RULEMAKING ISSUE
AFFIRMATION

April 3, 2007 SECY-07-0062

FOR: The Commissioners

FROM: Luis A. Reyes
Executive Director for Operations

SUBJECT: FINAL RULE: REQUIREMENTS FOR EXPANDED DEFINITION OF BYPRODUCT MATERIAL (RIN: 3150-AH84)

PURPOSE:

To request Commission approval to publish a final rule in the *Federal Register* that would amend Title 10 of the *Code of Federal Regulations* (10 CFR) Parts 20, 30, 31, 32, 33, 35, 50, 61, 62, 72, 110, 150, 170, and 171.

SUMMARY:

The staff has developed a final rule establishing the regulatory framework for certain radium sources, accelerator-produced radioactive material, and certain discrete sources of naturally occurring radioactive material (hereafter referred to as NARM). This rulemaking is required by Section 651(e) of the Energy Policy Act of 2005 (EPAct), which expanded the definition of byproduct material in Section 11e. of the Atomic Energy Act of 1954 (AEA). The final rule revises the definition of "byproduct material," adds a definition for "discrete source," and amends existing regulations and adds certain provisions in order to provide the regulatory framework for the newly added byproduct material.

CONTACT: Lydia Chang, FSME\DILR
(301) 415-6319

BACKGROUND:

The EPAct was promulgated on August 8, 2005. Section 651(e) of the EPAct expanded the definition of byproduct material, as defined in Section 11e. of the AEA, to include certain discrete sources of radium, certain accelerator-produced radioactive material, and certain discrete sources of naturally occurring radioactive material, thereby placing these materials under U.S. Nuclear Regulatory Commission (NRC) jurisdiction. Specifically, Section 651(e)(1) of the EPAct expanded the definition of byproduct material by:

> (1) Adding as Section 11e.(3)(A) of the AEA--any discrete source of radium-226 that is produced, extracted, or converted after extraction, before, on, or after the date of enactment of the EPAct for use for a commercial, medical, or research activity;
>
> (2) Adding as Section 11e.(3)(B) of the AEA--any material that has been made radioactive by use of a particle accelerator and is produced, extracted, or converted after extraction, before, on, or after the date of enactment of the EPAct for use for a commercial, medical, or research activity; and
>
> (3) Adding as Section 11e.(4) of the AEA--any discrete source of naturally occurring radioactive material, other than source material, that (a) the Commission, in consultation with other Federal officials named in the EPAct, determines would pose a threat similar to the threat posed by a discrete source of radium-226 to the public health and safety or the common defense and security; and (b) is extracted or converted after extraction, before, on, or after the date of enactment of the EPAct for use in a commercial, medical, or research activity.

The NRC is also required by the EPAct to include a definition of “discrete source” in the regulation for the newly added byproduct material.

The NRC is required under Section 651(e) of the EPAct to develop a regulatory framework for licensing and regulating this newly added byproduct material. The EPAct requires NRC to consult with the States and other stakeholders in establishing requirements, and, to the maximum extent practicable, to cooperate with the States and to use model State standards in developing regulations for the newly added byproduct material. To enhance cooperation with the States and to improve efficiency in rulemaking, the staff has coordinated with both the Organization of Agreement States, Inc. (OAS) and the Conference of Radiation Control Program Directors, Inc. (CRCPD) since the beginning of this rulemaking process. OAS and CRCPD representatives have participated in the NARM Rulemaking Working Group and the Steering Committee in developing and finalizing this rule. The staff also has engaged the States, other Federal agencies, and other stakeholders by working closely with their representatives and by making information on this rulemaking readily available to the public. To the maximum extent practicable, the staff used the Suggested State Regulations for the Control of Radiation (SSRs) developed by the CRCPD as the model State standards in formulating regulatory requirements for the newly added byproduct material.

The EPAct requires NRC to issue final regulations within 18 months from the date of enactment (by February 7, 2007). However, in order to ensure that the rule has a sound technical basis, and in order to provide the appropriate time for stakeholder input, the staff required additional time to develop the regulations and with the Commission approval extended the date. Appropriate members of Congress were then notified of the change in the expected publication date of the final rule.

DISCUSSION:

On July 28, 2006, the proposed rule was published in the *Federal Register* (71 FR 42952) for a 45-day public comment period. The staff held a public meeting in Las Vegas on August 22, 2006, during the public comment period, to solicit comments and to enhance stakeholder involvement. Several individuals provided written statements and oral comments during the public meeting. In addition, the NRC received a total of 39 comment letters on the proposed rule from States, other Federal agencies, professional organizations, universities, medical communities, industries, and individuals.

Comments from OAS and the States were primarily centered around implementation of the requirements for the Compatibility Category of Health and Safety designation for several definitions, especially the definition of "byproduct material." The basic concern was the need to amend definitions in State statutes and regulations. OAS and the States suggested that the Statements of Consideration for the final rule could indicate that the NRC's initial determination of the adequacy of definitions would rely on the Governor's certification that the State's program is adequate and that no changes to the State's definitions would be required. In response, the staff did modify the Statements of Consideration to indicate that States may continue to use the existing definitions including "radioactive material" in State statutes and regulations, although States may need to revise their regulations to adopt certain requirements of this rule.

In addressing the public comments, changes were made in finalizing the rule. The changes between the proposed and final rule are highlighted in the following paragraphs.

Definition of Discrete Source

Section 651(e)(4) of the EPAct requires NRC to include in its regulations a definition for "discrete source." This definition of "discrete source" will apply to radium-226 and other naturally occurring radioactive material, other than source material, that are now defined as byproduct material. The term "discrete source" does not apply to accelerator-produced radioactive material. The staff notes that this new NRC authority over radium-226 and other naturally occurring radioactive material does not extend to all naturally occurring radioactive material found in nature in its original form, concentration, and location.

The proposed rule included the following definition of discrete source: *"a source with physical boundaries, which is separate and distinct from the radiation present in nature, and in which the radionuclide concentration has been increased by human processes, with the intent that the concentrated radioactive material will be used for its radiological properties."* Some commenters on the proposed rule expressed concern about the clarity of the definition. Several commenters believed that such provisions as the requirement that the source have physical boundaries and that the materials have been concentrated for their radiological properties were

ambiguous and could lead to uneven regulation. As a result of public comments, the staff changed the wording of the definition. The changes are for clarification purposes only and do not alter the original intent or the scope of the definition as presented in the proposed rule. In the final rule, discrete source is defined as: "*a radionuclide that is distinct from the sources of radiation present in nature, and that has been processed so that its concentration within a material has been purposely increased for use for commercial, medical, or research activities*." This definition continues to exclude NRC jurisdiction over inadvertent movement or concentration of naturally occurring radioactive material, such as scale from pipes used in the fossil fuel industry, fly ash from coal power plant, phosphate fertilizers, or residuals from treatment of water. NRC's authority over source material is not changed.

Regulatory Approach for Old Timepieces Containing Radium-226

In the proposed rule, the NRC specifically requested comments regarding the proposed exemption and licensing approach for radium-226 and requested technical, health, and safety information in support of an exemption of old radium-226 sources but did not receive any substantive information. In order to obtain a sound technical basis for its proposed regulatory approach, the staff conducted a scoping study for estimating potential doses to individuals associated with use, storage, and repair of radium-226 timepieces. The staff used widely accepted methods and employed conservative assumptions for various scenarios. In order to evaluate the potential doses associated with the proposed exemption of radium-226 timepieces, 1 microcurie (µCi) [37 kilobecquerels (kBq)] of radium-226 per timepiece was used in the scoping study instead of the typical average activities for timepieces, which provided additional conservatism. The average activities for wristwatches, pocket watches, and clocks are 5.6 kBq (0.15 µCi), 13 kBq (0.35 µCi), and 18 kBq (0.5 µCi), respectively. Radon-222 is a decay product in radium-226 and may be emitted from the timepiece resulting in exposure to an individual in proximity to the timepiece. Although it is believed that most of the radon-222 would be trapped within the timepiece, the scoping study assumed that the entire inventory of decay products instantly escaped from the timepiece because there is no established method for quantifying the trapping behavior. As a result, the estimated inhalation doses associated with radon-222 are extremely conservative. The scoping study found that the estimated doses for radium-226 exposures and radon-222 inhalation of a collector for repair, storage, and use of one radium-226 timepiece range from a fraction of 0.01 millisievert/year (mSv/yr) [1 millirem/year (mrem/yr)] to a few 0.01 mSv/yr (1 mrem/yr) to over 1 mSv/yr (100 mrem/yr).

It is important to note that the manufacturing of timepieces containing radium-226 discontinued in 1968 for watches and in 1978 for clocks. To date, a large number of radium-226 timepieces are still owned by individuals as heirlooms or collectors' items or are on display in museums. Since collectors and museums normally collect a wide range of timepieces, only a portion of their collections may contain radium-226 timepieces. Collections of pocket watches and clocks are rare when compared to wristwatches. At one time, there were repair facilities refurbishing radium timepieces on a regular basis by replacing radium-226 paint with tritium paint, which may have resulted in contamination from scraping off radium-226 paint. The staff is not aware of any current operations in which individuals are still routinely handling radium watches in such a way that may create a contamination problem.

In finalizing the rule, the staff considered a number of factors such as that: (1) These timepieces were manufactured before the NRC assumed regulatory authority over radium-226;

(2) These timepieces are already in public possession; (3) These timepieces are mostly kept as collectors' items or museum pieces; (4) The scoping study indicates no significant risk to public health and safety and the environment; and (5) Most Agreement States have managed these items as if they were exempt. As a result of its review, the staff has determined that no change is needed from the proposed rule to exempt previously manufactured, intact timepieces containing no more than 37 kBq (1 µCi) of radium-226. However, a change was made to regulate the repair of timepieces and the possession of nonintact timepieces, hands and dials, and timepieces containing 37 kBq (1 µCi) or more of radium-226, under a general license, to be consistent with the SSRs and to provide regulatory flexibility for the Agreement States. The combination of the exemption and general license provisions should cover most of the current practices involving timepieces containing radium-226 and minimize impacts to individual collectors and small businesses. A general license is automatically granted by NRC regulations to any persons meeting the general license criteria. No action is required from these persons to obtain a general license, and license or annual fees are normally not applicable to these persons operating under this general license.

Regulating Other Radium-226 Sources

In response to public comments, the general license provisions for luminous gauges and other luminous products containing radium-226 were changed. Specifically, the provision for luminous items installed in aircraft was expanded to include those installed in air, marine, and land vehicles. Two subparagraphs in 10 CFR 31.12 for the general license were revised and simplified in the final rule. One subparagraph that allowed no more than 50 luminous products, including timepiece hands and dials, now covers only timepieces and timepiece hands and dials, and the number limitation was eliminated because it was determined to be unnecessary based on the scoping study. The other subparagraph that allowed no more than 100 luminous items no longer installed in aircraft, is simplified to allow all other luminous products, and the number of luminous items remains unchanged at 100 items. In addition, a provision was added to exempt individuals operating under a general license from reporting and recordkeeping requirements to further reduce the regulatory burden on stakeholders.

Regulating Accelerator-Produced Radioactive Material

Through reviewing the public comments, it became clear that the discussion in the proposed rule on the distinction between radionuclide production licensing and radioactive drug production licensing was confusing. The regulations were restructured and the Statements of Consideration expanded to give a clearer overview of the regulatory framework. The production of radionuclides by accelerators (including Positron Emission Tomography (PET) radionuclides from cyclotrons), as well as the subsequent possession and use of these radionuclides, will be licensed under existing requirements in 10 CFR Part 30. The producer of the accelerator-produced radionuclides (including PET radionuclides) can transfer these radionuclides to manufacturers and other specific licensees under the provisions of 10 CFR 30.41. This includes both commercial and noncommercial distribution of accelerator-produced radionuclides (including PET radionuclides) to specifically licensed universities and research laboratories, for basic research, but not for use on human beings which is specifically excluded in the definition of research and development in 10 CFR 30.4.

There is a distinction between the “production of radionuclides” and “preparation of radioactive drugs.” Production of radionuclides (including production of PET radionuclides using a cyclotron) is regulated under 10 CFR Part 30. Preparation of radioactive drugs (including PET radioactive drugs) from radionuclides is regulated under 10 CFR 32.72 and 10 CFR Part 35; preparation of radioactive drugs may occur at locations other than the production facility. In the proposed rule, a provision was included in 10 CFR 32.72 to authorize commercial nuclear pharmacies that were not registered with the Food and Drug Administration, or registered with a State as a PET drug production facility, to produce PET radionuclides if their radiation safety programs meet the criteria in 10 CFR 30.33. Since the purpose of 10 CFR 32.72 is to address the criteria and requirements for the production and commercial distribution of radioactive drugs, and not the production of radionuclides, this particular provision was removed from the rule. Activities related to production of radionuclides are governed under 10 CFR Part 30 regulations.

Noncommercial Distribution of PET Radioactive Drug

Because of the extremely short half-life of PET radionuclides for medical use, a PET radionuclide production facility is generally located near the medical use facility. Therefore, there is a need for noncommercial distribution of PET radioactive drugs, and provisions were included in the proposed rule to allow noncommercial distribution of PET radioactive drugs. Public comments indicated that there was some confusion about these provisions. As a result of public comments, the provisions for noncommercial distribution were restructured for clarification purposes. Specifically, provisions were moved from 10 CFR Part 35 to 10 CFR Part 30 to provide for the licensing of a radionuclide production facility and for noncommercial transfers of PET radioactive drugs to licensees within the same consortium. The provisions were moved because a PET radionuclide facility is regulated under 10 CFR Part 30 requirements, and it may not also have a medical use license under 10 CFR Part 35. In addition, a definition of consortium has been added.

Derived Air Concentrations for Nitrogen-13 and Oxygen-15

During the development of the proposed rule, the staff performed a preliminary calculation and found that the calculated values for nitrogen-13 and oxygen-15 are larger than the default values in Appendix B of 10 CFR Part 20 for Derived Air Concentration (DAC) and effluent concentration only by a factor of about 40 and 20, respectively. Because the approach used to calculate values for these radionuclides is different from that used for other radionuclides included in 10 CFR Part 20, Appendix B, due to lack of certain dose conversion factors and because the SSRs do not include DAC values for nitrogen-13 and oxygen-15, the NRC did not add specific values for these radionuclides in the proposed rule. In response to comments from the medical community, the staff conducted a study to develop scientifically sound inhalation dose coefficients for occupational and public exposures for nitrogen-13 and oxygen-15. Based on the results of the study, a specific DAC value of 1.48×10^{-2} becquerels per milliliter (Bq/ml) (4×10^{-6} µCi/ml) and a corresponding effluent concentration of 7.4×10^{-4} Bq/ml (2×10^{-8} µCi/ml) for both nitrogen-13 and oxygen-15 are added to 10 CFR Part 20, Appendix B, in the final rule.

Implementation Strategy

In the proposed rule, one aspect of the implementation approach provided that, in order for persons to continue to use NARM after the expiration or termination of the waiver, requests for licensing actions (e.g., amendments or new applications) would need to be received by the NRC on or before August 7, 2009 (the date that the waiver expires) or earlier, if the waiver was terminated earlier. This would essentially mean that all waivers would need to be terminated in August 2008, in order to provide all affected persons the same amount of time to submit licensing actions to the NRC. Public comments were received requesting that the NRC allow sufficient time for users to prepare for regulatory change, by terminating the waiver in conjunction with the waiver expiration date. In response to public comments, minor changes have been made to the final rule to provide for a limited number of waivers in certain States (including States expressing interest in becoming Agreement States) to be terminated in conjunction with the expiration date of the waiver on August 7, 2009. These minor implementation changes also compensate for the delay in the schedule for this rulemaking and provide sufficient time to transition regulatory authority to the NRC Regional offices, while closely coordinating with the impacted States and licensees. When these waivers are terminated, the final rule allows for persons to submit requests for a license amendment within 6 months from the waiver expiration date of August 7, 2009, and requests for a license within 12 months from the waiver expiration date. These minor changes have been coordinated with the States and are being communicated to licensees in a broad status update on the implementation of NRC's regulatory authority for NARM. Finally, consistent with the approach described in SECY-06-0195, the staff plans to publish the final transition plan after the final rule is published in the *Federal Register,* and prior to the effective date of the final rule.

The transition to the NRC regulation of these materials could present some challenges in the inspection and enforcement arenas. During the time between the termination of the waiver and the user's application for an NRC license or amendment (up to a year), users in Government agencies, Federally recognized Indian Tribes, and non-Agreement States will be under the NRC jurisdiction but will either not have an NRC license or not have one that has been amended to recognize the use of the newly regulated byproduct material. In such circumstances, the NRC will have authority to issue Orders and Notices of Violation; however, the use of civil penalties may be problematic. Further, the staff estimates that there will be a very small group of users of the newly regulated byproduct material who will be unaware of the need to seek a license from the NRC. The size of this group of users is estimated to be very small because in many applications such as medical and industrial uses, both NRC regulated and the previously unregulated materials are used within the same organization. Since these entities are licensed for other NRC regulated materials, these users will be informed of the need to add the newly regulated byproduct material to their license through NRC communications issued to licensees. The production of gauges and other devices using materials such as radium ceased years ago. The likelihood that there are significant numbers of such devices in use at companies not already possessing a license is very small. During the transition, the staff intends to handle enforcement cases involving the use of the newly regulated byproduct material on a case-by-case basis. However, should the number of cases involving these materials be larger than anticipated, the staff will prepare additional enforcement guidance to ensure consistency in handling such issues.

NRC Strategic and Performance Goals

The rule is consistent with NRC's strategic objectives and performance goals. Because the rule is based on NRC's statutory authority to ensure protection of the public health and safety and the environment and to ensure the secure use and management of radioactive material, the rule establishes the regulatory structure to ensure proper management and safe use of the newly added byproduct material. Regulating the newly added byproduct material in conjunction with the existing byproduct material would result in an overall improvement of public health and safety and the environment in the non-Agreement States because the regulatory structure varies from State to State. Furthermore, using the general license approach to regulate certain discrete sources of radium-226 would support NRC's risk-informed regulatory approach. Regulating the newly added byproduct material within the NRC's existing regulatory structure will make the NRC's actions more effective and efficient. To ensure openness in the regulatory process, the staff held a public meeting on this rulemaking in early November 2005 and again in August 2006 to solicit public input. In addition, the proposed rule was published for public comment, and a NARM Rulemaking Web Page was created to keep the stakeholders informed. The staff plans to post the draft final rule on the NARM Rulemaking Web Page once this Commission Paper is publicly released.

State Coordination

Since the beginning of the rulemaking process, the staff has coordinated closely with both OAS and CRCPD to enhance State involvement and to improve efficiency and effectiveness of rulemaking. The NRC has received continued support through State participation in the NARM Rulemaking Working Group and the Steering Committee. The State representatives who participated in these various groups have played a key role in the development of the rule and have provided valuable input to the rulemaking process.

During the public comment period, comments were received from OAS and from other individual States in support of the OAS comments as well as providing additional comments of their own on the proposed rule. State comments were addressed in finalizing the rule. On February 26, 2007, a copy of the draft final rule was posted on NRC's Technical Conference Forum so the States (both Agreement States and non-Agreement States) could have an early opportunity to review and comment on the draft final rule. Comments were received from the OAS and 5 Agreement States (Idaho, Illinois, Michigan, New Jersey, Washington, and Wisconsin). OAS was particularly concerned with the Compatibility Category designation of "B" for the revised definition of "Authorized User" and "Authorized Nuclear Pharmacist" to recognize those individuals who have used NARM. To address the OAS concern, the staff determined that it was not necessary to revise the existing definitions of these two terms and that individuals who use NARM may be recognized through the other grandfather provisions in the rule. The grandfather provisions have a Compatibility Category designation of "D" since Agreement States have regulated NARM and have included NARM users as "Authorized Users" and "Authorized Nuclear Pharmacists."

For definitions and sections with a Compatibility Category designation of "B," OAS stated that the definitions should be designated as "H&S." In the final rule, all definitions are designated as Compatibility Category (H&S) with the exception for the definition of "Waste," which still has the Compatibility Category designation of "B." Since the EPAct allows for disposal of the newly

added byproduct material at a disposal facility in accordance with any Federal or State solid or hazardous waste law, it is necessary for both the NRC and the Agreement States to include the same allowance in their regulations. Because categorization of waste and waste disposal have direct transboundary implications, the definition of “Waste” is assigned a Compatibility Category designation of “B.”

The State of Michigan expressed concern for allowing disposal of the newly added byproduct material, especially those large radiation sources, at solid and hazardous waste landfills and suggested a change to the rule allowing disposal only for discrete source of naturally occurring radioactive material meeting certain general license provisions. Since the suggested change would be in direct conflict with the statutory requirements of the EPAct, the staff did not make any change as a result of this comment.

The State of New Jersey had two concerns, both related to those previously expressed during the public comment period. These concerns were: (1) NRC's continued support of the exemption under 10 CFR 30.20 for smoke detectors containing up to 74 kBq (2 uCi) of radium-226. In this connection, the State took issue with the statement in the draft Federal Register notice that such smoke detectors are already being exempted by the States, because the State of New Jersey does not exempt such quantity of material and (2) the difficulties in proving whether old radium-226 sources were used for commercial, medical, or research activities. To address the first concern, a minor clarification in the response to public comments was made to correct the statement that all states exempt these smoke detectors. As for the second concern, the staff recognizes the difficulties associated with making this determination. However, the EPAct only gives the NRC authority to regulate any discrete sources of radium-226 that is produced, extracted, or converted after extraction for use for commercial, medical, or research activity. Inclusion of such phrase in the definition of “discrete source” is consistent with the EPAct. A discussion of these concerns is already included in Section III, "Summary and Analysis of Public Comments on the Proposed Rule," of the Federal Register notice.

Other State comments are mostly editorial or suggestions for clarification of the rule and some of the comments are not directly related to the rule. All comments were considered, and changes were made, where appropriate, to the *Federal Register* notice for the final rule.

Coordination with the Advisory Committee on the Medical Uses of Isotopes (ACMUI)

A copy of the draft final rule was sent to the ACMUI for comment at the same time that it was sent to the States, and comments were received from the ACMUI on March 13, 2007. ACMUI comments were primarily related to NRC’s licensing practice and not directly related to the rule. ACMUI comments also included some editorial suggestions to clarify statements in the discussion section of the *Federal Register* notice. ACMUI comments were considered, and appropriate changes were made.

COMMITMENTS:

Listed below are the actions or activities committed to by the staff in this paper.

1. The staff will post the draft final rule on the NRC Web site once the Commission paper is publicly released.

2. The staff plans to publish the final transition plan after the final rule is published in the *Federal Register* and prior to the effective date of the rule.

3. The staff plans to notice separately in the *Federal Register* the draft guidance associated with this rule, which is currently being finalized, for public comment in Spring of 2007.

RECOMMENDATIONS:

That the Commission:

1. Approve for publication in the *Federal Register* the final amendments to 10 CFR Parts 20, 30, 31, 32, 33, 35, 50, 61, 62, 72, 110, 150, 170, and 171 (Enclosure 1).

2. To satisfy the requirement of the Regulatory Flexibility Act, 5 U.S.C. 605 (b), certify that this rule if promulgated will not have significant impact on a substantial number of small entities. This certification is included in the enclosed *Federal Register* notice.

3. Note:

   a. The Chief Counsel for Advocacy of the Small Business Administration will be informed of the certification and the reasons for it, as required by the Regulatory Flexibility Act, 5 U.S.C. 605(b);

   b. A final Environmental Assessment has been prepared for this rulemaking (Enclosure 2);

   c. A final Regulatory Analysis has been prepared for this rulemaking (Enclosure 3);

   d. The staff has determined that this action is not a “major rule,” as defined in the Congressional Review Act (CRA) of 1996 [5 U.S.C 804(2)] and has confirmed this determination with the OMB. The appropriate Congressional and Government Accountability Office contacts will be informed (Enclosure 4);

   e. The appropriate Congressional committees will be informed;

   f. A press release will be issued by the Office of Public Affairs when the final rulemaking is filed with the Office of the Federal Register; and

g. The final rule contains amended information collection requirements subject to the Paperwork Reduction Act of 1995 (44 U.S.C. 3501, et seq.) that must be submitted to OMB for its review and approval before publication of the final rule in the *Federal Register*.

RESOURCES:

Less than 0.3 full-time equivalent (FTE) in FY 2007 is needed to complete this rulemaking. These resources are included within the FY 2007 total budget for this rulemaking of 1.8 FTE for FSME. The information on resources and schedule reflects the current environment. If a significant amount of time (greater than 30 days) passes, or the Commission provides the staff direction that differs from, or adds to, the staff's recommended actions, the resources may need to be revisited after issuance of the draft Staff Requirements Memorandum.

COORDINATION:

The Office of the General Counsel has no legal objection to the final rule. The Office of the Chief Financial Officer has reviewed this Commission Paper for resource implications and has no objections. Information collection requirements for the rule must be submitted to OMB for approval prior to publication in the *Federal Register*.

/RA Martin J. Virgilio Acting For/

Luis A. Reyes,
Executive Director
for Operations

Enclosures:
1. *Federal Register* Notice
2. Environmental Assessment
3. Regulatory Analysis
4. CRA forms

[7590-01-P]

NUCLEAR REGULATORY COMMISSION

10 CFR Parts 20, 30, 31, 32, 33, 35, 50, 61, 62, 72, 110, 150, 170, and 171

RIN: 3150-AH84

Requirements for Expanded Definition of Byproduct Material

AGENCY: Nuclear Regulatory Commission.

ACTION: Final rule.

SUMMARY: The Nuclear Regulatory Commission (NRC) is amending its regulations to include jurisdiction over discrete sources of radium-226, accelerator-produced radioactive materials, and discrete sources of naturally occurring radioactive material, as required by the Energy Policy Act of 2005 (EPAct), which was signed into law on August 8, 2005. The EPAct expanded the Atomic Energy Act of 1954 definition of *Byproduct material* to include any discrete source of radium-226, any material made radioactive by use of a particle accelerator, and any discrete source of naturally occurring radioactive material, other than source material, that the Commission, in consultation with other Federal officials named in the EPAct, determines would pose a similar threat to the public health and safety or the common defense and security as a discrete source of radium-226, that are extracted or converted after extraction for use for a commercial, medical, or research activity. In so doing, these materials were placed under the NRC's regulatory authority. The EPAct also mandated that the Commission, after consultation with the States and other stakeholders, issue final regulations establishing requirements that the Commission determines necessary under the EPAct. This rulemaking

effort has been undertaken in response to that mandate and includes significant contributions from many States that have regulated the naturally occurring and accelerator-produced radioactive material, the Organization of Agreement States, Inc., the Conference of Radiation Control Program Directors, Inc. (CRCPD), and other stakeholders. In addition, this final rule was informed and guided by the CRCPD's applicable Suggested State Regulations for the Control of Radiation. Licensees, individuals, and other entities who are engaged in activities involving the newly defined byproduct material in both Agreement States and non-Agreement States and United States Territories will be affected by this rulemaking.

EFFECTIVE DATE: This final rule is effective on **[insert 60 days from date of publication].**

FOR FURTHER INFORMATION CONTACT: Lydia Chang, Office of Federal and State Materials and Environmental Management Programs, U.S. Nuclear Regulatory Commission, Washington, DC 20555-0001, telephone (301) 415-6319, e-mail lwc1@nrc.gov.

SUPPLEMENTARY INFORMATION:

I. Background

The Energy Policy Act of 2005.

On August 8, 2005, the President signed into law the EPAct. Among other provisions, Section 651(e) of the EPAct expanded the definition of *Byproduct material* as defined in Section 11e. of the Atomic Energy Act of 1954 (AEA), placing additional byproduct material under the NRC's jurisdiction, and required the Commission to provide a regulatory framework for licensing and regulating this additional byproduct material.

Specifically, Section 651(e) of the EPAct expanded the definition of *Byproduct material* by: (1) adding any discrete source of radium-226 that is produced, extracted, or converted after extraction, before, on, or after the date of enactment of the EPAct for use for a commercial, medical, or research activity; or any material that has been made radioactive by use of a

particle accelerator and is produced, extracted, or converted after extraction, before, on, or after the date of enactment of the EPAct for use for a commercial, medical, or research activity (Section 11e.(3) of the AEA); and (2) adding any discrete source of naturally occurring radioactive material, other than source material, that the Commission, in consultation with the Administrator of the Environmental Protection Agency (EPA), the Secretary of the Department of Energy (DOE), the Secretary of the Department of Homeland Security (DHS), and the head of any other appropriate Federal agency, determines would pose a threat similar to the threat posed by a discrete source of radium-226 to the public health and safety or the common defense and security; and is extracted or converted after extraction before, on, or after the date of enactment of the EPAct for use in a commercial, medical, or research activity (Section 11e.(4) of the AEA).

Although Section 651(e) of the EPAct became effective on August 8, 2005, the NRC did not have regulations in place that would specifically apply to this newly covered byproduct material (hereafter referred to as NARM). The EPAct also allowed the NRC to issue waivers to States and other entities while developing final regulations for NARM. A waiver was issued on August 31, 2005 (70 FR 51581).

Previous Regulatory Structures for NARM.

The AEA authorizes the States to assume regulatory control of certain radioactive materials provided the State has an adequate program to protect the public health and safety and is compatible with the NRC's program for regulation of these materials and enters into an agreement with the NRC. As authorized by Section 274b of the AEA, 34 States have assumed responsibility for regulating certain activities related to radioactive material by entering into agreements with the NRC. The activities regulated by these "Agreement States" include the use of byproduct material, source, and special nuclear material. Each Agreement State issues

licenses to persons who use these materials in that State except for DOE, other Government agencies, and Federally recognized Indian Tribes. The NRC issues licenses to persons using these materials in non-Agreement States.

Before enactment of the EPAct, the NRC did not have authority over NARM or regulations for this type of material. Although the NRC has not regulated NARM in the past, all 34 Agreement States and certain non-Agreement States have regulatory programs for NARM. The NRC's regulations did require licensees to account for dose contributed from NARM, as well as dose contributed from other byproduct, source, or special nuclear material, because the definition of *Occupational dose* encompasses both licensed material and nonlicensed material such as NARM sources at a licensed facility. In addition, the NRC requires in its radiological criteria for license termination that licensees consider other nondiscrete sources, including radium, during decommissioning activities at sites contaminated with source material, such as rare-earth processing facilities.

Currently, there are 16 non-Agreement States plus United States (U.S.) Territories. Although most non-Agreement States and U.S. Territories have some type of programs for NARM, the regulatory structures vary greatly. Certain non-Agreement States have established a licensing structure for regulating their NARM users. As such, the regulatory structure could parallel the NRC regulations issued in Title 10 of the Code of Federal Regulations (10 CFR) applicable to the current materials program, or it could parallel the Suggested State Regulations for the Control of Radiation (SSRs) developed by the CRCPD. Other non-Agreement States or U.S. Territories have elected to use registration as their regulatory structure for managing the NARM users. Some States register facilities; others register both facilities and devices. Some States use registration information to conduct inspections; others use registration to identify facility locations for security purposes. In general, there is limited regulatory oversight where registration is used in non-Agreement States. It was, in part, due to this lack of national

consistency, that the EPAct placed these materials under the NRC's jurisdiction.

Agreement States have regulated NARM use for many decades in a fairly uniform and consistent manner. The Agreement States have accomplished this by using the same standards to regulate NARM as those used to regulate other byproduct, source, and special nuclear material under the NRC's authority. In many respects, regulations applicable to NARM adopted by the Agreement States are compatible with the NRC's regulations for the current materials program, or parallel the CRCPD's SSRs.

Although Agreement States do have some provisions specifically for NARM, in general, the regulatory structure used by Agreement States does not distinguish between NARM and other radioactive material. NARM users in the Agreement States are expected to implement all aspects of standards for their radiation protection programs with respect to NARM, including those aspects relating to receipt, possession, use, storage, transfer, transportation, and disposal of NARM. This regulatory structure also subjects NARM users in the Agreement States to the same licensing, inspection, and enforcement policies as those using other byproduct, source, or special nuclear materials. In addition, this regulatory structure allows for both specific and general licensing of various NARM products, the distribution of certain NARM items to persons exempt from regulation and, in most cases, includes provisions to review and approve proposals for sealed sources and devices containing NARM.

The Agreement States have regulated a vast array of NARM produced for medical, industrial, research and development, commercial, and consumer purposes. In many Agreement States, this regulatory structure also captures some types of nondiscrete sources found in the oil and gas industry or mining industry; moreover, it captures inadvertently produced activation products from the use of proton beams for medical radiation therapy. However, the regulation of these nondiscrete sources and activation products varies from Agreement State to Agreement State.

Other Federal Agencies' Regulatory Authority Over NARM.

Although the States had the primary responsibility for regulating the use of NARM before the passage of the EPAct, certain Federal regulations continue to apply under some circumstances, such as environmental protection, workplace safety, drug safety, transportation, and disposal. With the passage of the EPAct, the NRC will have primary responsibility for radiation safety and in regulating the use of these materials in cooperation with the States, with the exception of those activities that are self-regulated by the DOE.

Other Federal agencies have regulations or have established programs for self-regulating certain activities involving NARM. The Department of Transportation (DOT) regulates interstate transport of NARM. In cooperation with DOT, the NRC approves Type B packages through regulations in 10 CFR Part 71. The EPA has established controls for certain NARM through several authorities, including the Clean Air Act, the Safe Drinking Water Act, the Toxic Substances Control Act, the Resource Conservation and Recovery Act, and the Comprehensive Environmental Response, Compensation, and Liability Act. The Occupational Safety and Health Administration (OSHA) of the Department of Labor has the oversight for occupational health and safety for radiation protection. It has regulations governing radiation protection in the workplace, including provisions addressing the exposure of minors to radioactive material in the workplace, but defers to the NRC on AEA materials. The Department of Commerce (DOC) has controlled the export of radioactive material. Before the enactment of the EPAct, the DOC regulated the export of all radium-226. With the enactment of the EPAct, the NRC will regulate the export of discrete sources of radium-226; DOC retains jurisdiction to regulate the export of nondiscrete sources of radium-226. The Consumer Product Safety Commission regulations have addressed hazardous substances other than

byproduct, source, and special nuclear materials currently regulated by the NRC. The Food and Drug Administration (FDA) regulates all drugs (including drugs containing radioactive materials) by requiring good manufacturing practices to assure the purity, potency, and consistency of finished drugs with their labeling in establishing the safety and effectiveness of these drugs.

Section 651(e)(3) of the EPAct provides that byproduct material, as defined by Section 11e.(3) or 11e.(4) of the AEA, may only be transferred to and disposed of in a disposal facility that is adequate to protect public health and safety, and is licensed by either the NRC or a State that has entered into an agreement with the Commission under Section 274b of the AEA or at a disposal facility in accordance with any Federal or State solid or hazardous waste law, including the Solid Waste Disposal Act, also known as the Resource Conservation and Recovery Act (RCRA).

