: *castagna.kathy@epa.gov*

Region 2: New Jersey, New York, Puerto Rico, U.S. Virgin Islands

Name: Terry Wesley
Address: U.S. Environmental Protection Agency, 290 Broadway, 26th Floor, New York, NY 10007
Phone: 212–637–5027 F: 212–637–4943
e-Mail: *wesley.terry@epa.gov*

Region 3: Delaware, District of Columbia, Maryland, Pennsylvania, Virginia, West Virginia

Name: Reginald Harris
Address: U.S. Environmental Protection Agency, 1650 Arch St. (MC–3ECOO), Philadelphia, PA 19103
Phone: 215–814–2988 F: 215–814–2905
e-Mail: *harris.reggie@epa.gov*

Region 4: Alabama, Florida, Georgia, Kentucky, Mississippi, North Carolina, South Carolina, Tennessee

Name: Cynthia Peurifoy
Address: U.S. Environmental Protection Agency, 61 Forsyth Street, Atlanta, GA 30303
Phone: 404–562–9649 F: 404–562–9664
e-Mail: *peurifoy.cynthia@epa.gov*

Region 5: Illinois, Indiana, Michigan, Minnesota, Ohio, Wisconsin

Name: Karla Owens
Address: U.S. Environmental Protection Agency, 77 West Jackson Blvd. T–16J, Chicago, IL 60604–3507
Phone: 312–886–5993 F: 312–886–2737
E-Mail: *owens.karla@epa.gov*

Region 6: Arkansas, Louisiana, New Mexico, Oklahoma, Texas

Name: Olivia R. Balandran
Address: U.S. Environmental Protection Agency, Fountain Place, 12th Floor., 1445 Ross Ave., (RA–D), Dallas, TX 75202–2733
Phone: 214–665–7257 F: 214–665–6648
E-Mail: *balandran.olivia@epa.gov*

Region 7: Iowa, Kansas, Missouri, Nebraska

Name: Althea Moses
Address: U.S. Environmental Protection Agency, 901 North 5tth Street (ECORA), Kansas City, KS 66101
Phone: 913–551–7649 F: 913–551–7941
E-Mail: *moses.althea@epa.gov*

Region 8: Colorado, Montana, North Dakota, South Dakota, Utah, Wyoming

Name: Elisabeth Evans
Address: U.S. Environmental Protection Agency, 999 18th Street, Suite 500, Denver, CO 80202–2405
Phone: 303–312–6053 F: 303–312–6409
E-Mail: *evans.elisabeth@epa.gov*

Region 9: Arizona, California, Hawaii, Nevada, American Samoa, Guam

Name: Willard Chin
Address: U.S. Environmental Protection Agency, 75 Hawthorne Street, San Francisco, CA 94105
Phone: 415–972–3797 F: 415–947–3562
E-Mail: *chin.willard@epa.gov*

Region 10: Alaska, Idaho, Oregon, Washington

Name: Michael Letourneau
Address: U.S. Environmental Protection Agency, 1200 Sixth Avenue (CEJ–163), Seattle, WA 98101
Phone: 206–553–1687 F: 206–553–7176
E-Mail: *letourneau.mike@epa.gov*

Name: Victoria Plata
Address: U.S. Environmental Protection Agency, 1200 Sixth Avenue (CEJ–163), Seattle, WA 98101
Phone: 206–553–8580 F: 206–553–7176
E-Mail: *plata.victoria@epa.gov*

To submit nominations: Delta Valente, Office of Environmental Justice, Mail Code 2201A, U.S. EPA, 1200 Pennsylvania Avenue, Washington, DC 20460.

FOR FURTHER INFORMATION CONTACT: Delta Valente, Office of Environmental Justice, Mail Code 2201A, U.S. EPA, 1200 Pennsylvania Avenue, Washington, DC 20460, Telephone (202) 564–2594.

SUPPLEMENTARY INFORMATION: *What are the main goals of the IWG Environmental Justice/Revitalization Demonstration Projects:* (1) To support and encourage better leveraging of existing federal resources in supporting local efforts to address environmental justice concerns, (2) To support strong potential partnerships, and (3) To identify the ''best practices'' of effective collaborative partnerships for communities, governmental agencies, and other stakeholders working on solutions to environmental justice issues facing communities.

What are the benefits of being designated an IWG Environmental Justice/Revitalization Demonstration Project: Selection is not accompanied by any specific funding commitment from any federal agency; however, selection will bring the project national exposure and recognition, provide greater access to resources from various stakeholders, and promote the project as a model for future collaborative partnerships.

Who may apply to be an IWG Environmental Justice/Revitalization Demonstration Project: Any organization or group of organizations involved in collaborative multi-stakeholder partnerships to address local environmental justice concerns. These organizations include community-based organizations, non-profit organizations, academia, business and industry, faith-based organizations, and other interested groups, and all levels of government (federal, state, local or tribal). Each project must serve a minority, low-income, or tribal community and address one or more environmental justice concerns. Each project must include at least two federal agencies and a mix of other stakeholder partners.

How does one apply to be an IWG Environmental Justice/Revitalization Demonstration Project: Submit a proposal of approximately 10 pages in length, describing community based environmental justice issue(s) and how a project, through a community-based process that includes a multi-stakeholder partnership will address them. Proposal should include description of community vision, implementation approaches and work plan, roles and commitments of partners, and the project's expected benefits—including its contribution to community revitalization. Proposals should describe to what extent the project includes the following elements:

1. Community-based Leadership Formation and Issue Identification.
2. Capacity- and Partnership-Building in Multi-Stakeholder Process.
3. Supportive and Facilitative Role of Government.
4. Strategic Planning and Community Vision.

5. Sound Implementation.
6. Identification of Lesson Learned and Replication of Best Practices.

How can I get information and/or assistance about preparing a nomination: Detailed instructions are provided in the IWG Environmental Justice/Revitalization Demonstration Project Request for Nominations Announcement (IWGDP–02), available through the EPA Office of Environmental Justice (OEJ). Federal Agency Environmental Justice Coordinators and IWG Representatives also can provide assistance. Information can be obtained from Delta Valente, OEJ, 800–962–6215. The OEJ Web site is *http://www.epa.gov/compliance/recent/ej.html.*

Dated: April 17, 2002.

Barry E. Hill,

Director, Office of Environmental Justice.

Request for Nominations (April 15, 2002–August 16, 2002)

FY 2002

Identification Number: IWGDP–02

Date of Notification: April 15, 2002

Submission Due Date: August 16, 2002

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Appendix B. Federal Interagency Working Group on Environmental Justice (IWG)
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I. Introduction

The Federal Interagency Working Group on Environmental Justice (IWG) is soliciting a second round of nominations for collaborative partnerships working to address local environmental justice concerns and promote community revitalization. This announcement outlines the purpose, goals, and general procedures and guidelines for nominating demonstration projects, for Fiscal Year (FY) 2002.

The purpose of the demonstration projects is to examine how collaborative models can be utilized for achieving environmental justice and promoting community revitalization. The selected projects will be designated as IWG Environmental Justice Revitalization Projects. In FY 2000, the IWG selected 15 collaborative projects.

Selection is not accompanied by any specific funding commitment from any federal agency; however, selection will bring the project national exposure and recognition, provide greater access to resources from various stakeholders, and promote the project as a model for future collaborative partnerships.

Nominations must be submitted to the U.S. Environmental Protection Agency (EPA) and postmarked no later than midnight Friday, August 16, 2002. Nominations may be submitted via the U.S. Postal Service or other carriers. Nominations must be submitted to:

U.S. Environmental Protection Agency, 1200 Pennsylvania Avenue, NW (MC 2201A), Washington, DC 20460–0001, Attention: Delta Valente, IWG National Program Manager

Due to possible delays in postal delivery, project narratives also should be sent to Delta Valente via e-mail (*valente.delta@epa.gov*) or fax 202–501–1163. For further information, contact Delta Valente (800–962–6215) or visit *http://www.epa.gov/compliance/recent/ej.html.*

A. Background

The IWG is composed of representatives from different federal agencies and White House offices identified in Executive Order 12898. (''Federal Actions to Address Environmental Justice in Minority Populations and Low-Income Populations,'' February 11, 1994) The IWG's primary goal is to work with each federal agency to integrate environmental justice within its programs, policies, and activities. An important strategy to promote such integration is greater interagency cooperation and coordination within the context of multi-stakeholder collaborative partnerships. Interagency coordination and cooperation is needed to effectively identify available federal government-wide resources which are available to meet environmental justice opportunities presented by the stakeholders. Once the available federal agency resources are identified it is critical to identify all resources within the various stakeholders that can be partnered with or enhanced by the collaborative effort. The IWG has focused on three activities to support such partnerships: (1) Nurturing and promoting local demonstration projects; (2) promoting a national dialogue on collaborative models; and (3) identifying the elements of success for developing a coherent collaborative model.

Since environmental justice concerns are beyond the scope of any single federal agency, the IWG is working to ensure that federal agencies effectively coordinate and collaborate to address the range of issues that environmental justice embodies. At the heart of the IWG's efforts are demonstration projects, which are intended to serve as future models for successful environmental justice initiatives. These projects feature collaborative partnerships among two or more federal agencies, state and local governments, tribal governments, community-based organizations, academia, non-governmental organizations, and business/industry. As a result of the initial round of IWG demonstration projects, a coherent collaborative problem-solving model is beginning to emerge. In addition, it became clear that promoting community revitalization is an underlying goal of virtually all efforts to address environmental justice. To enhance this model, the EPA, as chair of the IWG, is coordinating a second round of demonstration projects to identify additional ''best practices'' for effective environmental justice collaborative partnerships to promote community revitalization.

B. Benefits of Participation

What are the benefits of being designated an IWG Environmental Justice Revitalization Project?

Being designated as an IWG Environmental Justice Revitalization Project enhances the ability of community-based collaborative efforts to address environmental justice issues and promote community revitalization. A project's selection enables local partnerships to better access technical assistance, resources, and other means of support. The benefits include the following:

- Opportunities for participants (community-based organizations, academia, business and industry, civic and faith-based organizations, other interested parties, and all levels of government, i.e., federal, state, tribal or local) to learn valuable lessons for addressing and positively impacting complex environmental justice issues in various communities by pursuing holistic, proactive strategies;
- Opportunities to increase the effective use of federal and other partner resources in addressing environmental justice and community revitalization concerns;
- Opportunities for community-based organizations to play a major role in identifying and defining environmental justice issues affecting the community, and actively participating, from the beginning, in the creation, design, and

implementation of a proposal to address that problem;

• Opportunities to strengthen community capacity-building skills and expertise (e.g., effective grant writing and development, business plan drafting, navigating governments and private institutions, understanding how to leverage resources, develop partnerships with greater capacity to address concerns, and improve use of limited budgets to meet project goals);

• Opportunities for a business to move beyond the morass of controversy over past incidents and problems and to focus proactively on new, constructive collaborations and partnerships to help improve the conditions of the communities in which businesses operate (businesses wishing to join others in understanding community needs and vision are invited to support their communities' application and be full participants in the collaborative process); and

• Opportunities to leverage resources through the participation of additional federal partners and the participation and commitments of other stakeholders (state, tribal and local government agencies, businesses/industry, foundations, redevelopment and financial groups).

What Do Current IWG Demonstration Project Participants Have To Say?

''The demonstration project designation elevated the interest of local government, where as before communities concerns were not on their radar screen. The federal interest in partnering with our community, and the federal recognition of our role as a major stakeholder, ensured our participation in the planning, decision-making, and implementation process. The federal interest and recognition secured our place at the table. Through initial support from federal agencies, funds were leveraged from the private sector to support project activities.''

Harold Mitchell, Executive Director, ReGenesis, Spartanburg, South Carolina, February 2002

''Bridges to Friendship (B2F) has benefitted in a number of ways from serving as a federal demonstration project. We came to the project with both a story to tell and a partnership to develop. We needed to do a better job at getting the word out on B2F accomplishments and the Interagency Work Group on Environmental Justice helped us to do that. We also wanted to connect with additional federal agencies with expertise, resources and a common desire to support our town, Washington DC. As a result of the project we are currently developing a Memorandum of Understanding to partner with US Department of Transportation. The most intangible but most important benefit is the extension of our networks, the connections. A new relationship, or just a conversation, that would not have otherwise taken place, brings tremendous value to our effort, our community and the EJ cause. Most importantly, serving as an EJ demonstration project has helped us in the most fundamental aspect of collaboration—that of building trust with our community.''

Rear Admiral Christopher Weaver, Commandant, Naval District Washington, January 2002

"Es grandioso participar en el proyecto. Es importante que los oficiales escuchen directamente de los residentes de la comunidad y que aprendan otros puntos de vista. Ha sido grandioso poder tener juntos a todas estas agencias, organizaciones, y residentes de la comunidad, en un mismo lugar."

(English Translation) ''It is great to participate in the project. It is important that the officials hear directly from the community residents and learn other points of view. It has been great to have all of the agencies, organizations and community residents come together, in the same place.''

Sonia Rodriguez, Barrio Logan Community Resident, San Diego, California, February 2002

''Rhodia is pleased to be part of the Arkwright demonstration project in Spartanburg, S.C. The project has helped us to build a stronger partnership with our community and gain a better understanding of our neighbors and their concerns. Being actively involved in our communities is important to us. We look forward to continuing our participation in the project and supporting community activities in the Arkwright neighborhood.''

Jim Trafton, Plant Manager, Rhodia Inc., Spartanburg, S.C., March 2002

Environmental Justice Revitalization Projects Overview

A. Purpose of an IWG Environmental Justice Revitalization Project

The purpose of an IWG Environmental Justice Revitalization Project is to demonstrate the effectiveness of collaborative models to achieve environmental justice and promote community revitalization. The projects selected are intended to demonstrate the ''best practices'' of comprehensive, collaborative, and integrated problem-solving approaches to address the range of interrelated environmental, public health, economic, and social concerns that collectively are known as environmental justice issues. These projects are based upon voluntary, local partnerships that build upon a holistic community vision. Centered in urban, tribal and rural communities across the country, the demonstration projects focus on improving the quality of life for minority, low-income, and tribal populations through environmental protection, economic development, neighborhood revitalization, community education, public health promotion, and capacity building.

The IWG demonstration projects foster proactive, collaborative efforts that bring agencies, at all levels of government, to partner with diverse stakeholders in impacted communities. Together at ''the table'' for the first time, in some cases, participants: (1) Better understand each other's perspectives; (2) identify mutual interests and priorities; and (3) with this broader and shared view, mobilize existing resources (i.e., social, human, and financial resources) for the purpose of creating win-win solutions.

B. Main Goals of an IWG Environmental Justice Revitalization Project

The main goals of the IWG Environmental Justice Revitalization Projects are: (1) To support and encourage better leveraging of existing federal resources to support local efforts to address environmental justice concerns and promote community revitalization, (2) to support strong potential partnerships, and (3) to identify the ''best practices'' of the effective collaborative partnerships with communities, governmental agencies, and other stakeholders working on solutions to environmental justice issues facing communities.

C. Elements of Success for Environmental Justice Collaborative Model

Six major design elements have been identified from the first round of IWG demonstration projects as key factors to the success of the environmental justice collaborative model. These are the following:

1. Community-based Leadership Formation and Issue Identification.
2. Capacity- and Partnership-Building in a Multi-Stakeholder Process.
3. Supportive and Facilitative Role of Government.
4. Strategic Planning and Community Vision.
5. Sound Implementation.
6. Identification of Lessons Learned and Replication of Best Practices.

A table with examples of these design elements is provided in Appendix A. These elements are offered as a framework for thinking about how to describe the proposed project. They provide useful parameters to identify a potentially successful project. Please note that no single project is expected to have all these elements.

D. Assistance in Developing Project Nominations

The IWG recognizes that putting together a project proposal for a multi-stakeholder collaborative partnership capable of addressing the issues in environmentally and economically distressed communities is difficult, particularly for community-based organizations with limited resources. The IWG suggests that project applicants rely on assistance from federal agencies as well as other potential project partners. In most cases, such relationships and partnerships already exist, and potential project applicants should build upon such relationships.

For example, interested parties who have an idea or question as to how a particular federal agency would fit into their vision could call one of the EJ Coordinators of the agency or that agency's IWG representative to discuss the possibility, ideas, and interest in the potential project. A community-based organization that does not have sufficient financial resources or skills in proposal writing might consider inviting and partnering with others (e.g., another organization, university, or local government agency) that have a greater capacity for preparing such a proposal. In addition, potential project applicants can obtain a description and contact information for each of the 15 current IWG demonstration projects from the EPA environmental justice Web site. These demonstration project contacts also can be a source of valuable advice.

A list of the IWG federal agency representatives and EPA Regional Environmental Justice Coordinators is provided in Appendix C. The EPA Environmental Justice Web site (Page 1) provides copies of the Federal Interagency Environmental Justice Directory as well as information on current IWG demonstration projects, including the IWG Demonstration Projects Status Report, Environmental Justice Collaborative Model: A Framework to Ensure Local Problem-Solving.

III. Project Technical Considerations

A. Potential Applicants

Any organization or group of organizations involved in collaborative multi-stakeholder partnerships to address local environmental justice concerns can submit their proposal for consideration. These organizations include community-based organizations, academia, business and industry, civic and faith-based organizations, other interested groups, and all levels of government (federal, state, tribal or local). Each project must include at least two federal agencies, and serve a minority, low-income, or tribal community by addressing one or more environmental justice concerns.

B. Essential Project Components

1. To be eligible, each project must include at least two federal agencies. Federal involvement must include some type of resource contributions to the project, such as contributions of staff time, grants, loans, invitational travel, meeting support, in-kind services, technical resources or other funds.
2. The project must have a mix or a potential mix of partnerships or established relationships that include local partners such as state, tribal and local government agencies, businesses and the private sector, community-based organizations, tribal organizations, local chapters of national associations (e.g., chambers of commerce or environmental organizations), community or economic development corporations, foundations, faith-based organizations, and other organizations that can contribute to the success of the project.
3. The proposal must have clear objectives, implementation guidelines, and benefits for environmentally and economically distressed communities.
4. The proposal must include non-federal partners committing resources to the project such as contributions of staff time, grants, loans, invitational travel, meeting support, in-kind services, technical resources, or other funds.
5. The proposal must include verifiable partners. Information provided should include, where available and appropriate: Organization Names, Contact Names, Mailing and Electronic Mailing Addresses, and Phone Numbers.

IV. Project Descriptions

A. Proposal Format

1. Proposal narratives should be approximately 10 pages in length. While it is estimated that 10 pages is an optimal length, all proposals, no matter how short or how long, will be given full consideration.
2. To the greatest extent possible, each project narrative should follow the six questions provided in the Project Narrative Section below. Project applicants should attempt to answer each question to the best of their abilities, but should not be discouraged if they cannot answer all questions completely. As emphasized in other sections of this document, no single project is expected to contain all the elements identified in the Elements of Success for Environmental Justice Collaborative Model (Page 11).
3. Supportive materials, where available, should be attached. These supportive materials may include photos, maps, news articles, and commitment or endorsement letters.

B. Proposal Narratives

1. Describe and discuss how the project will address one or more environmental justice concerns of a minority, low-income, or tribal community(ies). Provide a description of the project's overall objectives/expected benefits, the community(ies) being served, geographic location of the community, and implementation approaches. This should include the following:

a. Work plan which describes the project's overall objectives, milestones, and expected benefits.

b. Description of the community(ies) being served (e.g. demographics, geographic location, community history and assets, issues).

c. Description of the project's implementation process.

2. As stated earlier in Section II–C, six major design elements have been identified as being key factors to the success of environmental justice collaborative models. They are the following:

a. Community-based Leadership Formation and Issue Identification.

b. Capacity- and Partnership-Building in a Multi-Stakeholder Process.

c. Supportive and Facilitative Role of Government.

d. Strategic Planning and Community Vision.

e. Sound Implementation.

f. Identification of Lessons Learned and Replication of Best Practices.

Please provide the following responses as appropriate:

a. Description of any of the design elements that are in the project design and how they contribute to the overall success of the project.

b. Description of how the remaining elements not covered in the response to Question 2–a will be integrated into the project.

c. Description of ways that participating federal agencies can provide assistance in developing and incorporating any of the design elements in the project.

A great deal of thought should be given to the responses for Question 2 because these design elements are essential to the success of the environmental justice collaborative model. To assist in answering this question, a table containing examples of these design elements is provided in Appendix A. No single project is expected to have all these elements. Nor should the list of design element examples be used as a checklist because every community and every issue is unique.

3. Describe the partnership(s) and how they were formed, the roles and responsibilities of each partner, leadership role(s) of the relevant organizations, and the factors that enable the partnership to function well. This should include the following:

a. Description of how the relationship(s) or partnership(s) were formed.

b. Description of what elements or factors enable the partnership(s) to function well.

c. Description of the leadership roles of the local community organizations.

4. List the federal agency partners. Describe the federal agencies' role, commitment of staff, funding resources, and other contributions to the partnership. Include commitment letters from the federal agencies, and identify the agency's role in the project and an agency point of contact. This should include the following:

a. Description of the federal agencies' roles (e.g. responsibilities, commitment of staff, federal agency coordinator's contact information, funding resources, and other contributions).

b. Commitment letters from federal agencies discussing their roles and commitments.

c. Description of other federal agencies that should be involved in the future and ways by which IWG (or existing partners) can assist to bring about such involvement.

5. Describe how the non-federal partners (such as, state, local or tribal government agencies, businesses and the private sector, community-based organizations, local chapters of national associations such as chambers of commerce or environmental organizations, community development corporations (CDCs), and other organizations) are contributing to the success of the project. Include a list of the partners (contact name, address, phone number, electronic mail and fax numbers—if applicable), their resource commitments (e.g. staff, funds, meeting space), a clear description of their roles in the project, and letters of commitment from the leadership of the various partners is required. Describe how other government agencies and organizations (currently not partners) can contribute to the project. This should include the following:

a. Description of the roles and responsibilities of each non-federal partner, including the resource commitments of each partner (e.g. staff, funding, meeting space).

b. Provide a list of the partners' points of contact (e.g. name, address).

c. Discussion on how other (non-partner) government agencies and organizations can contribute to the project.

6. Describe how the proposed project will contribute to some aspect of community revitalization (e.g., land use, environmental and ecological, health, economic, social, and local capacity)?

V. Selection Process

A. Review Panel

A panel consisting of representatives from the various federal agencies participating in the IWG will review the proposals. Conference calls will be held with the ''finalists'' to ensure all parties understand the intent of the program and to confirm the roles of the partners, prior to selections. The IWG will make the final selections from among the top applicants.

Among the proposals receiving the highest ranking, the IWG may take into account the geographic location and diversity of the proposed projects when making final selections.