Development of the Suggested State Regulations (SSRs).

Since enactment of the AEA in 1954, scientists continue to develop new technologies in producing radionuclides, such as the use of particle accelerators. At the beginning of the 20th century, naturally occurring radioactive material, including radium-226, was routinely used in consumer products and in cancer treatment. Because there was no Federal mandate to regulate these materials, most States have since established regulatory structures for both accelerator-produced radioactive material and naturally occurring radioactive material, including radium-226.

In 1968, CRCPD was chartered as a nonprofit organization to provide a forum for enhancing communication among States and Federal agencies regarding radiation regulations and to promote a uniform radiation protection environment for all radioactive material.

Throughout the years, CRCPD developed policies and guidance for its member States. In addition, CRCPD is responsible for the development of model regulations, known as the SSRs. Under the SSRs' regulatory framework, NARM has been a regulated radioactive material comparable to byproduct material. Nearly all of the Agreement States have based their regulations on this model for NARM.

For NARM regulation only, CRCPD also established "Licensing States" similar to the Agreement State Program under Section 274 of the AEA. Licensing States recognized by CRCPD under criteria found in Publication 94-8, "CRCPD Recognition of Licensing States for the Regulation and Control of NARM," are those States that have demonstrated an adequate and consistent regulatory control program for NARM. Licensing State designation assures comparable regulatory structures with respect to NARM, and other States may grant reciprocal recognition of their licenses or acceptance of their licensees' manufactured products.

Issuance of Waiver on August 31, 2005.

Section 651(e) of the EPAct became effective immediately upon signature by the President on August 8, 2005. Before enactment of the EPAct, the NRC did not have authority over NARM or regulations in place that would specifically apply to this material. Nonetheless, persons engaged in activities involving NARM could be, and States seeking to continue regulation of NARM would be, in technical violation of the AEA.

Section 651(e)(5) of the EPAct authorized the Commission to issue a waiver of the requirements of Section 651(e) to any entity with respect to NARM for specified periods of time if the Commission determined that the waiver was in accordance with the protection of the public health and safety and the promotion of the common defense and security. The Commission determined that there was no basis to conclude that these materials would not

continue to be used in a manner that is protective of public health and safety while the waiver is in effect. The Commission also determined that it would be in the best interest of the public to allow continued use of NARM, especially for medical purposes, and to allow the States to continue to regulate NARM until the Commission could codify new regulations for these materials.

The Commission believed that granting the waiver would allow the States to continue with their regulatory programs, allow persons engaged in activities involving NARM to continue their operations in a safe manner, and allow continued access to medical radiopharmaceuticals. In addition, it would enable the Commission to work with the States in developing appropriate regulations for NARM and in formulating a sound Transition Plan for implementation of these regulations. It would also provide an opportunity for non-Agreement States that currently do not have Agreement State regulatory programs under Section 274b. of the AEA to consider entering into an agreement with the NRC. The Commission determined that issuance of the waiver would be in accordance with the protection of public health and safety and the promotion of the common defense and security.

The Commission granted a waiver (70 FR 51581; August 31, 2005) from the requirements of Section 651(e) of the EPAct to: (1) all persons engaged in export from or import into the U.S. of byproduct material through August 7, 2006, unless terminated sooner if the Commission determined that an earlier termination was warranted; and except with regard to the requirements of the DOC relating to export of byproduct material; (2) all persons acquiring, delivering, receiving, possessing, owning, using, or transferring byproduct material through August 7, 2009, unless terminated sooner if the Commission determined that an earlier termination was warranted; and (3) all States that had entered into an agreement with the Commission under Section 274b. of the AEA, and States that had not entered into such an Agreement, through August 7, 2009, unless terminated sooner if the Commission determined

an earlier termination was warranted, or for an Agreement State if the Commission made certain determinations required by Section 651(e)(5)(B)(ii) of the EPAct.

Stakeholder Involvement in the Rulemaking Process.

The NRC took several initiatives in an effort to enhance stakeholder involvement and to improve efficiency during the rulemaking process. With assistance from the Organization of Agreement States (OAS) and CRCPD, the NRC was able to obtain participation of several State representatives in various working groups in the development of the proposed rule. Principals from OAS and CRCPD, representing interests for both Agreement States and non-Agreement States, also participated in the steering committee forming a partnership with the NRC in making rulemaking decisions. In an effort to keep stakeholders informed, the NRC held a public roundtable meeting in early November and has established the “Expanded Definition of Byproduct Material (NARM Rulemaking)” Web page via the rulemaking website http://ruleforum.llnl.gov for posting rulemaking-related documents. In addition, the NRC has met with other Federal agencies to ensure coordination regarding this rulemaking.

The NRC held a public meeting on November 9, 2005, to discuss rulemaking activities to incorporate NARM into its regulatory framework. The public meeting was in a "roundtable" format to allow stakeholders an opportunity to discuss concerns and to enhance interaction among all interested parties on the subject of the NRC regulating NARM. Representatives from other Federal agencies, States, and a broad spectrum of interest groups were invited to participate in the "roundtable" discussion. A transcript of this meeting is available via the NRC’s rulemaking website at http://ruleforum.llnl.gov.

Following the public meeting, the NRC received five written comments from interested parties related to the discussion at the meeting and the rulemaking activities. These comment

letters are available via the NRC's rulemaking website at http://ruleforum.llnl.gov and were reviewed and considered by the NRC staff in the development of the proposed rule.

In addition to the public meeting, the NRC interacted and met with FDA staff to exchange information regarding the NRC's NARM rulemaking efforts and the FDA's regulations for accelerator-produced drugs. The primary objective of the FDA's regulations is to ensure medical safety, purity, potency, and effectiveness of the drugs, and that of the NRC's regulations is to ensure radiation safety. During the meeting, areas of potential dual regulation were discussed. Because the NRC and the FDA have different missions, the associated regulations are more complementary than duplicative. FDA has published a proposed rule (70 FR 55038; September 20, 2005), "Current Good Manufacturing Practice for Positron Emission Tomography Drugs," and expects to finalize the rule soon. The FDA's final rule will establish criteria for the production and process/quality controls for the Positron Emission Tomography (PET) drugs in PET centers registered with the FDA.

The NRC hosted a meeting of Federal agency representatives on November 22, 2005, to discuss the development of a definition of *Discrete source* to be added to the NRC's regulations. Agencies represented at this meeting were DOT, DOE, including the National Nuclear Security Administration, Department of Defense, DOC, EPA, and the U.S. Customs and Border Protection. A draft definition was formulated. This definition formed the basis for the definition in the proposed rule, with only minor changes and text rearrangement for clarity.

The NRC published the proposed rule to establish the regulatory framework for the newly defined byproduct material on July 28, 2006 (71 FR 42952). Thirty-nine comment letters were received. The commenters included a number of States, Federal agencies, professional organizations, universities, medical communities, industries, and individuals.

II. Discussion

A. ***The New, Expanded Definition of Byproduct Material.***

Section 651(e) of the EPAct expanded the definition of *Byproduct material* to include: (1) any discrete source of radium-226 that is produced, extracted, or converted after extraction, before, on, or after the date of enactment of the EPAct for use for a commercial, medical, or research activity; (2) any material that has been made radioactive by use of a particle accelerator and is produced, extracted, or converted after extraction, before, on, or after the date of enactment of the EPAct for use for a commercial, medical, or research activity; and (3) any discrete source of naturally occurring radioactive material, other than source material, that the Commission, in consultation with the Administrator of the EPA, the Secretary of DOE, the Secretary of DHS, and the head of any other appropriate Federal agency, determines would pose a threat similar to the threat posed by a discrete source of radium-226 to the public health and safety or the common defense and security, and that is extracted or converted after extraction, before, on, or after the date of enactment of the EPAct for use in a commercial, medical, or research activity. The NRC is revising the definition of *Byproduct material* in 10 CFR Parts 20, 30, 50, 72, 150, 170, and 171 to be consistent with the EPAct. The same revision to the definition of *Byproduct material* was made in a separate rulemaking for 10 CFR Part 110 (April 20, 2006; 71 FR 20336). A different definition for the term *Byproduct material* is used in 10 CFR Part 40, because 10 CFR Part 40 regulations are limited to source material and the tailings or wastes associated with the extraction or concentration of source material. Therefore, 10 CFR Part 40 regulations are not impacted by the EPAct, and the definition of *Byproduct material* in that Part remains unchanged by this rule.

Radium-226.

Radium is a chemically reactive, silvery white, radioactive, metallic element with an atomic number of 88 and symbol of Ra. Radium-226, the most abundant and most stable isotope of radium, is formed by the radioactive disintegration of thorium-230 in the decay series starting with uranium-238. Radium-226 can be found in all uranium ores. The half-life of radium-226 is 1599 years. Radium-226 emits alpha particles and gamma radiation and decays to radon gas.

Although radium was discovered in the ore pitchblende by the chemists Marie and Pierre Curie in 1898, no one understood the dangers of radium until later in the twentieth century. Based on radium's properties, especially its ability to stimulate luminescence, industries started manufacturing hundreds of consumer products containing radium. Radium was added to products such as hair tonic, toothpaste, ointments, and elixirs. Radium paint was used in the mid-1900s to paint the hands and numbers of some clocks, watches, doorknobs, and other objects to make them glow in the dark. Glow-in-the-dark watch and clock faces were particularly popular. Most of these uses were eventually discontinued for health and safety reasons, but its wide use in luminescent paints continued through World War II because radium's luminescent glow made aircraft and vehicle dials, gauges, and other instruments visible at night. Many of these early products still remain in the possession of museums and individual collectors. Large inventories of radium-226 luminescent military and aircraft devices remain and periodically turn up in repair shops, and have resulted in contamination incidents.

In more recent times, radium sources were used in industrial radiography and industrial smoke detectors. Currently, radium sources are still being used in some industrial products, such as industrial gauges, that measure certain physical properties such as moisture and density.

Accelerator-Produced Radioactive Material.

Particle Accelerators.

A particle accelerator is a device that imparts kinetic energy to subatomic particles by increasing their speed through electromagnetic interactions. Particle accelerators are used to produce radioactive material by directing a beam of high speed particles at a target composed of a specifically selected element, which is usually not radioactive. Nuclei in the target are struck by the high speed particles and undergo a nuclear transformation. A nuclide that is struck is transformed into a different nuclide. By careful selection of the target element, the particles accelerated, and the operating parameters of the accelerator (e.g., beam energy), a resultant proton-heavy nuclide can be produced. Usually the nuclide produced is radioactive and is created for the use of its radiological properties. The process of transforming nuclei from a stable element into a radionuclide is called activation. In some cases, the target is selected so that the accelerator produces a neutron beam that is, in turn, used to activate nuclides that are then used for their radioactive properties. Some particle accelerators are not used to produce radioactive material, but instead the high energy beam produced by the particle accelerator is used directly, for example, to treat cancer patients.

The two basic designs of particle accelerators are linear and circular, also known as cyclotron. In either case, charged particles are injected into the accelerator to form a beam. The beam is accelerated and focused onto the target. In the circular designs, the beam must be directed to travel in a circular shaped path. For all accelerators, the process of accelerating, focusing, and directing the beam is accomplished by a combination of electrically charged structures and magnetic fields in the accelerator. During operation, these internal structures will be struck by particles from the beam and activated incidentally.

Particle accelerators are often classified by the maximum energy of the accelerated particles, expressed in megaelectron-volts (MeV). An electron-volt is the amount of energy imparted to an electron by an accelerating potential of one volt. The small cyclotrons that produce radionuclides used in PET nuclear medicine usually operate at energies of up to about 30 MeV. By comparison, the accelerators used in basic physics research facilities reach energies in excess of 1000 MeV.

For the purposes of this rulemaking, the NRC divided particle accelerators into three groupings: (1) those that are always operated to intentionally produce radioactive materials in quantities useful for their radioactive properties for a commercial, medical, or research activity; (2) those that are operated to produce only particle beams and not radioactive materials; and (3) accelerators that are used to produce both radioactive materials and particle beams for other uses. Examples of accelerators that are operated to produce only particle beams and not radioactive materials include linear accelerators used for medical treatment of cancer and other health-related conditions. Other examples include the experimental particle physics research colliders used to probe the fundamental properties of nature (as long as that is their only use) and electron microscopes, i.e., particle accelerators that probe the structure of materials at a very small dimension (high magnification). Ion implanters are particle accelerators used to modify the electrical properties of materials in semiconductor fabrication. In these activities, no radioactive material is intentionally created; all activation is incidental to the intended use of the accelerator.

The NRC will regulate the radioactive material both intentionally and incidentally produced by all accelerators that are intentionally operated to produce a radioactive material for its radioactive properties. The NRC will not regulate the incidental radioactive material produced by accelerators that are operated to produce only particle beams and not radioactive materials for use for a commercial, medical, or research activity. For those accelerators that

are used to produce both radioactive material and particle beams, the NRC will regulate the intentionally produced radioactive material and all of the incidentally produced radioactive material, including incidental radioactive material produced when the accelerator is operated to produce radioactive material, as well as incidental radioactive material produced when it is operated to produce only a particle beam. The incidental radioactive materials produced in these accelerators are indistinguishable, so both will be considered byproduct material. The NRC believes very few, if any, accelerators are operated in this way.

The EPAct does not give the NRC authority to regulate the possession or use of particle accelerators. The NRC has not adopted any rule regarding the operation of a particle accelerator or the qualification of any person maintaining or operating a particle accelerator. However, nothing in the EPAct directs the NRC to change the policy that radiation safety standards must consider unregulated as well as regulated sources of radiation. The NRC will continue to require any person subject to the dose limits in 10 CFR Part 20 to continue to include the radiation dose from the operation of a particle accelerator in meeting the dose limitations. The NRC is aware that the operation of a particle accelerator may activate materials in the structure of the building and facilities housing the accelerator. The NRC intends to assure the safe decommissioning of particle accelerator buildings and facilities, including the removal and disposal of activated building materials, to assure that the dose limits to members of the public are not exceeded. The decommissioning of these facilities will be required to meet the radiation dose limits in 10 CFR Part 20 Subpart E--Radiological Criteria for License Termination.

The majority of accelerator-produced radioactive material is now created for use in medicine. The NRC is aware of only two operations in the U.S. and a few importers, mostly from Europe and Canada, that are commercial producers of accelerator-produced radioactive material for use in industrial activities. The regulatory approach for manufacturing accelerator-

produced radioactive material for industrial purposes is similar to the regulatory approach for manufacturing accelerator-produced radioactive material for medical purposes.

Accelerator-Produced Radioactive Material Used in Medical Activities.

Medical use of radioactive material began over 50 years ago. The medical use of sealed and unsealed radioactive materials continues to be an important component of medical specialties for both diagnosis and therapy purposes. The use of small quantities of unsealed radioactive materials (radiopharmaceuticals) in nuclear medicine is an integral part of patient care and is extremely valuable in the early diagnosis and treatment of medical conditions. Radiation oncology uses larger amounts of radioactivity in sealed sources to deliver therapeutic or palliative radiation doses.

Almost all reactor-produced byproduct radionuclides for radioactive drugs are imported into the U.S., as well as most reactor-produced radionuclides used in sealed sources, although some used in radioactive drugs and sealed sources are also produced in an NRC-regulated nonpower reactor. Commercial manufacturers primarily use the imported radionuclides to produce specific sealed sources, radioactive drugs, and biologics. Commercial nuclear pharmacies may use radiochemicals to prepare radioactive drugs, as well as commercially produced radioactive drugs and drug sources, such as molybdenum-99/technetium-99m generators, to prepare unit dosages of other radioactive drugs.

The U.S. has a limited number of commercial radionuclide production facilities that use accelerators to produce radionuclides, such as thallium-201, iodine-123, indium-111, and gallium-67 used in radioactive drugs. A larger number of radionuclide production facilities (often referred to as PET centers) use cyclotrons to produce the PET radionuclides fluorine-18, carbon-11, nitrogen-13, and oxygen-15 for use in PET radioactive drugs. PET radionuclides decay by positron emission and, because of their relatively short half-life (minutes to hours), are produced at locations in close proximity to the patients (e.g., in hospitals or academic

institutions) or at nearby locations.

Palladium-103, the most common accelerator-produced medical use radionuclide contained in a sealed source, was originally produced at reactor facilities. Other radionuclides used in medical radiation therapy can also be produced with either reactors or accelerators. With the new definition of *Byproduct material*, sealed sources that can be produced from either pathway will be uniformly regulated. At this time, there are no teletherapy or remote afterloader or gamma stereotactic radiosurgery units with accelerator-produced sources.

Because production accelerators for medical radionuclides (e.g., PET production facilities) and industrial radionuclides are used to intentionally produce radioactive material for use of its radioactive properties for a commercial, medical, or research activity, the NRC will regulate both the radionuclides produced in these accelerators as well as the incidentally activated radioactive material.

Other Naturally Occurring Radioactive Material with Similar Risk as Radium-226.

The EPAct amended the definition of *Byproduct material* to include any discrete source of naturally occurring radioactive material, other than source material, that the Commission, in consultation with the Administrator of the EPA, the Secretary of Energy, the Secretary of Homeland Security, and the head of any other appropriate Federal agency, determines would pose a threat similar to the threat posed by a discrete source of radium-226 to the public health and safety or the common defense and security, and is extracted or converted after extraction, before, on, or after the date of enactment of the EPAct for use in a commercial, medical, or research activity.

The inclusion of discrete sources of naturally occurring radioactive material into the definition of *Byproduct material* is contingent on the Commission's determination, in

consultation with other Federal agencies, that these discrete sources would pose a threat similar to the threat posed by a discrete source of radium-226. The NRC has not currently identified any discrete sources of naturally occurring radioactive material under this provision, and the rule does not contain criteria for making such a determination. For comparison, the International Atomic Energy Agency (IAEA) has identified a list of sources that are considered to pose a high risk to human health and safety if not managed safely and securely. The IAEA Code of Conduct on the Safety and Security of Radioactive Sources (Code of Conduct) identified certain quantities of 26 radionuclides that pose a significant risk to individuals, society, and the environment. The activity of these radionuclides at the IAEA Code of Conduct Category 1 or 2 level could be fatal or cause permanent injury to a person who handled them or was otherwise in contact with them for a short time, if not safely managed or securely protected. Of these 26 sources, only two naturally occurring radionuclides are listed: radium-226 and polonium-210. Because this rule addresses discrete sources of radium-226, the only other naturally occurring radioactive material similar in hazard to radium-226 when using the IAEA criteria is polonium-210. However, naturally occurring polonium is scarce. One ton of uranium ore contains only about 100 micrograms (0.0001 grams) of polonium. Due to its scarcity in nature, polonium-210 used for commercial purposes is usually produced by bombarding bismuth-209 with neutrons in a nuclear reactor and had been regulated by the NRC before the EPAct. Additionally, polonium-210 is unlikely to be commercially used in individual radioactive sources with activity levels that would place them within the IAEA Code of Conduct Category 1 or 2. Hence, the NRC has determined that no other discrete sources of naturally occurring radioactive material pose a threat similar to the radium-226-level or IAEA Code of Conduct Category 1 or 2 sources.

Through interaction with other Federal agencies and States during development of the rule, the NRC concluded that, at this time, only polonium-210 has the potential to pose a threat

similar to the threat posed by a discrete source of radium-226 to the public health and safety or the common defense and security. The NRC had already been regulating the use and possession of polonium-210 because it is produced in nuclear reactors and is rarely extracted as naturally occurring radioactive material. Therefore, although this rule adds this category of byproduct material to the definitions in the regulations, at this time, the NRC's regulations will not apply to any discrete sources of naturally occurring radioactive material, other than radium-226. The EPAct has provided a mechanism for the Commission to include additional discrete sources of naturally occurring radioactive material in the future following consultation with other Federal agencies, if the need arises to consider other naturally occurring radioactive material as byproduct material. No further revision to the regulations will be necessary to begin regulating a material identified through this mechanism. However, the NRC will provide an opportunity for public input before applying its regulations to other naturally occurring radionuclides that the NRC determines in consultation with other federal agencies, pose a threat similar to the threat posed by discrete source of radium-226.

B. *The NRC's Regulatory Approach.*

Consideration of Suggested State Regulations for the Control of Radiation (SSRs).

All 34 Agreement States have regulations for NARM. Twelve non-Agreement States and certain U.S. Territories have some type of regulatory structure for NARM, while four non-Agreement States have no program for regulating NARM. The EPAct mandated that the NRC use model State standards to the maximum extent practicable in issuing regulations for the expanded definition of *Byproduct material*. The NRC considered the SSRs published by CRCPD (http://www.crcpd.org/free_docs.asp) as the model State standard in developing this rule. Most Agreement States have regulated discrete sources of radium and accelerator-

produced radioactive material in a manner similar to and under the same requirements as reactor-produced radioactive material. Few provisions in the SSRs exist solely to address these materials. Where specific provisions do exist in the SSRs for these materials, they have been evaluated for possible inclusion in the NRC's regulations.

For radionuclide-specific values listed in 10 CFR Part 20, Appendices B and C, the NRC found that there are no other radionuclides identified in the SSRs that are not already included in 10 CFR Part 20. As discussed further in this document under Section C., "Changes to Existing NRC Regulations to Accommodate the New Byproduct Material," most of the specific provisions related to NARM radionuclides in the SSRs have been adopted in this rule. These include exempt quantities in 10 CFR 30.18 and 10 CFR 30.71, an exemption for timepieces in 10 CFR 30.15, a general license for calibration and reference sources in 10 CFR 31.8, a general license for use of radioactive material for certain in vitro clinical or laboratory testing in 10 CFR 31.11, contamination limits for strontium-82/rubidium-82 generators, and requirements to measure the contamination limits in 10 CFR 35.204 with corresponding recordkeeping requirements in 10 CFR 35.2204.

While SSRs do exist that address other types of naturally occurring radioactive material that are not covered by the EPAct or these new regulations, discrete sources of radium and accelerator-produced radioactive material are covered under the same provisions of the SSRs that apply to reactor-produced radioactive material. There is general agreement among the States, reflected in the SSRs, that the new categories of byproduct material should be regulated under the same requirements as reactor-produced radioactive material. This rule takes the same regulatory approach. Most of the requirements that will apply to users of the newly regulated material are preexisting NRC requirements.

Other Related Rulemakings.

The NRC amended its regulations in 10 CFR Part 110 revising the definition of *Byproduct material* to include discrete sources of radium-226, accelerator-produced radioactive material, and discrete sources of naturally occurring radioactive material (71 FR 20336; April 20, 2006). In addition, an earlier amendment (70 FR 37985; July 1, 2005) added discrete sources of radium to 10 CFR Part 110, Appendix P. Together, the two amendments satisfy the requirements of Section 651(d) of the EPAct pertaining to the export or import of Category 1 or Category 2 radiation sources as defined by the IAEA Code of Conduct. By this final rule, the NRC is again amending is regulations in 10 CFR Part 110 to include a definition of *Discrete source*.

Section 651(d) of the EPAct also requires the NRC to issue regulations establishing a mandatory tracking system for radiation sources, including radium-226, in the U.S. The NRC issued a final rule for national source tracking of sealed sources (71 FR 65686; November 8, 2006) that included radium-226 sources.

Definition of Discrete Source.

The EPAct extended the definition of *Byproduct material* in the AEA to include any discrete source of radium-226 that is produced, extracted, or converted after extraction, before, on, or after the date of the enactment of the EPAct, for use for a commercial, medical, or research activity. The EPAct gave the NRC authority over discrete sources of radium-226 but not over diffuse sources of radium-226. Thus, the EPAct did not extend the NRC's authority over radium-226 as it occurs in nature, or over other processes where radium-226 may be unintentionally concentrated. The focus was on those materials that presented a threat to public health and safety or to the common defense and security similar to the threat posed by

discrete radium-226 sources. Scale from pipes used in the fossil fuel industry, fly ash from coal power plants, phosphate fertilizers, or residuals from treatment of water to meet drinking water standards are not considered discrete sources. However, uranium and thorium within these materials may become licensable source material depending upon their concentration.

The term *Discrete source* is not defined in the EPAct, and the EPAct specifically mandates that the final regulations, in establishing requirements necessary to carry out the amendment, shall include a definition of the term *Discrete source*. The definition of *Discrete source* is used for purposes of the new definition of *Byproduct material* in the case of radium-226 and other naturally occurring radioactive material other than source material. The term *Discrete source* is not used in conjunction with accelerator-produced radioactive material in the EPAct language.

The definition of *Discrete source* in the proposed rule was *"*a radioactive source with physical boundaries, which is separate and distinct from the radioactivity present in nature, and in which the radionuclide concentration has been increased by human processes with the intent that the concentrated radioactive material will be used for its radiological properties." As a result of public comments on the proposed rule, the NRC changed the wording of the definition of *Discrete source* from that in the proposed rule. The changes are for clarification purposes only and do not change the original intent of the proposed definition of *Discrete source* or the scope of the NRC's regulation of radium-226 or other naturally occurring radioactive materials identified in the future. The intent of the revised definition continues to be consistent with the proposed rule in that the NRC's authority is not intended to extend to all naturally occurring radioactive material, specifically not to naturally occurring radioactive material that is found in nature in its original form and location, or that which is moved or concentrated inadvertently by some man-made process. *Discrete source* is defined in this final rule as "a radionuclide that is distinct from the sources of radiation present in nature, and that has been processed so that its

concentration within a material has been purposely increased for use in commercial, medical, or research activities." A discrete source will have the same radiological characteristics (e.g., type of radiation, half-life) as the radionuclide found in nature but will have been purposefully concentrated for use for its specific properties after it has been removed from its original location in nature. This definition excludes the NRC's jurisdiction over inadvertent movement or concentration of naturally occurring radioactive material such as scale from pipes used in the fossil fuel industry, fly ash from coal power plants, phosphate fertilizers, or residuals from treatment of water. It does not change the NRC's authority, in any manner, over source material. It should be noted that in accordance with this definition of *Discrete source*, once a discrete source meets the definition of *Byproduct material*, any contamination resulting from the use of such discrete sources of this byproduct material will also be considered byproduct material. This issue is discussed further in this document under "Summary and Analysis of Public Comments on the Proposed Rule."

C. *Changes to Existing NRC Regulations to Accommodate the New Byproduct Material.*

The Commission has authority to issue both general and specific licenses for the use of byproduct material and to exempt byproduct material from regulatory control under Section 81 of the AEA. A general license, as provided by regulation, grants authority to a person for certain activities involving byproduct material and is effective without the filing of an application with the Commission or the issuance of a licensing document to a particular person. Requirements for general licensees appear in the regulations and are designed to be commensurate with the specific circumstances covered by each general license.

In considering the expansion of the definition of *Byproduct material* to include discrete sources of radium-226 and accelerator-produced radioactive material, the NRC has evaluated

products and materials previously approved by the States for use under an exemption from licensing and under a general license. Generally, the NRC's intent in this rule is to accommodate existing products and materials that were previously regulated by the States under similar provisions, if the potential doses are similar to those expected from other currently regulated products and materials. Many of these products have not been made for some time, so some of the provisions in this rule are limited to items manufactured in the past, which may still be in use or in storage.

The bases of these exemptions and general licenses are primarily the SSRs and also information in NRC's sealed source and device (SS&D) registry. The SS&D registry is the NRC's national database of technical information on sealed sources and devices. Manufacturers or distributors may submit a request to the NRC for an evaluation of a product's radiation safety information and for registration of the product. After satisfactory completion of the evaluation, the NRC issues a certificate of registration to the person making the request, and this certificate is added to the SS&D registry. Many Agreement States have similar registration procedures, and registration certificates for the sources and devices they review are added to the national SS&D registry. The NRC also has included SS&D certificates for NARM, which have been issued by the States. While this is not a complete database with respect to NARM, it includes detailed information about many products containing NARM previously evaluated by the States. In addition to SSRs and the information in the SS&D registry, the specific provisions of the various States also were considered in developing this rule.

Regulating Items Containing Radium-226.

Currently, items or products containing radium-226 are unique in that there are no new items in consumer commerce using radium-226 byproduct material. Although certain industrial

devices such as moisture density gauges containing radium-226 are still in use, most radium-226 articles have not been produced for at least 20 years. Beginning in the early 1900s, radium-226 was used to make self-luminescent paint and incorporated in watch and clock dials and hands and later used to illuminate airplane instrumentation dials and gauges as well as markers and signs. Beginning in the 1950s, other radionuclides began to replace radium-226 as a self-luminescent material due to the recognition of the radiological hazard associated with radium-226. Currently, the radionuclides of choice for self-luminescent applications are promethium-147 and tritium due to the much reduced radiological hazard vis-a-vis radium-226.

Based on the National Council on Radiation Protection and Measurements in Report 95, "Radiation Exposure of the U.S. Population from Consumer Products and Miscellaneous Sources," radium-226 has not been used in radioluminescent watches since 1968 and clocks since 1978. In fact, radium-226 timepieces are currently kept largely as collectors' items and only infrequently used by consumers as timepieces. When originally manufactured, the quantity of radium-226 employed in watch and clock dials and hands varied by timepiece size, manufacturer, model, and from item to item. While the quantity of radium-226 varied in the timepieces, there is a general agreement for typical average and upper bound quantities. Based upon the spectrum of timepiece sizes, wristwatches have the smallest quantity, with pocket watches and clocks having quantities several times higher than wristwatches. The radioactivity associated with wristwatches is generally on the order of several kilobecquerel (kBq) (tenths of a microcurie (μCi)) with an average of 5.6 kBq (0.15 (μCi)). Pocket watches may have radioactivity of about 13 kBq (0.35 μCi), and clocks are typically 18 kBq (0.5 μCi). However, collections of pocket watches and clocks are rare when compared to wristwatches.

Before the discontinuation of the manufacturing of timepieces containing radium-226 in the 1970s, radium-226-illuminated timepieces were widely distributed throughout the country as a common consumer product. To date, a large number of radium-226 timepieces are still

owned by individuals as valued heirlooms or collectors' items or are on display in museums. Because museums and collectors normally collect a wide range of timepieces, a portion of their collection may contain radium-226 timepieces. Some businesses and a few collectors are also engaged in repairing and refurbishing timepieces either as a hobby or professionally, and these activities may occasionally involve timepieces containing radium-226. Because these timepieces were manufactured before the NRC assumed regulatory authority over radium-226, and because these timepieces are already in public possession, the NRC intends to minimize regulatory impact to individuals, museums, or other entities in possession of these timepieces. In finalizing the rule, the NRC made its determination based on no significant risk to public health and safety and the environment.

In the proposed rule, the NRC proposed to exempt intact timepieces containing no more than 37 kBq (1 μCi) of radium-226 per timepiece and repair of no more than 10 timepieces in any one year. In addition, the NRC proposed to generally license no more than 50 timepiece hands and dials used or stored at the same location at any one time. Due to lack of sufficient health and safety information to make a final regulatory decision, the NRC conducted a scoping study for estimating potential radiological doses to individuals associated with use, storage, and repair of radium-226 timepieces. The scoping approach taken by the NRC used widely accepted methods and employed conservative assumptions for various scenarios involving use, storage, and repair of radium-226 timepieces. Because the scoping study was designed to be conservative and meaningful and yet easy to perform, it is to be expected that the actual doses would be significantly lower than those predicted by the scoping study.

To evaluate the potential doses associated with the proposed exemption of radium-226 timepieces, 37 kBq (1 μCi) of radium-226 per timepiece was used in the scoping study instead of the typical average activities for timepieces, which provided for additional conservatism. Radon-222 is a decay product in the radium-226 decay series and may be emitted from the

timepiece into the surrounding atmosphere and thus result in exposure to an individual in proximity to the timepiece. It is believed that the radon-222 emanating from the paint is almost totally trapped within the watch. Because of the age of radium-226 timepieces, and because there is no established method for quantifying the trapping behavior, the scoping study conducted by the NRC assumed that the entire inventory of decay products instantly escaped and became uniformly distributed into the surrounding building volume. This assumption is obviously very conservative. As a result, the estimated inhalation doses associated with radon-222 are extremely conservative. The scoping study found that the estimated doses to a collector for repair, storage, and use of a radium-226 timepiece range from a fraction of 0.01 millisievert/yr (mSv/yr) [1 millirem/yr (mrem/yr)] to a few mSv/yr (mrem/yr) to over 1 mSv/yr (100 mrem/yr).

At one time, there were repair facilities refurbishing radium timepieces on a regular basis by replacing radium-226 paint with tritium paint. Scraping off the radium-226 paint may have resulted in significant contamination. The NRC is not aware of any current operations in which individuals are still routinely handling radium watches in such a way as to create a contamination problem. Based upon the estimated doses for repairs, the NRC believes that a specific limit on the annual number of repairs is not necessary. As long as these repairs are taking place under a general license, actions could always be taken if the Commission receives information that suggests that the public health and safety are not being adequately protected.

The NRC's intent is to minimize regulatory impact on those private collectors and museums as much as possible, and to be as consistent as possible with the regulatory approach taken by the Agreement States, many of whom have been regulating radium-226 for several decades. Accordingly, in light of the public comments received, the Agreement States' rulemaking involvement and the results of the scoping study in finalizing the rule, the NRC revised the proposed revisions related to radium-226 timepieces. Primarily, the change made

in this final rule is to broaden the general license provision for the radium-226 timepieces. Specifically, the NRC has concluded that a finite number of annual repairs as well as a limitation on the number of nonintact timepieces and timepiece hands and dials is unnecessary and not warranted based upon the NRC's understanding of radium-226 timepieces either in collections or in use. As a result of the scoping study and in response to public comments, the NRC has concluded that it is appropriate to recategorize the repair of timepieces from an activity allowed under an exemption from licensing to one covered by a general license. This categorization is also more consistent with the Agreement States' existing exemption provision.

Although not mandated by regulations, the NRC advises that individual collectors or persons engaged in repair of these devices should use good practices such as wearing gloves when handling radium-226 timepieces, hands, and dials, and washing hands to minimize potential exposure to the radioactive material. In addition, individual collectors should ensure that storage areas are well ventilated to minimize potential exposure due to accumulation of radon-222 gas and should avoid unnecessary exposure to these types of timepieces.

Exemptions from Licensing.