B. Selection Date

Selections are expected to be completed by November 15, 2002. Applicants will be notified by December 1, 2002.

VI. Program Schedule for 2002

Development of Proposals and Submission to EPA/IWG—April 15–August 16

IWG Reviews Proposals—September 1–October 15

Final Selections Completed—November 15

National Announcement of Selections—December 1, 2002

VII. Reporting

The lead coordinators of the selected demonstration projects will be asked to submit semi-annual reports to update the IWG on the project's progress. The reports should include, but not be limited to, information on:

- Tasks accomplished.
- Results achieved.
- Resources committed.
- Partners added.
- Issues/problems encountered and method for resolution.

Appendix A

Elements of Success for Environmental Justice Collaborative Model

The following major design elements have been identified as being key factors to the success of the environmental justice collaborative model. Examples are provided in the following table. The IWG identified these elements of success in order to develop a template for a holistic, integrated, and collaborative approach to addressing the environmental justice needs of distressed communities. Given that each community and each issue is unique, no single project is expected to have all these elements. Nor should the list of design element examples be used as a check list. The IWG believes that this template is a tool that all groups engaged in building collaborative community-based partnerships could find useful. Such groups should use these elements as a guide for strategic planning and project design.

Element of Success and Examples of Design Elements

1. Community-Based eadership Formation and Issue Identification

- Identify and build on existing leadership and expertise in impacted communities.
- Involve residents at the beginning in identifying concerns and crystallizing issues.

• Conduct local education, outreach, fact-finding and assessments.
• Build from a strong understanding of community history, practice and culture.
• Identify early on potential partners from all stakeholder groups.
• Provide training on environmental justice for all stakeholder groups.
• Assess whether or not conditions are ripe for collaboration.

2. Capacity- and Partnership-Building in a Multi-Stakeholder Process

• .Facilitate dialogue between different stakeholders.
• Build upon existing organizational capacity within community.
• Use consensus building or alternative dispute resolution, as appropriate.
• Secure commitments from multiple, appropriate government agencies and non-governmental organizations.
• Establish a formal multi-stakeholder partnership.
• Design processes to ensure fair treatment and meaningful participation of all stakeholders.
• Foster capacity-building through training, mentoring, technical assistance, or resource support.
• Integrate environmental justice into ongoing training efforts.
• Design processes that help ensure community education and capacity building in the future.
• Establish processes that allow for inclusion of new partners as they emerge.

3. Supportive and Facilitative Role of Government

• Ensure interagency coordination and cooperation between multiple federal agencies.
• Foster intergovernmental coordination and cooperation between federal, state, local and/or tribal agencies.
• Secure clear commitments (technical assistance, coordination, resources) from government agencies.

4. Strategic Planning and Community Vision

• Facilitate articulation of community vision, its aspirations based upon community-based planning and methods.
• Determine community assets (e.g., technical, financial, social, cultural, natural resource) and deficits (e.g., environmental degradation, abandoned buildings, lack of infrastructure).
• Utilize tools for comprehensive community planning (e.g. GIS, planning charettes).
• Identify, target and leverage assets from all sources (e.g. community, government, industry, academia, foundations).
• Reinforce community values.

5. Sound Implementation

• Develop Implementation Plan with shared goals, well defined objectives, timelines, action plans, commitments.
• Design projects to build on strengths, deficits, resources, and capacity of partners, especially the community's.
• Identify, nurture and promote collaborations with win/win scenarios.
• Obtain clear, written commitments from partners (possibly use a memorandum of agreement).
• Cluster and order tasks to promote efficient use of time and resources
• Develop methodology to measure and evaluate impact on community and stakeholders.
• Identify and build upon small successes.
• Add to and strengthen partnerships as new issues and relationships are understood.
• Build on community and organizational capacity through implementation to facilitate next phase.
• Ensure resolution of conflict or potential conflicts (possibly through the use of Alternative Dispute Resolution).

6. Identification of Lessons Learned and Replication of Best Practices

• Clearly define measures of success of project of objectives, processes, outputs, institutional effects, and quality-of-life results.
• Understand and evaluate, from different stakeholder perspectives, indicators used to measure success.
• Incorporate lessons learned into ongoing processes, both inside and outside of the community.
• Develop a ''template'' for successful collaborative models, based upon community experience.
• Develop mechanisms to integrate lessons into future efforts as new issues and challenges are identified.
• Share, publish, and disseminate experiences and lessons learned.

Appendix B

Federal Interagency Working Group on Environmental Justice

The Federal Interagency Working Group (IWG) on Environmental Justice was created by Executive Order 12898 (1994).

The Executive Order delineates the IWG agency responsibilities as follows: ''To the extent practicable and permitted by law, and consistent with the principles set forth in the report on the National Performance Review, each Federal agency shall make achieving environmental justice part of its mission by identifying and addressing, as appropriate, disproportionately high and adverse human health or environmental effects of its programs, policies, and activities on minority populations and low-income populations'. * * *'' Additionally, the order calls for the IWG to ''develop interagency model projects on environmental justice that evidence cooperation among Federal agencies'.

The IWG has focused on three activities to support collaborative, problem-solving partnerships: (1) Nurturing and promoting local demonstration projects, (2) promoting a national dialogue on collaborative models; and (3) identifying the elements of success for developing a coherent collaborative model.

Nurture and Promote Local Demonstration Projects

The IWG demonstration projects foster proactive, collaborative efforts that bring agencies, at all levels of government, together with diverse stakeholders in impacted communities. The main goal is to encourage better leveraging of existing federal resources, support local projects that promote among other federal agencies the addition of other federal resources to the projects.

Promote National Dialogue on Building Collaborative Models

In order to create a broad-based consensus on the appropriate use of a collaborative model, the IWG is promoting a national dialogue on building collaborative models to achieve environmental justice goals. One goal of such a dialogue is to ensure a common understanding among all stakeholder groups of this framework and share lessons which each group can apply. IWG members have conducted meetings and briefings for community, business, industry, faith-based groups, and state, local and tribal government partners and stakeholders. This also has identified new partners and builds interest in applying this model to their situations.

Identify Elements of Success for Developing a Coherent Collaborative Framework

Based upon the experience gained thus far, the IWG is systematically identifying the elements of success common to all collaborative models. In addition, the IWG, through the efforts of the EPA Office of Policy, Economics, and Innovation, is developing an evaluation framework for the IWG collaborative model. These activities have been instrumental for creating a common understanding of collaborative models to achieve environmental justice across the gamut of stakeholders. It is important to create a deeper understanding of the mechanisms involved and to help diverse stakeholders in impacted communities to understand the value and benefits of the voluntary and cooperative approach. Without a common understanding of the appropriate use and value of these models, stakeholders will lack the knowledge they need to overcome the lack of trust and adversarial relations.

Additional information on the Interagency Working Group on Environmental Justice can be found at the following Web address: *http://www.epa.gov/compliance/recent/ej.html*.

Appendix C—Contacts

Federal Interagency Environmental Justice Working Group Contacts

EPA: Charles Lee, Associate Director for Policy & Interagency Liaison, Office of Environmental Justice, U.S. Environmental Protection Agency, 401 M Street, SW-Mail Code 2201 A, Washington, DC 20460, Phone: 202/564–2597 Fax: 202/501–1163, E-mail: *lee.charles@epamail.epa.gov*

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HHS/NIEHS: Charles A. Wells, Director, Environmental Justice, Health Disparity and Public Health, Office of the Director, National Institute of Environmental Health Sciences (NIEHS), 31 Center Drive, Building 31-Room B1CO2–MSC 22–2256, Bethesda, MD 20892–22056, Phone: 301/496–2920 Fax: 301/496–0563, E-mail: *wells1@niehs.nih.gov*

HHS/ATSDR: Reuben C. Warren, Associate Administrator for Urban Affairs, Office of Urban Affairs, Agency for Toxic Substances &Disease Registry, 1600 Clifton Road, NE MS E28, Atlanta, GA 30333, Phone: 404/498–0111 Fax: 404/498–0087, E-mail: *RCW4@cdc.gov*

HUD: Richard Broun, Director, Office of Environment and Energy, U.S. Department of Housing and Urban Development, 451–7th Street, SW Room 7240, Washington, DC 20410, Phone: 202/708–2894 ext. 4439 Fax: 202/708–3363, E-mail: *richard—broun@hud.gov*

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Region 7: Iowa, Kansas, Missouri, Nebraska

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Region 8: Colorado, Montana, North Dakota, South Dakota, Utah, Wyoming

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Region 9: Arizona, California, Hawaii, Nevada, American Samoa, Guam

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Dated: April 11, 2002.

Barry E. Hill,

Director, Office of Environmental Justice.

[FR Doc. 02–9913 Filed 4–23–02; 8:45 am]

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Federal Register

Wednesday,
April 24, 2002

Part VI

Department of Transportation

Federal Aviation Administration

14 CFR Part 25

Revision of Braking Systems Airworthiness Standards to Harmonize With European Airworthiness Standards for Transport Category Airplanes; Final Rule and Notice

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

[14 CFR Part 25]

[Docket No. FAA–1999–6063; Amendment No. 25–107]

RIN 2120–AG80

Revision of Braking Systems Airworthiness Standards to Harmonize With European Airworthiness Standards for Transport Category Airplanes

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Final rule.

SUMMARY: This amendment revises the braking systems design and test requirements of the airworthiness standards for transport category airplanes. The amendment moves some of the existing regulatory text, considered to be of an advisory nature, to an advisory circular and adds regulations addressing automatic brake systems, brake wear indicators, pressure release devices, and system compatibility. These revisions were developed in cooperation with the Joint Aviation Authorities (JAA) of Europe, Transport Canada, and the U.S. and European aviation industry through the Aviation Rulemaking Advisory Committee (ARAC). These changes benefit the public interest by standardizing certain requirements, concepts, and procedures contained in the airworthiness standards without reducing, but potentially enhancing, the current level of safety.

DATES: Effective May 24, 2002.

FOR FURTHER INFORMATION CONTACT: Mahinder K. Wahi, FAA, Propulsion/Mechanical Systems Branch, ANM–112, Transport Airplane Directorate, 1601 Lind Avenue SW., Renton, WA 98055–4056; telephone (425) 227–2142; facsimile (425) 227–1320, e-mail *mahinder.wahi@faa.gov*.

SUPPLEMENTARY INFORMATION:

Availability of Rulemaking Documents

You can get an electronic copy using the Internet by taking the following steps:

(1) Go to the search function of the Department of Transportation's electronic Docket Management System (DMS) Web page (*http://dms.dot.gov/search*).

(2) On the search page type in the last four digits of the Docket number shown at the beginning of this notice. Click on ''search.''

(3) On the next page, which contains the Docket summary information for the Docket you selected, click on the document number for the item you wish to view.

You can also get an electronic copy using the Internet through the Office of Rulemaking's web page at *http://www.faa.gov/avr/armhome.htm* or the **Federal Register's** web page at *http://www.access.gpo.gov/su_docs/aces/aces140.html*.