In 10 CFR Part 30, a number of exemptions from licensing requirements are included. These exemptions allow for certain products and materials containing byproduct material to be used without any regulatory requirements imposed on the user. The two exemptions in 10 CFR 30.19, Self-luminous products containing tritium, krypton-85, or promethium-147, and 10 CFR 30.20, Gas and aerosol detectors containing byproduct material, are class exemptions which cover a broad class of products. Under these provisions, new products can be approved for use through the licensing process if the applicant demonstrates that the specific product is within the class and meets certain radiation dose criteria. This contrasts with other exemptions

for which the level of safety is controlled through such limits as specification of radionuclides and quantities. Section 30.14, Exempt concentrations, and Section 30.18, Exempt quantities, of NRC's regulations, are broad materials exemptions, which allow the use of a large number of radionuclides. The specific radionuclide limits on these concentrations and quantities are contained in tables in 10 CFR 30.70 and 10 CFR 30.71, respectively. The remaining exemptions from licensing are product specific, for which many assumptions can be and have been made concerning how the product is distributed, used, and disposed of. This final rule adds some products and materials containing NARM to some of the previously existing exemptions. The table of exempt concentrations in 10 CFR 30.70 already included all of the radionuclides and associated limits contained in the equivalent section of the SSRs. Thus, the NRC is not revising the exempt concentration table in this final rule.

Exempt Quantities.

Part C of the SSRs includes a list of exempt quantities which are identical to those in 10 CFR 30.71 but includes an additional 13 radionuclides, which are accelerator produced. This final rule adds these 13 radionuclides and their respective quantities, as already included in the SSRs, to the list of exempt quantities in 10 CFR 30.71. The technical bases of these values are similar to those used for the existing values in 10 CFR 30.71.

The NRC considered whether there were additional radionuclides in use under comparable State exemptions that should be accommodated under 10 CFR 30.71. It was noted that a few of the States' regulations for exempt quantities include additional radionuclide-specific values, each appearing in only one or two States' regulations. These radionuclides are specifically exempted in only one or two States; thus, they do not represent nationally recognized exemptions. It was also not clear as to what approach was used to calculate their exemption values. Therefore, the NRC is adding only the 13 radionuclides and values from the SSRs for which there are adequate technical bases, and no further additions to 10 CFR 30.71

are included in this final rule. It is noted, however, that for other byproduct material, excluding alpha emitters, which is the last item on the list in 10 CFR 30.71, Schedule B allows for 3.7 kBq (0.1 μCi) to be used as an exempt quantity. This will apply to accelerator-produced radionuclides as well. Minor changes are also being made to 10 CFR 30.18 to accommodate any materials that may have been received before September 25, 1971, under a general license of a State similar to that then provided in 10 CFR 31.4.

Timepieces Containing Radium-226.

The exemption in 10 CFR 30.15(a)(1) is being revised to include intact timepieces that were manufactured before the effective date of this final rule and containing no more than 37 kBq (1 μCi) of radium-226. This provision is consistent with the SSRs, except that the rule is limited to "intact" timepieces. In the final rule, the repair of timepieces was moved from the exemption to the general license to be more consistent with the SSRs and to broaden the general license provision. As discussed earlier, the possession of nonintact timepieces, hands, and dials, and the repair of timepieces would be covered by a new general license. This general license provision should cover most current practices involving radium-226 and minimize impacts upon individual collectors and small businesses. A general license is automatically granted by NRC regulations to any person meeting the general license criteria. No action is required from these persons to obtain a general license, and no license or annual fees are applicable to persons operating under this general license.

Self-Luminous Products.

Although the SSR section similar to 10 CFR 30.19 includes an exemption for previously acquired self-luminous articles containing less than 3.7 kBq (0.1 μCi) of radium-226, 10 CFR 30.19 is not being amended to include this exemption. The basis for not including this exemption is that, as currently written, 10 CFR 30.19 only applies to products manufactured and distributed under a specific license issued under 10 CFR 32.22. The SSR exemption does

not require that these products be previously manufactured and distributed under a specific license, nor do the SSRs provide for such a license with regard to radium-226. Instead, the possession, use, and transfer of these items will be subject to the general license for certain items and self-luminous products containing radium-226 established in 10 CFR Part 31.

Smoke Detectors.

Smoke detectors are included in the class exemption in 10 CFR 30.20 for gas and aerosol detectors. This exemption is being revised to include previously manufactured detectors containing radium-226. The provision for smoke detectors is different from the SSRs in that the SSRs contain a specific limit of 3.7 kBq (0.1 μCi) for radium-226 that manufacturers may incorporate into the currently manufactured detectors. However, the SS&D registry includes certificates for smoke detectors categorized as exempt containing up to 74 kBq (2 μCi) of radium-226. While some of these certificates are categorized as "Active," meaning that continued distribution is permitted, a survey of the States with these certificates confirmed that the distribution of radium-226 in smoke detectors was, in fact, a past practice. The provision added to 10 CFR 30.20 for detectors containing radium-226 is limited to detectors previously manufactured and distributed under a specific license issued by a State under comparable provisions to 10 CFR 32.26. Thus, similar standards were used in approving distribution of these detectors for use under an exemption from licensing. This exemption does not cover smoke detectors manufactured earlier with larger quantities of radium-226 and authorized for use under a general or specific license, or smoke detectors that may not have been distributed under a specific license.

Distribution to Exempt Persons.

The NRC retains the authority for authorizing distribution of products and materials

where the end user is exempt from licensing and regulatory requirements by regulation in 10 CFR 150.15(a)(6), which states, in part, that persons in Agreement States are not exempt from the Commission's licensing and regulatory requirements with respect to the transfer of possession or control of any equipment, device, commodity, or other products containing byproduct material to persons who are exempt from licensing and regulatory requirements of the Commission. The NRC does not transfer this authority when a State enters into an Agreement with the NRC. Therefore, persons who initially transfer products containing byproduct material to persons who are exempt from licensing must have a license from the NRC authorizing these activities. These distributors also need a specific license from either an Agreement State or from the NRC authorizing the possession and use of the byproduct material. As a result of the expansion of the definition of *Byproduct material*, the distribution of NARM to exempt persons, including distribution by licensees in Agreement States, will also be authorized only by the NRC. Currently, the States have only a few licensees authorized to distribute to persons exempt from licensing requirements. These are for exempt quantities of accelerator-produced radioactive material. In finalizing this rule, the NRC has determined that most, if not all, of these distribution licensees already have an NRC license under 10 CFR 32.18 authorizing the distribution of exempt quantities of pre-EPAct byproduct material. For these distribution licensees, only a simple amendment of those NRC licenses will be required as a result of this aspect of this final rule.

Existing General Licenses.

General License for Devices in 10 CFR 31.5.

Section 31.5 is the primary general license provision in 10 CFR Part 31. It covers a broad range of devices "designed and manufactured for the purpose of detecting, measuring,

gauging, or controlling thickness, density, level, interface location, radiation, leakage, or qualitative or quantitative chemical composition, or for producing light or an ionized atmosphere." These devices must be distributed under specific licenses issued under 10 CFR 32.51 or equivalent regulations of an Agreement State. There are numerous SS&D certificates for devices containing NARM that have been approved by the States for use under a general license. These are almost all for devices containing cobalt-57, sodium-22, or radium-226. In many cases, models have been approved which are authorized to contain one of these radionuclides or one or more other radionuclides that were byproduct material before the EPAct. They have been evaluated under equivalent, in most cases, or at least comparable, standards by the States. The rule will accommodate generally licensed devices meeting the restrictions of the general license that were previously approved by the States under comparable provisions to 10 CFR 32.51. Active certificates would stand with amendments, if needed, being made to the distributors' licenses to cover the new categories of byproduct material. Any new certificates would be issued by the NRC or the Agreement States under the AEA encompassing the new definition of *Byproduct material*.

The criteria for registration of generally licensed devices under 10 CFR 31.5(c)(13)(i) are revised to include a criterion for registration by general licensees of devices containing 3.7 megabecquerels (MBq) (0.1 millicurie (mCi)) or more of radium-226. This registration process is separate and quite different from the SS&D registry. It requires physical inventories and certification of device information by general licensees, allows the NRC and Agreement States with equivalent regulations to more fully track generally licensed devices meeting these criteria, and serves to remind general licensees of their responsibilities under the general license. SS&D certificates for generally licensed devices that will now come under 10 CFR 31.5 include devices with more than 3.7 MBq (0.1 mCi) of radium-226. These devices will be subject to the registration requirement in 10 CFR 31.5(c)(13). Other certificates, which include devices

with radium-226, allow only much smaller quantities. These devices will not be required to be registered. This criterion for registration of radium-226 was chosen because of the low concentration levels which typically are required for decontamination and decommissioning involving radium-226, as well as the relative dispersibility of radium-226. A principal purpose of the registration process concerns reducing losses of devices that could significantly contaminate a smelter, if inadvertently melted. The NRC does not believe there are accelerator-produced materials used in significant quantities in these types of generally licensed devices to warrant registration.

Distributors of NARM have typically also been distributors of pre-EPAct byproduct material. Many of them have not excluded information about transfers of devices containing NARM from reports of transfers made to the NRC on generally licensed devices transferred into the NRC jurisdiction. Therefore, the NRC already has information on some of these devices in its general license tracking system. The NRC will work with the States to examine methods to include State information. It is expected that the registration process will identify additional devices containing registrable quantities of radium-226, as users in many cases will already be registering other devices with the NRC containing other radionuclides and will need to add devices containing radium-226 during the registration process. The requirements in 10 CFR 32.51, 32.51a, and 32.32 applicable to the manufacture or initial transfer of these devices did not need revision to accommodate NARM.

Calibration and Reference Sources in 10 CFR 31.8.

Section 31.8 provides a general license for the use of up to 185 kBq (5 μCi) of americium-241 in calibration and reference sources. This final rule adds radium-226 to 10 CFR 31.8, consistent with the SSRs. This general license is only applicable to specific licensees that have calibration and reference sources as defined in 10 CFR 31.8, and simply eliminates certain administrative requirements to address these sources under the specific

license. The sources are covered by requirements applicable under the specific license, as well as additional requirements in 10 CFR 31.8. The requirements in 10 CFR 32.57, 32.58, 32.59, and 32.102 applicable to licenses to manufacture or initially transfer these sources are also amended to include radium-226.

General License for In Vitro Test Kits in 10 CFR 31.11.

In keeping with the equivalent section of the SSRs, cobalt-57, in units not exceeding 370 kBq (10 μCi) each, is added to the general license in 10 CFR 31.11 for use in certain in vitro clinical or laboratory testing. Also, the requirements in 10 CFR 32.71, which provide the licensing criteria for the manufacturer and distributor of the products used under this general license, are revised to apply to the cobalt-57 products included in the general license.

New General License for Certain Items and Self-Luminous Products Containing Radium-226.

The Commission specifically requested information on the types and quantities of products containing radium-226 and any information that could assist the NRC in more fully evaluating the potential impact to public health and safety and the environment due to activities involving radium-226 sources. As discussed earlier, the general license provisions for radium-226 timepieces were changed to remove, from the proposed rule, a limitation on the number of timepieces that could be possessed. In response to public comment, the general license provision within this section for luminous gauges and other luminous products containing radium-226 was also changed with respect to the categories of products covered and the numbers of products allowed to be kept at any one location. This is discussed in this document under the section, “Summary and Analysis of Public Comments on the Proposed Rule.” Because 10 CFR 31.2 delineates the applicability of specific provisions in 10 CFR Part

30 to the general licenses of 10 CFR Part 31, an exemption from the reporting and recordkeeping requirements of 10 CFR 30.50 and 30.51 is added to further reduce the regulatory burden on stakeholders. Furthermore, because many of the circumstances that would require reporting under 10 CFR 30.50 are unlikely to occur, the NRC believes that it is unnecessary to apply these requirements to this general license and that the reporting requirements in 10 CFR 31.12 are adequate.

The new section added to 10 CFR Part 31 provides a general license to any person for other products and discrete sources containing radium-226 that are not exempted, and are apparently in the public domain, but were not otherwise covered under a license and are not specifically addressed in the SSRs. The general license includes: (1) Antiquities originally intended for use by the general public and distributed in the late 19th and early 20th centuries, such as radium emanator jars, revigators, radium water jars, radon generators, refrigerator cards, radium bath salts, and healing pads; (2) Nonintact luminous timepieces and timepiece hands and dials not contained in timepieces; (3) Luminous gauges and other items containing radium-226 installed in air, marine, or land vehicles (These include airplanes, helicopters, jeeps, trucks, tanks, ships, landing vessels, artillery pieces, and any other former military use vehicle no longer in control of the military.) Since the publication of the proposed rule, and after considering the comments on the new definition of *Byproduct material* with respect to discrete sources of radium-226, the Commission has taken a closer look at the scope of the Commission's jurisdiction over discrete sources of radium-226. With respect to radium-226, the EPAct covers any material that is "produced, extracted, or converted after extraction, before, on, or after August 8, 2005, for use for commercial, medical, or research activity." Notwithstanding that a discrete source of radium-226 may have originated from a commercial supplier, the Commission has determined that discrete sources of radium-226 still under the control of the military do not constitute "commercial use" under the EPAct and are, therefore,

outside the Commission's jurisdiction. Defining "commercial use" to include all material supplied to the military from a commercial supplier would result in virtually all military use of this material to be "commercial use." This would vitiate any distinction that the EPAct intended to make for military use, as opposed to commercial use, by excluding military use from its coverage; (4) All other luminous products, provided that no more than 100 are used or stored at the same location at any one time; and (5) Small radium sources containing no more than 37 kBq (1 μCi) of radium-226 as discrete survey instrument calibration sources, sources contained in radiation measuring instruments, sources used in educational demonstrations (such as cloud chambers, and spinthariscopes), electron tubes, lightning rods, ionization sources, and static eliminators. As discussed earlier, this general license allows any person to acquire, receive, possess, use, or transfer radium-226 contained in the previously mentioned products. Persons who receive, possess, use, or transfer the radium-226 items under the general license are exempt from the provisions of 10 CFR Parts 19, 20, 21, and 10 CFR 30.50 and 30.51 to the extent that the receipt, possession, use, or transfer is within the terms of the general license.

The general license prohibits the manufacture, assembly, disassembly, repair, or import of products containing radium-226 except for the repair of timepieces; prohibits export under the general license; and requires that the product only be disposed of by transfer to a specific licensee authorized to receive it or to a disposal facility authorized to dispose of the material in accordance with any Federal or State solid or hazardous waste law. The general license also prohibits abandonment of the product. The general license requires notifying the NRC if there is any indication of a possible failure of, or damage to, the product that could result in a loss of the byproduct material and requires persons possessing these devices under the general license to respond to written requests for information from the NRC.

It should be noted that 10 CFR 31.2 delineates the terms and conditions of 10 CFR Part 30 which apply to general licensees. These provisions generally will not require general

licensees to initiate any actions.

It is the NRC's intent, through the general license provision, that the Agreement States, to a large extent, will be able to maintain the existing "status quo" in regulating these categories of discrete sources of radium-226. The Agreement States may continue with their programs, including requiring a specific Agreement State license or decommissioning plan when larger numbers of products may be involved or significant contamination of property has resulted.

Specifically Licensed Sealed Sources and Devices.

Registration of Safety Information and Licensing of Sealed Sources and Devices.

The NRC is revising 10 CFR 30.32(g) to allow for the specific licensing of sealed sources and devices containing NARM that were previously regulated by the States. Sources and devices registered by the States may be licensed under 10 CFR 30.32(g)(1), and the user is only required to provide the manufacturer and model number as registered in the SS&D registry.

A new paragraph (3) is also being added to 10 CFR 30.32(g) to allow for the licensing of sealed sources and devices containing NARM for which all of the information otherwise required is not available. This second provision has been added in this final rule as a result of public comment. Previously, if a source or device were not registered in the SS&D registry, the applicant who wanted to use the source or device would be required to submit all of the safety information identified in 10 CFR 32.210(c), because this information had not been submitted previously by the manufacturer or distributor as part of registering the source or device. For older "legacy" devices for which the manufacturer is no longer in existence, it may be impossible to provide all of the categories of information identified in 10 CFR 32.210, as required by 10 CFR 30.32(g)(2). The provision being added as 10 CFR 30.32(g)(3) delineates

additional information that will be required to license a source or device for which all of the information previously required is not available. The information must include a description of the source or device, a description of radiation safety features, intended use and associated operating experience, and results of a recent leak test. The NRC licensing staff will review the submitted information to make a licensing decision regarding possession and use of the source and device. This new provision is only applicable to sources and devices containing NARM manufactured before the effective date of this final rule.

The information to be provided must demonstrate that there is reasonable assurance that the radiation safety properties of the source or device are adequate to protect health and minimize danger to life and property. The amount of detail needed to make this finding will depend on such things as the nature of the source or device and the amount of information identified in 10 CFR 32.210(c) that is available. However, generally, the source or device description might include the radionuclide(s), source activity, chemical and physical form, manufacturer's name, distributor's name, model number, construction details such as source or device dimensions, source encapsulation, any labeling, and a radiation profile. A description of device radiation safety features might include shielding, on-off mechanisms or indicators, methods for locking beam shutters, any safety warning labels, type of installation including method of attachment to its mounting if installed in a fixed location and means of relocation if portable, and any automatic safety features. The description of the intended use of the source or device could include how the source or device is used, the types of users, the locations of use, the occasions when persons will be near the device and the frequency of these occasions, and the likely environments to which the source or device will be subjected during normal use and likely accident conditions. A description of associated operating experience using the source or device should describe how the device has been used, particularly if the device will be used in this manner in the future, should include routine maintenance procedures and how

frequently performed, should note any operating problems and their resolution, and should identify any parts that were repaired or replaced. A description of a recent leak test should identify when the swipe was taken and evaluated and describe how the leak test swipe was taken, the results, and who conducted the evaluation.

Applicants are not authorized to remove sources from a device to obtain source details, unless qualified and specifically authorized to perform these activities under a license. For "uncontained" sources, applicants will need to use caution and minimize exposure time when attempting to gather details or information directly from the source.

Regulating the Accelerator-Produced Radioactive Material Used in Medical Activities.

When reviewing the public comments, it was clear that the discussion in the proposed rule of the NRC's existing regulatory framework for medical products, the distinction between radionuclide production licensing and radioactive drug production licensing, and the commercial and noncommercial distribution provisions, as well as the introduction of the term "consortium," were confusing to commenters. In addition to responding to individual comments on these subjects in the "Summary and Analysis of Public Comments on the Proposed Rule" section of this document, the following discussion is provided to give a clearer overview of the NRC's regulatory framework than was provided in the proposed rule discussion, particularly with respect to the delineation between production of radionuclides and radioactive drugs.

Section 651(e) of the EPAct requires the NRC to consider the impact of its regulations on the availability of radioactive drugs to physicians and patients. After consideration, the NRC concluded that its well established regulatory framework for the production, distribution, and use of in vitro test kits, radioactive drugs (which include biologics), and SS&Ds for medical use activities involving byproduct material is also appropriate in large part to similar products

containing accelerator-produced radioactive materials. Using the existing regulations could, with minor changes, minimize the impact on the availability of radioactive drugs containing accelerator-produced radionuclides. Therefore, this regulatory framework is applied to the producers, distributors, and medical users of in vitro test kits, radionuclides, radioactive drugs, and SS&Ds containing NARM that are included in the EPAct's expanded definition of *Byproduct material*.

Radionuclide Production.

The preexisting regulatory framework is directly applicable to the commercial production and distribution of NARM radionuclides. Longer-lived accelerator-produced radionuclides used in medicine may include: thallium-201, cobalt-57, and palladium-103. The shorter half-life PET radionuclides may include: fluorine-18, oxygen-15, and carbon-11. The production of radionuclides by accelerators (including PET radionuclides from cyclotrons), as well as the subsequent possession and use of these radionuclides, will be licensed under existing requirements in 10 CFR Part 30. The producer of the accelerator-produced radionuclides (including PET radionuclides) can transfer these radionuclides to manufacturers and other specific licensees under the provisions of 10 CFR 30.41. This includes both commercial and noncommercial distribution of accelerator-produced radionuclides (including PET radionuclides) to specifically licensed universities and research laboratories for basic research but not for use on human beings, which is specifically excluded in the definition of *Research and development* in 10 CFR 30.4.

These radionuclide production facilities include commercial nuclear pharmacies with PET centers, i.e., facilities with cyclotrons used to produce PET radionuclides. The NRC will review applications and the associated radiation safety programs of these radionuclide production facilities in accordance with the criteria in 10 CFR 30.33 and other existing requirements such as 10 CFR Parts 19 and 20. In meeting the general training and experience

requirement in 10 CFR 30.33(a)(3), these applicants will need to have individuals with training and experience in the production of PET radionuclides, i.e., the processes from insertion of targets in the accelerator or cyclotron to radiochemical isolation, purification, and testing. Individuals, such as radiochemists, physicists, engineers, and others identified by the applicant with appropriate training and experience, will be recognized as authorized users (AUs) under the manufacturer's, producer's, or pharmacy's 10 CFR Part 30 license for the production of accelerator-produced radionuclides (including PET radionuclides) using cyclotrons or other types of accelerators. To ensure the continued availability of accelerator-produced radionuclides used to manufacture or prepare radioactive drugs, it is expected that individuals, who can demonstrate that they performed the radionuclide production activities using an accelerator at a radionuclide production facility under the NRC's waiver (70 FR 51581; August 31, 2005), will be recognized as AUs as long as their duties and responsibilities do not significantly change. The applicant will be required to document that these individuals were responsible for the production of radionuclides using a cyclotron or accelerator when the waiver was in effect.

The NRC is distinguishing between the "production of radionuclides" and "preparation of radioactive drugs." Production of radionuclides, which would include production of PET radionuclides using a cyclotron (or other accelerator), is regulated under 10 CFR Part 30. Preparation of radioactive drugs for medical use from radionuclides, including PET radionuclides, is regulated under 10 CFR 32.72 and 10 CFR Part 35. Preparation of radioactive drugs for medical use may occur at locations other than the production facility. In the proposed rule, 10 CFR 32.72 included a provision to authorize commercial nuclear pharmacies that were not registered with FDA or registered with a State as a PET drug production facility to produce PET radionuclides if their radiation safety programs meet the criteria in 10 CFR 30.33. However, the purpose of 10 CFR 32.72 is to address the criteria and requirements for the

production and commercial distribution of radioactive drugs for medical use, and not the production of radionuclides. Therefore, the final rule does not include this provision. Based on a review of the requirements in 10 CFR Part 30, no revisions to the regulations are needed to license PET radionuclide production under 10 CFR Part 30.

10 CFR Part 32 Specific Production and Distribution Requirements.

Byproduct material may be transferred under 10 CFR 30.41 from one specific licensee to another person authorized to receive the material. However, not all transfers can be made under this provision, and certain transfers (or distributions) require that the manufacturer, preparer, or distributor meet specific provisions of 10 CFR Part 32. Specifically, a commercial radioactive drug manufacturer or a commercial nuclear pharmacy must obtain a distribution license issued under 10 CFR 32.71 to distribute certain in vitro test kits to generally licensed medical and veterinary clinical laboratories, and a medical distribution (MD) license issued under 10 CFR 32.72 to commercially distribute radioactive drugs to 10 CFR Part 35 (and equivalent Agreement State) medical use licensees. The proposed rule included revisions to the qualifications for a licensee to obtain a 10 CFR 32.72 MD license to more accurately describe the FDA registration criteria and to include licensees registered with a State as a PET drug production facility. These provisions are unchanged in the final rule. No changes are necessary for MD licenses issued to medical SS&D manufacturers under 10 CFR 32.74. The MD licenses issued under 10 CFR 32.72 and 10 CFR 32.74 authorize distribution for medical use (10 CFR Part 35 and equivalent State) licensees. Under the NRC's licensing practice, most of the 10 CFR Part 32 distribution licenses do not authorize the possession and use of byproduct material; rather, separate 10 CFR Part 30 licenses are issued for this purpose.

PET radioactive drugs are made with radionuclides that are usually very short lived. In addition to the commercial drug manufacturers and commercial nuclear pharmacies, individual hospitals, educational institutions, and Federal facilities may have cyclotrons used to produce

PET radionuclides and may also prepare PET drugs from these PET radionuclides. Although most PET radionuclides are very short lived, certain PET radionuclides with longer half-lives may be transported from the production facility to the user's site. The longer-lived PET radionuclides may also be combined with nonradioactive chemicals and biologics to produce new PET radioactive drugs. Hence, there are production and commercial distributions of some PET radioactive drugs (e.g., fluorine-18 deoxyglucose) to medical users (10 CFR Part 35 licensees).

Consortiums and Noncommercial Distribution.

The extremely short-lived radionuclides used for medical use have to be made into drugs and administered immediately after production, essentially necessitating that the cyclotron be located in the medical facility or in very close proximity. Some educational institutions, medical use facilities, or Federal facilities may form "consortiums" with adjacent or nearby hospitals to jointly own or share in the operation and maintenance costs of the PET radionuclide production facility. "Consortium" in this context means an association of medical use licensees, and a PET radionuclide production facility, in the same geographical area, that jointly own or share in the operation and maintenance cost of the PET radionuclide production facility that produces PET radionuclides, for use in producing radioactive drugs within the consortium, for noncommercial distributions among its associated members for medical use. The PET radionuclide production facility within the consortium must be located at an educational institution or a Federal facility or a medical facility. These facilities may produce PET radionuclides and radioactive drugs for members of their consortium and make these PET radionuclides and drugs available to these associated facilities through noncommercial distributions. Before this rulemaking, the NRC's regulations did not allow for the noncommercial distribution of radioactive drugs to medical use licensees. The NRC's regulations in 10 CFR 32.72 for the manufacture, preparation, or transfer of radioactive drugs

cover only commercial distribution. Medical uses of drugs under 10 CFR 35.100, 35.200, and 35.300 were previously limited to drugs obtained from a 10 CFR 32.72 licensee, or Agreement State equivalent, or prepared by the medical use licensee under specific provisions in 10 CFR Part 35. Because the NRC did not allow noncommercial distribution of radioactive drugs, failure to address noncommercial distribution of PET radioactive drugs in the this final rule would impact the availability of these drugs to physicians and patients.

Therefore, the NRC developed a new regulatory process based upon existing practices to minimize impact on the noncommercial distribution of PET radioactive drugs to medical use licensees within such a consortium. In accordance with this process, a Part 35 medical use facility that uses its own cyclotron to produce PET radionuclides for use under its own medical use license, would not need to be licensed for medical distribution under 10 CFR 32.72, but it would have to be specifically authorized under 10 CFR Part 30 for the production of PET radionuclides.

The definition of *Consortium* incorporates the unique features associated with the noncommercial distribution of PET radioactive drugs. For example, the consortium members must be in the same geographical area because of the short half-lives of PET radionuclides, e.g., 1.8 hours for fluorine-18, 20 minutes for carbon-11, and 2 minutes for oxygen-15. The location of the PET radionuclide production facility is limited to an educational institution or a Federal facility or a medical facility because these are the noncommercial facilities that would have cyclotrons that could produce PET radionuclides.

The NRC will review PET radionuclide production applications and their radiation safety programs in accordance with the criteria in 10 CFR 30.32 and 30.33 and other applicable requirements. In the proposed rule, only the noncommercial transfer of PET radioactive drugs between 10 CFR Part 35 medical use licensees was considered. However, the NRC recognized that the entity within the consortium with the PET production operation may not be a

medical licensee, but a university or Federal facility. In addition, the radionuclide production facility requires a specific license under 10 CFR Part 30. For this reason, the labeling provisions in 10 CFR 35.69, which would only have applied to medical licensees, were relocated from 10 CFR Part 35 to 10 CFR Part 30.

The new definition of *Consortium* and the provisions for noncommercial distribution are added to 10 CFR 30.4, 30.32, and 30.34 to allow for authorization of the production of PET radioactive drugs for noncommercial transfer to medical use licensees within a consortium. Thus, under these new provisions, a medical use facility, educational institution, or Federal facility with a licensed PET radionuclide production facility within its consortium does not need a medical distribution license under 10 CFR 32.72 if it intends to transfer PET radioactive drugs to members of its consortium. If it intends to commercially distribute PET radioactive drugs or distribute to medical licensees outside of its consortium, then a medical distribution license under 10 CFR 32.72 would be required. In any event, a specific authorization would be required to produce the PET drugs for noncommercial transfer to medical use licensees within its consortium. The requirements for authorization to produce PET drugs for noncommercial transfer to consortium members and the definition of *Consortium* are being added to 10 CFR 30.4. Specific requirements applicable to this licensed activity are added to 10 CFR 30.34(j). These requirements parallel the requirements for the commercial distribution of PET radioactive drugs, e.g., the licensee is qualified to produce radioactive drugs, the labeling contains consistent information, transport containers are adequately shielded, and radioactivity is accurately determined. Noncommercial distribution of PET radioactive drugs within a consortium may occur among members that are located in the same geographical area even if in different jurisdictions (e.g., Federal facility or other NRC licensees and Agreement State licensees). Thus, these new provisions are being assigned a Compatibility Category B.

Minor revisions were proposed to 10 CFR Part 35 to permit medical use facilities to

receive PET radioactive drugs by noncommercial transfer and to permit the medical use licensee to use activity values or activity concentration values for these PET radioactive drugs based on the measurements made by a PET radioactive drug producer within its consortium. The final rule also includes these provisions (in 10 CFR 35.65(b)(2) and (c)(3), 35.100(a), 35.200(a), and 35.300(a)), but the provisions are revised to clarify that the PET radioactive drugs have been produced by, and the measurements made by, the licensee authorized under 10 CFR 30.32(j) to produce PET radioactive drugs for noncommercial transfer to members of its consortium.

Authorized Nuclear Pharmacists (ANPs) and Authorized Users (AUs).

No regulatory changes were needed for ANPs to use all byproduct material (i.e., reactor-produced radionuclides, PET radionuclides, and other accelerator-produced radionuclides) to prepare PET radioactive drugs and other radioactive drugs under the practice of pharmacy. Medical use licensees that receive PET radionuclides that are added to "cold kits" may continue to prepare them under the same authorization in 10 CFR 35.100(b), 35.200(b), and 35.300(b) as other unsealed byproduct materials for medical use. However, a minor revision was made to each of these sections to clarify that the ANP and the qualified AU were not authorized under these sections to produce radionuclides.

Further, to ensure the availability of radioactive drugs made from accelerator-produced radionuclides, nuclear pharmacists responsible for the preparation of only PET or other NARM radioactive drugs under the NRC's waiver(70 FR 51581; August 31, 2005) will be "grandfathered" and will not be required to meet the new training and experience requirements as long as their duties and responsibilities under the new license do not significantly change. The "grandfathering" provisions are included in the revised provisions of 10 CFR 35.57 and 10 CFR 32.72(b)(4). The licensee is required by 10 CFR 32.72(b)(5) or 10 CFR 35.14(a) to document that these individuals were responsible for the preparation of only PET or other

NARM radioactive drugs when the waiver was in effect.

To ensure a smooth transition and availability of radioactive drugs and sealed sources made from accelerator-produced radionuclides for medical use, those individuals, i.e., physicians, podiatrists, dentists, and radiation safety officers (RSOs), who used only NARM byproduct materials for medical uses under the NRC's waiver (70 FR 51581; August 31, 2005) will also be "grandfathered" in 10 CFR 35.57 as long as their duties and responsibilities do not change significantly. These new grandfathering provisions are limited to those who used only NARM during the waiver, because any prior use of "old" byproduct material would have been subject to the existing requirements for being an AU or ANP or RSO.

These grandfathering provisions were in the proposed rule. However, the final rule does not include revisions to the definition of an *Authorized user* or *Authorized nuclear pharmacist* in 10 CFR 35.2. The NRC concluded that the definitions did not need to be revised because the grandfathering provisions for the RSOs, medical physicists, nuclear pharmacists, physicians, dentists, and podiatrists, who used only accelerator-produced radioactive material, were included in 10 CFR 35.57. Language has been added to 10 CFR 35.57 to clarify that these individuals qualify as AUs and ANPs for purposes of the regulations in Part 35. In addition, these individuals could continue to work as AUs, Authorized medical physicists (AMPs), or ANPs under the notification provisions of 10 CFR 35.13 and 10 CFR 35.14.

The radiation safety knowledge needed to safely use NARM for medical uses or for use in the practice of pharmacy is similar to that for other byproduct material. Therefore, individuals who only used NARM radioactive drugs or sealed sources in the practice of medicine or pharmacy will be authorized for use of all similar byproduct material for the same uses. The reverse is also true that individuals already authorized to use byproduct material in 10 CFR Part 35 for medical use or for use in the practice of pharmacy are authorized to use NARM. Further, no changes were made to the training and experience criteria in 10 CFR Part 35 for

any authorized individual.

Actions Taken to Ensure Availability of Accelerator-Produced Radioactive Drugs.

In summary, to minimize the regulatory impact on the availability of accelerator-produced radioactive drugs, the NRC is taking the following actions: (1) applying its established regulatory framework to the commercial distribution of these drugs; (2) expanding the regulations to permit production of PET drugs by medical use licensees, educational institution licensees, and Federal licensees for noncommercial distribution to members of their consortium; (3) permitting medical use licensees to use activity or activity concentration values measured by the PET radioactive drug producer in their consortium when determining dosages; (4) "grandfathering" current medical and pharmacy users of accelerator-produced radioactive drugs; and (5) retaining the existing training and experience criteria in 10 CFR Part 35 for authorized individuals.

In addition, as discussed under "Implementation Strategy" in this document, the NRC is revising Parts 30, 32, and 35 to authorize persons that used accelerator-produced radioactive material under the NRC's waiver (70 FR 51581; August 31, 2005) to continue to use these materials after the waiver is terminated, provided that these persons apply for a license or request for a license amendment within the allotted time frames. This regulatory provision allows all persons, including those who manufacture, produce, transfer, receive, acquire, own, possess, or use these materials, to continue with their activities including medical activities until the NRC makes its final licensing decision. This provision also ensures the availability of accelerator-produced radionuclides, radioactive drugs, and sealed sources and devices used for medical uses.

Amendments and Notifications for PET Radionuclide Production and Delivery Lines.

The NRC reviewed its regulations in 10 CFR Part 35 to determine if there were radiation safety provisions in its existing regulations that needed revision to incorporate unique radiation

safety issues associated with the use of accelerator-produced radionuclides for medical use. The medical use of extremely short-lived radionuclides, e.g., oxygen-15, requires that a PET radioactive drug containing this radionuclide be administered in the imaging and localization medical use area (10 CFR 35.200) immediately after the radionuclide is produced by the cyclotron and processed as a radioactive drug. This necessitates that the medical use area be co-located with the cyclotron or have a PET radioactive drug delivery line from the PET radionuclide production/PET radioactive drug processing area. This introduces the potential for a high radiation area in a medical use area that would otherwise be a low radiation area. This is a unique situation and was not envisioned when the NRC developed the requirements that permitted licensees to make changes in the areas where byproduct material is used only in accordance with 10 CFR 35.100 or 10 CFR 35.200 without submitting a license amendment. As a result, changes have been made to the requirements in revised 10 CFR 35.13, "License amendments," 10 CFR 35.14, "Notifications," and 10 CFR 35.15, "Exemptions regarding Type A specific licenses of broad scope." The final rule provides that an amendment is required for a limited specific medical use licensee in the unique situation described previously if the changes involved movement of the cyclotron or a PET radioactive drug delivery line from the PET radionuclide production/PET radioactive drug processing area. Changes to the typical 10 CFR 35.100 and 10 CFR 35.200 medical use areas are not affected. Section 35.15 is revised to clarify that a licensee possessing a Type A specific license of broad scope would not need to meet the notification requirements in 10 CFR 35.14(b)(4) for any changes to the area of use identified in its application where byproduct material is used in accordance with 10 CFR 35.100 or 10 CFR 35.200. This provision was revised from the proposed rule.