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Small Business Regulatory Enforcement Fairness Act

The Small Business Regulatory Enforcement Fairness Act (SBREFA) of 1996 requires FAA to comply with small entities' requests for information or advice about compliance with statutes and regulations within its jurisdiction. Therefore, any small entity that has a question regarding this document may contact their local FAA official, or the person listed under **FOR FURTHER INFORMATION CONTACT.** You can find out more about SBREFA on the internet at our site, *http://www.faa.gov/avr/arm/sbrefa.htm.* For more information on SBREFA, e-mail us *9-AWA-SBREFA@faa.gov.*

Background

This amendment is based on Notice of Proposed Rulemaking (NPRM) No. 99–16, which was published in the **Federal Register** on August 10, 1999 (64 FR 43570) and Supplemental Notice of Proposed Rulemaking (SNPRM) No. 99–16A, which was published in the **Federal Register** on December 18, 2000 (65 FR 79298). The related background leading to NPRM No. 99–16, and SNPRM No. 99–16A is discussed below.

In 1988, the FAA, in cooperation with the Joint Aviation Authority (JAA) and other organizations representing the American and European aerospace industries, began a process to harmonize the airworthiness requirements of the United States and the airworthiness requirements of Europe, especially in the areas of Flight Test and Structures. Starting in 1992, the FAA harmonization effort for various systems related airworthiness requirements was undertaken by the ARAC. An ARAC working group of industry and government braking systems specialists of Europe, the United States, and Canada was chartered and named as the Braking System Harmonization Working Group (HWG) by notice in the **Federal Register** (59 FR 30080, June 10, 1994).

Statement of the Problem

The ARAC working group was tasked to develop a harmonized standard, such as a Technical Standard Order (TSO), for approval of wheels and brakes to be installed on transport category airplanes and to develop a draft notice of proposed rulemaking (NPRM), with supporting economic and other required analyses, and/or any other related guidance material or collateral documents, such as advisory circulars (AC), concerning new or revised requirements and the associated test conditions for wheels, brakes and braking systems, installed in transport category airplanes (§§ 25.731 and 25.735). The harmonization task was completed by the ARAC working group and recommendations were submitted to the FAA by letter dated May 1, 1998. The FAA concurred with the recommendations and proposed them in NPRM No. 99–16. A Notice of Availability of proposed AC 25.735–1X and request for comments, and a Notice of Availability of proposed TSO–C135 and request for comments, were also published in the **Federal Register** on August 10, 1999 (64 FR 43579). On August 25, 1999, the JAA issued a Notice of Proposed Amendment (NPA) 25D–291 and NPA TSO–7: ''Brakes and Braking Systems,'' which included the proposed advisory material joint (AMJ) 25.735. The amendments proposed in NPA 25D–291 and the advisory material proposed in AMJ 25.735 were substantively the same as the amendments proposed by the FAA in Notice No. 99–16 and the advisory material in proposed AC 25.735–1X. The NPA TSO–7 was substantively the same as proposed in FAA TSO–C135.

As a result, the FAA received comments from the public in response to the proposed rule (Notice No. 99–16), as well as comments on the proposed AC and the proposed TSO. The JAA received comments from the public in response to NPA 25D–291 and NPA TSO–7 (which includes the AMJ 25.735). The comments received on the FAA and the JAA notices are interlinked and addressed jointly. Therefore, the FAA has considered both sets of comments in preparing the final rule contained herein, the new AC, and the new TSO. The FAA will publish a Notice of Availability in the **Federal Register** when the final version of AC 25.735–1 and TSO–C135 are issued. Interested persons have been given an opportunity to participate in this

rulemaking, and due consideration has been given to all matters presented.

The FAA determined that an incremental cost identified by commenters to Notice No. 99–16 must be subject to public scrutiny. Therefore, this resulted in a supplemental notice of proposed rulemaking (SNPRM), No. 99–16A, being published for public comment on December 18, 2000 (65 FR 79278).

Comments received on Notice No. 99–16 are discussed first, followed by comments received on Notice No. 99–16A.

Discussion of Comments: Notice No. 99–16

Twenty-one commenters responded to the request for comments contained in Notice No. 99–16, the notices of availability of proposed AC 25.735–1, and TSO–C135, and the corresponding JAA documents NPA 25D–291, NPA TSO–7, and AMJ 25.735.

Comments were received from eight foreign and domestic airplane and brake manufacturers, nine foreign airworthiness authorities, one operator, and three foreign and domestic industry organizations. The majority of the commenters agree with the proposal and recommend its adoption. However, some commenters disagree with the proposal while providing alternative proposals that appear to merit further consideration by ARAC. Therefore, the FAA tasked the ARAC on Transport Airplane and Engine (TAE) issues area by letter dated February 8, 2000, to consider the comments and provide recommendations for the disposition of the comments along with any recommendations for changes to the proposal. The disposition of the comments below is based on the agreement reached by the Braking Systems HWG and submitted by ARAC on TAE issues area to the FAA by letter dated June 19, 2000. Several of the commenters address multiple issues, while many commenters address the same issue. As a result, the FAA responses to the comments are organized by individual comment under each proposal, i.e., proposals 1 through 17.

Proposals 1, 2, 4, 5, 6, 8, 9, 12, 15, and 17: §§ 25.735(a), (b), (c), (c)(2), (e), (e)(1), (g), (i) and (k)

No comments were received for these proposals. Sections 25.735(a), (c), (c)(2), (e), (e)(1), (g), (i), and (k) are therefore adopted as proposed.

Proposal 3, § 25.735(b)

One commenter questions the justification of deleting the parenthetical phrase ''(excluding the operating pedal or handle)'' from the current § 25.735(b). The commenter states that excluding the operating pedal or handle is justified to allow use of maximum asymmetric braking capability, use of auto-brakes, and/or thrust reversers in stopping scenarios involving a jammed pedal or high rudder deflection.

FAA's Response: The FAA disagrees with the commenter. Currently, certified airplanes can meet this requirement using rudder and nosewheel steering while providing full braking on one side of the airplane without reverse thrust or autobrakes. The regulations do not require consideration of adverse crosswinds.

Proposal 7, § 25.735(d)

One commenter recommends deleting the idle thrust requirement as use of idle thrust may result in nose gear sliding on high thrust twin engine aircraft. The commenter's suggested text is ''Thrust on any, or all, other engine(s) is to be determined by the applicant.''

FAA's Response: The FAA disagrees with the commenter. The rule, as stated, does not preclude the use of thrust in excess of idle on other engines. The advisory material is expanded to state that compliance is not limited to ground idle thrust; therefore, the applicant may choose what is critical.

Proposal 10, § 25.735(e)(2)

One commenter states that the intent of the rule could probably be better expressed by changing the text from ''(2) It must, at all times, have priority over the automatic braking system, if installed'' to ''If both Anti-Skid and Auto-Brake systems are fitted to the aircraft, then the anti-skid system shall always work independently of the auto-brake and irrespective of the auto-brake configuration/status.''

FAA's Response: The FAA does not concur with the comment. The intent of the rule is to make sure the antiskid function releases a wheel which is going into a skid regardless if the braking is commanded by the pilot or the autobrake function. An explanation to this effect is added in the AC.

Proposal 11, § 25.735(f)

For the comments and response that follow, the heat sink is the mass of the brake that is primarily responsible for absorbing energy during a stop. For a typical brake, this would consist of the stationary and rotating disc assemblies. One commenter states: ''It does not appear that the proposed § 25.735(f) requires the brake with fully worn heat sink to complete 100 cycles of the design landing stop. A brake assembly with fully worn heat sink will not be capable of completing these 100 landing stops. If the proposed § 25.735(f) requires the wheel and brake assembly with fully worn heat sink to complete ONE design landing stop dynamometer test, this test would be unnecessary since the maximum kinetic energy accelerate-stop test will be much more severe. The energy capacity of the accelerate-stop is generally three times the energy capacity of the design landing stop.''

FAA's Response: The FAA concurs; the proposed TSO–C135 does not require the brake with fully worn heat sink to complete 100 cycles of the design landing stop. However, the FAA disagrees that one design landing stop with fully worn brakes is unnecessary; it is required because the one design landing stop requirement cannot be met by the worn brake accelerate-stop test due to differing deceleration requirements.

The same commenter also states that ''the most severe landing stop should not be added until this new regulation is harmonized with other part 25 sections, especially subpart B-Flight (Performance) and § 25.1001, Fuel jettisoning system.''

FAA's Response: The FAA does not agree. The § 25.775(f)(3) requirement is for brake qualification via a dynamometer test per TSO–C135 standard, and not a flight performance test on the aircraft. Compliance with the current § 25.1001 may also result in similar design requirements, especially for aircraft without fuel jettisoning systems.

A second commenter, while supporting the general intent of harmonizing, expresses a concern

> with some aspects of the proposed rule that create significant additional constraints on braking system design and other systems architecture, and on compliance demonstration, without any clear safety benefit. In particular, the Summary of Costs and Benefits in the NPRM preamble, indicates a type certification testing cost increase from $20,000–$60,000, resulting from proposal 11 on ''most severe landing stop'' that would be balanced by the savings expected from rule harmonization. Then this summary adds considerations on potential safety benefits: ''Although there were numerous (approximately 170) accidents involving brake failures during landings in the period 1982–1995, none were determined to have been directly preventable by the subject provisions. Different designs in future type certifications, however, could present other problems (unexpected) and raise future accident rates.''

The commenter concludes ''that, in fact, the expected safety benefit is so

vague that it is hard to justify the additional certification expenses, even if balanced by administrative simplifications, especially for a technically questionable requirement.''

FAA's Response: The FAA does not agree with this commenter. The requirement is conditional in that ''it need not be considered for extremely improbable failure conditions or if the maximum kinetic energy accelerate-stop energy is more severe.'' Without specifying it in the regulations, the applicant may not consider such a situation, however likely.

The second commenter continues, adding: ''Contrary to what is indicated in the Regulatory Evaluation Summary, the Most Severe Landing Stop (MSL) requirement has not been in effect in Europe per British Civilian Aviation Authority (CAA), and there is no evidence that 'many large part 25 airplane manufacturers currently meet this standard.' '' The JAR–25 does not contain this concept. Before JAR–25 adoption, British Civil Airworthiness Requirments (BCAR) Section D was the U.K. Certification code for large airplanes. The brake energy absorption capacity was based on different concepts, namely Certified Normal Brake Energy Capacity and Certified Emergency Brake Energy Capacity (BCAR chapter D–4–5, § 3.8). It is meaningless to determine a ''most severe landing stop'' case for the sole purpose of brake system certification, without considering the global use of return to land capability that will take into account such other parameters as controllability, other retardation means, landing distances, and operational procedures. The commenter therefore suggests withdrawal of the MSL concept, and proposes modifying paragraph (f) in § 25.735 as follows:

(1) Replace the first sentence with: ''Kinetic energy absorption requirements of each wheel and brake assembly must be determined for the design landing stop and the maximum kinetic energy accelerate-stop.''

(2) Delete the last sentence: ''The most severe landing stop need not be considered for extremely improbable failure conditions or if the maximum kinetic energy accelerate-stop energy is more severe.''

(3) Replace the last sentence with: ''In addition to the design landing stop and maximum kinetic energy accelerate-stop, the brake energies associated with forseeable cases of immediate return to land must also be considered. For these cases, operational procedures, possible fuel jettisoning for a maximum of 15 minutes, use of retardation means, and landing distances must be taken into account.''

The same recommendations, (1), (2), and (3) above, are made by a third commenter who states that ''the concept of an MSL is inter-related to an FAA document regarding Return Landing Capability (Issue Paper F–7), and a recent recommendation No. 99–23 from the UK Air Accidents Investigation Branch (AAIB).'' A fourth commenter, the UKCAA, states that the AAIB recommendation is a result of a serious incident at London Heathrow airport in July 1998. An aircraft, following illumination of a caution light during climb and shutdown of one engine, returned for an overweight landing in a crosswind. During this landing, the brakes overheated, the tires deflated, and the aircraft went off the runway. The third commenter continues, stating that the problem of aircraft retardation in foreseeable abnormal operating conditions cannot be adequately addressed by looking at the brakes and brake system alone. The third commenter recommends (1) that this proposal should be reassessed in view of the other current regulatory activity (Issue Paper F–7 and AAIB recommendation No. 99–23); and (2) rewording the regulation per recommendations (1), (2), and (3), above.

FAA's Response: The FAA does not agree. The FAA has reviewed the recommendation and determined that prior to the formation of the ARAC Braking Systems HWG, the requirement for the most severe landing stop condition was included in the European JAA-industry harmonized document ED–69, published in December 1992. In addition, as pointed out by two other commenters, an existing FAA issue paper (FAA Issue Paper F–7) has required applicants to address a return landing capability condition for compliance with § 25.1001. This means the applicant should address the effects and consequences of typical single and multiple failure conditions which are foreseeable events and can necessitate landings at abnormal speeds and weights. The most severe landing stop requirement is therefore retained.

The AAIB recommendation specifically states that the FAA, CAA, and JAA review the requirements for aircraft brake system certification to cover the need to consider overweight landing situations, together with the effects of crosswind and asymmetric engine thrust during ground roll.

The commenter references the existing FAA Issue Paper F–7 on this subject that indicates that the FAA too see the need to expand the scope of the requirement. The commenter continues stating that the FAA position seems to indicate that this incident would be regarded as a ''foreseeable operating condition'' when considering compliance with § 25.1309(a).

In accordance with the AAIB Safety Recommendation, the fourth commenter (UKCAA) proposes that JAR 25.735(f) be further amended to include consideration of crosswind and asymmetric engine thrust, in combination with the severe landing stop condition maximum weight.

FAA's Response: The FAA does not concur with this comment. The FAA has reviewed the UKCAA recommendation and considers that there is sufficient conservatism in the proposed requirements. This conservatism, while not provided specifically to accommodate the possible crosswind effects in an overweight return to land case, is nevertheless available as follows:

(a) The capability to stop the aircraft with only half the brakes functioning;

(b) Dynamometer testing to demonstrate the capability to complete the maximum kinetic energy rejected takeoff (RTO) stop with all brakes worn to the limit;

(c) Dynamometer testing to demonstrate the capability to complete the most severe landing stop with all brakes worn to the limit, should this be more severe than the maximum kinetic energy RTO stop, and not shown to be extremely improbable;

(d) No allowance being given for the reverse thrust capabilities for the demonstration of (b) and (c) above.

The FAA has added appropriate advisory material to the AC 25.735–1, Brakes and Braking Systems Certification Tests and Analysis.

A fifth commenter suggests changing the wording of the second sentence of § 25.735(f) from ''* * * most severe landing stop brake kinetic energy absorption requirements of each wheel and brake assembly * * *'' to ''* * * most severe landing stop kinetic energy absorption requirements of each brake-wheel-tire assembly * * *'' The commenter suggests the same change in terminology for the third sentence.

FAA's Response: The FAA concurs with the commenter. The final rule text is revised accordingly.

A sixth commenter states that, as proposed, § 25.735(f) is difficult to read and contains too many separate requirements, which could create undue difficulties during the finding of compliance. The commenter suggests that the paragraph be rearranged such that:

(1) There is a distinct sub-paragraph that can be identified for the requirement for the determination of the levels of kinetic energy and the energy absorption rates. This should indicate that three cases are to be considered (design landing stop, accelerate-stop and most severe landing stop). This sub-paragraph could also mention the caveats about the need to consider, or not consider, during testing the most severe landing stop.

(2) There is a distinct sub-paragraph for the requirement for the wheel and brake assembly to meet the levels of kinetic energy.

(3) There is a distinct sub-paragraph for the requirement for the wheel and brake assembly to meet the energy absorption rates.

(4) The definitions of the three stop cases (the last nine lines of the currently proposed paragraph, starting with: ''* * * Design landing stop is an operational * * *'') are taken out of the requirement and placed in the proposed AC 25.735–1X.

FAA's Response: The FAA concurs with the commenter that rearranging § 25.735(f) into three distinct sub-paragraphs clarifies the requirement. The FAA, however, has decided that it is more appropriate to retain the definitions as part of the regulatory text since this is the only place where these terms are identified. The text of this paragraph is divided into three subparagraphs (f)(1), (f)(2), and (f)(3) with appropriate headings. The subparagraphs cover each of the three tests and include the definitions.

Two of the commenters suggest adding a requirement that the accelerate-stop test, reference: paragraph 3.3.3.2 of the proposed TSO–C135 and § 25.735(f) of Notice No. 99–16 must be completed on both a new brake and a fully worn brake. The fully worn brake is the worst case condition for energy absorption capability; however, the new brake condition is the worst case condition for performance for some heat sink materials.

FAA's Response: The FAA concurs with these commenters. Applicable text in the final TSO–C135 paragraph 3.3.3.2, and the final rule new subparagraph § 25.735(f)(2) add a new brake accelerate-stop test requirement with the new brake defined as a brake worn no more than 5 percent of its usable wear range. The accelerate-stop applicable portion of § 25.735(f) text, NPRM No. 99–16, is revised from: ''It must be substantiated by dynamometer testing that at the declared fully worn limit(s) of the brake heat sink, the wheel and brake assemblies are capable of absorbing not less than these levels of kinetic energy'' to ''(f)(2): It must be substantiated by dynamometer testing that the wheel, brake, and tire assembly is capable of absorbing not less than this level of kinetic energy throughout the defined wear range of the brake.'' Although not a part of the TSO, large airplane manufacturers currently require a new brake RTO test as part of brake qualification. Small airplane manufacturers may experience a cost increase of $20,000 per certification.

Proposal 13, § 25.735(g)

The first commenter wonders whether the case specified in the rule (immediate application of the parking brake after the RTO for at least 3 minutes, with no fire allowed for at least 5 minutes) is indeed the worst case. The commenter opines that a more severe case, representing a likely in-service scenario, would be for the aircraft to taxi off the runway before the parking brake is applied, and that it should be allowable for the aircraft manufacturer to incorporate this scenario into the test if so desired. However, this is specifically precluded due to the current wording of the rule.

FAA's Response: The FAA does not concur. The regulation does not preclude the applicant from considering such a scenario and addressing it in their brake specification.

A second commenter states that as proposed under § 25.735(g), it must be demonstrated that with the parking brake applied for three minutes after the high kinetic energy stop demonstration of § 25.735(f), no condition (including fire) that could prejudice the safe and complete evacuation of the airplane shall occur for at least five minutes.

The commenter continues, stating: ''In recent aircraft certification programs, Transport Canada (TC) has required that the parking brake be applied for a minimum of five minutes. This is a more stringent requirement that impacts the design, testing and certification of the braking system that is currently only being applied to Canadian certifications and is violating the premise of harmonization.''

The commenter adds that ''the ARAC sub committee does not recommend the increased parking brake period, however, the significant issue is that all National Airworthiness Authorities must accept the same standard to realize the benefits of harmonization.''

FAA's Response: The FAA agrees with the second commenter that clarification of the parking brake set period is needed. The FAA has reaffirmed the 3-minute parking brake applied period for the dynamometer test. There is no intent by the FAA to dictate that the parking brake must be released at 3 minutes, but that it must be applied at least that long. Figures 3–1 and 3–2 and paragraphs 3.3.3.5 and 3.3.4.5 in the TSO will be changed to minimize ambiguity in this respect.

The certification test on the airplane (worn brake RTO) need not follow the procedure prescribed in the TSO. But it is important that the brake manufacturer know early in the development period what procedure will be used on the airplane (i.e. the certification basis) since it can impact the design. This approach allows authorities that are not part of the harmonization process the needed flexibility.

A third commenter adds that the new JAR 25.735(g) requires the parking brake to be promptly and fully applied for at least 3 minutes; in addition, it must be demonstrated that for at least 5 minutes no condition occurs that could prejudice the safe and complete evacuation of the airplane (a similar requirement is also included in JTSO–C135 paragraph 3.3.3.5). Both the 3- and 5-minute timeframes, according to the proposals, are related to a safe evacuation of the airplane, however, there are no data to support the use of those figures. The commenter states that advice is needed from the Cabin Safety Study Group (CSSG) on the use of three and five minutes in conjunction to a safe evacuation.

FAA's Response: The FAA does not agree that the CSSG advice is needed. The criteria are based on regulations for 90-second cabin evacuation; pilot recognition time; time to deploy slides; and time for fire trucks to arrive at the scene of the fire, as well as previous certification tests experience. If the CSSG changes the criteria (3 minutes versus 5 minutes), then a change to § 25.735(g) should be evaluated.

Proposal 14, § 25.735(h)

One commenter states that ''although this rule is only invoked if the aircraft relies on accumulators to provide back-up brake pressure, and this is generally not the case with AIRBUS aircraft, [the commenter] is not aware of an existing system that would satisfy this requirement. The display of available brake energy is a complex task, and a system would need to be devised to allow this information to be obtained.'' The commenter suggests that overall safety would probably be better enhanced by placing a reliability requirement on the accumulator system, rather than demanding a new monitoring system be developed which could degrade the system safety.

FAA's Response: The FAA disagrees with this comment. Alternate means of

compliance will be discussed in AC 25–735–1. As explained in the preamble and advisory circular material, the intent is to ensure proper indication of available accumulator energy, not just pressure which has been determined to be insufficient indication. Unless available energy is displayed, there is no assurance that a backup system is available.

Proposal 16, § 25.735(j)

One commenter recommends that the proposed § 25.735(j), Overtemperature burst prevention, should be moved to § 25.731.

FAA's Response: The FAA does not concur with this comment. The overtemperature condition is caused by brake heat and, therefore, needs to be addressed in the brake section. Cross references are provided in both §§ 25.735 and 25.731.

Another commenter suggests that the intent would be better expressed by changing the words ''* * * wheel failure or tire burst * * * '' to '' * * * wheel failure and/or tire burst * * *''

FAA's Response: The FAA concurs that clarification is necessary. The final rule text is revised to read ''* * * a wheel failure, a tire burst, or both * * *''

Discussion of Comments: Notice No. 99–16A

Five commenters responded to the request for comments contained in Notice No. 99–16A. Three commenters fully support the proposal and recommend its adoption. Two other commenters made recommendations as follows.

The first commenter states ''Airplane braking systems differ between airplane models. Consideration must be given to the additional braking equipment, which is installed on certain model airplanes. When that additional equipment fails or has been rendered inoperative, a more critical condition can exist with the three proposed testing conditions for kinetic energy capacity, i.e., design landing stop, accelerate-stop, and most severe landing stop. This SNPRM does not account for model specific test qualifications for airplanes equipped with additional braking equipment such as brake fan systems. For example, the brake fan system on an airplane may be rendered inoperative due to system failure or by deactivation in accordance with the airplane minimum equipment list (AMEL). The lack of additional brake cooling, coupled with the additional mass (heat sink) of the brake fan, will further deteriorate conditions at the brake installation. Consequently, braking performance is reduced.'' Recognition of such abnormal conditions must be part of the qualification testing for kinetic energy capacity in all three proposed conditions.