Strontium/Rubidium Generators.

Contamination limits for strontium-82/rubidium-82 generators and related requirements consistent with similar provisions of the SSRs are added to 10 CFR Part 35. The contamination

limits are no more than 0.02 kBq of strontium-82 per MBq of rubidium-82 chloride injection (0.02 µCi of strontium-82 per mCi of rubidium-82 chloride), or no more than 0.2 kBq of strontium-85 per MBq of rubidium-82 chloride injection (0.2 µCi of strontium-85 per mCi of rubidium-82). These limits and requirements to measure the contamination for compliance with these limits are added to 10 CFR 35.204, with corresponding recordkeeping requirements added to 10 CFR 35.2204. A corresponding provision for these tests and associated recordkeeping is also added to 10 CFR 30.34 for nonmedical use licensees, such as commercial nuclear pharmacies, using these generators.

Appendix B to Part 20--Annual Limits on Intake (ALIs) and Derived Air Concentrations (DACs) of Radionuclides for Occupational Exposure; Effluent Concentrations; Concentrations for Release to Sewerage.

The comparable provisions in Part D of the SSRs do not include any new accelerator-produced radionuclides other than the ones already in 10 CFR Part 20, Appendix B. The NRC considered whether some other radionuclide-specific values should be added to 10 CFR Part 20, Appendix B. Because nitrogen-13 and oxygen-15 are two of the accelerator-produced radionuclides that are produced for medical uses, the NRC performed a preliminary calculation of values based on dose factors published in National Council on Radiation Protection and Measurements (NCRP) Report No. 123 on Screening Models for Releases of Radionuclides to Atmosphere, Surface Water, and Ground. Certain dose conversion factors were not readily available. Results from these preliminary calculations yielded a derived air concentration (DAC) based on the submersion scenario for both nitrogen-13 and oxygen-15 of about 1.48×10^{-2} becquerels per milliliter (Bq/ml) (4×10^{-6} µCi/ml) for occupational exposure and a corresponding effluent concentration of 7.4×10^{-4} Bq/ml (2×10^{-8} µCi/ml) for exposure of members of the

public. These calculated values are larger than the default values for DAC and effluent concentration by a factor of 40 and 20, respectively, in 10 CFR Part 20, Appendix B. Because the approach used in calculating values for nitrogen-13 and oxygen-15 is different from that used for other radionuclides included in 10 CFR Part 20, Appendix B, the NRC did not include adding specific values for these radionuclides in the proposed rule. Because certain medical communities had expressed the desire of having specific DACs for these two radionuclides, the Commission specifically requested public comment on the default values, and whether it should include larger specific values for oxygen-15 and nitrogen-13 in the final rule. As a result of comments, these values have been added to 10 CFR Part 20, Appendix B, in the final rule. This is discussed further in this document under “Summary and Analysis of Public Comments on the Proposed Rule.”

Emergency Planning.

The regulations in 10 CFR 30.32(i)(1) require applications for specific licenses for byproduct material in unsealed form, on foils or plated sources, or sealed in glass in excess of the quantities in 10 CFR 30.72, "Schedule C--Quantities of radioactive materials requiring consideration of the need for an emergency plan for responding to a release," to contain either an evaluation showing that the maximum dose to a person offsite, due to a release of radioactive materials, would not exceed 0.01 sievert (Sv) (1 rem) effective dose equivalent or 0.05 Sv (5 rems) to the thyroid, or an emergency plan for responding to a release of radioactive material. Schedule C also contains a release fraction for each radionuclide against which aspects of the evaluation submitted in place of an emergency plan must be compared in accordance with 10 CFR 30.32(i)(2).

Although Part P, “Contingency Planning for Response to Radioactive Material

Emergencies," of the SSRs addresses an emergency plan, a value for radium-226 is not specifically listed. The NRC staff therefore considered NUREG-1140, "A Regulatory Analysis on Emergency Preparedness for Fuel Cycle and Other Radioactive Material Licensees," dated August 1991. NUREG-1140 was used as the technical basis in a past rulemaking effort related to quantities of radioactive materials requiring an emergency plan. NUREG-1140 provided the basis for 10 CFR 30.72 Schedule C values. Schedule C also contains a default value for alpha emitters of 74 gigabecquerels (GBq) (2 curies (Ci)) (with release fraction 0.001), which would apply to discrete sources of radium-226 absent a specific value being added to the table. However, the quantity value for radium-226 in NUREG-1140 is 3.7 terabecquerels (TBq) (100 Ci) along with a release fraction value of 0.001. This final rule adds radium-226 with the quantity 3.7 TBq (100 Ci) and release value 0.001 to 10 CFR 30.72 Schedule C, which is consistent with the technical basis for the original emergency planning requirements. It is expected that few, if any, licensees, or applicants for a license, would have 3.7 TBq (100 Ci) of discrete sources of radium-226. Because the "rule of ratios" applies (See Footnote 1 to 10 CFR 30.72), licenses authorizing other byproduct material, in quantities approaching values that would require emergency planning, which are being amended to add significant quantities of discrete sources of radium-226, could potentially result in authorizing total quantities of byproduct material that would meet the criteria for emergency plan requirements. It is not expected that accelerator-produced radioactive materials are used in significant enough quantities to affect the applicability of emergency plan requirements.

Low-Level Radioactive Waste and Decommissioning.

Low-Level Radioactive Waste.

Section 651(e)(3) of the EPAct mandates that the newly added byproduct material is not

considered to be low-level radioactive waste for the purposes of the Low-Level Radioactive Waste Policy Amendments Act (42 U.S.C. 2021b) (LLRWPAA). The intent of this provision is that the newly added byproduct material is not to be impacted by the compact process of the LLRWPAA. This provision does not have an impact on the NRC's policy and requires only a minor change to the regulations to ensure that the term "low-level radioactive waste," when used in the NRC's requirements, does not include the newly added byproduct material.

Although the newly added byproduct material is not considered low-level radioactive waste, it does pose a similar hazard, and it does need to be disposed of appropriately. Section 651(e)(3) of the EPAct requires that the newly added byproduct material must be disposed of in a facility that: (1) is adequate to protect public health and safety; and (2) is licensed by the Commission or by an Agreement State. Even though it is not low-level radioactive waste, this provision clarifies that the newly added byproduct material is to be disposed of in a facility licensed by the NRC under 10 CFR Part 61 or the Agreement State requirements, which are compatible to 10 CFR Part 61. This provision also allows for the disposal of the newly added byproduct material in a facility licensed by the NRC under other parts of the NRC's regulations, such as facilities licensed under 10 CFR Part 40, Appendix A.

To ensure that disposal facilities licensed under 10 CFR Part 61 continue to be adequate to protect public health and safety, the NRC must consider the specific health and safety issues associated with disposal of discrete sources of radium. Rather than making any changes to 10 CFR Part 61 at this time, the NRC will evaluate any specific disposals of discrete sources of radium at an NRC-licensed disposal facility under 10 CFR 61.58, "Alternative requirements for waste classification and characteristics." The NRC has not identified any other radionuclides being added to the definition of *Byproduct material* that require any specific evaluations to ensure the proper disposal of waste in accordance with 10 CFR Part 61.

Notwithstanding the previously mentioned provisions for the NRC or Agreement State

licensing of the disposal facility for the newly added byproduct material, Section 651(e)(3) of the EPAct does not affect the authority of any entity to dispose of the newly added byproduct material at a disposal facility in accordance with any Federal or State solid or hazardous waste law, including the Solid Waste Disposal Act. This means that Federal and State solid or hazardous waste laws can continue to be used as an authority to permit disposal of this newly added byproduct material. Disposal solutions already in place to allow disposal of the newly added byproduct material are unaffected by the EPAct. To implement this provision of the EPAct, the NRC is changing its regulations in 10 CFR Part 20 to redefine *Waste* to allow disposal of the newly added byproduct material in the NRC-regulated disposal facilities or in a disposal facility permitted under Federal or State solid or hazardous waste laws.

Appendix G of 10 CFR Part 20, the uniform manifesting requirements for low-level radioactive waste, includes numerous requirements containing the words “low-level radioactive waste” and “waste.” This is potentially confusing because the newly added byproduct material is not low-level radioactive waste in accordance with the provisions of the EPAct. However, no changes have been made to Appendix G to 10 CFR Part 20. The text changes made to the 10 CFR Part 20 regulations to clarify that the newly added byproduct materials are not “low-level radioactive waste” make it clear that the Appendix G to 10 CFR Part 20 requirements must be met if any of the newly added byproduct material waste is to be disposed of at a facility licensed under 10 CFR Part 61 or an equivalent Agreement State rule.

Decommissioning Issues.

The inclusion of accelerator-produced radioactive material that is used for a commercial, medical, or research activity, in the definition of *Byproduct material*, requires the NRC to ensure that decommissioning funding is adequate at accelerator facilities to adequately decontaminate and decommission their facilities for license termination. Radioactive materials produced in accelerator facilities, that are produced, extracted or converted after extraction for use for

commercial, medical, or research purposes and that are no longer residing in the accelerator, are not a concern for decommissioning. However, materials intentionally or incidentally made radioactive as a result of the production of the radioactive materials for use for commercial, medical, or research purposes must be managed safely. Any radioactive material residing in the accelerator or within the facility that houses the accelerator must be adequately considered for safe operation, and managed appropriately at the time of decommissioning of the accelerator-produced radionuclide production facility, including the accelerator, and the NRC must ensure that adequate financial assurances are put in place to address the costs of decommissioning when the radionuclide production operation ceases, and the accelerator is shutdown, and the license is terminated. As with all decontamination and decommissioning situations, short-lived radionuclides are expected to decay to safe levels before license termination. Therefore, only radionuclides with a half-life of more than 120 days, that are present in sufficient quantities specified in 10 CFR 30.35, need to be addressed for the purposes of establishing adequate financial assurances for decommissioning.

Similarly, the addition of discrete sources of radium-226 in the definition of *Byproduct material* requires the NRC to ensure that decommissioning funding is adequate for holders of specific licenses for possession of discrete sources of radium-226. Radium-226 is already included in Appendix B of 10 CFR Part 30 to determine the required level of financial assurance for holders of specific licenses in accordance with the requirements of 10 CFR 30.35. Therefore, applicants for specific licenses to possess discrete sources of radium-226 will need to assure that adequate financial assurances are provided for the types of sources and the total amount of radium-226 contained in the sources they will possess. Holders of general licenses for possession of discrete sources of radium-226 do not need financial assurance for decommissioning. However, in accordance with the approach for general and specific licensing of discrete sources of radium-226 being undertaken by the NRC in this final rule, a general

licensee may become subject to specific licensing if the accumulated number of discrete sources of radium-226 exceeds the allowable quantities of a general license. If a general licensee becomes subject to specific licensing, the licensee would be required to acquire the financial assurances required under 10 CFR 30.35.

The NRC believes that the financial assurance requirements included in 10 CFR 30.35 are adequate to ensure that any person who will receive a specific license authorizing possession and use of byproduct material will be required to have adequate financial assurance in place for decommissioning the facility. Therefore, the NRC is not changing the regulations governing financial assurance for decommissioning.

The NRC is cognizant of the potential existence of facilities and sites which may be, or have the potential to become, contaminated with significant amounts of radium-226 from past practices or operations. Additionally, the potential exists for significant quantities of discrete sources of radium-226 to have been previously disposed of by both licensees and nonlicensees at their facilities. The existing requirements for licensing and decommissioning in 10 CFR Part 30 are sufficient to address these situations for any facilities that will apply for a specific license or amendment to authorize possession of discrete sources of radium-226 for their current operations. The applications to the NRC, in these cases, would include a facility-specific decommissioning plan that addresses the current contamination and any previous onsite disposals.

There are no similar assurances for any facility that is currently contaminated from discrete sources of radium-226 but is not licensed. With the inclusion of discrete sources of radium-226 in the definition of *Byproduct material*, the NRC acquires the regulatory authority to address these situations where a specific license has not been issued (or where a potential licensee cannot be identified). At this time, there is not enough known about the breadth or depth of these potential radium-226 contamination situations to determine if any additional

requirements may be needed to address them. Therefore, the NRC will address these situations on a case-by-case basis as they are identified following the effective date of this final rule.

D. *License Application and Annual Fees.*

The NRC is required to recover approximately 90 percent of its budget authority each year under the Omnibus Budget Reconciliation Act of 1990 (OBRA-90), as amended. Therefore, the NRC charges licensing, inspection, and annual fees to its applicants and licensees. Each type of fee includes agency and program overhead. The NRC revises these fees each year in light of its current fiscal year budget and other factors, including changes in the regulatory efforts associated with the different classes of licensees.

Persons applying for a license with the NRC, or requesting an amendment to their current licenses that may result in the addition of a new fee category, are required to pay a license application fee under 10 CFR Part 170, unless exempt under the fee exemption provisions of 10 CFR 170.11. The application fees for materials users are “flat” fees that are calculated by multiplying the average professional staff hours needed to process the application by the Materials Program hourly rate in 10 CFR 170.20 ($256 in the FY 2007 proposed fee rule). An application fee must generally be paid for each applicable fee category.

Additionally, all persons who hold licenses issued by the NRC are subject to annual fees under 10 CFR Part 171, unless exempt under the provisions of 10 CFR 171.11. The 10 CFR Part 171 fee categories, and the associated fees for materials users, are provided in 10 CFR 171.16, and must generally be paid for each applicable fee category. A licensee may request consideration as a small entity for the annual fees which may result in a reduced fee, as described in 10 CFR 171.16.

The annual fees for the materials users fee class are calculated based on the NRC's budgeted resources allocated to regulating these types of licensees, less any receipts received from this fee class for 10 CFR Part 170 activities. The net dollar value of budgeted resources for this fee class is allocated to all materials user fee categories (subclasses) based on the average application and inspection costs associated with each category. This approach provides a proxy for allocating the generic and other regulatory resources to the diverse categories of licensees based on how much it costs the NRC to regulate each fee category. The fee calculation also considers the inspection frequency (priority based), which is indicative of the safety risk and resulting regulatory costs associated with these categories of licenses.

The license application fees schedule is in 10 CFR 170.31. The annual fees schedule is in 10 CFR 171.16. The fee amounts included in the proposed rule were based on the FY 2005 fees. The fee amounts noted in the final rule are based on the proposed FY 2007 fees. The proposed rule for the FY 2007 Fee Schedules was published in the Federal Register (72 FR 5108; February 2, 2007). The fee amounts may change once the final FY 2007 Fee Schedules become effective (currently estimated to be in August 2007).

The NRC believes that the majority of the NRC’s licensees affected by this final rulemaking will be using radioactive material in a manner similar to their existing authorizations, and their existing fee categories should not change as a result of this rule. However, some licensees may need to amend their licenses to add one or more new fee categories, if applicable, for new uses and radioactive material now considered byproduct material, i.e., accelerator-produced radioactive material or discrete sources of radium-226.

The NRC is establishing three new fee categories for activities that were not previously covered by its regulations. The new fee categories apply to certain items previously manufactured and self-luminous products containing radium-226 and to the production of accelerator-produced radioactive material. In determining the fees for these new categories,

the NRC evaluated existing fee categories that the NRC believes require a similar level of regulatory effort as these newly regulated activities for actions such as licensing, inspection, and event response.

Most individuals and other entities collecting items containing radium-226 are expected to be eligible to be exempt from license under 10 CFR 30.15 or for a general license under the new 10 CFR 31.12, "General license for certain items and other self-luminous products containing radium-226." Therefore, they would be subject to the requirements of 10 CFR 30.15 or 10 CFR 31.12 (e.g. proper disposal of the radioactive material). However, if a person collects more than the number of items or limits specified in these sections, that person will be required to obtain a specific license and be subject to the regulations regarding license application and annual fees. The NRC is establishing a new fee category, 3.R., with a two-tiered fee level, for those persons requiring a specific license for items containing radium-226. The distinction between the two fee levels is based on the number of items or limits specified in 10 CFR 31.12(a)(4) or (5) and the estimate of the level of regulatory effort between the two levels. Licensees who currently possess radium sources in amounts that exceed the general license provisions of 10 CFR 31.12 would be required to add the sources to their specific license. This would normally subject the licensee to the fees in this new fee category. However, if the radium-226 sources are used for operational purposes that are covered under another fee category, the licensee will not be subject to the fees in this new fee category. This exception will not apply if the radium sources are possessed for storage only.

The first new fee Category 3.R.1. is for persons possessing quantities greater than the number of items or limits in 10 CFR 31.12(a)(4) or (5), but less than or equal to 10 times these quantities. Because the estimated level of regulatory effort is comparable to the level of effort for Category 8, Civil defense, the license application and annual fees for 3.R.1. will be $590 and $2,100, respectively. The second new fee Category 3.R.2. is for persons possessing quantities

greater than 10 times the number of items or limits in 10 CFR 31.12(a)(4) or (5). The license application and annual fees for this new category, 3.R.2., will be $1,400 and $2,700, respectively, comparable to the fees for Category 3.P., “All other specific byproduct material licenses, except those in Categories 4A through 9D.”

Persons who wish to disassemble, repair, or assemble products containing radium-226 will be required to obtain a specific license and will be subject to the applicable license application and annual fees. The NRC is including this use in fee Category 3.B., “Other licenses for possession and use of byproduct material issued under 10 CFR Part 30 of this chapter for processing or manufacturing of items containing byproduct material for commercial distribution.” The license application fee for this category will be $4,500, and the annual fee will be $8,300.

The NRC is adding a new fee Category 3.S. for the production of accelerator-produced radioactive materials. The NRC is adding this new fee category because these production activities need to be distinguished from those activities that only involve the use of already-prepared radionuclides. The regulatory effort for the new fee Category 3.S. is estimated to be comparable to that for fee Category 3.C. The license application and annual fees for this new category will be $8,000 for the application fee and $11,800 for the annual fee. Fee amounts included in this final rule are different from those included in the proposed rule because they are based on the proposed FY 2007 Fee Schedules instead of the FY 2005 Fee Schedules.

E. *Implementation Strategy.*

Specific provisions are included in this rule, and several actions are planned in conjunction with, or following, the issuance of this final rule covering the newly added byproduct material, including:

(1) Issuance and publication of a Transition Plan for the orderly transition of regulatory authority for the newly added byproduct material;

(2) Termination of the waiver issued by the NRC (70 FR 51581; August 31, 2005) for the States and users of the newly added byproduct material; and

(3) Inclusion of specific provisions allowing users of the newly added byproduct material to continue with their activities for a period of time while coming into compliance with the newly issued regulations.

Transition Plan.

Section 651(e) of the EPAct requires the NRC, in issuing new regulations for the newly added byproduct material, to prepare and publish a Transition Plan for the orderly transition of regulatory authority over the newly added byproduct material for Agreement and non-Agreement States. The EPAct requires that the Transition Plan describe the conditions under which a State (including U.S. Territories and the District of Columbia) may exercise authority over the newly added byproduct material, and include a statement of the Commission, that any agreement between the Commission and a State under Section 274b. of the AEA, covering byproduct material, and entered into before the date of publication of the Transition Plan, be considered to include the newly added byproduct material. The statement of the Commission is subject to a certification provided by the Governor of the State to the Commission on the date of publication of the Transition Plan that: (1) the State has a program for licensing the newly covered byproduct material that is adequate to protect the public health and safety, as determined by the Commission; and (2) the State intends to continue to implement the regulatory responsibility of the State with respect to the byproduct material. The NRC also will include in the Transition Plan the process it will use to terminate the waiver issued

by the NRC on August 31, 2005, and for the transition of regulatory authority following expiration or earlier termination of the waiver.

Termination of Waiver.

The waiver issued by the NRC (70 FR 51581; August 31, 2005) is effective through August 7, 2009 (except terminated August 7, 2006, for the import and export of materials covered by the waiver), unless terminated earlier by the Commission. The waiver applies to Agreement and non-Agreement State regulatory programs and users of the newly added byproduct material, and allows persons owning, using, and otherwise engaging in activities involving the material to continue with their activities and the States to continue to regulate this material during the applicable waiver period. All persons in States (including U.S. Territories and the District of Columbia) that do not have an agreement with the Commission under Section 274b. of the AEA that covers the newly added byproduct material on or before August 7, 2009, will automatically be subject to the NRC regulatory authority for the material on August 8, 2009. The waiver also may be terminated earlier than August 7, 2009, if the Commission determines that an earlier termination is warranted.

For a new or existing Agreement State that intends to implement the regulatory program of the State with respect to the newly added byproduct material, Section 651(e) of the EPAct requires that the waiver be terminated for the State when the Commission determines that the State has entered into an agreement with the Commission, under Section 274b. of the AEA, that the State program covers the newly added byproduct material, and that the State program for licensing the newly added byproduct material is adequate to protect the public health and safety. The Commission determination and termination of the waiver will be noticed in the Federal Register (Notification of Waiver Termination). Users of the newly added byproduct

material currently licensed, or registered, by an Agreement State that continues to implement its regulatory program, with respect to the newly added byproduct material, will continue to be subject to the Agreement State regulatory authority.

With regard to the States that do not have an existing agreement with the Commission under Section 274b. of the AEA (non-Agreement States), the waiver period provides additional time for those States that desire to establish such an agreement for the newly added byproduct materials to develop a program. To establish this agreement with the Commission, the Governor of the current non-Agreement State will need to request an agreement with the Commission. The process of establishing these agreements can take 3 or more years to complete. Options will be considered, on a case-by-case basis, to limit the impact of the transition of authority on affected users of the new byproduct material in the State.

Additional details on the process that the NRC will use to terminate the waiver for Agreement and non-Agreement States and users in these States will be provided in the Commission's Transition Plan, as required by Section 651(e) of the EPAct. The NRC plans to publish the Transition Plan following publication of this final rule and before the effective date of this final rule.

Notification of Waiver Termination.

The Commission is terminating the waiver for Government agencies and Federally recognized Indian Tribes on the effective date of this final rule because there is currently limited regulatory oversight for the newly added byproduct material at these facilities. Waiver termination is necessary to require Government agencies and Federally recognized Indian Tribes to comply with the new requirements and for the NRC to ensure protection of public health and safety for the newly added byproduct material.

The Commission has also determined that an earlier termination is warranted and is therefore terminating the waiver for persons owning, using, and otherwise engaging in activities involving the newly added byproduct material in the following States on the effective date of this final rule: Delaware, Indiana, Wyoming, and Montana, as well as the District of Columbia, Puerto Rico, and the U.S. Virgin Islands. The effective date of this final rule is 60 days after the date of publication in the Federal Register. Waiver termination is necessary to require persons owning, using, and otherwise engaging in activities involving the newly added byproduct material in these States, U.S. Territories, and the District of Columbia to comply with the new requirements and for the NRC to ensure protection of public health and safety for the newly added byproduct material.

Implementation Period.

Although Government agencies, Federally recognized Indian Tribes, and certain persons owning, using, and otherwise engaging in activities involving the newly added byproduct material in the States of Delaware, Indiana, Wyoming, and Montana, and the District of Columbia, Puerto Rico, and the U.S. Virgin Islands are already being regulated by the NRC for the AEA 11e.(1) and 11e.(2) byproduct material, the NRC is allowing a transitional period for them to submit a license amendment or a new license application for the newly added byproduct material. This final rule allows an additional 6-month period from the effective date of the final rule to apply for a license amendment; and an additional 12-month period from the effective date of the final rule to apply for a new license.

In addition, the rule contains specific provisions that gives Governmental agencies, Federally recognized Indian Tribes, and persons owning, using, and otherwise engaging in activities involving the newly added byproduct material, in the States of Delaware, Indiana,

Wyoming, and Montana, and the District of Columbia, Puerto Rico, and the U.S. Virgin Islands, the authority to continue to use the newly added byproduct material during the period following the waiver termination until the date of the NRC's final licensing determination, provided that either a license amendment or a license application is submitted within the specified time frame and while complying with all other aspects of the regulations (e.g., event reporting, personnel dosimetry) upon the effective date of this final rule.

For persons owning, using, and otherwise engaging in activities involving the newly added byproduct material, compliance with the rule will be required depending on the date of waiver termination. For certain States and persons, the NRC plans to terminate the waiver earlier than the final date of the waiver, i.e., August 7, 2009. A decision for early termination will depend on a number of factors, including the status of an Agreement State Governor's certification of adequate program for the newly added byproduct material, status of a non-Agreement State's application to become an Agreement State, and activities or areas under exclusive NRC jurisdiction. Upon waiver termination, all persons that possess the new byproduct materials must be in compliance with NRC regulations. It is noted that being in compliance with the NRC regulations includes, for example, meeting the reporting and recordkeeping requirements for the new byproduct material once the waiver is terminated. In addition, such persons will either be required to: (1) apply for license amendments for the new byproduct material within 6 months from the date the waiver is terminated, if they hold an NRC specific byproduct materials license; or (2) submit a license application for the new byproduct material within 12 months from the date the waiver is terminated. It is noted that authorization statements for certain licenses are inclusive of byproduct materials and their uses so that an amendment may not be needed to specifically add NARM to the license.

During the time between the termination of the waiver and the user's application for an NRC license or license amendment, users in Government agencies, Federally recognized

Indian Tribes, and non-Agreement States will be under the NRC's jurisdiction for enforcement purposes. The NRC will handle enforcement cases involving the use of the newly regulated materials on a case-by-case basis. However, should the number of cases involving these materials be larger than anticipated, the staff will prepare additional enforcement guidance to ensure consistency in handling such issues.

III. Summary and Analysis of Public Comments on the Proposed Rule.

The proposed rule on Requirements for Expanded Definition of Byproduct Material was published on July 28, 2006 (71 FR 42952). The comment period ended on September 11, 2006. The NRC received 39 comment letters on the proposed rule. Comment letters were submitted from the States, other Federal agencies, professional organizations, universities, medical communities, industries, and individuals. On August 22, 2006, the NRC held a public meeting in Las Vegas, Nevada, on the proposed rule during the comment period. Copies of the public comments and the public meeting transcripts are available for review in the NRC Public Document Room, 11555 Rockville Pike, Rockville, Maryland, or on the NRC's rulemaking Website located at http://ruleforum.llnl.gov.

In addition to requesting public comments on the proposed rule, the NRC specifically requested additional information or comments on 15 specific items outlined in Section II.G. of the proposed rule. A synopsis of the items and type of comments received are as follows:

Item 1 - Technical Information to Support Exemption of Old Radium-226 Sources. One commenter provided information on potential pressure build-up within radium sources that could lead to the release of radium into the environment. Another commenter provided a reference to an FDA document. There were comments on the availability of information on radium-226

items and on exemption of antiquities. The NRC appreciates the information. A discussion of the comments on exemption of antiquities and associated response is included later in this document under “Comments Related to Radium-226.”

Item 2 - Extent of Use of Accelerators. No comments were received regarding the extent of accelerators that are used to intentionally produce radioactive material and also used to generate particle beams for basic science research. One commenter indicated that the commenter’s organization does not operate any particle accelerators for the purpose of producing radioactive materials and producing particle beams for other uses. Another commenter informed the NRC that it will be building a new accelerator facility where radionuclides will be produced.

Item 3 - Information on Decommissioning of Accelerator Facilities. Several comments were received regarding information on decommissioning of accelerator facilities, including accelerator components and facility building materials that may become activated. A detailed discussion of the comments and response is included later in this document under “Comments on Waste and Decommissioning.”

Item 4 - Inclusion of Specific ALI and DAC Values. In response to the NRC’s question on whether to develop specific ALI and DAC values for oxygen-15 and nitrogen-13 for inclusion in 10 CFR Part 20, Appendix B, several commenters provided specific DAC values. A discussion of the values and the methodology used can be found later in this document under “Comments on Other General Requirements.”

Item 5 - Exemption of Radium-226 Timepiece Repairs. In regard to the appropriateness of the proposed exemptions to allow repairs of 10 radium-226 timepieces per year, one commenter suggested increasing the proposed limit of 10 per year to 18. The commenter did not provide specific data concerning how active the repair of radium-226 timepieces may be or the safety significance of the proposed exemption. However, there were several comments

related to radium-226 exemptions. Detailed discussion of these comments and the associated responses is included later in this document under “Comments Related to Radium-226.”

Item 6 - Health and Safety Information of Radium-226 Sources. The NRC requested information on the health and safety impact from activities involving radium-226 sources, in particular, information to support a technical basis for an exemption as an alternative to the proposed general licensing approach. Several commenters indicated that they believed that an exemption would be preferable to a general license for items containing radium-226, but no specific health and safety impact information was provided. Most commenters agreed that more information about risk is needed to make a final decision. Discussion of comments associated with this issue is included later in this document under “Comments Related to Radium-226.”

Item 7 - Existing and Proposed Fee Categories. The NRC requested information on whether the majority of licensees would remain in the existing fee categories and whether new NARM licensees would fall under the current fee categories or the new proposed fee categories. No specific information on this issue was received from the commenters. However, several commenters indicated that they believed that there is no need to establish a new fee category for the production of accelerator-produced radioactive material. All of the comments related to fees are discussed later in this document under “Comments on Licensing Fees and Fee Categories.”

Item 8 - Licensing Boundaries for Radium-226 Private Collectors. No information was received on whether private collectors of items or products containing radium-226 would remain within the boundaries of the proposed general license or be required to obtain a specific license and be charged with the associated licensing fees. One commenter recommended that an “exception” be extended to certain organizations. A discussion of radium-226 exemptions is included in subsection “Comments Related to Radium-226,“ and a discussion of fees is

included later in this document under “Comments on Licensing Fees and Fee Categories.”

Item 9 - Two-Tiered Fees for Radium-226. No information was received regarding the two-tiered license fees proposed for possession of different quantities of radium-226 items. Comments received on the proposed fee categories and amounts are discussed later in this document under “Comments on Licensing Fees and Fee Categories.”

Item 10 - Effective Date and Implementation Periods. Several comments were received on the proposed effective date and implementation periods of the rule. A discussion is included later in this document under “Comments on Waiver Termination and Transitioning.”

Item 11 - Compatibility Category Designations. All comments related to the compatibility category designations are discussed later in this document under “Comments Related to Agreement States and Other Government Agencies.”

Item 12 - Environmental Assessment. Comments received on the draft Environmental Assessment were considered in the final Environmental Assessment and Finding of No Significant Impact.

Item 13 - Information Collections. No comments were received on the information collections aspects of the rule.

Item 14 - Regulatory Analysis. No comments were received on the draft Regulatory Analysis.

Item 15 - Impact to Small Business. No comments were received on the impacts of the rule on small businesses.

General information and editorial suggestions received on the proposed rule are appreciated but do not need to be discussed in this final rulemaking. Comments associated with nuclear reactors and the high-level waste repository are outside the scope of this rulemaking; therefore, they will not be addressed in this section. All other comments have been grouped into broad categories, and a detailed discussion of the comments and the NRC’s

responses are as follows:

Comments Related to Agreement States and Other Government Agencies.

Agreement State Compatibility Designations.

Comment: The comments received on "compatibility" are primarily centered around one main concern: implementation of the requirements for the Compatibility Category of Health and Safety (H&S) for several definitions. The basic concern expressed by these commenters was that the States should not be required to amend their definitions in their State statutes and regulations. In particular, some commenters were concerned about the designation of H&S for the definition of *Byproduct material*. These commenters indicated that they would support an H&S designation if the Statements of Consideration to the final rule provided that the NRC's initial determination of the adequacy of definitions would rely on a Governor's certification that the State's program was "adequate," and that if the Governor's certification was accepted, no changes to the State's definitions would be required. As an alternative, some commenters suggested that the Statements of Consideration recognize that the States could use alternative language in their definitions including the use of the more generic term of "radioactive material," rather than revise the definitions to conform with the new definitions. In the absence of implementing those suggestions, these commenters recommended that the Compatibility Category designation for definitions be changed from H&S to D.

These commenters generally indicated that if those suggestions could not be implemented, they would recommend that the NRC designate the definitions it was changing as Compatibility D.

NRC Response: The NRC does not agree with the commenters' assertion that the designation for the definition of *Byproduct material* should be changed from H&S. The NRC

also does not agree that the Governor's certification of the adequacy of an Agreement State's program should relate to the need for the State to revise its regulations. However, the States may continue to use the existing definition including *Radioactive material* in State statutes and regulations, although there may be limited areas where a State may need to revise its regulations to include material now under the jurisdiction of the NRC (e.g., exempt distribution for certain materials).

The NRC applied the criteria in Management Directive (MD) 5.9, *"Adequacy and Compatibility of Agreement State Programs*," in evaluating the compatibility category of the definitions, and determined that a category of H&S is appropriate for the definition of *Byproduct material*. MD 5.9 provides that an H&S designation is appropriate for elements that are not required for compatibility but have been identified as having a particular health and safety role in the regulation of agreement material within the State. In accordance with this designation, the State should adopt program elements, based on those of the NRC, that embody the essential objectives of the NRC program elements because of particular health and safety considerations. A category of H&S is appropriate for the definition of *Byproduct material* because the absence of the essential objectives of the program element from an Agreement State program could create a situation that could directly result in exposure to an individual in excess of basic radiation protection standards.

MD 5.9 provides that the NRC program elements in Compatibility Category D are those that do not meet the criteria of Compatibility Categories A, B, or C, and thus, do not need to be adopted by the Agreement States for purposes of compatibility. The NRC has determined that a Compatibility D designation is not appropriate for the definition of *Byproduct material* because if the definition of *Byproduct material* or another term which encompasses all of the byproduct material regulated by the State were not somewhere within the State program (i.e., in statute or in regulations), it is possible that some byproduct material could escape regulatory oversight

with a result of exposure to an individual in excess of the 10 CFR Part 20 limits. The State regulatory program must include Sections 11e.(3) and 11e.(4) byproduct material in its regulatory program if the Agreement includes this material, thus, an H&S designation (an assessment of adequacy) is appropriate.