FAA's Response: The FAA does not concur with this comment. While the revised regulations do not specifically address items such as brake cooling fans, they provide the basic requirements that must be met. The final AC, once it is published, will provide information on how the regulations are applied. In the case of brake cooling fans, two paragraphs are appropriate. Paragraph 4a(1)(c) of the AC will state that the brake must meet the energy requirements without the use of auxiliary cooling devices. Paragraph 4f(2)(a) states that, in calculating the energy requirements for the accelerate-stop, use of cooling fans may not be considered in determining the heat sink state at the beginning of the stop. No change in the rule text is necessary.

The second commenter recommends the following changes to §§ 25.735(f)(2) and (f)(3) for consistency with § 25.735(f)(1):

''(1) In § 25.735(f)(2) remove the words 'defined by the airplane manufacturer must be achieved,' and add the words, 'derived from the airplane manufacturer's braking requirements must be achieved.' ''

''(2) In § 25.735(f)(3), add the sentence 'The energy absorption rate derived from the airplane manufacturer's braking requirements must be achieved.' ''

FAA's Response: The FAA concurs with (1) and the final rule text has been revised accordingly. The FAA does not concur with (2) because the HWG specifically decided not to put a deceleration requirement on the most severe landing. Addition of the proposed sentence to § 25.735(f)(3) is not necessary and doing so would not have any any impact on brake design.

With the exceptions of the changes noted in §§ 25.735(f) and (j), this final rule is adopted as proposed in Notice No. 99–16 and Notice No. 99–16A.

Paperwork Reduction Act

In accordance with the Paperwork Reduction Act of 1995 (44 U.S.C. 3507(d)), the FAA has determined that there are no new requirements for information collection associated with this amendment.

International Compatibility

In keeping with U.S. obligations under the Convention on International Civil Aviation, it is FAA policy to comply with International Civil Aviation Organization (ICAO) Standards and Recommended Practices to the maximum extent practicable. The FAA has determined that there are no ICAO Standards and Recommended Practices that correspond to these regulations.

Regulatory Evaluation Summary, Regulatory Flexibility Determination, International Trade Impact Assessment, and Unfunded Mandates Assessment

Changes to Federal Regulations must undergo several economic analyses. First, Executive Order 12866 directs that each federal agency shall propose or adopt a regulation only upon a reasoned determination that the benefits of the intended regulation justify its costs. Second, the Regulatory Flexibility Act of 1980 requires agencies to analyze the economic effect of regulatory changes on small entities. Third, the Trade Agreements Act (19 U.S.C. 2531–2533) prohibits agencies from setting standards that create unnecessary obstacles to the foreign commerce of the United States. In developing U.S. standards, this Trade Act requires agencies to consider international standards, and, where appropriate, to use those standards as the basis of U.S. standards. Fourth, Title II of the Unfunded Mandates Reform Act of 1995 requires each Federal agency, to the extent permitted by law, to prepare a written assessment of the effects of any Federal mandate in a proposed or final agency rule that may result in the expenditure by State, local, and tribal governments, in the aggregate, or by the private sector, of $100 million in any one year. In conducting these analyses, the FAA has determined that this rule: (1) Will generate benefits that justify its costs and is not ''a significant regulatory action(as defined in Executive Order 12866 or in the Department of Transportation's Regulatory Policies and Procedures; (2) will not have a significant impact on a substantial number of small entities; (3) will not constitute a barrier to international trade, and (4) does not contain a Federal intergovernmental or private sector mandate that exceeds $100 million in any one year.

These analyses, available in the docket, are summarized below. All estimates are expressed in year 2000 dollars.

Regulatory Evaluation Summary

None of the commenters to Notice No. 99–16 disputed FAA's estimates of specific incremental certification costs. One commenter, however, questioned FAA's contention that costs would be balanced by the savings expected from rule harmonization.

In answer to that commenter's concerns, and based on industry experience with recent type certifications, the FAA re-calculated both the harmonization cost savings and the costs attributable to the ''proposed'' amendments (in the original NPRM), and estimated the costs associated with the proposed new requirement in Notice No. 99–16A. These cost estimates are delineated in the next several paragraphs.

Based on the previous analyses in the economic evaluations for both notices, the FAA has determined that only two changes in § 25.735(f) *Kinetic energy capacity*, will result in any incremental cost increases; those are the dynamometer testing requirements in (f)(2) and (f)(3), pertaining to the ''Maximum kinetic energy accelerate-stop'' and the ''Most severe landing stop (MSL),'' respectively.

The dynamometer test, also called a new brake rejected takeoff test, is currently conducted by brake manufacturers as specified by large airplane manufacturers in the brake qualification specification and is an industry practice as such. For some small airplane manufacturers, however, the new ''accelerate-stop'' test will result in a cost increase of $20,000 per certification. This incremental, but nonrecurring, cost for some manufacturers of part 25 small airplanes will easily be offset by the harmonization cost savings cited below. Any potential safety benefits from avoiding even one minor accident would add to such benefits.

The MSL requirement, while a new FAA requirement, has been in effect in Europe (per British CAA); consequently, many large part 25 airplane manufacturers currently meet this standard. Notwithstanding, large part 25 airframe and brake manufacturers note that in almost all cases either the MSL stop energy would not exceed the maximum kinetic energy accelerate-stop energy, or the MSL stop condition is extremely improbable. One part 25 large airplane manufacturer, however, estimates one additional dynamometer test in the $20,000–$40,000 range. Manufacturers of small part 25 airplanes will experience incremental one-time testing costs totaling approximately $20,000 per type certification.

These incremental, but nonrecurring, costs for some manufacturers of part 25 (large and small) airplanes will easily be offset by the estimated harmonization cost savings. Any potential safety benefits from avoiding even one minor accident would add to such benefits.

In summary, the incremental costs for the aforementioned new dynamometer tests will total between $20,000 and $40,000 per type certification for one manufacturer of part 25 large airplanes. Similar costs for some manufacturers of part 25 small airplanes are estimated at $40,000 per type certification.

As stated in the Regulatory Evaluation Summary in Notice No. 99–16A, the FAA had contacted industry sources to obtain estimated harmonization cost savings attributable to the revisions originally proposed in Notice No. 99–16. These cost savings are estimated to be, at a minimum, between $50,000 and $75,000 for a part 25 small airplane type certification and $100,000 to $300,000 for a part 25 large airplane type certification. These harmonization benefits exceeded the incremental costs of all the revisions specified in the NPRM as well as the costs attributable to the SNPRM change. Since there were no public comments to the SNPRM disputing these estimates, the FAA includes these same benefits in this final rule economic assessment. Given that the rule's incremental benefits exceed the incremental costs for both part 25 large and small airplane manufacturers, the FAA finds the final rule cost-beneficial.

Regulatory Flexibility Determination

The Regulatory Flexibility Act of 1980 (RFA) establishes ''as a principle of regulatory issuance that agencies shall endeavor, consistent with the objective of the rule and of applicable statutes, to fit regulatory and informational requirements to the scale of the business, organizations, and governmental jurisdictions subject to regulation.'' To achieve that principle, the Act requires agencies to solicit and consider flexible regulatory proposals and to explain the rationale for their actions. The Act covers a wide-range of small entities, including small businesses, not-for-profit organizations, and small governmental jurisdictions.

Agencies must perform a review to determine whether a proposed or final rule will have a significant economic impact on a substantial number of small entities. If the determination is that it will, the agency must prepare a regulatory flexibility analysis as described in the Act. However, if an agency determines that a proposed or final rule is not expected to have a significant economic impact on a substantial number of small entities, section 605(b) of the 1980 act provides that the head of the agency may so certify and a regulatory flexibility analysis is not required. The certification must include a statement providing the factual basis for this determination, and the reasoning should be clear.

The subject rule will affect manufacturers of part 25 transport category airplanes produced under future new airplane type certifications. For manufacturers, a small entity is one with 1,500 or fewer employees. No part 25 airplane manufacturer has 1,500 or fewer employees. Notwithstanding, the relatively low annualized incremental certification costs are not considered significant. Consequently, the FAA certifies that the final rule will not have a ''significant economic impact on a substantial number of small entities'' (manufacturers).

International Trade Impact Assessment

The Trade Agreement Act of 1979 prohibits Federal agencies from engaging in any standards or related activities that create unnecessary obstacles to the foreign commerce of the United States. Legitimate domestic objectives, such as safety, are not considered unnecessary obstacles. The statute also requires consideration of international standards and where appropriate, that they be the basis for U.S. standards. In accordance with the above statute, the FAA has assessed the potential effect of this final rule and has determined that it will eliminate regulatory differences between the airworthiness standards of the U.S. and the Joint Aviation Requirements of Europe, without affecting current industry practice. This is consistent with the Trade Agreement Act.

Unfunded Mandates Reform Act

Title II of the Unfunded Mandates Reform Act of 1995 (the Act), enacted as Public Law 104–4 on March 22, 1995, requires each Federal agency, to the extent permitted by law, to prepare a written assessment of the effects of any Federal mandate in a proposed or final agency rule that may result in the expenditure by State, local, and tribal governments, in the aggregate, or by the private sector, of $100 million or more (adjusted annually for inflation) in any one year. Section 204(a) of the Act, 2 U.S.C. 1534(a), requires the Federal agency to develop an effective process to permit timely input by elected officers (or their designees) of State, local, and tribal governments on a proposed ''significant intergovernmental mandate.'' A ''significant intergovernmental mandate'' under the Act is any provision in a Federal agency regulation that will impose an enforceable duty upon State, local, and tribal governments, in the aggregate, of $100 million (adjusted annually for inflation) in any one year. Section 203

of the Act, 2 U.S.C. 1533, which supplements section 204(a), provides that before establishing any regulatory requirements that might significantly or uniquely affect small governments, the agency shall have developed a plan that, among other things, provides for notice to potentially affected small governments, if any, and for a meaningful and timely opportunity to provide input in the development of regulatory proposals. The FAA determines that this final rule does not contain a significant intergovernmental or private sector mandate as defined by the Act.

Executive Order 3132, Federalism

The FAA has analyzed this final rule under the principles and criteria of Executive Order 13132, Federalism. We determined that this action will not have a substantial direct effect on the States, or the relationship between the national Government and the States, or on the distribution of power and responsibilities among the various levels of government. Therefore, we determined that this final rule does not have federalism implications.

Regulations Affecting Intrastate Aviation in Alaska

Section 1205 of the FAA Reauthorization Act of 1996 (110 Stat. 3213) requires the Administrator, when modifying regulations in Title 14 of the CFR in a manner affecting intrastate aviation in Alaska, to consider the extent to which Alaska is not served by transportation modes other than aviation, and to establish such regulatory distinctions as he or she considers appropriate. Because this final rule applies to the certification of future designs of transport category airplanes and their subsequent operation, it could affect intrastate aviation in Alaska. The Administrator has considered the extent to which Alaska is not served by transportation modes other than aviation, and how the final rule could have been applied differently to intrastate operations in Alaska. However, the Administrator has determined that airplanes operated solely in Alaska would present the same safety concerns as all other affected airplanes; therefore, it would be inappropriate to establish a regulatory distinction for the intrastate operation of affected airplanes in Alaska.

Environmental Analysis

FAA Order 1050.1D defines FAA actions that may be categorically excluded from preparation of a National Environmental Policy Act (NEPA) environmental impact statement. In accordance with FAA Order 1050.1D, appendix 4, paragraph 4(j), this rulemaking action qualifies for a categorical exclusion.

Energy Impact

The energy impact of the final rule has been assessed in accordance with the Energy Policy and Conservation Act (EPCA) Public Law 94–163, as amended (42 U.S.C. 6362) and FAA Order 1053.1. It has been determined that the final rule is not a major regulatory action under the provisions of the EPCA.