In implementing the Commission's policy on Agreement States, a designation of H&S for the definition of *Byproduct material* will require NRC staff to continue to assure that the essential objectives (i.e. Sections 11e.(3) and (4) byproduct materials are addressed in the regulatory program) are met. The NRC staff notes that under a designation of D, this assurance would not be obtained because program elements designated D are not a required part of an Agreement State program (they could be dropped from or not included in the Agreement State program, and the program could still be found adequate and compatible).

Comment: With regard to the definitions in 10 CFR 35.2 of *Authorized nuclear pharmacist*, *Authorized user*, and *Positron Emission Tomography (PET)*, one commenter recommended that any Agreement State that has rule language essentially the same as the current CRCPD's SSRs should be considered to have compatible rules and should not have to revise those rules regardless of the level of compatibility assigned by the NRC. The commenter further recommended that the NRC might include this recognition in the Statements of Consideration.

NRC Response: The NRC has determined that it is not necessary to change the current definitions for an *Authorized user* or *Authorized nuclear pharmacist*. This rule does not change the existing definitions or impact the existing compatibility designation for these definitions. The definition of *Positron Emission Tomography* is not in the SSRs, and it is identified in the final rule as having a designation of "H&S," which assures that the State's regulatory programs adequately address the essential objectives of the NRC program elements when using the term *Positron Emission Tomography*.

Comment: For each of the sections with a Compatibility B Category, it is not clear that the NRC accepts the language of the States that is essentially identical to the SSRs.

NRC Response: For the definitions and sections assigned a Compatibility B designation, the NRC cannot automatically accept the States' language; the States' regulations must be reviewed. Agreement State regulations will be reviewed according to Office of Federal and State Materials and Environmental Management Programs (FSME) Procedure 201 (formerly SA-201) and should be submitted within 3 years of publication, in accordance with the NRC's 1997 Policy Statement on Adequacy and Compatibility of Agreement State Programs (62 FR 46517; September 3, 1997). The NRC notes that portions of the SSRs may be outdated and do not reflect recent amendments (e.g., definitions of *Authorized user and Authorized nuclear pharmacist*) and so cannot be used.

Comment: Referring to 10 CFR 32.72, a commenter recommends that the NRC specifically recognize that an Agreement State will not be required to amend its comparable regulation, as long as that comparable regulation provides for the same control of the manufacture and initial distribution of radium-226 sources under a general license as was provided in the proposed regulation.

NRC Response: The NRC does not agree with the comment. Section 32.72 in 10 CFR Part 30 authorizes specific licensees to manufacture, prepare, and distribute radioactive drugs to medical use licensees. This provision does not include generally licensed material. Further, the NRC is unaware of any radioactive drugs containing radium-226. Agreement States have 3 years to adopt regulatory requirements compatible with 10 CFR 32.72 revisions.

For a specific license to allow the manufacture or initial transfer of calibration or reference sources containing radium-226, under 10 CFR 32.57, for distribution to persons generally licensed, the NRC has included provisions in 10 CFR 31.8 to recognize specific licenses issued for these sources by a State with comparable regulations.

Comment: A commenter stated that the NRC's deliberate use of Compatibility B and H&S categories sets the tone that its considerations are preeminent. Another commenter stated that the language of the EPAct indicates that the burden should be on the NRC to bring its regulations into conformance with the Agreement State regulations. The commenter also stated that whether or not the NRC is making an effort to obey the EPAct language to cooperate with the States or use model State standards will depend on whether the NRC accepts the Agreement States' regulations. The commenter believes that the Agreement State regulations do not need to be changed to be exactly like the NRC's.

NRC Response: In accordance with AEA Section 274b, for an agreement between the NRC and a State, a State program must be adequate to protect public health and safety and be compatible with the NRC. The EPAct gives the NRC jurisdiction over NARM byproduct material, and does not mandate that the NRC bring its regulations into conformance with the Agreement State regulations, but only requires that the Commission, to the maximum extent practicable, cooperate with the States and use model State standards. The Commission has fulfilled this mandate by working closely throughout the development of this final rule with OAS, the CRCPD, and other stakeholders, and by considering the model State standards. As discussed previously, the NRC applied criteria laid out in MD 5.9, "*Adequacy and Compatibility of Agreement State Programs,*" which includes criteria for the NRC to designate compatibility and adequacy categories to the NRC's regulations and coordinating amendments for radioactive material included in the Agreement. In promulgating the final rule, these criteria were applied to the definitions and other requirements of the EPAct to determine the appropriate compatibility categories.

Interaction with Other Federal Agencies.

Comment: A commenter asked if any Memorandum of Understanding (MOU) between the NRC and the DOT on byproduct materials would be affected by the changes in the proposed rule.

NRC Response: The roles and responsibility between DOT and the NRC in the regulation of the transportation of radioactive material are clearly described in an MOU signed on June 8, 1979, and published in the Federal Register (44 FR 38690; July 2, 1979). As delineated in the MOU, the DOT is generally responsible for regulating safety in transportation of all hazardous material, including radioactive material, and the NRC is responsible for regulating safety in receipt, possession, use, and transfer of byproduct, source, and special nuclear materials. The NRC is also responsible for approval of package designs for fissile materials and for other radioactive materials in quantities exceeding Type A limits. In reviewing the language of the existing MOU, the NRC has determined that no change is necessary as a result of this final rule. The MOU stated that the NRC is authorized to regulate, among other things, byproduct material under the AEA of 1954, as amended, and the Energy Reorganization Act of 1974, as amended. Because the EPAct amends the AEA, the expanded definition of *Byproduct material* will automatically be subject to the MOU. In addition, there are routine interactions between the NRC and the DOT, and the DOT is aware of the expanded definition of *Byproduct material*.

Comment: A commenter asked if the proposed changes in the regulations would have any impact on accelerators or accelerator radionuclides that are taken to sea or out of the U.S., and if those changes would also impact the EPA's responsibilities, treaty requirements, or Status of Forces agreements. For example, the commenter noted that a research vessel, military hospital, or Centers for Disease Control vessel leaving the U.S. for foreign ports and returning to the U.S. may have an electron microscope or metabolic (Na, Cl, K) studies with accelerator-produced radionuclides on board. The commenter asked if activation from neutron

radiography on board these ships would be an issue. The commenter also asked if the proposed changes would affect machines that the U.S. Customs uses to radiograph containers in foreign ports before they are placed on shipboard if the machine is greater than 1 MeV. The commenter also wanted to know how replaced parts of those machines will be handled, whether all parts would be controlled, and whether they could be disposed of in a foreign state.

NRC Response: The commenter appears to be concerned, in part, about regulatory requirements pertaining to U.S. originated accelerator-produced radioactive material taken outside of the U.S., i.e., export of accelerator-produced radioactive material. Part 110 of the NRC's regulations governs export and import of radioactive material within the NRC's regulatory jurisdiction. On April 20, 2006 (71 FR 20336), the NRC issued a final rule amending 10 CFR Part 110 to reflect the EPAct's augmentation of the NRC's regulatory jurisdiction to include accelerator-produced radioactive material. Specifically, the rule added "accelerator-produced radioactive material" to the definition of *Byproduct material* in 10 CFR 110.2 and Appendix L to 10 CFR Part 110. Export and import of all byproduct material, including accelerator-produced radioactive material, are governed by 10 CFR Part 110. There is no difference in regulatory treatment between byproduct material produced by an accelerator and byproduct material produced in a reactor.

The commenter also asks whether this rule would affect U.S. Customs' use of "radiograph machines." The NRC does not believe this final rule would have any impact on the Customs and Border Protection's use of radiograph machines because these machines use byproduct material that is already regulated by the NRC because the material is produced in a reactor. With the revised definition of *Byproduct material*, there will be no difference in regulatory treatment between byproduct material produced by an accelerator and byproduct material produced in a reactor. If the radiograph machine uses the accelerator-produced radioactive material, it would now be subject to the same regulatory requirements as the

machine-used byproduct material produced in a reactor. The NRC's or any other requirements on the use of byproduct material in radiograph machines would be no different from the pre-EPAct condition for both the domestic and export context.

Neutron radiograph machines do not use byproduct material; they are actually accelerators. Only neutron beams are generated in these types of radiograph machines for imaging purposes. Because these types of radiograph machines (or accelerators) do not produce radioactive material for use for commercial, medical, or research activities, the NRC has no regulatory authority over these machines or the activation material produced incidental to imaging operation.

Comment: A commenter recommended that the NRC pursue an MOU with OSHA in order for the NRC to assume regulatory jurisdiction over the occupational exposure to ionizing radiation in non-Agreement States. The commenter noted that before the expansion of the NRC's jurisdiction over NARM, OSHA had jurisdiction for occupational health and safety in non-Agreement States. The commenter noted that OSHA published a request for information to better understand what, if any, changes OSHA needed to consider in its regulation of the use of ionizing radiation in the workplace (See: Occupational Exposure to Ionizing Radiation–Request for Information; 70 FR 22828; May 3, 2005). The commenter recommended that the NRC work actively with OSHA to streamline the regulatory requirements and eliminate duplication of authority over the use of NARM in non-Agreement States.

NRC Response: The NRC has been working, and continues to work, with OSHA and other Federal agencies through the Interagency Steering Committee on Radiation Standards (ISCORS) to coordinate issues and activities, including the development of Federal Guidance for Occupational Exposure to Radiation and regulations related to radiation protection and safety. The NRC recognizes that the existing MOU is now out of date with respect to references of enabling legislation and the respective jurisdictions of the two agencies as a

result of the EPAct. However, the procedures specifying the interactions between OSHA and the NRC and the authority and responsibilities of each agency remain appropriate and valid to cover interactions in the newly enacted jurisdictional framework. Thus, the NRC does not believe that there is an imminent need to reexamine and update the MOU.

Comment: Several commenters requested clarification on the NRC's jurisdiction and role regarding radium-226 contaminated sites or old landfills, especially for sites currently under remediation by either the EPA or an authorized State under the RCRA or the Comprehensive Environmental Response, Compensation, and Liability Act (CERCLA, also known as Superfund) programs. One commenter asked if the NRC and EPA have executed an MOU for Superfund sites. Another commenter asked if the NRC/EPA MOU on decommissioning (2002) will be impacted by this rule. Another commenter suggested that the NRC and EPA should have a dialogue to discuss a collaborative approach to address licensing of discrete sources covered by this rule that are already considered as part of the Superfund efforts. The commenter indicated that such dialogue would complement ongoing coordination between EPA and the NRC under the existing MOU, "Consultation and Finality on Decommissioning and Decontamination of Contaminated Sites."

NRC Response: Under the EPAct, the NRC has the regulatory authority over any discrete source of radium-226 that is produced, extracted, or converted after extraction, before, on, or after the date of enactment of the act for use for a commercial, medical, or research activity. Hence, the NRC has the jurisdiction over old landfills or disposal sites contaminated with radium-226 due to past operations or disposal of discrete sources of radium-226.

The NRC typically has regulatory authority over sites undergoing radiological decommissioning, even those sites that also contain EPA hazardous materials (CERCLA and RCRA). The NRC and EPA have entered into site-specific agreements via formal letters in which the license for a site undergoing decommissioning was put in abeyance and regulatory

authority for decommissioning the site deferred to the EPA. There is no MOU for these agreements because they are rare and very site specific. The NRC anticipates that this site-specific process will continue.

The current MOU "Consultation and Finality on Decommissioning and Decontamination of Contaminated Sites" between the NRC and EPA defines the policy for deferral of regulatory authority between the two agencies for radiological decommissioning and decontamination of the NRC-licensed sites. The MOU specifically provides that under certain clearly defined criteria, EPA agrees to a basic policy of EPA deferral to the NRC decisionmaking in the decommissioning of the NRC-licensed sites without the need for consultation. If the criteria are not met, the MOU directs the NRC to consult with the EPA regarding the site. The MOU does not provide for the deferral of regulatory authority from the NRC to the EPA.

The NRC has routine interactions with EPA through ISCORS and through informal communications among staff on a multitude of subject areas. Currently, there are seven subcommittees in ISCORS, including Cleanup, Federal Guidance, Mixed Waste, Naturally Occurring Radioactive Material, Recycle, Risk Harmonization, and Sewage Sludge Subcommittees. The NRC will continue to work closely with EPA though ISCORS and other informal mechanisms regarding decommissioning and decontamination of sites.

Because the NRC had been deferring regulatory authority to the EPA on a site-by-site basis in the past, the NRC believes, at this time, that there may not be a need to revise the existing MOU. Once the NRC has gained sufficient experience in dealing with old disposal sites contaminated with the newly added byproduct material and if significant issues arise regarding shared regulatory authority, the NRC will cooperate with EPA in evaluating the need to amend the existing MOU and in determining an approach in resolving issues in managing these old disposal sites.

Comment: A commenter noted that the discussions on current regulatory structures for

NARM, and on other Federal agencies' regulatory authority over NARM, do not mention that some Federal licensees, such as licensees who hold a Master Materials License (MML), have established self-regulation requirements for NARM use. The commenter recommended that the NRC should describe the MML licensees' role in the regulation of NARM.

NRC Response: MML licensees are the NRC licensees and are required to comply with the NRC regulations. The fact that some MML licensees have established self-regulating requirements for accelerator-produced radioactive material and may have issued permits to their permittees for these materials is noted.

Comment: A commenter stated that requirements under several sections related to a master materials license address "a permit issued by a Commission master material license broad scope permittee" with the implication that a broad-scope permittee is required to issue such a permit. The commenter stated that, in most cases, the permittee might issue an authorization or other type of document for an AU. The commenter requested that the regulatory requirement be revised as "a permit, or other authorization, issued by a Commission master material license broad-scope permittee."

NRC Response: The NRC does not agree that this language is ambiguous. The use of the phrase "a permit issued by a Commission broad scope licensee" has been used by the NRC in 10 CFR Part 35 since the 1994 "Radiopharmacy Rule" (59 FR 61781; December 2, 1994) to designate the document that the broad-scope Radiation Safety Committee issues to individuals to permit or authorize them to use specific radionuclides for licensed activities. The same term was used in the major revision to 10 CFR Part 35 (67 FR 20370, April 24, 2002) for the same type of documentation issued by the MML broad-scope permittee to individuals at its facility.

Comments on Defining the Byproduct Material.

Comment: A commenter, discussing the proposed *Byproduct material* definition in 10 CFR 20.1003 and 30.4, believes the wording "produced, extracted, or converted after extraction, before, on, or after August 8, 2005," was confusing and ambiguous, stating that the phrase, "before, on, or after August 8, 2005," appears to be meaningless and that it was not clear whether the phrase referred only to material "converted after extraction," or to material "produced, extracted, or converted after extraction."

NRC Response: The phrase, "before, on, or after August 8, 2005," has been incorporated into the definition of *Byproduct material* in the AEA as a result of the language of the EPAct. It is included in the definition in the final rule because it is important to be clear that materials that have been produced, extracted, or converted after extraction at any time, even before promulgation of the EPAct, are included. This phrase is intended to apply to all of these activities, i.e., the production, extraction, and conversion after extraction. Not having such an explicit phrase in the definition may raise questions regarding applicability of the regulations for materials resulting from past activities.

Definition of Discrete Source.

Comment: Commenters generally supported the stated result of the definition as to the limits of NRC's authority and specifically the proposed limitation of the definition to exclude radium-bearing wastes generated by many facilities, including drinking water treatment plants and oil and gas production facilities. One commenter specifically agreed with the definition stating that it captured the important aspects of the discussions at the public and interagency meetings, as well as the original intent of earlier versions of legislation incorporated into the EPAct. However, other commenters expressed concerns about the clarity of the definition. Several commenters stated that some of the provisions in the proposed definition of discrete

source, such as the requirements that the source have physical boundaries and that the materials have been concentrated for their radiological properties, were ambiguous and could lead to uneven regulation. The commenters recommended that the NRC revise the proposed definition, and two commenters suggested alternate definitions.

One commenter stated that the phrases "with physical boundaries" and "which is separate and distinct from the radioactivity present in nature" in the proposed definition of *Discrete source* could cause confusion. The commenter stated that the requirement for physical boundaries without further description or statement of the purpose of the physical boundaries is ambiguous and leaves room for uneven regulation. Commenters were also concerned with the words, "which is separate and distinct from the radioactivity present in nature," particularly with the usage of "radioactivity." One commenter stated that a workable definition is crucial to keep unintended materials from being captured.

Other commenters expressed concern about the phrase, "with the intent that the concentrated radioactive material will be used for its radiological properties," with one commenter recommending that it be deleted. This commenter noted that it has encountered situations where discrete sources of radium-226 were deposited over a large area of land in which there were discrete nuggets and that there was no way of determining whether the discrete nuggets were produced for their radiological properties or not.

NRC Response: The proposed definition of *Discrete source* was *"*a radioactive source with physical boundaries, which is separate and distinct from the radioactivity present in nature, and in which the radionuclide concentration has been increased by human processes with the intent that the concentrated radioactive material will be used for its radiological properties." It is clear from some of the comments that the proposed definition of *Discrete source*, particularly the phrase "with physical boundaries," creates confusion that would, among other things, present problems with the regulation of material no longer in its original form, but which the

NRC intends to regulate.

The wording in the final rule has been revised to clarify the ambiguities that gave rise to these comments. The revised definition of *Discrete source* is "a radionuclide that is distinct from the sources of radiation present in nature, and that has been processed so that its concentration within a material has been purposely increased for use for commercial, medical, or research activities."

With the modification of the definition of *Discrete source* to remove the word "separate" and the phrase "with physical boundaries," radium contamination resulting from the use of purposely concentrated radium-226 falls within the definition of *Discrete source*. These changes should make it clearer that the NRC's jurisdiction continues through decommissioning. The radiological criteria for unrestricted use in 10 CFR 20.1402 refer to residual radioactivity that is distinguishable from background. Some commenters appeared concerned that for purposes of decommissioning, it would not be possible to distinguish between the atoms of material that had been purposely concentrated for use for its radiological properties from atoms of material present in nature. This concern is not warranted because, in practice, this is not the methodology used to determine the need for decontamination.

The revised definition also removes the requirement that the purpose for concentrating radium-226 (or other identified naturally occurring radioactive material) be specifically for use of its radiological properties. However, this change is not expected to have any practical effect on the regulation of radium-226, as all known uses of radium-226 have been for its radiological properties and not primarily its chemical or physical properties. The only effect of revising the definition would be if a future use is made of a highly radioactive naturally occurring material involving chemical or physical, but not radiological, properties. To constitute byproduct material as it is now defined in Section 11e.(4) of the revised AEA, this material would have to have been determined by the Commission to meet the standard of threat similar to that of

radium-226.

The comments on the definition of *Discrete source* relate mainly to questions concerning what naturally occurring radioactive material will be considered byproduct material, and thus be regulated by the NRC. In revising the definition of *Discrete source,* the Commission has also added the condition that to be a discrete source, the radionuclide has been processed so that its concentration within a material has been purposely increased "for use for commercial, medical, or research activities." The addition of this limiting phrase may appear redundant, as the words "for use for a commercial, medical, or research activity" are already in the definition of *Byproduct material*, and a discrete source is a subcategory of byproduct material. However, the addition of these words to the definition of *Discrete source* ensures an understanding that the term "discrete source," where used in the regulations other than in the definition section of the regulations, will be subject to this limitation.

The Commission interprets the words in the definition of *Byproduct material*, "produced, extracted, or converted after extraction for use for a commercial, medical, or research activity," to mean a purposeful activity whereby the radium-226, or other specific radionuclide, if identified in accordance with Section 11e.(4) of the revised AEA, is processed for the use of the radium-226 (or other specific radionuclide). This purposeful activity must relate to the radium-226 (or other radionuclide) and not to the overall material that inadvertently contains radium-226, for example, fertilizer. However, this activity need not involve an actual isotopic separation process specifically separating radium-226 from radium-228. In addition, the "new" byproduct material consists of the specific radionuclides only, and not the associated material. For example, in a radium salt, the atoms other than those of radium in the salt are not part of the byproduct material. The NRC notes that the original definition of *Discrete source*, as it had been proposed, was written to contain strict constraints to guard against any potential interpretation that the NRC was extending its jurisdiction in an unintended or unauthorized

manner. However, the NRC has found that these constraints were, in a large part, unwarranted because, as already noted, a discrete source is a subset of the specifically delineated byproduct material that is being regulated and must, therefore, be constrained by the general definition of the new *Byproduct material*.

Comment: Some commenters had questions concerning the regulatory authority over the manufacture of radiological sources and the associated waste management. One commenter noted that the EPAct does not assign responsibility to the NRC for regulating the manufacture of discrete sources, rather, the NRC's responsibility applies after a discrete source is produced. The commenter asked whether the Agreement States would be required to regulate the manufacturing and waste management aspects of source production, and also who is responsible for radiological safety if the manufacturing occurs in a non-Agreement State. Another commenter asserted that the manufacture of radium sources should be specifically licensed, even though the radium may not yet meet the definition of a *Discrete source*.

NRC Response: The EPAct gave the NRC authority to regulate radium-226 that is produced, extracted, or converted after extraction, before, on, or after the date of enactment for use for a commercial, medical, or research activity. Therefore, the NRC does have authority for regulating the manufacture of sources, and the NRC's responsibility applies before, on, or after a source is produced. This should be more evident with the revised wording of the definition of *Discrete source*. Radium-226 is byproduct material and under the NRC's jurisdiction if it is purposely concentrated and is distinct from the radioactive material found in nature, and produced, extracted, or converted after extraction, for use for a commercial, medical, or research activity.

Section 30.3, "Activities requiring license," states "Except as provided in paragraphs (b)(2), (b)(3), (c)(2), and (c)(3) of this section and for persons exempt as provided in this part and part 150 of this chapter, no person shall manufacture, produce, transfer, receive, acquire,

own, possess, or use byproduct material except as authorized in a specific or general license issued in accordance with the regulations in this chapter." Therefore, the NRC will regulate the manufacture of products involving the intentional use of discrete sources of radium-226, as well as resulting wastes. A specific license will be required for the manufacture of such radium sources.

Comment: A commenter asked if the proposed definition of *Discrete source* would include sources that are electroplated, i.e., where the radioactivity is on the surface of the source and is not encapsulated and therefore is not separate from nature (such as radium needles).

NRC Response: Electroplated sources are included as the wording of the definition in the final rule clarifies.

Comment: A commenter recommended that the NRC add the definition of *Discrete source* to 10 CFR Part 35 in addition to 10 CFR Parts 20 and 30.

NRC Response: The NRC Part 35 licensees are required to comply with 10 CFR Parts 20 and 30. The term *Discrete source* is being defined in those regulations. Therefore, it is not necessary to repeat the definition in Part 35.

Other Naturally Occurring Radioactive Material

Comment: Two commenters asserted that they believe the NRC should consider other criteria in addition to the International Atomic Energy Agency Code of Conduct Categories 1 and 2 to determine if there are any other nuclides that would pose a threat to public health and safety and common defense and security similar to that posed by a discrete source of radium-226.

One commenter did not believe that using IAEA Categories 1 and 2 to measure the risk

of other nuclides against the risk posed by discrete sources of radium-226 meets the EPAct requirement to consider comparative risk to public health and safety as well as common defense and security. The commenter stated that within the U.S., IAEA Categories 1 and 2 have been associated with "high-risk" sources and activities of concern to common defense and security, not to health and safety. The commenter argued that instead, because IAEA regards uncontrolled Categories 1, 2, and 3 sources as potentially dangerous to human health, Category 3 is also a threat, and the NRC's analysis should at least include that Category in addition to Categories 1 and 2.

However, the commenter agreed with the NRC that polonium-210 does not need to be included in the definition of *Byproduct material* under the category of naturally occurring radioactive materials posing a similar risk as radium because the production of polonium-210 discrete sources for commercial, medical, or research use is by activation in a reactor, and therefore it is already regulated as byproduct material.

Another commenter asked if, by using IAEA Categories 1 and 2 to measure other nuclides' comparative risk to radium-226, the NRC meant to only regulate materials that could be fatal or cause permanent injury if they are not safely managed or securely protected. The commenter asked whether discrete sources of radium-226 that do not meet the IAEA Category 1 or 2 definitions would not be regulated in the expanded definition of *Byproduct material*. The commenter asserted that regulations for radioactive materials should not be based solely on acute effects.

NRC Response: The EPAct expanded the definition of *Byproduct material* to include any discrete source of naturally occurring radioactive material, other than source material, that the NRC, in consultation with the Administrator of the EPA, the Secretary of Energy, the Secretary of Homeland Security, and the head of any other appropriate Federal agency, determines would pose a threat similar to the threat posed by a discrete source of radium-226

to the public health and safety or the common defense and security. The legislation, and the proposed rule, do not contain criteria for making such a comparison or determination. The NRC, in its meeting with other Federal agencies, considered the IAEA list of sources in its Code of Conduct that are considered to pose a high risk to human health and safety if not managed safety and securely as a point of initiation for comparison. The NRC did not intend the Code of Conduct listing to be the sole criterion to measure comparative risk to public health and safety. Currently, the NRC, in consultation with other Federal agencies, has not found any other naturally occurring radioactive material that is extracted or converted after extraction that is used for a commercial, medical, or research activity that poses a threat to public health and safety, or to common defense and security, similar to radium-226. Discrete sources of radium-226 much lower in activity than discussed in the IAEA Code of Conduct are addressed in the regulations that will protect public health and safety. For instance, there are no exempt concentration or quantity levels for radium-226 in 10 CFR Part 30. There are Annual Limits on Intake and Derived Air Concentration limits in Appendix B to 10 CFR Part 20 for radium-226. The EPAct has provided a mechanism for the Commission to include additional discrete sources of naturally occurring radioactive material in the future following consultation with other Federal agencies, if the need arises to consider other naturally occurring radioactive material for byproduct material. The NRC, along with other Federal agencies, will use all of these criteria to determine if there are any other naturally occurring radioactive material posing a threat to public health and safety similar to radium-226. In addition, the NRC did not intend to imply that it was limiting its regulatory authority over radium-226 at quantities which could be fatal or cause permanent damage, or basing its regulations for radioactive material solely on acute effects.

Comments Related to Radium-226.

Comment: A commenter, noting that radium-226 is a naturally occurring material present in most city water supplies, asked how the NRC proposes to differentiate regulated doses from background doses, and normal levels of radium-226 in building materials from regulated radium-226 contamination. The commenter also noted that because of radium's high excretion rate, bioassays may need to include weekly to monthly fecal analyses to suppress the missed dose to a value less than a few Roentgen Equivalent Man (Rem) per year. The commenter asserted that it is highly unlikely that licensees will be able to determine if a nonoccupational individual received less than 1 mSv (100 mrem).

NRC Response: The NRC's regulations in 10 CFR 20.1502 specify the criteria that licensees must address to show compliance with monitoring requirements for occupational dose limits. The regulation requires licensees in monitoring occupational exposure to take into account radiation from both licensed and unlicensed radiation sources under the control of the licensee. Occupational exposure does not include doses from background radiation. It is true that radium is ubiquitous in nature. However, there are methods that can be used to determine and subtract background radiation from dose measurements of occupational dose, such as determining ambient exposure by surveys or monitoring in the absence of byproduct material, and using this information to subtract background component from readings that include a total of both background and occupational exposure.

External exposure from radium-226 sources comes from its daughter product and gamma radiation, and occupational exposure is usually determined by a radiation dosimeter (badge). For internal exposure, a licensee can measure the concentration of radioactive material in the air in the work area, the quantity of radionuclide in the body, the quantity of radionuclide excreted by the body, or a combination of all these measurements. Excretion

measurement is not the only method to determine dose from internal exposure.

Comment: A commenter asked if, for source activity reporting and internal/external dosimetry, owners would be required to report any information about the radionuclide products that come from radium (daughter products). The commenter asked whether the most current International Commission on Radiological Protection (ICRP)/National Council on Radiation Protection and Measurements (NCRP) internal/external dosimetry standards will be used by the NRC, and if the newer consensus standards regarding actinide uptakes would be acceptable. The commenter also asked whether the American National Standards Institute (ANSI)/Health Physics Society (HPS) N43.4-2000 Classification of Radioactive Self-Luminous Light Sources Standard is a reference document that will be used by the NRC.

NRC Response: If the daughter products came from byproduct material (i.e., the radium-226 parent was byproduct material), the internal and external exposure would be required to be considered. Daughters from radium-226, which are not byproduct material, would not fall under the NRC's jurisdiction. However, 10 CFR 20.1502 specifies that, for occupational exposure, licensees must take into account radiation from both licensed and unlicensed radiation sources under the control of the licensee.

The current methodology used in 10 CFR Part 20 is from Federal Guidance Report Number 11, "Limiting Values of Radionuclide Intake and Air Concentration and Dose Conversion Factors for Inhalation, Submersion, and Ingestion," for internal dose coefficients, and ICRP 26, "Recommendations of the International Commission on Radiological Protection, January 1977," for external exposure. Radium-226 values in Appendix B to 10 CFR Part 20 came from the Federal Guidance Report Number 11. The methodologies are not being changed at this time.

The ANSI/HPS N43.4-2000 Standard, Classification of Radioactive Self-Luminous Light Sources, was not specifically referenced in the regulations or in the Statements of

Consideration to the proposed rule. The N43.4-2000 Standard classifies certain radioactive self-luminous light sources but does not establish design or safety standards. It is more for the use of the supplier or user to establish design features by providing minimum prototype testing requirements for these types of sources, and promoting uniformity in the production of these types of light sources.

Comment: A commenter stated that under the proposed rulemaking (10 CFR 30.32(g)), any specific license applications authorizing prostate brachytherapy must identify source manufacturers and model numbers of Palladium-103 brachytherapy sources. The commenter suggested that this requirement could be avoided by amending 10 CFR 30.32(g) to remove the requirement for identifying manufacturers and model numbers for sources authorized for any medical uses (specifically those per 10 CFR 35.400).

The commenter also believes that the proposed rule was unclear about how some legacy radium-226 sources that were not eligible for a general license could be specifically licensed per the 10 CFR 30.32(g) requirements.

NRC Response: Revision of 10 CFR 30.32(g) to remove the requirement for identifying manufacturers and model numbers for sources authorized for any medical uses (specifically those per 10 CFR 35.400) is outside the scope of this rulemaking effort. However, the NRC is revising 10 CFR 30.32(g) to address the issue of sealed sources to address the information required from licensees that have legacy sources containing the newly defined byproduct materials that are not in the SS&D registry.

Comment: A commenter asserted that the radium-226 issues are likely to be much larger and broader than believed. The commenter also noted that there are few consultants available with radium experience and asked whether the NRC has considered that it may have to act as a resource to answer questions and resolve problems.

NRC Response: The NRC recognizes that there may be broad issues regarding radium

and that, although radium-226 was widely used in the past, there does not appear to be a significant volume of information concerning its health and safety implications and past uses. The NRC plans to develop a link on its public website under Nuclear Materials for "Frequently Asked Questions" to try to help answer some of the questions about radium as they arise.

Regulating Items Containing Radium-226.

Comment: In response to Question 1 in NRC's request for additional information on issues in the proposed rule, technical information to support an exemption for old radium-226 sources, several commenters discussed the availability of data on the possession and disposal of radium items. The commenters stated that they do not believe that a consolidated source of information on the items, their location, or owners exists that could provide enough safety information for the NRC to make an informed decision on the regulation of these items.

One commenter recommended that the NRC conduct a systematic study to assess the potential individual and collective (population) radiation doses associated with the use, possession, transfer, and disposal of regulated radium items, especially antiquities, and suggested that the study could be similar to NUREG-1717, "Systematic Radiological Assessment of Exemptions for Source and Byproduct Materials." The commenter further recommended that the NRC review NUREG/CP-0001, "Radioactivity in Consumer Products," dated August 1978, for more information on radium in watches, smoke detectors, lightning rods, and other consumer products.

NRC Response: The NRC agrees that there does not appear to be a consolidated source of information concerning radium items, their location, or who may be in possession of these items. The NRC staff contacted several organizations, such as the National Association of Watch & Clock Collectors, to alert them of the publication of the proposed rule because they

might have an interest in this rulemaking. In addition, these organizations might be able to provide further information to assist the NRC in making regulatory decisions regarding radium items. The NRC staff has also secured the services of a contractor to help it better characterize the likely activities and potential doses to users, initially, from the proposed exemption for radium timepieces, and, at a later date, other radium antiquities that will be subject to general licensing. The NRC staff has used NUREG/CP-0001 as part of its evaluation and has referred the NUREG to its contractor for use in its review. Evaluations of previously manufactured items would be somewhat different than those in NUREG-1717 as no new distribution is being allowed for many of these items.

Comment: In response to the NRC's Issue for Public Comment Q.1, a commenter noted that pre-WWII naval warships used radium luminescent buttons as deck edge markers. The commenter was concerned that these marker buttons may not meet the NRC's descriptions of the various radium sources. The commenter suggested that the NRC expand the coverage of radium-226 items beyond light sources in aircraft and medical uses. The commenter also asked if the NRC will bring enforcement actions against persons who discover previously unknown radium-226 items, and who would be financially responsible for those items.

NRC Response: The NRC has become aware that radium luminous items were also commonly used on military vehicles and naval ships in addition to aircraft. The NRC believes that vehicles with radium luminous items may be found in military museums and owned by private collectors. With regard to ships, it is the NRC's understanding that the Navy made a concerted effort years ago to remove and dispose of radium luminous items. However, there may be some of these items remaining on "mothballed" ships. The NRC agrees that the general license in 10 CFR 31.12 should be expanded to include additional military vehicles. As restructured, the 10 CFR 31.12 general license would automatically apply to all possessors of

antiquities originally intended for use by the general public, nonintact timepieces, and timepiece hands and dials no longer installed in timepieces; luminous items installed in air, marine, or land vessels or ships (This would include airplanes, helicopters, jeeps, trucks, tanks, ships, landing vessels, artillery pieces, and any other former military use vehicle no longer under the control of the military.) See discussion under New General License for Certain Items and Self-Luminous Products Containing Radium-226, above; all other luminous products, provided that no more than 100 items are used or stored at the same location at any one time; and small radium sources containing no more than 0.037 MBq (1 μCi) of radium-226. While the general license does not authorize the manufacture, assembly, disassembly, or repair of most of the listed items, the disassembly and repair of timepieces would be allowed. The general license is automatically granted by NRC regulations to persons meeting the general license criteria. No action is required from these persons to obtain a general license. The NRC foresees no issue regarding possession of these items provided that the restrictions on the general license are complied with. The NRC would hold persons who possess the items financially responsible for the items with regard to such things as disposal or meeting other requirements of the general license.

The general license established in 10 CFR 31.12 is revised from the proposed rule as follows: paragraph (a)(2) is revised to read, “Nonintact timepieces and timepiece hands and dials no longer installed in timepieces”; paragraph (a)(3) is revised to read, “Luminous items installed in air, marine, or land vehicles”; paragraph (a)(4) is revised to read, “All other luminous items, provided that no more than 100 are used or stored at the same location at any one time”; and paragraph (d) is revised to read, “The general license in paragraph (a) of this section does not authorize the manufacture, assembly, disassembly, repair, or import of products containing radium-226, except that timepieces may be disassembled and repaired.”