List of Subjects in 14 CFR Part 25

Aircraft, Aviation safety, Reporting and recordkeeping requirements.

The Amendment

In consideration of the foregoing, the Federal Aviation Administration amends Chapter I of Title 14, Code of Federal Regulations as follows:

PART 25—AIRWORTHINESS STANDARDS: TRANSPORT CATEGORY AIRPLANES

1. The authority citation for part 25 continues to read as follows:

Authority: 49 U.S.C. 106(g), 40113, 44701, 44702 and 44704.

2. Amend § 25.731 by adding paragraphs (d) and (e) to read as follows:

§ 25.731 Wheels.

* * * * *

(d) *Overpressure burst prevention.* Means must be provided in each wheel to prevent wheel failure and tire burst that may result from excessive pressurization of the wheel and tire assembly.

(e) *Braked wheels.* Each braked wheel must meet the applicable requirements of § 25.735.

3. Revise § 25.735 to read as follows:

§ 25.735 Brakes and braking systems.

(a) *Approval.* Each assembly consisting of a wheel(s) and brake(s) must be approved.

(b) *Brake system capability.* The brake system, associated systems and components must be designed and constructed so that:

(1) If any electrical, pneumatic, hydraulic, or mechanical connecting or transmitting element fails, or if any single source of hydraulic or other brake operating energy supply is lost, it is possible to bring the airplane to rest with a braked roll stopping distance of not more than two times that obtained in determining the landing distance as prescribed in § 25.125.

(2) Fluid lost from a brake hydraulic system following a failure in, or in the vicinity of, the brakes is insufficient to cause or support a hazardous fire on the ground or in flight.

(c) *Brake controls.* The brake controls must be designed and constructed so that:

(1) Excessive control force is not required for their operation.

(2) If an automatic braking system is installed, means are provided to:

(i) Arm and disarm the system, and

(ii) Allow the pilot(s) to override the system by use of manual braking.

(d) *Parking brake.* The airplane must have a parking brake control that, when selected on, will, without further attention, prevent the airplane from rolling on a dry and level paved runway when the most adverse combination of maximum thrust on one engine and up to maximum ground idle thrust on any, or all, other engine(s) is applied. The control must be suitably located or be adequately protected to prevent inadvertent operation. There must be indication in the cockpit when the parking brake is not fully released.

(e) *Antiskid system.* If an antiskid system is installed:

(1) It must operate satisfactorily over the range of expected runway conditions, without external adjustment.

(2) It must, at all times, have priority over the automatic braking system, if installed.

(f) *Kinetic energy capacity*—(1) *Design landing stop.* The design landing stop is an operational landing stop at maximum landing weight. The design landing stop brake kinetic energy absorption requirement of each wheel, brake, and tire assembly must be determined. It must be substantiated by dynamometer testing that the wheel, brake and tire assembly is capable of absorbing not less than this level of kinetic energy throughout the defined wear range of the brake. The energy absorption rate derived from the airplane manufacturer's braking requirements must be achieved. The mean deceleration must not be less than 10 fps^2.

(2) *Maximum kinetic energy accelerate-stop.* The maximum kinetic energy accelerate-stop is a rejected takeoff for the most critical combination of airplane takeoff weight and speed. The accelerate-stop brake kinetic energy absorption requirement of each wheel, brake, and tire assembly must be determined. It must be substantiated by dynamometer testing that the wheel, brake, and tire assembly is capable of absorbing not less than this level of kinetic energy throughout the defined wear range of the brake. The energy absorption rate derived from the

airplane manufacturer's braking requirements must be achieved. The mean deceleration must not be less than 6 fps ^{2}.

(3) *Most severe landing stop.* The most severe landing stop is a stop at the most critical combination of airplane landing weight and speed. The most severe landing stop brake kinetic energy absorption requirement of each wheel, brake, and tire assembly must be determined. It must be substantiated by dynamometer testing that, at the declared fully worn limit(s) of the brake heat sink, the wheel, brake and tire assembly is capable of absorbing not less than this level of kinetic energy. The most severe landing stop need not be considered for extremely improbable failure conditions or if the maximum kinetic energy accelerate-stop energy is more severe.

(g) *Brake condition after high kinetic energy dynamometer stop(s).* Following the high kinetic energy stop demonstration(s) required by paragraph (f) of this section, with the parking brake promptly and fully applied for at least 3 minutes, it must be demonstrated that for at least 5 minutes from application of the parking brake, no condition occurs (or has occurred during the stop), including fire associated with the tire or wheel and brake assembly, that could prejudice the safe and complete evacuation of the airplane.

(h) *Stored energy systems.* An indication to the flightcrew of the usable stored energy must be provided if a stored energy system is used to show compliance with paragraph (b)(1) of this section. The available stored energy must be sufficient for:

(1) At least 6 full applications of the brakes when an antiskid system is not operating; and

(2) Bringing the airplane to a complete stop when an antiskid system is operating, under all runway surface conditions for which the airplane is certificated.

(i) *Brake wear indicators.* Means must be provided for each brake assembly to indicate when the heat sink is worn to the permissible limit. The means must be reliable and readily visible.

(j) *Overtemperature burst prevention.* Means must be provided in each braked wheel to prevent a wheel failure, a tire burst, or both, that may result from elevated brake temperatures. Additionally, all wheels must meet the requirements of § 25.731(d).

(k) *Compatibility.* Compatibility of the wheel and brake assemblies with the airplane and its systems must be substantiated.

Issued in Renton, Washington on April 10, 2002.

Vi L. Lipski,

Manager, Transport Airplane Directorate, Aircraft Certification Service.

[FR Doc. 02–9845 Filed 4–23–02; 8:45 am]

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DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

Advisory Circular 25.735–1, Brakes and Braking Systems Certification Tests and Analysis

AGENCY: Federal Aviation Administration, DOT.

ACTION: Notice of issuance for advisory circular and disposition of comments.

SUMMARY: This action announces the issuance of Advisory Circular (AC) 25.735–1, Brakes and Braking Systems Certification Tests and Analysis, and documents the disposition of comments received in response to the notice of availability for the proposed AC, published in the **Federal Register** on August 10, 1999. This AC sets forth an acceptable means, but not the only means, of demonstrating compliance with the braking system requirements of Title 14, Code of Federal Regulations (14 CFR) for transport category airplanes. Like all AC's, it is not regulatory but is to provide guidance for applicants in demonstrating compliance with the objective safety standards set forth in the rule. The FAA will publish the Revision of Braking Systems Airworthiness Standards final rule and a Notice of Availability of Technical Standard Order (TSO) C135 in the **Federal Register** when they are issued.

DATES: The subject advisory circular was issued in the FAA Transport Airplane Directorate in Renton, Washington, on April 10, 2002.

FOR FURTHER INFORMATION CONTACT: Mahinder K. Wahi, FAA, Propulsion/Mechanical Systems Branch, ANM–112, Transport Airplane Directorate, 1601 Lind Avenue SW., Renton, WA 98055–4056; telephone (425) 227–2142; facsimile (425) 227–1320, e-mail *mahinder.wahi@faa.gov*.

SUPPLEMENTARY INFORMATION:

How To Obtain a Copy of the AC

Copies of this AC can be found and downloaded from the Internet at *http://www.faa.gov/certification/aircraft/air—index.htm* by taking the following steps: Under ''Aircraft Certification Related Information'' click on Advisory Circulars. Under ''Search Help'' click on Related Links. Then click on Advisory Circulars. You may also go to the Regulatory and Guidance Library web site at *http:\\www.airweb.faa.gov/rgl*, at the link titled ''Advisory Circulars.'' Paper copies of the AC's will be available in approximately 6–8 weeks from the U.S. Department of Transportation, Subsequent Distribution Office, SVC–121.23, Ardmore East Business Center, 3341 Q 75th Avenue, Landover, MD 20785.

Discussion of Comments

Twenty-one commenters responded to the Notice of Proposed Rulemaking (NPRM), Proposed Advisory Circular (AC), and Notice of Availability of Proposed TSO and request for comments, published in the **Federal Register** on August 10, 1999 (64 FR 43579).

Comments were received from eight foreign and domestic airplane and brake manufacturers, nine foreign airworthiness authorities, one operator, and three foreign and domestic industry organizations. Six of the twenty-one commenters have comments on the proposed advisory circular. The majority of the six commenters agree with the proposal and recommend its adoption. However, some commenters disagree with the proposal, while providing alternative proposals that appear to merit further consideration by the Aviation Rulemaking Advisory Committee (ARAC). Therefore, the FAA tasked the ARAC Braking Systems Harmonization Working Group (HWG) by letter dated February 8, 2000, to consider the comments and provide recommendations for the disposition of the comments along with any recommendations for changes to the proposal. The disposition of the comments below is based on the agreement reached by the HWG and submitted to the FAA by letter, dated June 19, 2000. Several of the commenters address multiple issues, while many commenters address the same issue. As a result, the FAA responses to the comments are organized by paragraph number and subject.

1. *Purpose.* One commenter suggests using ''14 CFR'' or ''Federal Aviation Regulations'' instead of ''FAR.'' Although most people in the aerospace industry understand the informal use of the acronym FAR as pertaining to the requirements of Title 14 of the Code of Federal Regulations (14 CFR), it is not correct. The acronym FAR is an abbreviation for Federal Acquisition Regulations.

FAA's Response: The FAA concurs. The FAA is to use CFR to when referring to the Code of Federal Regulations. For Title 14, it appears as 14 CFR.

2. *Related Documents.* The same commenter suggests including a statement that all section numbers, such as § 25.735, refer to regulations in 14 CFR, unless otherwise noted.

FAA's Response: As stated in the ''Purpose'' paragraph, this AC provides guidance material for demonstrating compliance with the braking system requirements of 14 CFR.

3. *Background.* No comments were received for this paragraph.

4. *Discussion.*

Paragraph 4a(1)(e): One commenter explains the need to clarify the statement ''Combinations of any additional wheel and brake assemblies should meet applicable airworthiness requirements.'' In this context it is unclear what ''additional'' wheels and brakes mean. Also it is not recognized how meeting JAR 21.101(a) and (b) will eliminate situations that may have adverse consequence on airplane braking control and performance.

FAA's Response: The FAA concurs that a clarification is necessary. The second sentence is revised to read: ''Following initial airplane certification, any additional wheel and brake assemblies should meet the applicable airworthiness requirements.'' The FAA has decided that reference to § 21.101 and JAR 21.101 is appropriate.

Paragraph 4a(2) and 4a(3)(b): One commenter suggests deleting ''Refurbished and Overhauled Equipment'' from paragraph 4a(2) as this advisory material is not applicable for showing compliance to § 25.735(a). The same commenter suggests deleting ''monitoring plan'' from paragraph 4a(3)(b), again because this advisory material is not applicable for showing compliance to § 25.735(a).

FAA's Response: The FAA does not agree. The FAA considers the advisory material to be relevant to the continued airworthiness of qualified equipment, reference paragraph 2.1 of the TSO–C135.

Paragraph 4b(1): One commenter states that there is a significant difference between the Advisory Material Joint (AMJ) associated with the Joint Aviation Authority (JAA) rule and the AC associated with the FAA rule. The FAA material includes the word ''tire'' when referring to multiple failures originating from a single cause. It is pointed out that earlier drafts of the AMJ material also referred to tire failures potentially causing multiple hydraulic failures. The commenter recommends that the proposal should be re-worded to clarify that the rule refers to multiple failures from a single source occurring within the system itself. Failures from outside the system are adequately dealt with elsewhere in the regulations. Suggested text: ''Multiple failures resulting from a single cause shall be considered a single failure, for example, failure of a single component within the system leading to

the loss of two or more hydraulic supplies.''