Comment: A commenter asked whether the NRC’s reporting requirements apply to

owners of past accelerators or radium-226 items if they do not presently have control over the item. For example, the commenter noted that wrecked ships and airplanes could contain radium dials, and luminous dial instruments could be disposed of in a sanitary landfill, and the original owners of these items would not necessarily have any knowledge of their current location.

NRC Response: The NRC's regulations apply to persons who currently, or will in the future, possess byproduct material. The NRC would not hold persons responsible for reporting any previous possession, transfers, or disposals of materials that may have been disposed into locations such as municipal landfills over which they have no control. However, while the NRC will not hold anyone accountable for past disposals in a landfill, these persons might be accountable under EPA's Superfund regulations.

Comment: In response to the NRC's Issue for Public Comment Q.1, a commenter stated that the trade of radium-dial watches has increased in the past 10 years with most of these sold through Internet auction sites or on personal web sites. The commenter does not believe that the majority of the people buying these watches are aware that the watches are radioactive or the degree of their radioactivity and is concerned about the effect of these watches on people who are inadvertently exposed to the watches by their incidental close proximity to someone wearing or carrying one. The commenter also noted that most owners of these watches are not aware that the radiation is still active because the luminous scintillating material in the paint mixture is no longer working. In the commenter's opinion, the sale and use of vintage radium dial watches is not in keeping with the goal of "as low as is reasonably achievable" (ALARA).

The commenter stated that many people open these watches to try to repair them, to clean their dials, and to replace hands, that many of these watches are bought and sold in poor condition (e.g., open, not sealed), and that often a watch is sold with the crystal (glass) missing

and the radium paint on the dial exposed to the outside air. The commenter noted that radium powder/dust can and does flake off of exposed dials and broken watch cases.

The commenter indicated that the NRC should require possessors of these kinds of watches to follow the same shipping requirements as businesses, because the watches exhibit the same types of hazards. The commenter recommended that the NRC consider these concerns in connection with defining byproduct material. The commenter does not think activity thresholds will be useful or practical, but that any rulemaking would have to consider "radium dial watch" as an entity.

NRC Response: To further support the exemption and the related general license with regard to timepieces, the NRC conducted a scoping study to determine the typical and maximum radium activities used in various types of timepieces and the potential exposures that might result to users, collectors, and repair technicians. The results of this study indicate that the doses expected to an individual user, collector, or repair technician are acceptably low.

As directed by the EPAct, the NRC's development of the proposed rule considered the CRCPD's applicable SSRs. As provided in the SSRs, the NRC has included an exemption from licensing for persons who possess intact timepieces that contain no more than 0.037 megabecquerel (1.0 microcurie) of radium. The NRC regulation is more restrictive than the SSRs in that the exemption only applies to intact timepieces. In the proposed rule, the exemption would also have allowed antique collectors and watch repair facilities to repair up to 10 timepieces in any year. In the final rule, however, the allowance for repair is eliminated from the exemption and is now authorized under the general license provision. As noted, the exemption only applies to intact timepieces. Possession of nonintact timepieces, or radium luminous parts such as hands, dials, or faces, and timepiece disassembly and repair would be subject to the general license provided in 10 CFR 31.12.

Shipment of radium timepieces are currently and will continue to be subject to

regulations established by the DOT and the United States Postal Service. Such shipments will now also come under the NRC's regulations in 10 CFR Part 71.

The NRC has specifically included radium in the definition of *Byproduct material*. The NRC appreciates that most consumers will probably not know how much activity there may be in a particular timepiece. However, the NRC's evaluation indicates that most timepieces that were produced in the past contained less than the 1-microcurie (37 kBq) exempt limit. If a particular intact timepiece contains more than 1 microcurie (37 kBq), then possession would fall under the general license provided in 10 CFR 31.12.

Comment: In response to the NRC's Issue for Public Comment Q.1, a commenter stated that it has never found or been informed of a leak from any of the double-encapsulated and welded radium-226/beryllium sources in their gauges. The commenter noted that even in some worst-case accidents that occurred, such as compactors running over gauges, no source has leaked radioactive material, and no accident has caused the source to be separated from its shield.

NRC Response: The NRC notes that the commenter appears to be describing sources used in portable moisture-density measuring devices used in roadbed and other construction activities. Generally, these devices are possessed under a specific license, although there is a possibility some devices may have been authorized by a State under a specific license similar to 10 CFR 32.51 for distribution to general licensees under requirements comparable to 10 CFR 31.5. As noted in response to another comment, if a device is generally licensed, a label on the product should indicate its generally licensed status. In either case, the licensing authorization would remain the same. Periodic source leak testing is generally required for such devices.

Exemption of Certain Radium-226 Items.

Comment: One commenter recommended that the proposed limit for repairing timepieces containing radium-226 be increased from 10 to 18 units per year. This commenter also suggested that the limitation should not be restricted by company, but by the number of qualified timepiece repair technicians employed. The commenter suggested that this change is needed to provide necessary consideration for industry consolidation, the emergence of specialized repair centers, and the expansion of geographic markets brought about by the Internet and globalization.

NRC Response: The NRC conducted a scoping study regarding potential risk associated with handling timepieces containing radium. Based on the results of the scoping study on the potential health and safety impacts of repairing timepieces containing radium-226 (including the storage of loose parts likely to be associated with repair facilities and not covered by the exemption), the Commission has decided not to limit the number of repairs. However, the repair will be subject to the general license in 10 CFR 31.12. There may be limited circumstances where companies with a number of timepiece repair technicians specifically involved with handing radium-226 should be specifically licensed or may be required to conduct cleanup activities. See additional comment and response discussion on General License of Certain Radium-226 Items and on Specific Licenses for Radium-226.

Comment: A commenter disagreed with the NRC's proposal under 10 CFR 30.20 to exempt smoke detectors containing up to 74 kBq (2 μCi) of radium-226 from the licensing requirements in 10 CFR Parts 20, 30 through 36, and 39. The commenter stated that radiation detection equipment at landfills and scrap facilities are very sensitive and are often set to thresholds less than twice the background radiation. The commenter noted that low activity sources, such as smoke detectors containing up to 74 kBq (2 μCi) of radium-226, will trigger these detectors and cause the arriving load to be rejected. The commenter stated that this would increase the number of incidents that the States would be required to respond to, which

would result in an increased expenditure of time, human resources, and funds. The commenter recommended that these sources should not be allowed to be disposed of in the general waste stream, and that facilities with devices containing these levels of activity should be generally licensed and should be required to dispose of the sources properly.

NRC Response: The exemption for smoke detectors is only being expanded to cover detectors previously distributed in accordance with a specific license issued by a State under comparable provisions to 10 CFR 32.26 authorizing distribution to persons exempt from licensing. Smoke detectors meeting this criteria are already exempted by most States. Documentation of the individual safety evaluations made to demonstrate that these detectors meet the applicable safety criteria is incomplete. However, the Bureau of Radiological Health (BRH) of the FDA, in consultation with the States and other Federal agencies including the NRC and its predecessor, the Atomic Energy Commission (AEC), developed NARM guides in the 1970's, to assist the States to develop more uniform regulations for NARM. These guides included one for gas and aerosol detectors, which was essentially equivalent to the NRC's regulations in 10 CFR 32.26, 32.27 and 32.28. By the late 1970's, the SSRs included comparable provisions. The guide and the SSRs also included a quantity limit of 3.7 kBq (0.1 μCi) for radium-226.

Some information on potential impacts of disposal of these detectors is contained in the Nuclear Energy Agency document, "Recommendations for ionization chamber smoke detectors in implementation of radiation protection standards, 1977," and NUREG/CR-1156, "Environmental Assessment of Ionization Chamber Smoke Detectors Containing Am-241," November 1979. According to these documents, americium-241 had almost completely replaced radium-226 in smoke detectors being sold by the late seventies, and the quantities of radium-226 used had generally been reduced to no more than 37 kBq (1 μCi), typically 1.8 kBq (0.05 μCi). It is not expected that there are large numbers of smoke detectors with radium-226

still in existence, with the smaller quantities being more common among those that are. Thus, it is not expected that large numbers of detectors containing radium-226 would be disposed of concurrently. The disposal of small numbers of such detectors in a landfill or municipal incinerator is not expected to result in a significant impact to public health and safety or the environment.

The commenter was particularly concerned with the cost related to detectors containing radium being detected at landfills and scrap facilities. Exempting from the NRC's regulations those detectors which have been previously exempted from regulation by the States will not add to the number of these incidents nor will not exempting them be able to prevent all such incidents. However, a significant part of the cost is incurred after identification of a source, if it requires a more expensive disposal route. In many cases, once a radioactive source has triggered a monitor, it can still be disposed of at the landfill if this is determined to be an acceptable disposal option. Because the EPAct allows for the disposal of the newly added byproduct material in disposal facilities permitted under Federal or State solid or hazardous waste laws, acceptability at landfills for disposal of an exempted product or material should be improved. What happens after identification will depend, in part, on the label, which would have been required by the State at the time of distribution. If intact and legible, it would indicate whether the product had been exempted from State regulations or generally licensed. However, the NRC recognizes, as one commenter pointed out, that some landfill operators may not be obligated to accept such material at their facilities.

The Commission continues to consider the exemption of these previously distributed detectors to be justified. The final rule includes this exemption in revised 10 CFR 30.20.

Comment: Two of the State commenters stated that the NRC should add 3.7 kilobecquerel (kBq) [0.1 microcurie (μCi)] of radium-226 to 10 CFR 30.19 for self-luminous products or otherwise include exemption language from the SSRs for low activity radium-226

sources rather than including those sources under a general license. One of these commenters specifically mentioned types of products other than self-luminous products listed in the proposed general license in 10 CFR 31.12 and indicated that they should also be exempt if containing the same low quantity of radium-226. Both of these commenters asserted that there are no problems known to exist with these exempt sources so there is no sufficient reason for the NRC to not exempt them as the States have done for many decades, and stated that if the NRC is aware of some risk to public health and safety from these very low activity sources, then it should provide the information.

NRC Response: There is only limited information on these items. However, there is some indication that the applied radium may be subject to such concerns as flaking off due to aging. The NARM guides developed by BRH/FDA in the 1970's included a guide for radioluminous products which contained safety criteria for approval of a product for use under a general license, but not for use under an exemption. The SSRs do not include provisions similar to those in 10 CFR 32.22, 32.23, and 32.24, for the manufacture or initial distribution of self-luminous products for use under an exemption. The SSR provision similar to 10 CFR 30.19 covers only previously acquired products in the case of items containing radium-226. It appears that these products were generally not evaluated under provisions comparable to those in 10 CFR 32.22, 32.23, and 32.24 for self-luminous products. This SSR provision exempts “articles” containing radium under the heading “Self-luminous products.” While the quantity limit is less than that for watches, the category of product is very open-ended and could include items where the radium is not contained.

For these reasons, the Commission considers it prudent not to exempt this category of products that is covered by an exemption in the SSRs, or other unspecified products with no more than 3.7 kBq (0.1 μCi) of radium-226. In addition, there are many self-luminous products containing more than 3.7 kBq (0.1 μCi) of radium-226 and most would not be labeled with the

quantity or activity of the radium-226. It would be difficult to determine which products would fall under the exemption and which would fall under the general license in 10 CFR 31.12.

Comment: One commenter noted the proposed graded approach for different levels of radium-226 sources and also mentioned the discussion in the Statements of Consideration of various approaches used by the non-Agreement States. This commenter responded to the NRC's request for input on whether a general license approach or exemption approach would be better for some of the devices containing radium-226, by saying that an exemption would gather no data, and therefore not be the desired path except for the smallest amounts (e.g., 1 μCi). This commenter also stated that an exemption concentration level of 1 μCi (and an appropriate corresponding exempt quantity limit) could be considered with the specific/general license approach for materials above that de minis amount.

NRC Response: The SSRs do not include an exempt quantity or exempt concentration for radium-226. With the exception of an exempt quantity of polonium-210, these exemptions do not include alpha emitters. Given that there are no materials in use that have been previously universally exempt from licensing under State regulations, there is no justification for adding such exemptions now. Without a demonstrated need, the NRC does not consider it prudent to allow introduction of radium-226 into materials and products to be used by persons exempt from licensing or to allow the distribution of radium-226 as exempt quantities.

The requirements for registration of generally licensed devices only apply to those generally licensed under 10 CFR 31.5 and then only if the device contains a radium source of 3.7 MBq (0.1 mCi) or greater. The new general license in 10 CFR 31.12 will not require registration by possessors of the items identified in the regulation nor does the NRC believe there is a need to impose such a regulatory burden on the general licensee.

Comment: A commenter recommended that the NRC include an exemption in the final rule for Internal Revenue Service (IRS)-designated 501(c)(3) organizations that existed before

the effective date of the final rule that operate, in whole or in part, as an accredited school of watch and/or clock repair and/or speciality museum with a primary focus on housing and exhibiting timepieces and related objects. The commenter noted that it is important for students to have access to examples of radium parts and watches as part of their training, and museums must be able to preserve and present practices and objects through exhibits to fulfill their educational mission. The commenter stated that without this exemption, the proposed inventory process and licensing fees would create an undue burden on these organizations.

NRC Response: The status of an organization as a nonprofit institution and whether its mission is educational are not appropriate bases for exemption from licensing requirements. Exemptions from licensing are based primarily on findings with respect to health, safety, and environmental impacts. It should be noted, however, that organizations categorized as small entities in accordance with 10 CFR 2.810 are eligible for reduced annual licensing fees in accordance with 10 CFR 171.16. Also, a licensee, such as a nonprofit educational institution, may be exempt from application fees under 10 CFR 170.11 and annual licensing fees under 10 CFR 171.11, depending on the licensed activities. Also, a museum or school may possess watches under the exemption in 10 CFR 30.15(a)(1) irrespective of whether other products or activities require these entities to be a general or specific licensee.

General License of Certain Radium-226 Items.

Comment: Several commenters responded to the NRC's Issue for Public Comment Q.6 request for information on health and safety impact from activities involving radium-226 sources that would support a regulatory framework other than general licensing, such as an exemption. In general, the commenters agreed that an exemption would be preferable to a general license for items containing radium-226; however, most of the commenters also agreed that more

information on the risks of these items is needed before a final decision is made.

Several of the commenters, citing a number of reasons, recommended that the NRC create a time-limited exemption for antiquities containing radium-226 until such time as sufficient data are gathered and analyzed to determine whether these items exhibit high enough risk to require a license rather than a permanent exemption.

Two commenters noted that their States have had to respond to scrap metal yards, steel mills, and municipal waste sites where radium-226 items had caused loads to be rejected and noted that this happens because possessors of these items do not usually know how to safely dispose of them.

Other commenters suggested that an exemption for items containing radium-226 is better as long as enough safety data exist proving a low risk level for these items to justify the exemption and recommended that more investigation, which might include working groups and a public outreach effort, is needed into the safety risks of these items. One commenter noted that such an outreach effort would place a burden on State financial and human resources, and recommended that the NRC conduct a cost-benefit analysis to analyze these impacts on the States.

While the commenters were in general agreement with the NRC's proposed approach regarding the specific constraints in the proposed exemption in 10 CFR 30.15(a)(1)(viii), one commenter asked how the NRC proposes to regulate radiological antiquities that are bought and sold on the Internet.

NRC Response: The NRC notes that, for the most part, there appears to be no existing regulatory approach for many of the radium items identified in the 10 CFR 31.12 general license, and that very little information exists. Therefore, the NRC believes it is more appropriate to regulate the products under a general license until the NRC has had the opportunity to further document and evaluate these items and practices, and determine whether

or not additional exemptions may be appropriate. The NRC also recognizes that many individuals may not be aware that they possess radium items and that "incidents" where these items are identified at waste sites may continue into the future.

Based on its initial evaluations, the NRC has been able to find only limited information regarding existing safety data which show a low risk level for these items which is necessary to justify an exemption. The NRC currently has plans to conduct further evaluations, including gathering information concerning the products, to help it better characterize the likely activities and potential doses to users from radium antiquities that will be subject to general licensing. The NRC will consider the commenter's suggestion regarding a public outreach program and the program's impact on State and Federal resources.

The general license in 10 CFR 31.12 allows general licensees to transfer possession of antiquities and other products between general licensees, and this includes antiquities bought and sold over the Internet. The NRC believes this is acceptable while the NRC conducts evaluations and because the limited information available does indicate a low risk associated with these items.

Comment: Several commenters discussed the appropriate regulation of the repair and disassembly of items containing radium-226. One commenter stated that it believes a "prohibition of these activities under general licensure" is appropriate. The commenter recommended that disassembly, repair, and assembly work on an antique item should be authorized by a specific license, not a general license. Another commenter recommended that facilities disassembling or repairing timepieces containing radium be generally licensed until a study is conducted and completed to assess the potential individual and collective (population) radiation doses associated with this industry.

NRC Response: The NRC agrees that the repair and dissassembly of certain items containing radium-226 should only be conducted under a specific license and notes that

10 CFR 31.12(d) prohibits these activities under the general license. The NRC conducted a scoping study on potential exposures regarding activities involving timepieces containing radium-226. Based on the results of the scoping study, the NRC will allow timepiece disassembly and repair under the general license provision.

Comment: Several commenters were in support of a general license for items containing radium. One commenter requested clarification of the general license requirements for radium dials, gauges, and buttons installed in aircraft used as static displays, in aircraft used in museums, in aircraft that are in storage for potential re-use as refurbished piloted aircraft, as unmanned drone aircraft (potentially used as targets), or as a source for spare parts, and in dials, gauges, buttons, and/or painted lettering or numbering that do not have a glass or crystal face covering, or for which the covering is damaged or broken. The commenter also expressed concern that the transfer requirements of proposed 10 CFR 31.12(c)(2) may place an undue burden on the licensees and recommended that the NRC should allow for easier transfer under the general license from one entity to another.

One commenter stated that some museums possess devices containing radium-226 in gauges and other safety devices installed in ground vehicles (e.g., trucks, armored tanks, artillery pieces), portable radios, and submarine instrument panels on display and that public access to these devices is controlled in the same manner as aircraft at these museums. The commenter recommended that the NRC expand the 10 CFR 30.12 general license to include radium containing devices installed on other types of vehicles and equipment besides just aircraft.

Another commenter stated that a common practice on World War II aircraft was to apply radium paint over the words and numbers engraved on cockpit instrument panels so that they were visible in the dark. The commenter noted that in these cases, the painted surfaces are not contained behind glass as in gauges.

NRC Response: The rule allowing possession under the general license rule applies to all luminous items installed in aircraft regardless of whether the material is in an intact gauge, a gauge missing a face plate, or as luminous paint applied on the outside of a gauge. The general license also applies to all aircraft regardless if the aircraft is routinely used or in storage.

Paragraph (a) of 10 CFR 31.12 allows any general licensee to transfer any generally licensed item identified in this section to another general licensee for possession and use without restriction. The provisions in 10 CFR 31.12(c)(2) only restrict transfers to specific licensees or as otherwise authorized by the NRC under 10 CFR 20.2008 when the general licensee is intending to dispose of the item.

The NRC agrees that the general license should be extended to include luminous items installed in additional large military transport vehicles no longer under the control of the military and has modified 10 CFR 31.12 to include marine ships and land vehicles in addition to aircraft. The general license also allows for the possession of up to 100 other luminous items, including uninstalled aircraft safety devices.

Specific License for Radium-226.

Comment: A commenter stated that there should be a threshold level for possession of radium-226 luminous items that are not contained in an intact product beyond which a specific license is preferable, whether or not the items are intact. The commenter recommended that the NRC consider requiring a specific license for a number of items that is at least the exempt quantity value times 10 to 100. The commenter also stated that commercial transfers of items containing radium-226 should not be treated the same as possession and use and recommended that the NRC require a specific license for commercial transfers.

NRC Response: The NRC does not agree, based on other comments and the information currently available, that it should impose more restrictive requirements beyond those provided in 10 CFR 31.12. However, the NRC may consider the commenter's suggestions in a future rulemaking should the results from further evaluations, and characterization of the likely activities and potential doses to users from radium antiquities, indicate a need for additional restrictions in these areas.

Comment: With regard to proposed 10 CFR 31.8(b), which relates to the general license for radium-226 in calibration or reference sources, one commenter recommended that the NRC provide a "grandfather clause for [radium-226] items" that were approved for manufacture before 10 CFR 32.57 was adopted in its current form. The commenter stated that the States should be able to simply attest that the calibration or reference sources were manufactured to standards or criteria that have been demonstrated through years of use to be adequate to protect the public health and safety and the users of the sources. The commenter asserted that, unless the NRC has knowledge of problems of leaking sources of this type, the NRC should provide clarification that these sources are acceptable as manufactured.

NRC Response: The general license in 10 CFR 31.8 contains a footnote to include any sources labeled in accordance with the provisions applicable before January 19, 1975, i.e., with labels referring to the AEC before the creation of the NRC. In addition to the revision of paragraph (b) of 10 CFR 31.8, this footnote is being revised to include a requirement that sources containing radium-226 be labeled as required by the authorizing State at the time of manufacture. Therefore, the NRC believes that there is no need for any further grandfathering. Any calibration and reference source (or its container) containing radium-226, that was manufactured or initially transferred under requirements comparable to 10 CFR 32.57, would be labeled accordingly. As suggested by the commenter, the NRC expects that these sources are acceptable as manufactured.

Comment: A commenter noted that the proposed 10 CFR 32.59 required testing for leakage "with a filter paper" and "application of moderate finger pressure." The commenter believes this is overly prescriptive, prohibiting the use of other materials and requiring the use of "the fingers."

NRC Response: The requirements referred to by the commenter are the existing requirements for distributors of calibration and reference sources containing americium-241 for use under the general license in 10 CFR 31.8 and equivalent general licenses of the Agreement States, to which radium-226 is being added. It is consistent with the SSRs. The commenter's request for this general revision is outside of the scope of this rulemaking.

Comments Related to Accelerator and Accelerator-Produced Radioactive Material.

Comment: One commenter believes that the definition of *Cyclotron* was unclear, noting the statement that particles are "bent."

NRC Response: To address the commenter's concern, the NRC is revising the definition of *Cyclotron* to indicate that the charged particles travel in an outward spiral or circular path.

Comment: A commenter stated that the definition of *Particle accelerator* should be revised. The commenter noted that the definition currently states that a particle accelerator is a machine capable of "discharging the resultant particles or other radiation into a medium at energies in excess of 1 megaelectron volt (MeV)." The commenter noted that cathode ray tube television sets were developed from early particle accelerators, and that while commercial television sets operate at 0.035 MeV, overzealous application of the rule might include these and other smaller particle accelerators. The commenter also stated that it is possible that any beta-emitting source with energies greater than 1 MeV in a vacuum might also be considered an accelerator. The commenter noted that the "NRC is now regulating exotic particles such as

muons, but that [the commenter's] search of 10 CFR Part 20 did not find any reference to muons." The commenter noted that the NRC should also "expect to see extremity doses approaching 50 REM per year for the preparers of the accelerator-produced medical isotope unit doses" and apparently that the NRC should consider those health effects in its regulation of NARM.

NRC Response: The definition of *Particle accelerator* has been used by State radiation control programs for many years. The lower limit of 1 MeV was chosen to avoid regulation of lower energy accelerators. Consistent with the intent of the EPAct, the NRC will regulate byproduct material as defined in the EPAct as radioactive material produced by use of a particle accelerator. The NRC will not regulate the possession or operation of any particle accelerators that will not produce the byproduct material that the NRC will regulate. Also, note that the NRC will not regulate particles such as protons or electrons, or exotic particles such as muons generated in these particle accelerators that will not produce byproduct material.

The NRC is aware that high radiation doses are possible from handling accelerator-produced radioactive materials. Because licensees are required to comply with the radiation safety program requirements in 10 CFR Part 20, the NRC expects that licensees will use handling methods and equipment as part of their radiation safety program to prevent high radiation doses. No change is made to the definition.

Comment: A commenter noted that for hadronic beams, measurements of energy per nucleon (MeV/nucleon) may provide more useful information (apparently rather than the maximum energy of the accelerated particles). The commenter gave as an example that a 1-MeV proton will have different activation potential than a uranium-238 nucleus with (collectively) 1 MeV.

NRC Response: The commenter's view on energy level is noted. Because the NRC only regulates the radioactive material produced by using a particle accelerator and not the

radiation beam itself, the activation potential of the beam or particle has no direct impact in the NRC's determination of the regulated material. Radioactive material is defined as byproduct material if it is produced for use for commercial, medical, or research activities and is produced by irradiation or activation in a particle accelerator regardless of the type or energy level of the particle.

Comment: A commenter asked if the NRC's jurisdiction over accelerators includes particle beam weapons in space, the ion drive technologies being developed for interplanetary use, or laser wake field accelerators; or if the NRC's jurisdiction would extend to such items and materials as beam energy, interlock requirements, minimization of activated/spallated materials, ion species accelerated/charge state, or minimization of beryllium components (neutron spallation targets). The commenter also asked what parts of an accelerator (e.g., magnets, power supplies, RF cavities, beam pipe, nuts, bolts, wire, shielding, tools) the NRC will regulate. The commenter noted that these parts are transferred between the DOE-owned/NRC-regulated accelerators and worldwide researchers.

NRC Response: The NRC's authority does not include regulating accelerators or parts of an accelerator, nor does it include particles or particle beams. The NRC does not regulate accelerator or accelerator operating parameters. However, certain Agreement and non-Agreement States may regulate accelerators, accelerator operations, and accelerator safety requirements within their State's radiation control programs. Under the EPAct, the NRC will regulate radioactive materials produced in an accelerator used to intentionally produce radioactive material for use for commercial, medical, or research activities. This will also include any activated radioactive material that may still reside within the accelerator as a result of using the accelerator to intentionally produce radioactive material. The determination of the regulated material is based on whether a radioactive material is produced in a particle accelerator for use for commercial, medical, or research activities. In addition to regulating the

accelerator-produced radioactive material, the production facility will also be regulated through the NRC or Agreement State licensing process to ensure safe handling of the material and to ensure protection of public health and safety and the environment.

Comment: A commenter stated that most activation/spallation in accelerators occurs in high loss areas. The commenter noted that beam dumps can become very radioactive in higher energy machines. The commenter stated that caution should be exercised because the efficiency of Geiger-Mueller (GM) photon counters for photon-only emitting radionuclides that are common in accelerator environments is 0.17 percent as opposed to a GM photon-counting efficiency of 30 percent for medium energy beta emitters.

NRC Response: The NRC appreciates the commenter's insight. The NRC expects licensees to be knowledgeable, based on their qualification through training and experience, of the response characteristics of survey and measurement instrumentation relative to the radioactive material being produced or used. Licensee RSOs are required to show evidence of such training and experience as part of the licensing process.

Comment: Two commenters asked if entities other than particle accelerator users would be regulated by the NRC. One commenter asked if the NRC will license accelerator producers and distributors. Another commenter asked who the NRC anticipates will regulate the safety of accelerator facilities and their operation in both Agreement and non-Agreement States. The commenter noted that many States have implemented the SSR accelerator regulations. However, the commenter stated that "the regulatory responsibility for the radiation safety of the accelerator facility, the production of the radionuclides (licensing of accelerator targets), and the radioactive waste management (specifically, accelerator targets) is unclear in Non-Agreement States, particularly in Federal institutions."

NRC Response: The NRC has no jurisdiction over accelerators; therefore, the NRC will not license or regulate producers, distributors, or users of particle accelerators. The NRC will,

however, regulate persons that handle radioactive material from an accelerator that is used to intentionally produce radioactive material for use for commercial, medical, or research activities. Although the NRC will not license or otherwise regulate the sales or distribution of particle accelerators, certain Agreement States and non-Agreement States may have regulatory programs for registration, licensing, and/or safe operation of accelerators.

As provided by the EPAct, the NRC or the Agreement States have the regulatory authority for regulating the accelerator-produced radioactive material, the production of accelerator-produced radioactive material, and the associated waste. Once the Agreement State certifies, and the NRC determines that the State's program is adequate to protect the public health and safety for the newly added byproduct material, the State will have regulatory authority over the newly added byproduct material. If an Agreement State did not certify or the NRC determined that the State's program is inadequate, the NRC will retain its regulatory authority over the newly added byproduct material. In a non-Agreement State, the NRC has the regulatory authority for all AEA materials including the newly added byproduct material. As for Federal facilities, the NRC has the regulatory authority regardless if the Federal facility is located in an Agreement State or in a non-Agreement State.

Comment: Two commenters agreed with the NRC's proposed delineation of particle accelerators into three varieties, especially with the one category specific to accelerators that are operated to produce only particle beams and not radioactive materials. The commenters agreed that these types of accelerators, which include linear accelerators used in radiation therapy, should not be regulated. One commenter supported the NRC's proposal to not include incidental radioactive material produced by medical linear accelerators in the regulation.

One commenter recommended that the NRC should, in the final rule, include a specific exemption for commercially available linear accelerators used only for medical purposes to treat patients. The commenter recommended modifying the definition of *Particle accelerator* for such

exemption and provided specific language for the modification.

NRC Response: Under the EPAct, the NRC only has regulatory authority over accelerator-produced radioactive material and not over the accelerator. Because the NRC can only exempt material or activity under its jurisdiction, it would not be appropriate for the NRC to exempt accelerators in its regulation.

Comment: A commenter asked if the NRC would regulate neutron generators as accelerators. The commenter noted that these neutron generators operate by D,T [deuterium, tritium] reactions that use a 4-MeV (2 MeV per nucleon) deuteron to produce up to a 12-MeV evaporation neutron. The commenter stated that confusion will occur if the NRC regulates accelerators based on their acceleration potential. As an example, the commenter stated that a 4-MeV electron will accelerate a nucleon to 4 MeV if only one electron is removed from the electron shell (charge state), but if two electrons are stripped, then the acceleration energy will be 8 MeV (4 MeV X 2).

NRC Response: The NRC will not regulate accelerators nor the operation of an accelerator. The NRC will only regulate the radioactive material produced in an accelerator intentionally operated to produce radioactive material for use for commercial, medical, or research activities. Therefore, the acceleration potential is irrelevant to the NRC's regulatory program. A minimum accelerator potential of 1 MeV is specified in the definition of *Particle accelerator* to be consistent with the SSRs.

If a neutron generated by the accelerator is used to produce radioactive material via neutron activation, and the resulting radioactive material is used for a commercial, medical, or research activity, the radioactive material (and any incidentally produced radioactive material) would be regulated as byproduct material under Section 11e.(3) of the AEA as amended by the EPAct.

Comment: A commenter recommended that the NRC add the definition of *Particle*

accelerator to 10 CFR Part 35 in addition to 10 CFR Parts 20 and 30.

NRC Response: The NRC Part 35 licensees are required to comply with 10 CFR Parts 20 and 30, in which the term *Particle accelerator* is defined. Therefore, it is not necessary to repeat this definition. In addition, including the definition of *Particle accelerator* in 10 CFR Part 35 may inaccurately reflect that Part 35 includes regulations for particle accelerators.

Accelerator-Produced Radioactive Material.

Comment: A commenter stated that certain materials have low nuclear binding energy. As with neutron sources using a "(gamma, N) reaction," particle beams can produce substantial neutron fluxes if they strike a beryllium target. The commenter asked whether the NRC would consider the materials activated by these neutrons as byproduct material or accelerator-produced material.

NRC Response: Before the EPAct, the NRC regulated americium/beryllium neutron generators but not radium/beryllium neutron generators because americium-241 was included in the definition of *Byproduct material*, and radium-226 was not. Both generators will now be regulated by the NRC because they both contain byproduct material. The NRC also considers activation products produced by neutron emissions from byproduct material (e.g., californium-252) to be byproduct material. The NRC also regulates the tritium targets in well logging tools and other accelerators that produced neutron beams because tritium is a byproduct material. The EPAct gives the NRC regulatory authority over discrete sources of radium-226 and accelerator produced radioactive materials. Therefore, the NRC now regulates, as byproduct material, the activation products produced by a neutron beam accelerator, when the activation products are used for commercial, medical or research and development uses.

Comment: A commenter noted that DOE may begin production of radionuclides and

radioactive material accelerators [Reference: See http://www.eh.doe.gov/nepa/eis/eis0310/eis0310.html Volume I, Chapter 2a (see page 7 of the first enclosure)]. The commenter asked if this would cause any problems.

NRC Response: As an initial matter, the EPAct did not give the NRC jurisdiction over the production of accelerators. Therefore, the production of radioactive material accelerators would not impact the NRC's regulatory authority. In addition, DOE activities are not subject to licensing unless they fall within the purview of certain activities specified in Section 202 of the Energy Reorganization Act. The production of radionuclides would not fall within the scope of these activities. Therefore, DOE would not need a license to produce radionuclides. With the exception of restrictions in 10 CFR Part 35 for medical use licensees and in 10 CFR Part 30 for general licensees, there are no restrictions on who may transfer the radioactive materials to the NRC licensees. If DOE were to begin to produce radioactive material, it could transfer radionuclides to the NRC licensees provided the NRC licensee was specifically authorized to receive the radioactive material. However, if DOE pursued production of radioactive drugs or sealed sources for direct distribution to medical use licensees, the NRC may have to change its regulations because the existing regulations only allow medical use licensees to obtain these products from a 10 CFR Part 32 licensee. Similar changes may be needed to distribute material to general licensees or to persons exempt from licensing.

Comment: A commenter asked if the NRC will allow the use of the most current ANSI/IRCP/NCRP neutron flux to dose conversion factors because the accelerator neutron spectrum may exceed the maximum energy of only 400 MeV listed in 10 CFR Part 20.

NRC Response: For those cases in which greater than 400-MeV neutrons are encountered during a licensed activity, the licensee can request prior approval to use a specific ANSI/ICRP/NCRP neutron flux to dose equivalent conversion.

Comment: Three commenters provided their views on the NRC's proposal not to

regulate incidental radioactive material produced by accelerators that are operated only to produce particle beams.

Two commenters agreed with the NRC's suggested regulatory approach of not regulating incidental radioactive material produced by accelerators that are operated only to produce particle beams. One commenter indicated agreement with this approach because only small amounts of the incidental radioactive materials are produced in the particle beam-generating process, and those typically have a short half-life. The other commenter agreed because it believed that the incidental radioactive materials are indistinguishable from the particles produced intentionally in particle beams and would not be an undue burden on licensees. A third commenter disagreed with the NRC's proposed regulatory approach and recommended that all incidentally produced radioactive material be regulated by the NRC regardless of the use of the accelerator. The commenter questioned treating incidental material that was made radioactive from an accelerator used only to produce particle beams differently than incidental material made radioactive from an accelerator used to produce both radioactive material and particle beams. The commenter stated that the incidental accelerator-produced material is radioactive material regardless of the purpose for which the accelerator is being used, and that in certain situations during disposal of the accelerator, the activated internal components of all accelerators will enter the waste stream. Furthermore, the commenter noted that in its experience, some activation products in the accelerator components were still radioactive a month after removal.

NRC Response: The NRC agrees that there is essentially no radiological difference between incidental radioactive material made from an accelerator used only to produce particle beams and an accelerator used to produce both radioactive material and particle beams. However, the NRC's authority under the EPAct does not extend to incidentally produced radioactive material unless the incidentally produced radioactive material was made during the

process of making radioactive materials for commercial, medical, or research uses.

Comment: One commenter agreed with the NRC's proposed approach to regulate intentionally and incidentally produced radioactive materials without regulating the actual possession or operation of the accelerator. However, the commenter requested clarification of the NRC regulatory oversight of the radioactive material produced by an accelerator and the decommissioning of accelerator facilities in a non-Agreement State if the NRC does not have the authority under the EPAct to regulate the possession and operation of the accelerators that produce these materials. The commenter noted that some States do not have licensing requirements for operating an accelerator or for the material an accelerator produces.

NRC Response: Although the NRC does not regulate the operation of the accelerator, it will regulate the production of byproduct material and the byproduct material once it is produced. The NRC will also regulate the use of the radioactive materials produced by the accelerator including operational steps that expose individuals to radioactive materials being produced, or the radiation from these materials and maintenance processes that involve handling components of the accelerator that have become radioactive. The NRC will issue a specific license to any person, as defined in 10 CFR 30.4, "Definitions," that produces byproduct material with an accelerator, provided the person meets the requirements in 10 CFR 30.33, "General requirements for issuance of a specific license." This license will authorize the production of radioactive materials by the accelerator and the incidental radioactive materials produced during the production process.

Under the provisions of the waiver that the NRC issued on August 31, 2005, a person producing byproduct material with an accelerator may continue that activity until the waiver is terminated. Under the waiver, the person was not required to have a license. When the NRC terminates the waiver under which the person is producing byproduct material with an accelerator, the person is subject to all the NRC regulations pertaining to the production,

possession, use, transfer, and disposal of the radionuclides produced by the accelerator, and must apply for a license or an amendment to continue these activities. The person is permitted to continue producing radionuclides with the accelerator until the NRC takes final licensing action provided the person applies for an NRC license (or an amendment to an NRC license) within the time specified in the regulations. Therefore, the NRC's authority applies to the owner and operator of the accelerator facility in a non-Agreement State, and a license does not have to be in place for the transition of authority from a non-Agreement State to the NRC.

The NRC will regulate all radioactive materials and the disposal of components and decommissioning of facilities made radioactive during the use of the accelerator if the accelerator is used to produce byproduct material for a commercial, medical, or research activity. If the accelerator is never used to produce byproduct material for such a purpose, then the NRC will not regulate the incidental radioactive material produced during the operation of the accelerator.

Regulating Accelerator-Produced Radioactive Material

Comment: One commenter noted that the NRC has set up a regulatory framework that would issue one license for production and distribution and another for possession and use. The commenter recommended that the NRC continue to allow flexibility for the States to either follow the NRC's licensing approach or to streamline the licensing process by combining both license authorizations into a single license. Some States use the single license approach so facilities are not being required to pay multiple fees for multiple licenses or so a single facility with a single operator has only one radiation safety program for the State to evaluate. The commenter concluded that the additional authorizations require only a few extra lines of text in a license document, so the licensee should not have to pay separate licensing fees.

Another commenter requested that the NRC clarify whether a single license might include authorizations under both 10 CFR Part 30 and 10 CFR 32.72 or whether separate licenses are required by the NRC.

NRC Response: Licensing procedures are considered as a matter of adequacy for the Agreement States, not compatibility. As long as the license or licenses written by an Agreement State are adequate to assure that the licensed program will protect public health and safety, the licensing procedures need not be the same as those used by the NRC. The NRC will continue to consider the adequacy of Agreement State licensing procedures for all byproduct licenses, including those for the newly added byproduct material, as part of the Integrated Materials Performance Evaluation Program (IMPEP) reviews.

The NRC fees are based on the number of the NRC-regulated activities conducted by the licensee. The NRC regulations list fee categories for the various activities. A license may include more than one fee category, and each fee category has a separate fee to recover the budgeted resources associated with that regulated activity.

The NRC intends to license the production of radionuclides by accelerators as a separate Part 30 license and has developed a separate licensing guide for this activity (i.e., NUREG-1556, Volume 21, “Program Specific Guidance About Possession Licenses for Production of Radioactive Materials Using an Accelerator”). Commercial distribution will continue to be licensed under 10 CFR 32.72 for radioactive drugs and under 10 CFR 32.74 for medical sealed sources. This licensing process provides a clear delineation between radionuclide production or radioactive drug manufacture and commercial distribution of radioactive drugs or medical sealed sources to medical use licensees.

Historically, a radioactive drug manufacturer has to obtain a Part 30 license for possession of the licensed material. A Part 30 license also authorizes the transfer of byproduct material under 10 CFR 30.41 to other licensees, but it does not authorize distribution of

radioactive drugs to medical use licensees. Distribution of radioactive drugs containing byproduct material to medical use licensees for medical use must be authorized by a "Medical Distribution" (MD) license under 10 CFR 32.72 or 10 CFR 32.74.

The NRC issues MD licenses to commercial nuclear pharmacies for distribution of radioactive drugs to medical use licensees with a Part 30 authorization for possession and use. However, the NRC does not consider commercial nuclear pharmacies to be drug manufacturers, i.e., registered with FDA or a State as a drug manufacturer.

Comment: A commenter stated that medical radionuclides can initially produce very high doses of radiation from the exterior of a patient after treatment. The commenter asked whether, because of this, there are any patient releasability issues such as those for the release of iodine-131 therapy patients. The commenter also asked whether there would be any releasability issues for activated or spallated patients.

NRC Response: The requirements in 10 CFR 35.75, "Release of individuals containing unsealed byproduct material or implants containing byproduct material," apply to all medical uses and all medical use licensees. It is the licensee's responsibility for a release determination of a patient or human research subject to determine whether he or she: (1) cannot be released under 10 CFR 35.75; (2) can be released with written instructions; or (3) can be released without written instructions. These decisions are based on whether the total effective dose equivalent to any other individual is likely to exceed certain values. These values apply to the evaluation of all patients including activated patients.

Comment: Several commenters supported the "grandfathering" of individuals (i.e., not requiring individuals to meet new training and experience requirements in order to continue their previous responsibilities), discussed in the Statements of Consideration for individuals producing accelerator-produced radionuclides and in the proposed rule text for ANPs, medical use AUs, and RSOs. These commenters wanted a grandfathering provision for AUs

responsible for the production and use of PET radionuclides included in 10 CFR Part 30. Some of these commenters requested that the NRC strengthen the language to clarify the extent of the grandfathering authorizations. Several commenters requested that the NRC consider using this rulemaking to resolve other general issues related to grandfathering of AMPs and RSOs. The commenters agreed that individuals already authorized to use byproduct materials in 10 CFR Part 35 should also be authorized to use the newly covered accelerator-produced materials. One commenter wanted the NRC to clarify that the reverse was also true, i.e., individuals who previously only used NARM were now qualified to use all byproduct material.

NRC Response: Unlike 10 CFR Part 35 medical use licensees that are required to meet specific training and experience requirements, 10 CFR Part 30 licensees that use accelerators to produce byproduct material are required to meet general performance criteria in 10 CFR 30.33(a)(3). The training and experience of individuals involved in the licensing activities to produce the newly added byproduct material are reviewed during the licensing process to ensure that they are qualified to perform those activities. Because the NRC does not have specific requirements for these individuals, there is no need to provide a "grandfather provision" for them. Applicants with accelerators used to produce byproduct material will be required to describe the radiation safety training and work experience of those individuals using materials that they are seeking authorization to use. It is expected that these individuals that used the newly added byproduct materials will be able to document that their radiation safety training and work experience from using these materials are sufficient to meet the general performance criteria and that they be recognized as authorized individuals.

Section 35.57 was amended in the proposed rule to provide that certain authorized individuals who used only the newly defined byproduct material may be grandfathered (i.e., need not comply with the relevant training requirements in Part 35) for performing the same uses. The NRC does not believe that the language in the provisions should be revised.

The NRC has determined that revising the regulations to address general issues related to the grandfathering of AMPs and RSOs would be outside of the scope of this rulemaking. These issues will be addressed separately in response to a petition for rulemaking (PRM 35-20) filed by the American Association of Physicists in Medicine on September 10, 2006.

Comment: There were several comments on the NRC's proposal for the noncommercial transfer of PET radionuclides, drugs, and biologics to other medical facilities in its consortium by a medical use facility that uses its own cyclotron to produce PET radionuclides. One commenter stated that it agreed that facilities authorized by a State to produce PET radionuclides for noncommercial distribution be allowed to do so without a medical distribution license.

Generally, the commenters agreed that distribution licenses should not be required for distribution of radionuclides from PET facilities to medical facilities under contract to them, but thought it was unclear which facilities would be included in the definition of "medical facilities in its consortium." As an example, one commenter was not sure whether a cyclotron producing PET radionuclides, that is located at a facility owned by Company A but operated under a separate license by a different Company B, would need a commercial distribution license. The commenter also asked for clarification on whether Company B would need a medical distribution license if it also supplied PET radionuclides to other facilities in its geographical area under contract.

Another commenter noted that only noncommercial distribution to a medical consortium was addressed, and not the noncommercial distribution within the consortium in support of research and development. The commenter asked that the NRC expand its proposed regulatory framework to include authorization for licensees producing PET radionuclides, drugs, and biologics to allow noncommercial transfer to any licensee approved for research and development uses of these materials. This commenter also asked the NRC to provide specific

guidance on what is considered commercial transfer and noncommercial transfer in advance of requiring license application and amendment submissions for the production of accelerator-produced radionuclides. The commenter's interest was based on its being funded to do research involving nonstandard radionuclides and to make the results available to the research community and others. The commenter asserted that the NRC, in the past, approved similar efforts by universities to produce and supply nonstandard radionuclides not otherwise available.

NRC Response: The NRC recognizes that the PET radionuclide production facility may be located in a medical facility, educational institution, or Federal facility that has formed a consortium to produce PET radioactive drugs for its members. The NRC is adding a definition of *Consortium* in 10 CFR 30.4 to clarify the purpose and members of a consortium. In general, the members of the consortium jointly own or share in the operation and maintenance cost of the PET radionuclide production facility, and the production facility or another member of the consortium produces PET radioactive drugs (including radioactive biologics) only for its consortium member's medical uses. The NRC's authorization for the noncommercial distribution of PET radioactive drugs within a medical use consortium is not dependent on an authorization by a State to produce PET radionuclides for noncommercial distribution. A person or a licensee that has or receives PET radionuclides from a PET radionuclide production facility may request authorization for noncommercial distribution of PET radioactive drugs within its consortium. The NRC will review the request along with the description of the consortium during the licensing review process to ensure eligibility for noncommercial distribution and issuance of the authorization.

For clarification purposes, the NRC, in the final rule, has moved the noncommercial distribution provisions for PET radioactive drugs to 10 CFR Part 30. For noncommercial distribution of PET radioactive drugs, the NRC is applying the same requirements as those included in 10 CFR 32.72 for commercial distribution of these drugs.

Regarding different licensing situations, a university that has both a 10 CFR Part 30 license and a 10 CFR Part 35 license could transfer PET radioactive drugs to its medical facility without a commercial distribution license. If the PET radionuclide production facility produces PET radioactive drugs and is located at a medical facility, but owned, operated, and licensed by another entity under a 10 CFR Part 30 license, then the PET radionuclide production facility licensee would need a 10 CFR 32.72 license to distribute PET radioactive drugs to the medical facility for medical use. If a PET radionuclide production facility produces PET radioactive drugs and wants to distribute excess PET radioactive drugs to other licensees outside its consortium, a 10 CFR 32.72 commercial medical distribution license would be required. In general, a PET radionuclide production facility may transfer excess PET radionuclides to other licensees that are authorized to receive such PET radionuclide transfer under 10 CFR 30.41. However, if a PET radionuclide production facility produces radionuclides for commercial distribution, then a distribution authorization would be required as well. An applicant's intent regarding noncommercial distribution, transfer, or commercial distribution will be evaluated as part of the licensing review process to ensure that the proper license or authorization is issued.

A PET radionuclide production facility is required to obtain a 10 CFR Part 30 license for production, possession, and use of byproduct material. Under 10 CFR 30.41, a licensee is allowed to transfer byproduct material (including PET radionuclide) to any person authorized to receive such byproduct material. However, as required in 10 CFR Part 35 regulations, medical use licensees can only obtain PET radioactive drugs for medical use from persons meeting specific requirements for commercial distribution of radioactive drugs in 10 CFR 32.72. There are no such limitations for nonmedical use. Therefore, a specific provision would be needed to allow medical use licensees to obtain PET radioactive drugs through noncommercial distribution or from persons not covered under 10 CFR 32.72. A new provision is added in 10 CFR 30.32(j) to allow a PET radionuclide production facility to noncommercially distribute PET radioactive

drugs to members of its consortium. Such a provision is not needed for a PET radionuclide production facility to transfer PET radionuclides because transfer is already allowed under 10 CFR 30.41.

Comment: A commenter requested that the NRC clarify whether facilities that prepare PET drugs for use in research under Investigational New Drug exemptions (INDs) filed with the FDA, or used in research conducted under approvals granted by Radioactive Drug Research Committees (RDRCs) operating as branches of the FDA under 21 CFR 361.1, would be considered "registered" by the FDA.

NRC Response: As specified in 10 CFR 30.32(j) and 10 CFR 32.72, being registered with the FDA is only one of the five ways that an applicant can demonstrate that it is qualified to produce PET radioactive drugs for noncommercial or commercial distribution to medical use licensees. Because the NRC neither interprets nor enforces FDA requirements, it is the applicant's responsibility to provide documentation of the proper FDA registration. If there is a question as to whether a specific facility that prepares PET drugs under INDs or RDRCs is "registered" by the FDA, the applicant should contact FDA for a determination.

It is important to note that a 10 CFR Part 35 medical use licensee may obtain unsealed byproduct material for uptake, dilution, excretion, imaging, or localization from an NRC or Agreement State licensee that prepared the material for research in accordance with an RDRC-approved protocol or an IND protocol accepted by FDA as permitted in current provisions of 10 CFR 35.100 and 35.200. This provision is separate from the provision that the byproduct material must be obtained from a commercial manufacturer or preparer licensed under 10 CFR 32.72 or by noncommercial distribution from a member of its consortium under 10 CFR 30.32(j).

Comment: A commenter expressed concern that language in the proposed rule could place undue burden on health care providers who use cyclotrons for the production of radiotracers by requiring them to meet FDA's Good Manufacturing Practices (GMPs) standard

that is applied to commercial entities producing products for sale to the public. The commenter stated that it was inappropriate to apply GMPs to noncommercial production of radiotracers. The commenter stated that: (1) the EPAct does not give the NRC the authority to require health care providers to follow GMPs in their clinical practices; (2) enforcing drug production quality standards falls under FDA's jurisdiction, and the NRC should not enforce FDA requirements; (3) such a requirement would have a detrimental effect on exploration of new treatment pathways; and (4) health care providers have not been required to apply commercial GMP standards previously. The commenter asserted that regulation of cyclotron byproduct material should not include processes involving drug production and patient care. The commenter further indicated that the production of radiopharmaceuticals using a cyclotron is no different than using a molybdenum or rubidium generator.

NRC Response: The NRC disagrees that its regulations would require health care providers to follow GMPs in their clinical practice. The NRC requires licensees that distribute radioactive drugs (including radioactive biologics) to medical use licensees to be qualified to produce radioactive drugs for medical use. To demonstrate this qualification, the NRC requires in 10 CFR 30.32(j) and 10 CFR 32.72 that the applicant or licensee submit evidence that it meets at least one of the following criteria: (1) be registered with the FDA, (2) be registered or licensed with a State agency as a drug manufacturer, (3) be licensed as a pharmacy by a State Board of Pharmacy, (4) be operating as a nuclear pharmacy within a Federal medical institution, or (5) be a PET drug production facility registered with a State agency. The FDA's rule on Good Manufacturing Practice for PET drugs establishes criteria for the production and process/quality controls of PET drugs in PET centers registered with the FDA. While the NRC recognizes the FDA registration in the NRC's regulations, registration with the FDA is only one of five different criteria that licensees may meet to demonstrate they are qualified to distribute radioactive drugs to medical use licensees.

The NRC agrees that the production of radiopharmaceuticals using radionuclides from a cyclotron is no different than using molybdenum or rubidium generators. The producer of the molybdenum generator is registered with the FDA as a drug manufacturer and is licensed by the NRC under both 10 CFR Part 30 and 10 CFR 32.72. The use of the generator to prepare other radioactive drugs is required in 10 CFR 32.72 to be done by a commercial nuclear pharmacy or in 10 CFR 35.200 to be done at the medical use facility by an AU meeting specific training and experience criteria or an ANP. The NRC has applied the same flexibility in recognizing that certain drugs are produced by facilities registered with the FDA or States and that other drugs are prepared by or under the supervision of AUs or ANPs.

Comment: A commenter recommended that the NRC should include an exemption for changes that involve the addition or relocation of either a PET radionuclide production area or a radionuclide delivery line from the PET production area from license amendment or the NRC notification requirements for broad scope Type A licenses under 10 CFR 35.15. The commenter stated that this allowance is consistent with the level of authority the NRC has historically granted under this list of exemptions.

NRC Response: The NRC agrees with the commenter and revised proposed 10 CFR 35.15(f) to make it clear that a Type A specific license of broad scope is exempt from the notification provisions in 10 CFR 35.14(b)(4). In this final rule, the NRC's licensing practice for Type A specific licenses of broad scope is to have the licensee describe significant facilities, such as the PET radionuclide production area or radionuclide delivery tube, and provide the NRC its criteria for reviewing and approving the addition or relocation of these facilities. The broad scope licensee with a PET radionuclide production facility will need to submit an application to license the production facility and, if applicable, increase its radionuclide possession levels.

Comments on Waste and Decommissioning.

Decommissioning and Decontamination.

Comment: A commenter noted that under the proposed rule, activities under the new definition of *Byproduct material* would need to be licensed within 6 to 12 months after the final rule takes effect. The commenter requested clarification as to whether this new requirement would result in MML licensees having to permit/license all sites containing radium or radium contamination due to radium paint operations or gauge maintenance. The commenter noted that current U.S. Air Force (USAF) policy is to forgo permitting sites, until intrusive characterization of the site has been performed. The commenter requested that the NRC state whether this rule would affect the current USAF policy.

NRC Response: As previously discussed, since the publication of the proposed rule, and after considering the comments on the new definition of *Byproduct material* with respect to discrete sources of radium-226, the Commission has taken a closer look at the scope of the Commission's jurisdiction over discrete sources of radium-226. With respect to radium-226, the EPAct covers any material that is "produced, extracted, or converted after extraction, before, on, or after August 8, 2005, for use for commercial, medical, or research activity." Notwithstanding that a discrete source of radium-226 may have originated from a commercial supplier, the Commission has determined that discrete sources of radium-226 still under the control of the military do not constitute "commercial use" under the EPAct and are, therefore, outside the Commission's jurisdiction. Defining "commercial use" to include all material supplied to the military from a commercial supplier would result in virtually all military use of this material to be "commercial use." This would vitiate any distinction that the EPAct intended to make for military use, as opposed to commercial use, by excluding military use from its coverage.

Comment: A commenter stated that Actinide/radium-226 surface contamination levels less than 1000-1500 dpm/100cm^2 are typically not detectable at 1-2 sigma counting statistics. The commenter stated that radium-226 captured in clothing/porous materials could have much higher counting errors and asked if the NRC has accepted the technological shortfall for detection of radium-226 and proposed an alternative.

NRC Response: Licensees are required to "demonstrate" to the NRC that post remediation contamination levels meet the release criteria for their sites. "Demonstration" includes specifically addressing instrumentation used for detecting and measuring the contamination. If instruments can't detect the contamination, other means to identify contamination levels (such as taking more samples or scaling) must be addressed in the licensee's Decommissioning Plan. The NRC guidance documents NUREG-1757, "Consolidated NMSS Decommissioning Guidance," and NUREG-1575, "Multi-Agency Radiological Survey and Site Investigation Manual," both address instrumentation.

Comment: Two commenters requested that the NRC modify its regulations in 10 CFR 30.36 to allow a longer time frame of at least 10 years for completion of decommissioning for accelerator production facilities. One commenter stated that decommissioning of a particle accelerator and its associated facility can range from a return of a self-shielded cyclotron unit to the manufacturer to a major clean up of an older accelerator unit and its facility. The commenter stated that cost for decommissioning will be significantly impacted by the time frame allowed to complete this action. Under the current 10 CFR 30.36 regulations, completion of decommissioning for an accelerator production facility could be required in as little as 48 months following cessation of operation. On the other hand, under 10 CFR 50.82, decommissioning of a power reactor is required to be completed within 60 years following cessation of operation. Hence, the commenter requested that the NRC modify its regulations in 10 CFR 30.36 to allow a longer time frame of at least 10 years for completion of

decommissioning for accelerator production facilities.

NRC Response: The NRC's regulations in 10 CFR 30.36 require that the site or any separate building or outdoor area that has not been used for 2 years must be promptly remediated if the remediation activities are allowed by the existing license. If remediation activities are not allowed under an existing license, the licensee must develop a decommissioning plan and submit a request for a license amendment within 1 year. The decommissioning process must be completed within 2 years, unless an alternative schedule for completion of decommissioning is approved by the Commission.

The level of effort for decommissioning a radioactive material production facility depends on many factors such as the design, age, operating condition, and usage of the accelerator and the type of facility where the accelerator is located. Decommissioning activity can range from simply a return of a self-shielded cyclotron unit to the original manufacturer to a more complicated clean up of an older accelerator unit and its facility. Because alternative schedules for decommissioning are allowed within the existing regulations, there is no need to modify 10 CFR 30.36.

Comment: In response to the NRC's request for comments on the decommissioning of accelerator facilities and accelerator components, one commenter requested clarification in Part 35 that the term decommissioning does not apply to the removal or replacement of a linear accelerator used for medical treatment. Another commenter recommended that the NRC include a specific exemption that states that "decommissioning" does not include: (a) replacement of one medical accelerator for another; (b) upgrading of a medical accelerator; (c) replacement of one cyclotron for another within the same facility; or (d) upgrading of an existing cyclotron.

NRC Response: The EPAct gave the NRC the authority to regulate any material that has been made radioactive by use of a particle accelerator and is produced, extracted, or

converted for use for a commercial, medical, or research activity. Under the EPAct, the NRC only has authority over the radioactive material and not over accelerators including linear accelerators used for medical treatment. Because linear accelerators used for medical treatment do not produce radioactive material that is used for commercial, medical, or research activities, the NRC will not be regulating the activated material that may be produced during medical treatment.

Because medical linear accelerators and activated material associated with these types of accelerators are not regulated by the NRC, no specific exemption is needed for non-NRC regulated material, including replacement or upgrade of a medical linear accelerator. Decommissioning regulations are not applicable to nonregulated material such as a medical linear accelerator.

Replacement or upgrade of a cyclotron is not typically considered a decommissioning activity; therefore, an exemption for such activity would not be required. However, if the cyclotron is used to produce radioactive material for commercial, medical, or research activities, and accelerator components become activated incidental to the production of radioactive material, both the radioactive material and the components would be regulated as licensed material. The activated components would require decommissioning upon cessation of licensed activity. If licensed activity continues, the replacement or upgrade of a cyclotron or its activated components would be addressed in the license. The removed cyclotron and its activated components are considered licensed material and would be treated as radioactive waste.

Comment: A commenter stated that the NRC should address volumetric contamination of materials by activation/spallation and recommended that the NRC develop release criteria for the various accelerator-produced radionuclides.

NRC Response: For decommissioned sites, the release criterion for unrestricted use is

25 mrem per year (0.25 mSv per year) as listed under 10 CFR Part 20, Subpart E, and 10 CFR 30.36, including all radionuclides and all pathways. If an accelerator is used to produce regulated material, and accelerator components become activated incidental to the production of the regulated material, the activated components would be licensed and subject to 10 CFR Part 20, Subpart E, and 10 CFR 30.36 requirements.

Even though the NRC has, in the past, considered exposure criteria for release of waste and contaminated scrap, no rule has been adopted regarding exposure criteria. Currently, the NRC does not plan to develop release criteria for various accelerator-produced radionuclides. Activated waste produced in an accelerator will be treated like any other radioactive waste. Guidance regarding decommissioning and waste disposal can be found in NUREG-1757, "Consolidated NMSS Decommissioning Guidance."

Comment: Two commenters asked whether the NRC will be proposing acceptable de minimus values, release criteria, or remediation criterion for surficial and volumetric radium contamination on building structures and soil that can be generally applied to decommissioning operations. One commenter asked if the NRC accepts 5 pCi/gram of soil as volumetric de minimus values that EPA or States have approved for radium-226 contamination release value at certain remediation sites.

NRC Response: Currently, there are no de minimus values or release criteria for decommissioning sites. As provided in 10 CFR 20.1402, the release criterion for unrestricted use is 25 mrem per year (0.25 mSv per year) for all sources and all pathways. The NRC will only accept a release value of 5 pCi/gram (0.185 Bq) for radium-226 contamination in soil if the site will also meet the NRC's release criterion of 25 mrem per year (0.25 mSv per year).

The NRC does have screening values for building surfaces and surface soil concentrations. Screening values are based on the 25-mrem per year (0.25-mSv per year) release criterion and can be used to simplify decommissioning efforts where low levels of

contamination exist. Screening values are listed in tables included in Appendix B of NUREG-1757, "Consolidated Decommissioning Guidance-Decommissioning Process for Materials Licensees," for each radionuclide for building surfaces and soil surfaces. These screening values are not de minimus values. Unlike de minimus values, the screening values were developed under certain site conditions (e.g., type of facility, depth of soil contamination, type of surface contamination); therefore, screening values may only be used if a site meets these specific conditions. For a site with mixed radionuclides, the "unity rule" (or sum of the fractions rule) applies, and screening values would change depending on the site's isotopic mixture. There are only a few sites that can use the screening method for decommissioning because sites are very different from each other, and most sites do not meet the conditions for using screening values.

Comment: One commenter provided some insight on a radium-226 dosimeter calibration source breach at a facility in the 1950s and indicated that current survey equipment has difficulty detecting actinide contamination under 1000-1500 dpm/100cm^2. The commenter stated that if the radium-226 breach occurred before the 1970s, it is likely that the contamination still exists. Because the NRC has taken authority over all past, present, and future radium-226 sources, the commenter asked whether the NRC's authority includes authority over the contamination resulting from a radium-226 source breach.

NRC Response: Under the EPAct, the NRC has the regulatory authority over all past, present, and future discrete sources of radium-226 and any contamination associated with the discrete sources. However, the NRC does not intend to require nonlicensed owners of properties that may be contaminated with radium-226 to obtain licenses. If contamination is discovered at a nonlicensed person's facility, such as contaminated buildings or grounds, the NRC will work with the facility owner to perform decommissioning of the site. If the site presents a significant threat to the public health and safety, the NRC may order the owner to

obtain a license and to perform decommissioning of the site. In addition, the NRC may seek assistance from EPA to consider listing the site on EPA's National Priority List and clean up the site under the CERCLA or Superfund Program. Any arrangement between the NRC and EPA regarding regulatory authority over decommissioning would be agreed upon on a site-specific basis.

Comment: One commenter indicated that a number of gaslight and luminous production sites are abandoned, and some are Superfund sites. The commenter asked whether the NRC has the financial ability to clean up these sites.

NRC Response: The NRC does not perform or provide funds for cleanup of contaminated sites because the NRC does not have authority in spending Federal funds for conducting cleanup activities. The NRC relies solely on licensees or property owners to perform the necessary cleanup work. Unlike the NRC, EPA has the funds under the CERCLA or Superfund Program to evaluate the extent of the contamination and to conduct the cleanup efforts. EPA also has the statutory authority to recover the cost associated with the cleanup activities from the potentially responsible parties.

Comment: One commenter asked whether there will be any requirements for the NRC's review of radium-contaminated sites that have been remediated before the effective date of this rule.

NRC Response: The NRC does not intend to revisit sites that have already been remediated. If sites are discovered to be contaminated with sufficient quantities of radionuclides to potentially warrant additional decommissioning, the NRC will contact and work with the owner of the property to re-commence the decommissioning process.

Comment: One commenter asked how the NRC will review decommissioning plans and final status surveys for sites where AEA Section 91(b) materials may be the predominant contaminant with respect to AEA materials regulated by the NRC and whether there is a limit of

the NRC's interests in these sites.

NRC Response: Decommissioning of a licensed facility falls under the requirements of 10 CFR Part 20, Subpart E, and 10 CFR 30.36. The NRC will review decommissioning plans and the final status survey to ensure that the licensed facility meets the release criterion of 25 mrem per year (0.25 mSv per year) for unrestricted use for all radionuclides and all pathways. The NRC will use this approach for all sites that are contaminated by any licensed material including sites where unlicensed radionuclides such as Section 91(b) material contribute to the dose estimates in the all-pathway analysis. The NRC has no regulatory authority over a site that is contaminated with only Section 91(b) material and not licensed material.

Comment: One commenter raised a question on whether the NRC will subsume the predominant regulatory role for remediation of sites that predate the USAF MML and were established under AEC purview.

NRC Response: The NRC has the predominate regulatory role in the decommissioning of sites under the MML. Sites containing licensed material must be decommissioned under 10 CFR Part 20, Subpart E, and 10 CFR 30.36 requirements regardless of whether such sites predate the MML or were under the purview of AEC.

Comment: Two commenters expressed their concern regarding the statement in the Statements of Consideration for the proposed rule that only radionuclides with a half-life of more than 120 days, that are present in sufficient quantities to cause a public health and safety concern, need to be addressed for the purpose of establishing adequate financial assurances for decommissioning leading to license termination. One commenter requested that the final rule include specifications of which radionuclides and the threshold amounts would be sufficient to lead to license termination. Another commenter recommended that the term "sufficient quantities" be defined in terms of 10 CFR Part 20 dose limits.

NRC Response: In the proposed rule, the term "sufficient quantities" is referring to quantities of radionuclides with a half-life of more than 120 days for the purpose of establishing adequate financial assurance for decommissioning leading to license termination. The specific quantities are established in 10 CFR 30.35. For unsealed byproduct material in quantities exceeding 10^5 times, or for sealed sources or plated foils in quantities exceeding 10^{12} times the applicable quantities in Appendix B to 10 CFR Part 30, the licensee is required to submit a decommissioning funding plan. For unsealed byproduct material in quantities exceeding 10^3 but less than or equal to 10^5 times, or for sealed sources or plated foils in quantities exceeding 10^{10} but less than or equal to 10^{12} times the applicable quantities in Appendix B to 10 CFR Part 30, the licensee is required to submit either a decommissioning funding plan or a certification that financial assurance for decommissioning had been provided in the amount prescribed in 10 CFR 30.35(d). Revising the quantities requiring financial assurance is beyond the scope of this rule.

For license termination, the release criterion for unrestricted use is 25 mrem per year (0.25 mSv per year) as listed under 10 CFR Part 20, Subpart E, and 10 CFR 30.36. All radionuclides, regardless of the quantities present, must be considered in the all-pathway analysis in demonstrating compliance with the release criteria.

Waste Disposal.

Comment: One commenter asked whether radioactive waste site licenses will need to be changed to reflect the newly regulated radioactive materials and whether it is the waste site licensee's responsibility to incur the cost of changing the license.

NRC Response: Waste site licenses may or may not need to be amended to include newly regulated radionuclides. The need for amending a license will depend on how the existing license identifies the licensed material (listed as a group of radionuclides or listed by each individual radionuclide). The cost for a license amendment would be the responsibility of the licensee.

Comment: One commenter asked whether there are disposal sites that can inexpensively dispose of consumer products and luminous light sources. If not, the commenter stated that abandonment may become the only method of disposal.

NRC Response: There are radioactive waste disposal sites, licensed by the Agreement States, and hazardous or solid waste disposal sites, permitted by the EPA or its authorized States, available for disposal of the newly added byproduct material. Disposal charges are set by each of the disposal facilities based on the type of material and the contamination level. It is the licensee's responsibility to locate a disposal facility that could accept the waste and to negotiate disposal cost.

There are also certain manufacturers that accept returned or spent sources from their customers. In the past, DOE has, in certain unique situations, cooperated with the NRC and the CRCPD in collecting certain orphaned sources for storage and/or disposal at DOE facilities due to lack of disposal options. However, these programs are typically limited in scope and designed for urgent needs.

In general, consumer products are manufactured by a specific license and distributed to consumers as an exempt product. These consumer products contain very small amounts of

radioactive material in order to meet the stringent criteria for an exempt product. There are no disposal requirements for exempted products based on the amount of the radioactive material present and the negligible impact to public health and safety. Hence, exempt products are allowed to be disposed of in municipal landfills.

Comment: One commenter was concerned regarding the disposal of exempted smoke detectors containing radium-226.

NRC Response: This issue is discussed earlier in this document under "Exemption of Certain Radium-226 Items."

Comment: One commenter asked if the NRC will accept decay-in-storage as a method of disposal for accelerator-produced medical radionuclides. The commenter also asked whether decay-in-storage could also be applied to accelerator components that are volumetrically activated or spallated, and whether the time period under which the accelerator is turned off or in a low energy mode could be counted as the decay-in-storage time.

NRC Response: Decay-in-storage has been, and will continue to be, an accepted means for disposal of radionuclides with short half lives, including medical radionuclides. Activated components either within or removed from the accelerator will be treated as any other radioactive source. Therefore, activated components contaminated with short-lived radionuclides with half lives less than 120 days will be allowed to use decay-in-storage as a disposal method. Activated components contaminated with radionuclides with half lives greater than 120 days would either have to be disposed of as radioactive waste or have to be addressed later during decommissioning as part of the license termination process.

Comment: For decay-in-storage or disposal, a commenter asked whether accelerator-produced medical radionuclide users will be able to ignore short-lived radionuclides. As an example, the commenter noted that many "hundreds of thousands" of fluorine-18 disintegrations on the skin surface will produce only microrem doses to the skin or deep tissue.