FAA's Response: The FAA concurs and the JAA agrees to modify the AMJ text to agree with the AC text. The FAA disagrees with the suggested rewording. The wording is correct as stated. The tire is considered a part of the braking system. The tire failure example is appropriate and relevant for a single failure leading to multiple failures of hydraulic power.

Paragraph 4b(2)(c): One commenter states that if more than one fluid is allowed for the airplane hydraulic system, then the one resulting in the worst case scenario should be used for showing compliance. For example, LD–4 has a lower auto-ignition point than Skydrol 500B–4 and, if both are allowed for use on a particular airplane, the former should be used for showing compliance. A statement should be added accordingly. Note that the same comment has been made with respect to the proposed TSO–C135.

FAA's Response: The FAA concurs that if the applicant can identify one fluid that exhibits all the worst case properties, then that one fluid may be used to show compliance. However, fluids are tested and qualified for a multitude of properties and the same fluid is unlikely to possess all worst case scenario properties. Therefore, the statement ''If more than one fluid is allowed for the hydraulic system, compliance should be addressed for all fluids'' is added in the AC.

Paragraph 4f(1) and (2): Two commenters state that if the most severe landing stop is not added to 14 CFR 25.735(f) or included in TSO–C135, then it should not be included in the advisory material.

FAA's Response: The FAA concurs that the contents of the AC should reflect the regulation. The most severe landing stop test requirement is retained; hence no change in the AC is necessary.

Paragraph 4f(2)(a): One commenter suggests replacing the text ''conservative assessments of typical ambient conditions'' with ''assessment of ambient conditions within the operational limits established by the applicant and the typical time the airplane will be on the ground.'' The commenter states that the use of a typical ambient condition is inconsistent with the general requirements for landing performance that requires horizontal distances to be determined for standard temperatures within the operational limits established by the applicant.

FAA's Response: The FAA concurs and the text is revised accordingly.

Paragraph 4f(2)(b): One commenter states that the phrase ''with the airplane in a configuration that would enable such a return to be made'' might seem to indicate that the analysis is not to consider an immediate return to land in cases where the airplane configuration is less than ideal. This is obviously not the intent as illustrated in the NPRM discussion for § 25.735(f). Furthermore, there is no discussion about the acceptable probability of failure conditions in such cases (*i.e.* not extremely improbable), which is an important element of the rule. Finally, it should be specified how single failure cases are to be considered since their acceptability is linked to the effect, not the probability. For example, would it be acceptable that an applicant foregoes a most severe landing stop case test on the basis that it involves an extremely improbable single failure case resulting in a hazardous failure condition (such designs have been encountered in the past)? It is suggested that the discussion in the guidance material be expanded accordingly.

FAA's Response: The FAA concurs. The following statement is added to the AC: The applicant should address effects and consequences of typical single and multiple failure conditions which are foreseeable events and can necessitate landings at abnormal speeds and weights. The critical landing weight for this condition is the Maximum Takeoff Weight, less fuel burned and jettisoned during a return to the departure airfield. A 30-minute flight should be assumed, with 15 minutes of active fuel jettisoning if equipped with a fuel jettisoning system.

Paragraph 4f(3)(b): One commenter states that the concern about not allowing a brake application speed higher than the ones used in the determination of the kinetic energy requirements to ensure that proper energy absorption rates are achieved is understood. However, it is felt that ''as close as practicable'' is too subjective and should be quantified. This would alleviate the certification office to have to argue with the applicant as to what a lesser but appropriate brake application speed can be for a particular project and help ensure a level playing field nation wide. Note that a similar comment has been made on the proposed TSO–C135.

FAA's Response: The FAA disagrees. Quantifying the speed tolerance may lead to more restrictive inertia plate increments that may be incompatible with dynamometer setups ''As close as practicable'' provides the desired flexibility.

Paragraph 4f(3)(b): The following comment is made relative to TSO–C135 paragraph 3.3.1.3, but its disposition affects the AC paragraph 4f.(3)(b) as follows: The reason stated for not exceeding the speed specified is that ''for a target test deceleration,'' the rate of energy input will decrease as speed increases. However, for the same stop distance or torque, the deceleration must increase for a higher initial brake-on speed, which causes the rate of energy input to increase as speed increases. In general, experience has shown that for the same energy and torque requirement, higher initial brake-on speed is a more severe condition. The commenter suggests adding the following statement to the TSO paragraph 3.3.1.3, which is also included in proposed AC 25.735–lX: ''However, a brake having a higher initial brakes-on speed is acceptable If the dynamometer test showed that both the energy absorbed and the energy absorption rate required by § 25.735(f) had been achieved.''

Alternatively, a tolerance on initial brake application speed of ± 2 knots could be included, which is currently allowed by at least one airplane manufacturer. This will allow continuation of the current practice of matching Inertia Equivalent (IE) as close as possible and varying speed slightly to achieve the required energy, which has worked well for many years. If the specified speed cannot be exceeded, combined margins to allow for tire energy absorption (when brake energy is specified) and the inability to initiate a stop at a precise brake-on speed may drive the IE and brake-on speed farther from the specified conditions, than for the current practice.

FAA's Response: The FAA disagrees. The TSO wording for paragraph 3.3.1.3 is correct as stated. The FAA agrees that there was confusion in the text of AC 25.735–1X, and that rearrangement of some text in paragraph 4f(3)(b) is necessary. As a result, the sentence: ''However, a brake having a higher initial brakes-on speed is acceptable if the dynamometer test showed that both the energy absorbed and the energy absorption rate required by § 25.735(f) had been achieved.'' is removed from 4f(3)(b). This sentence is relocated under a separate paragraph, 4f(3)(c), to read as follows: ''(c). For certification purposes, a brake having a higher initial brakes-on speed is acceptable if the dynamometer test showed that both the energy absorbed and the energy absorption rates required by § 25.735(f) had been achieved.'' Existing paragraph ''4f(3)(c)'' is redesignated as ''4f(3)(d).''

Paragraph 4f(3)(c): One commenter suggests rewording this statement to say that brake qualification tests are not intended to verify expected performance on the airplane. Brake qualification tests are intended to predict expected performance on the airplane. This is the main reason for conducting these tests.

FAA's Response: The FAA disagrees. Airplane performance is determined by airplane tests, therefore, no change in the AC text is necessary.

Paragraph 4g(3): One commenter states that keeping the brake pressure applied throughout the 5-minute post stop period would help determine whether it might contribute to a fire hazard. It would, however, be acceptable for the parking brake pressure to fail to be maintained after 3 minutes, since the tires would most likely be deflated by that time anyway, thereby holding the aircraft stationary. It is important to determine whether the parking brake design aspects of the brake assembly could be potentially deficient at the time of qualification. Consequently, a statement to the effect that parking brake should remain applied throughout a 5-minute period should be added. Note that similar comments have been made about the proposed TSO–C135.

FAA's Response: The FAA does not concur that the parking brake should remain applied for 5 minutes and reaffirms the 3-minute parking brake applied period for the dynamometer test. The FAA agrees that clarification of the parking brake set period is needed. There is no intent by the FAA to dictate that the parking brake must be released at 3 minutes, but that it must be applied at least that long. Changes are made to the TSO Figures 3–1 and 3–2 and paragraphs 3.3.3.5 and 3.3.4.5 to minimize ambiguity in this respect.

The certification test on the airplane (worn brake RTO) need not follow the procedure prescribed in the TSO. But it is important that the brake manufacturer know early in the development period what procedure will be used on the airplane (i.e. the certification basis) since it can impact the design.

The Transport Canada (representative) agrees that this is an acceptable harmonized solution allowing authorities that are not part of the harmonization process the needed flexibility. Also see the disposition of comments under NPRM proposal 13, and TSO paragraphs 3.3.3.5 and 3.3.4.5.

Paragraph 4h(4): One commenter suggests changing ''A full brake application * * *'' to ''A full brake application cycle * * *'' The term ''brake application'' or ''brake actuation'' is commonly used to mean increasing pressure from fully released to fully applied, while ''brake retraction'' is commonly used to define returning brake pressure from fully applied to fully released. Using the term ''brake application cycle'' will help avoid the possibility of confusion.

FAA's Response: The FAA concurs and the AC text is changed accordingly.

Conclusion

With the exceptions of the changes noted in paragraph 4(a)(1)(e), 4b(2)(c), 4f(2)(a), 4f(2)(b), 4f(3)(b), 4f(3)(c), and 4h(4), this AC is adopted as proposed.

Issued in Renton, Washington, on April 10, 2002.

Ali Bahrami,

Acting Manager, Transport Airplane Directorate, Aircraft Certification Service.

[FR Doc. 02–9846 Filed 4–23–02; 8:45 am]

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LIST OF PUBLIC LAWS

This is a continuing list of public bills from the current session of Congress which have become Federal laws. It may be used in conjunction with ''P L U S'' (Public Laws Update Service) on 202–523–6641. This list is also available online at *http://www.nara.gov/fedreg/plawcurr.html*.

The text of laws is not published in the **Federal Register** but may be ordered in ''slip law'' (individual pamphlet) form from the Superintendent of Documents, U.S. Government Printing Office, Washington, DC 20402 (phone, 202–512–1808). The text will also be made available on the Internet from GPO Access at *http://www.access.gpo.gov/nara/nara005.html*. Some laws may not yet be available.

H.R. 1432/P.L. 107–160
To designate the facility of the United States Postal Service located at 3698 Inner Perimeter Road in Valdosta, Georgia, as the ''Major Lyn McIntosh Post Office Building''. (Apr. 18, 2002; 116 Stat. 123)

H.R. 1748/P.L. 107–161
To designate the facility of the United States Postal Service located at 805 Glen Burnie Road in Richmond, Virginia, as the ''Tom Bliley Post Office Building''. (Apr. 18, 2002; 116 Stat. 124)

H.R. 1749/P.L. 107–162
To designate the facility of the United States Postal Service located at 685 Turnberry Road in Newport News, Virginia, as the ''Herbert H. Bateman Post Office Building''. (Apr. 18, 2002; 116 Stat. 125)

H.R. 2577/P.L. 107–163
To designate the facility of the United States Postal Service located at 310 South State Street in St. Ignace, Michigan, as the ''Bob Davis Post Office Building''. (Apr. 18, 2002; 116 Stat. 126)

H.R. 2876/P.L. 107–164
To designate the facility of the United States Postal Service located in Harlem, Montana, as the ''Francis Bardanouve United States Post Office Building''. (Apr. 18, 2002; 116 Stat. 127)

H.R. 2910/P.L. 107–165
To designate the facility of the United States Postal Service located at 3131 South Crater Road in Petersburg, Virginia, as the ''Norman Sisisky Post Office Building''. (Apr. 18, 2002; 116 Stat. 128)

H.R. 3072/P.L. 107–166
To designate the facility of the United States Postal Service located at 125 Main Street in Forest City, North Carolina, as the ''Vernon Tarlton Post Office Building''. (Apr. 18, 2002; 116 Stat. 129)

H.R. 3379/P.L. 107–167
To designate the facility of the United States Postal Service located at 375 Carlls Path in Deer Park, New York, as the ''Raymond M. Downey Post Office Building''. (Apr. 18, 2002; 116 Stat. 130)

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