NRC Response: All accelerator-produced radionuclides, including short-lived radionuclides, will be regulated. Licensees may not ignore short-lived radionuclides in meeting the NRC's regulatory requirements. However, licensees may use decay-in-storage as a means for disposal in accordance with the NRC criteria.

Comment: One commenter stated that decommissioning of accelerator facilities can result in the removal of building materials and accelerator parts that are activated. Recycling and disposal of material that meet the NRC's materials contamination limits may still trigger detectors at landfill and scrap facility checkpoints. The commenter recommended that the NRC consider exposure criteria for release of these materials.

NRC Response: In the past, the NRC has considered development of exposure criteria for release of waste and scrap through the rulemaking process. Due to public comments on the rulemaking effort, the NRC decided to defer the rulemaking to a later date, and no rulemaking on this issue was promulgated.

Sites released for unrestricted use based on the 25-mrem per year (0.25-mSv per year) criterion specified in 10 CFR Part 20, Subpart E, have no restrictions placed on the use of the site or disposition of material located on the site or disposal of waste or materials from the site. If a detector is triggered at a landfill, the operator of the landfill should notify the State or another regulatory authority. Typically, the NRC would be notified of the event, but, in most cases, no action would be taken because the material met the NRC's release criteria.

If the site is discovered to be recontaminated to levels above the release criteria, the NRC may contact the site owner or former licensee to begin the decommissioning process.

Comment: A commenter concurred with the NRC's proposed approach towards waste disposal to change Part 20 to redefine the definition of *Waste* to allow disposal of the newly added byproduct material in the NRC-regulated disposal facilities or in a disposal facility permitted under Federal or State solid or hazardous waste laws. However, the commenter

questioned whether such an approach may be arbitrary or capricious, since other similar low-level wastes may still fall under the Compact jurisdiction (i.e., Section 11e.(1) byproduct material). The commenter suggested that this situation could be avoided by managing the radium as radioactive material instead of byproduct material.

NRC Response: The commenter appears to be concerned that it may be arbitrary to treat some byproduct materials as low-level waste and some as non-low-level waste and suggested to manage the newly added byproduct material as radioactive material instead of as byproduct material. However, the EPAct defines the newly added byproduct material; i.e., discrete sources of radium-226 and accelerator-produced radioactive material, as a byproduct material. Defining the newly added byproduct material as radioactive material would be inconsistent with the statutory requirement. In addition, the NRC only has authority to regulate AEA material and not all radioactive material. Because the discrete source of radium-226 is a byproduct material, and byproduct material is only a subset of radioactive material, treating radium-226 as radioactive material instead of byproduct material would have the appearance that the NRC has regulatory authority over all radioactive material.

The EPAct provides an additional disposal approach for the newly added byproduct material to include disposal at a disposal facility permitted under Federal or State solid or hazardous waste laws. This approach is consistent with many existing State programs that regulate naturally occurring and accelerator-produced radioactive material as radioactive material and not as byproduct material. In addition, this approach would enhance proper and timely disposal of the newly added byproduct material. Similar to low-level waste disposal facilities, disposal facilities permitted under Federal or State solid or hazardous waste laws also need to consider all radionuclides as source terms in conducting the performance assessment and in formulating the waste acceptance criteria to ensure protection to public health and safety and the environment.

Comment: One commenter concurred with providing multiple options for disposal of the newly added byproduct material but was not sure if this is consistent with some compacts' definitions. The EPAct and the NRC state that the new byproduct material is not low level radioactive waste (LLW) such that it is not to be impacted by the compact process of the Low-Level Radioactive Waste Policy Amendments Act (LLRWPAA). The commenter stated that this seems "backward," as the Rocky Mountain Compact specifically captures radium in its definitions and traditionally has treated discrete radium as LLW.

NRC Response: Although the newly added byproduct material would not be considered LLW with respect to the compact process of the LLRWPAA, the newly added byproduct material may still be disposed of at an LLW disposal site. The EPAct provides additional options for disposal of the newly added byproduct material and does not prohibit the existing option of LLW disposal.

Comment: Because the newly added byproduct material would be allowed to be disposed of in either the NRC-regulated disposal facilities or in a disposal facility permitted under Federal or State solid or hazardous waste laws, a commenter asked if waste disposed of in a CERCLA site would incur "potential responsible parties" (PRP) status should the solid or hazardous waste facility fail.

NRC Response: Currently, disposal sites already dispose of radium-226 and other accelerator-produced and naturally occurring radioactive material as daughter products or as radioactive waste. The EPAct allows these disposal sites to continue with their current practice. Therefore, nothing would change for these disposal sites under the new regulations. The EPA has jurisdiction over any site that becomes a CERCLA or a Superfund site, and the EPA has the statutory authority to recover cleanup cost from PRPs. Under the Superfund, any party who is associated with the site, used the site, disposed of material at the site, or contributed to the contamination at the site could all be considered as a PRP and liable for the clean up.

Comment: A commenter indicated that any disposals in solid or hazardous waste facilities must take into account potential release of radium from the discrete source and therefore radon. The commenter suggested that discrete sources can be further encapsulated before burial as a treatment to reduce the potential for radium leakage and mitigate the potential for radon.

NRC Response: Disposal facilities need to consider all radionuclides and their daughter products when conducting the performance assessment and when developing the waste acceptance criteria regarding the type of radioactive waste that may be safely disposed of at the site. Depending on the performance assessment and the waste acceptance criteria, certain disposal facilities may require additional treatment of certain wastes to control the daughter products or migration of certain radionuclides. However, the NRC sees no reason to require further encapsulation of discrete sources before disposal because waste forms would depend on site-specific waste acceptance criteria for each disposal site.

Financial Assurance.

Comment: Two commenters strongly support an exemption for facilities with 18-MeV or less cyclotrons from the requirements of 10 CFR 30.35 for financial assurance for decommissioning because they do not believe these cyclotrons are capable of producing activation products in the quantity sufficient to trigger the financial assurance requirements. One commenter stated that this approach should be the standard in all non-Agreement States. In addition, these commenters stated that many burdensome expenditures are associated with calculating and securing financial assurance for decommissioning, including expensive concrete bunker boring and analysis. These costs would inevitably put some existing medical and scientific accelerator facilities out of business and would also deter prospective hospitals and educational institutions from obtaining onsite cyclotrons, potentially impacting patient

access to services. In support of an exemption, one commenter stated that it could provide data to the NRC on incidental activation resulting from a 16.5-MeV cyclotron running at maximum beam current at maximum duty cycle.

NRC Response: Although the commenters do not believe cyclotrons operating at 18 MeV or less are capable of producing activation products in the quantity sufficient to trigger the financial assurance requirements, supporting data have not been provided to the NRC. Financial assurance is required for the cost associated with decommissioning. Cost for decommissioning a cyclotron depends heavily on the complexity of decommissioning activities, which would be impacted by multiple factors such as design of the cyclotron, operating conditions, maintenance practices, and usage period. A standardized approach would not be suitable for all cyclotrons with various designs. The NRC's financial assurance regulations require financial assurance for decommissioning costs based on the type, quantity, half-life, and physical form of the radionuclides authorized in the license. The regulations implement a graded approach that requires increased financial assurance as the authorized quantity of licensed material increases. If the license authorizes a quantity above a threshold amount, financial assurance is required. Financial assurance is required because the cost of decommissioning should be borne by the organization that obtains the benefits of using the licensed material. The need for financial assurance increases where the decommissioning activities are complex or costly.

The cost of preparing a cost estimate for decommissioning cannot be avoided because the licensee must perform its obligation to decommission the facility at the end of licensed operations. Likewise, the cost of characterizing the extent of contamination cannot be avoided because characterization is necessary to prepare a decommissioning plan.

A licensee can reduce its financial assurance costs in several ways allowed by the regulations. The licensee can reduce its licensed possession limits to a level below the

threshold that requires financial assurance, or to a level that allows lower amounts of financial assurance. The financial assurance regulations permit a licensee to submit a site-specific decommissioning funding plan. If the prescribed amounts of financial assurance exceed a reasonable estimate of decommissioning costs, the licensee may submit a site-specific decommissioning funding plan to justify a lower amount of financial assurance. Information relevant to the amount of radioactive material that must be removed to permit license termination, and the cost of doing so, can be presented in the license application.

The financial assurance regulations allow for a number of different financial instruments to provide financial assurance, which allows the licensee to select the lowest cost alternative. Consequently, the NRC does not anticipate creating an exception from financial assurance requirements for cyclotron licensees.

Comment: One commenter stated that the NRC should urge the Agreement States to adopt their current requirements for decommissioning through IMPEP for Agreement States.

NRC Response: Agreement States are required under AEA Section 274 b. to adopt the NRC's regulations according to the compatibility designations within 3 years. Agreement State programs are regularly evaluated through IMPEP reviews. The NRC has worked, and will continue to work, closely with the Agreement States to ensure that State programs are compatible with the NRC.

Comment: One commenter indicated that there should also be surety requirements for decommissioning of facilities used to manufacture sealed sources.

NRC Response: If the manufacturer of sealed sources has possession limits that exceed the threshold amount, it will be required under existing NRC regulations to provide financial assurance. Threshold quantities are included in 10 CFR 30.35.

Comment: One commenter stated that decommissioning funding should account for activation products because some activation products, such as rebar and steel structural

components from accelerator facilities, have half lives longer than 120 days and could pose a disposal issue. Gamma exposure due to activated products could be an issue in certain scenarios. If a licensee were to abandon its facility, the potential certainly exists for new legacy sites that the NRC is trying to avoid.

NRC Response: If an accelerator is used to produce regulated material, and accelerator components become activated incidental to the production of the regulated material, the activated components would be licensed and subject to 10 CFR Part 20, Subpart E, and 10 CFR 30.36 requirements. In accordance with 10 CFR 30.35, financial assurance for decommissioning of licensed material is required based on the radionuclides and threshold quantities authorized in the license. Financial assurance provides funds for the licensee to conduct decommissioning activities or to hire a third-party contractor to decommission a facility. These funds could be used in the event a licensee abandoned its facility.

Comments on Other General Requirements.

10 CFR Part 20, Appendix B, Derived Air Concentration (DAC).

Comment: Several commenters recommended that the NRC should use specific values for nitrogen-13 and oxygen-15 in 10 CFR Part 20, Appendix B. One commenter stated that the use of default values does not allow the licensee to use a risk-based approach for compliance.

Most of the commenters endorsed the DAC values for nitrogen-13 and oxygen-15 calculated by Dr. Michael Stabin at Vanderbilt University. The commenters noted that Dr. Stabin based his calculations on EPA Federal Guidance Report No.12 (FGR-12) in conjunction with exposure limits and times used by the NRC in other calculated values in 10 CFR Part 20, Appendix B. The commenters also noted that the dose conversion values from FGR-12 are used by the NRC in other applications and for other radionuclides currently in 10 CFR Part 20, Appendix B.

The commenters recommended that the DAC values for nitrogen-13 and oxygen-15 calculated by Dr. Stabin should be rounded to one significant number and added to Part 20, Appendix B.

NRC Response: In Section G of the proposed rulemaking, the NRC requested comments on a number of specific issues, including the adequacy of the applicable default ALIs and DACs in 10 CFR Part 20, Appendix B, for oxygen-15 and nitrogen-13, and whether staff should develop larger specific values for these radionuclides. All six commenters addressing this issue believed that specific values for DAC should be used rather than the current default DAC value of 10^{-7} and 10^{-9} microcuries per milliliter of air for occupational and member of the public, respectively. Reasons given that the default values in 10 CFR Part 20, Appendix B, were not appropriate included: (1) they are unnecessarily restrictive default values that can result in unjustified cost for unnecessary radiological monitoring and controls; (2) the use of default values in general does not allow the licensee to use a risk-based approach to compliance; (3) values in the proposed rule would be unreasonably low; and (4) FGR-12 dose conversion values are endorsed and used by the NRC in other applications, such as dose modeling in support of the License Termination Rule.

One commenter submitted an analysis and DAC values for nitrogen-13 and oxygen-15 to be incorporated in 10 CFR Part 20, Appendix B, Table 1, Column 3, and Table 2, Column 1, for the DAC occupational value and air effluent concentration value. This was endorsed by several commenters. The analysis used dose equivalent conversion factors for submersion in a semi-infinite cloud from FGR-12, “External Exposure To Radionuclides in Air, Water, and Soil,” along with exposure parameters used by the NRC in other calculations in 10 CFR Part 20, Appendix B.

Models describing deposition and retention in the respiratory tract, levels and times of absorption to blood, and the biokinetics involved were not available. The ICRP publications for

workers or members of the public do not have dose coefficients for radionuclides with half-lives less than 10 minutes. ICRP Publication 53, Radiation Dose to Patients from Radiopharmaceuticals (1987), does have dose coefficients for inhalation of these radionuclides, but the biokinetic models generally are not directly applicable to worker intakes or environmental emissions. Because information was not available for dose conversion factors for intakes of oxygen-15 and nitrogen-13 to compare with the dose conversion factors for submersion, the NRC arranged for a study during the comment period. The purpose of the study was to develop scientifically sound inhalation dose coefficients for occupational and public exposures to forms of nitrogen-13 and oxygen-15, in order to compare DAC values from inhalation with DAC derived from submersion in contaminated air. The study developed biokinetic models describing deposition and respiratory tract retention, levels and time for absorption into blood, and systemic biokinetics of absorbed activity. Dose coefficients and derived air concentrations were developed for inhalation of nitrogen-13 as a gas and as ammonia, and oxygen-15 as molecular oxygen and as water vapor. The dose coefficients for submersion in air contaminated with nitrogen-13 and oxygen-15 were taken from FGR 12. These coefficients for air submersion are virtually identical because of their similar photon emissions. The study can be viewed or downloaded electronically via the NRC's rulemaking Website at http://ruleforum.llnl.gov.

The study verified that the limiting dose is from submersion in a cloud of the radionuclide and also arrived at limiting values for submersion that were submitted by the commenter, above, and that were endorsed by three other commenters. In light of the supporting documentation and technical basis for providing a specific value for the DACs for oxygen-15 and nitrogen-13 from submersion in a semi-infinite cloud, the NRC is incorporating values of 4E-6 microcuries per milliliter for the occupational value in Table 1, Column 3, and 2E-8 microcuries per milliliter for the effluent concentration in Table 2, Column 1, of Appendix B to

10 CFR Part 20, for submersion values of both radionuclides.

Other Comments on Exemptions and General License.

Comment: Some commenters agreed with the NRC's proposed delineation of particle accelerators into three varieties. The commenters agreed that the category of accelerators operated to produce only particle beams and not radioactive material, which include linear accelerators used in radiation therapy, should not be regulated. One commenter supported the NRC's proposal not to regulate incidental radioactive material produced by medical linear accelerators.

The commenters recommended that the NRC expand the exclusion in the final rule to include a specific exemption for commercially available linear accelerators used only for medical purposes to treat patients. One of the commenters recommended that the following or similar language may be appropriate: "Particle accelerator means any machine capable of accelerating electrons, protons, deuterons, or other charged particles in a vacuum and of discharging the resultant particulate or other radiation into a medium at energies usually in excess of 1 megaelectron volt and does not include machines that only produce particle beams and not radioactive materials. For purposes of this definition, accelerator is an equivalent term."

NRC Response: The NRC regulates radioactive material produced by using particle accelerators but does not regulate particle accelerators, including linear accelerators. Therefore, the NRC cannot include in its regulations the exemption suggested by the commenters. The definition for particle accelerator incorporated in the NRC regulation is the same as the definition found in the SSRs. The commenter suggested adding a statement to the definition indicating that it does not include machines that produce particle beams and not radioactive material. The NRC does not believe this statement needs to be added because the NRC does not regulate accelerators and revising the definition of *Particle accelerator* as

suggested by the commenter would introduce unnecessary confusion and inconsistency with State regulations.

Comment: A commenter noted a potential case in which the use of byproduct material may not be covered by the proposed regulations. The commenter asked if a person, in an Agreement State who received byproduct material before September 25, 1971, for use under an Agreement State's general license similar to the general license then provided in 10 CFR 31.4, could still possess the radioactive material under 10 CFR 30.18(b). The commenter asserted that the new 10 CFR 30.18(b) should cover the old byproduct material as well as newly regulated accelerator-produced radioactive material.

NRC Response: The Commission agrees that the proposed wording of 10 CFR 30.18 did not cover materials distributed for use under the previous equivalent general license of Agreement States that may now be used within the NRC's jurisdiction. The wording has been corrected in the final rule to address this comment.

Comment: A commenter noted that in the Section-by-Section Analysis under Section 30.18 exempt quantities, it was stated that Paragraph (b) would be revised to include accelerator-produced radioactive material that had been received or acquired under the general license in 10 CFR 31.4. The commenter did not believe that 10 CFR 31.4 provided coverage of accelerator-produced radioactive material.

NRC Response: The Commission agrees that the Section-by-Section Analysis on this provision did not appropriately describe the proposed change, and this is corrected in this notice.

Comment: A commenter stated that the discussion for general licenses in 10 CFR 31.5 does not address consistency with 10 CFR 35.65, which authorizes sealed source possession. The commenter requested clarification of regulatory requirements for sealed sources under 10 CFR Part 35 that are also generally licensed under 10 CFR 31.5. A similar clarification was

also suggested with respect to the general license in 10 CFR 31.8.

In addition, the commenter noted that the proposed rule does not address possible alternative licensing methods for a generally licensed sealed source that is subject to registration requirements and fees but that might also be listed as a sealed source on a specific license and achieve the same level of regulatory oversight and tracking. Further, the commenter stated that the discussion does not clearly indicate whether the requirements in 10 CFR 31.5 are for all sealed sources or only registered sealed sources.

NRC Response: The possession and use of a source or device is not authorized by both a general and a specific license concurrently, or by more than one general license. The general license in 10 CFR 31.5 only covers sealed sources incorporated into a device, although in some cases, a specialized source housing may also be considered a device. The general license in 10 CFR 31.8 only covers americium-241, and now radium-226, calibration and reference sources with a maximum possession limit of 5 μCi (185 kBq) at any one time in any one place. All devices under 10 CFR 31.5 and sources under 10 CFR 31.8 must have a label that identifies them as generally licensed devices or sources.

The regulations in 10 CFR 35.65 provide specific authority for medical use licensees to receive, possess, and use certain specifically licensed sealed sources and other byproduct material. This section does not authorize the possession of generally licensed sources or devices. Although a 10 CFR Part 35 licensee may also possess sealed sources and devices as authorized by these general licenses, it does so under the general license provisions of 10 CFR 31.5 and 10 CFR 31.8.

A specific licensee may use a source or device authorized under a general license under the authority of its specific license if the licensee requests transferring the authority from the general license to the specific license and provides assurance that requirements of both licenses are met. This practice normally arises because of the registration and fees associated

with certain devices covered by the 10 CFR 31.5 general license.

Devices being authorized for use under 10 CFR 31.5 and equivalent Agreement State regulations are evaluated for registration in the SS&D registry. In large part, SS&D certificates for devices containing radium-226 and accelerator-produced radioactive material have been added to the SS&D registry, as a means of sharing this information amongst the States, even though NRC did not regulate these materials in the past. If these devices have been authorized under State regulations that are similar to NRC requirements, the NRC would accept these devices containing radium-226 or accelerator-produced radioactive material as generally licensed under 10 CFR 31.5, and would also expect users to follow the requirements of 10 CFR 31.5 without regard to whether or not the State registered the device in the SS&D registry before the effective date of this final rule.

Comments on Licensing Fees and Fee Categories.

Comment: One commenter felt that the discussion in the Statements of Consideration for the proposed rule related to license application and annual fees was not clear in providing the average professional staff hours for the licensing categories, and suggested that to assist stakeholders in reviewing this proposed rulemaking, the average and total professional staff hours be listed by categories. The commenter suggested that the breakdown for these categories, and any possible changes in the annual fee for existing licenses that might require an amendment based on the proposed rule, be in 0.25 full time equivalent (FTE) units. The commenter also felt that the discussion related to accelerator-produced radioactive material was unclear as to whether the discussion applied only to commercial distribution or also applied to noncommercial distribution.

NRC Response: The FTE breakdown for the proposed new fee categories could be calculated based on the hourly rate and the time spent in reviewing license applications or in

conducting inspections. The average license application hours used to calculate the license application fees (as presented in the proposed rule), for the proposed new fee categories 3.R.1, 3.R.2, 3.S., and the proposed revised 3.B. fee category, are 2.3, 5.4, 24, and 17.7, respectively. These values could be calculated by dividing the FY 2005 application fees by the hourly rate of $197, as described in the proposed rule.

As explained in the proposed rule, the annual fees for the materials users fee class are calculated based on the NRC's budgeted resources allocated to regulating these types of licensees, less any receipts received from this fee class for 10 CFR Part 170 activities. The net dollar value of budgeted resources for this fee class is allocated to all materials users fee categories (subclasses), based on the average application and inspection hours associated with each fee category. The average inspection hours (associated with the annual fees presented in the proposed rule) for the proposed new fee categories 3.R.1, 3.R.2, 3.S., and revised 3.B. fee category, are 11.2, 12.2, 21.8, and 18.6, respectively.

The NRC's fee calculations are described in further detail each year in its fee rulemakings and supporting documentation. These rulemakings include details on the FTE and contract dollars allocated to the materials users fee class, for each agency-planned activity level. On February 2, 2007 (72 FR 5108), the NRC published in the Federal Register its FY 2007 proposed fee rule. The proposed fee rule, and its supporting documentation, presents and explains the fee calculations for all fee categories, including the new fee categories included in this rule. Note that the NRC does not plan to assess fees for the new fee categories of 3.R.1, 3.R.2, and 3.S. until the effective date of the FY 2007 fee rule or the effective date of this final rule, whichever is later.

The proposed new fee category 3.S. applies to production of accelerator-produced byproduct material, i.e., a radionuclide production facility. Because specific provisions for noncommercial distribution of PET radioactive drugs within a consortium, which includes a PET

radionuclide production facility, have been added to 10 CFR 30.32(j), there is no additional fee for noncommercial distribution of PET radioactive drugs. If an accelerator-produced radionuclide production facility wants to commercially distribute radioactive drugs, then the existing fee categories 3.C. and 3.D. would apply for the commercial distribution portion as well as the proposed new fee category 3.S. for the radionuclide production portion of the activities.

Comment: A number of commenters did not agree that there was a need to establish the new fee category for the production of accelerator-produced radioactive materials, 3.S., in Section II.G.(7). These commenters felt that the existing fee categories covered byproduct materials whose possession, use, processing, manufacturing, distribution, and redistribution were similar to accelerator-produced byproduct material. One commenter stated further that using these existing fee categories was consistent with the NRC's conclusion regarding the "grandfathering" of medical uses, and that the choice of existing fee categories should be based on the type of particle accelerators used and the types and quantities of radioactive materials being produced. This commenter stated that the establishment of a new fee category was inconsistent with the NRC's attempt to minimize impact on the noncommercial distribution of PET radionuclides, drugs, and biologics.

While not supporting the 3.S. fee category, another commenter requested that, if retained, the language of the final rule explicitly state that fee category 3.S. would be applied per facility, not per accelerator, and that the NRC should be mindful that additional costs would inevitably be passed on to the health care system and patients.

NRC Response: The NRC is retaining the new fee category 3.S. because the NRC incurs budgeted resources in regulating the production of accelerator-produced radioactive material, which are in addition to the budgeted resources the NRC incurs in regulating the activities covered by existing fee categories. Therefore, the NRC believes a separate fee for this activity is appropriate. The fee is applicable for each licensed facility regardless of how

many accelerators reside in the facility.

Comment: One commenter recommended that exceptions be extended to IRS-designated 501(c)(3) organizations operating in whole or in part as an accredited school of watch and/or clock repair and/or specialty museum with a primary focus on housing and exhibiting timepieces and related objects.

NRC Response: Exemptions of persons from the NRC's regulations for timepieces and repairs of timepieces are discussed earlier in subsection "Comments Related to Radium-226." In 10 CFR 170.11 and 171.11, the NRC lists fee exemptions for license fees and annual fees for certain licensees, including those for nonprofit educational institutions. In 10 CFR 170.3 and 171.5, a nonprofit educational institution is defined as "a public or nonprofit educational institution whose primary function is education, whose programs are accredited by a nationally recognized accrediting agency or association, who is legally authorized to provide a program of organized instruction or study, who provides an educational program for which it awards academic degrees, and whose educational programs are available to the public." Historically, the NRC has not included any fee exemptions for museums. Because the final rule contains exemption for intact timepieces containing less than 37 kBq (1 µCi) of radium-226 and general license provisions for various items containing radium-226, the NRC does not expect this rule to have major impacts on museums that would necessitate the NRC to establish a fee exemption in its regulations. Under 10 CFR Parts 170 and 171, an applicant or a licensee may file a fee exemption request with the NRC, and the NRC will evaluate each request on a case-by-case basis. Requests for a fee exemption must be filed with the NRC within 90 days from the effective date of this final rule establishing the annual fees for which the exemption is sought. However, filing of an exemption request does not extend the date on which the bill is payable.

Comments on Waiver Termination and Transitioning.

Comment: A commenter noted that some non-Agreement States may continue to require licenses or registration for the production of accelerator-produced radioactive materials, along with their associated fees. The commenter stated that some States have already indicated that they will require a NARM license regardless of whether an NRC license is required. The commenter stated that this situation would expand, rather than streamline, regulation of radioactive materials.

The commenter noted that it understood that the States will continue to regulate radiation-producing accelerators because the NRC will not have jurisdiction over the possession and operation of these machines. The commenter stated that the NRC should be aware of its concern that some States will not discontinue their current license requirements for the resulting accelerator-produced materials and recommended that the NRC address this in its Transition Plan.

NRC Response: Upon expiration of the waiver, non-Agreement States will no longer have authority to license the radioactive material produced in an accelerator for use for commercial, medical, or research activities. The production of the radioactive material, however, is only one facet of the operation of the accelerator. Because the NRC only has regulatory authority over the radioactive material and not the accelerator, some non-Agreement States may continue to license the accelerator and its operation. It is possible that certain producers of radioactive material may be required to hold two licenses: one from the State for possession and operating the accelerator, and one from the NRC for the possession and use of the byproduct material produced by the accelerator. This would not be an issue for the Agreement States because the Agreement State will be the only regulatory authority for radiation control within its State.

The NRC has worked very closely with both Agreement States and non-Agreement States in developing the Transition Plan. The Transition Plan includes various scenarios and

implementation guidance to ensure a smooth regulatory transition. On October 25, 2006, the NRC transmitted the proposed Transition Plan to the States for comments. The proposed Transition Plan is publicly available and can be viewed or downloaded electronically via the NRC's rulemaking Web site at http://ruleforum.llnl.gov. The NRC will consider State comments in finalizing the Transition Plan and plans to publish the final Transition Plan subsequent to the publication of the final rule but before the effective date of this final rule.

Comment: A commenter requested that to protect the supply chain with regard to radiopharmaceuticals, the NRC should work closely with OAS and the CRCPD, as well as the States themselves, to address any licensing or transactional issues that may arise as a result of the transition of authority.

NRC Response: The NRC has worked closely with OAS and CRCPD and involved the Agreement States and non-Agreement States throughout the rulemaking process and the development of the Transition Plan. The NRC is committed to continued cooperation with the States during the transition process.

Comments: A number of respondents emphasized the importance of stakeholder education and guidance to assure a smooth transition to the NRC's regulatory control. Two commenters expressed interest in the development of a comprehensive guidance document to be released upon implementation of the rule, and another commenter mentioned assistance to stakeholders through an outline of proposed revisions to the existing regulatory guidelines. One commenter also offered its organization's publications, websites, and meetings to assist the NRC with outreach to the medical user community.

NRC Response: The NRC is developing guidance in a separate action parallel to this rulemaking. A writing team was established in July 2006 to amend existing guidance and, if necessary, to develop new guidance within the NUREG-1556, "Consolidated Guidance About Materials Licenses," series of volumes to reflect the new authority over discrete sources of

radium-226 and the accelerator-produced radioactive material. The NRC is in the process of revising Volume 9, "Consolidated Guidance About Materials Licenses Program-Specific Guidance About Medical Use Licenses" and Volume 13, "Consolidated Guidance About Materials Licenses Program-Specific Guidance About Commercial Radiopharmacy Licenses." The NRC is developing new guidance, Volume 21, "Consolidated Guidance About Materials Licenses Program-Specific Guidance About Possession Licenses for Production of Radioactive Materials Using An Accelerator." The NUREG-1556 series provides guidance in areas of the NRC's jurisdiction and may be helpful to Agreement States. The NRC made the draft final guidance publicly available for comment after the draft final rule was made publicly available. The draft guidance documents were provided for comment to the States and the Advisory Committee on Medical Uses of Radioisotopes at that time. The NRC expects to finalize the guidance documents near the effective date of this rule (60 days after publication). The guidance documents are being published for use by current or potential NRC licensees. It is important to note that some Agreement States may already have similar guidance documents.

Comment: A commenter requested the NRC to confirm that on the effective date of the proposed rule, holders of licenses that authorize the use of licensed material at temporary job sites, where the NRC maintains jurisdiction, would be able to amend them to include accelerator-produced radionuclides. The commenter also requested the NRC to confirm that once such licenses were amended, the licensees would be able to perform activities using accelerator-produced materials authorized in the licenses, at temporary locations within non-Agreement States, upon termination of the waiver period on August 8, 2009.

NRC Response: On the effective date of this final rule or on the date of waiver termination, if that date is later, persons who use accelerator-produced radionuclides at temporary job sites may continue those activities regardless of whether they have an NRC license, provided that: (1) The person, with an NRC license that does not authorize use of

byproduct material at temporary job sites where the NRC has jurisdiction, applies for an amendment to its license to authorize uses at these temporary job sites on or before 6 months from the effective date of this final rule or on the date of waiver termination, if that date is later; or (2) The person without an NRC specific license applies for a license on or before 1 year from the effective date of this final rule or on the date of waiver termination, whichever is later.

If the person already has an NRC license authorizing the use of byproduct material at temporary job sites where the NRC has jurisdiction, the person may continue those activities. With the amended definition of *Byproduct material* in the NRC's regulations, the term "Byproduct material" in the existing license will be interpreted as including accelerator-produced radioactive material. It is possible that an amendment may be needed to increase the maximum activity limits or add specific sealed sources or devices to the license.

If the person did not use accelerator-produced materials at temporary job sites before the date of waiver termination, and its existing license does not authorize the use of byproduct material at temporary job sites, the person must apply for and receive a license or amendment before using these materials.

Comment: Two commenters stated that if the NRC required the States to change their statutes, then the effective date for the final rule should be extended by 5 years in order for Agreement States to amend their State statutes and regulations. One commenter stated that it agreed with the proposed effective date for the final rule and other implementation periods only if the NRC did not require such a change from the States.

NRC Response: The NRC does not believe that changes to the State statutes would be required by this rulemaking. The NRC will apply existing policies and procedures to work with the Agreement States in implementing this rule. These existing policies and procedures allow considerable flexibility by the States in meeting the compatibility requirements. The Agreement States will have up to 3 years to adopt the compatible requirements of this rule. The NRC will

continue to work with the States to resolve any issues that may arise.

Comment: A commenter called attention to the discussion in the Statements of Consideration for the proposed rule concerning the termination of the waiver issued by the NRC on August 31, 2005. The commenter noted that the discussion included a reference to a "special arrangement" that would need to be made between a State and the NRC if the State had not become an Agreement State by August 7, 2009, when the waiver will terminate. The commenter requested additional information on what would constitute a "special arrangement" between a State and the NRC, and how one could be obtained.

NRC Response: The NRC has considered this comment and has determined that the wording referred to by the commenter did not accurately describe the Commission's intent in this regard. What the Commission intended to convey was that it understands that situations may arise which may delay the completion and effective date of an Agreement. If an Agreement cannot be completed for a State before the waiver expires on August 8, 2009, the staff will determine, on a case-by-case basis, options to limit the impact of the transition of authority on affected users of the new byproduct material in the State.

The NRC has been communicating with the non-Agreement States that the Commission believes might be seeking an Agreement in order to avoid this type of situation. The Commission will continue to closely coordinate with these States and monitor the process of completing any Agreements with these States in order to decrease the likelihood that this type of situation will arise.

Comment: A commenter recommended that the NRC clarify whether any additional actions are needed on the part of licensees that are currently covered by the waivers issued to the States.

NRC Response: The waiver was issued to all persons, including individuals and licensees as well as States, that acquire, deliver, receive, possess, own, use, or transfer the

newly regulated byproduct material. No actions are needed on the part of these entities. Once the waiver is terminated, these persons or licensees are required to comply with the requirements of this rule or the corresponding requirements of the Agreement States.

Comment: A commenter felt that the discussion in the Statements of Consideration for the proposed rule under termination of the waiver for government agencies was not consistent with an earlier discussion in the Supplementary Information that concluded that radioactive materials would continue to be used in a manner protective of public health and safety. The commenter believed that the later discussion appeared to equate regulatory oversight with outcomes more protective of public health and safety. The commenter felt that the basis for concluding the waivers to be acceptable for a period of time, and then requiring termination of those waivers, should be explained.

NRC Response: The NRC does not agree that there are inconsistencies, as stated by the commenter, in the discussion in the Statements of Consideration for the proposed rule. As explained in the discussion concerning issuance of the waiver on August 31, 2005, the NRC was given regulatory authority over the new byproduct material when the EPAct became effective. Therefore, although the NRC did not have regulations in place that would specifically apply to this material, persons continuing to engage in activities involving the newly regulated byproduct material, and States seeking to continue to regulate this byproduct material would be in technical violation of the AEA. The NRC determined that it would be prudent to establish a mechanism to allow these activities to continue while the NRC established a regulatory framework for the new byproduct material. Section 651e(5) of the EPAct provides that the Commission could achieve this goal through issuing a waiver of the requirements of Section 651(e) if the Commission determined that the waiver was in accordance with the protection of public health and safety and the promotion of the common defense and security. The Commission determined that the waiver that it issued on August 31, 2005, met this

requirement. However, the EPAct also mandated that any such waiver issued would have to expire no more than 4 years after the date of the enactment of the EPAct. Therefore, the waivers must expire no later than August 8, 2009, although under the EPAct, the Commission may terminate waivers at an earlier time if it finds such termination is warranted.

As explained in the discussion concerning the termination of the waiver, the NRC established a Transition Plan, as required by Section 651(e) of the EPAct, to facilitate an orderly transition of regulatory authority once the Commission had established a regulatory framework for regulating the new byproduct material. This regulatory framework has now been established through promulgation of this final rule. In accordance with the provisions of the Transition Plan, and to facilitate the transition of regulatory authority in an orderly manner, the waivers will be terminated in stages for users of the new byproduct material. As explained in the discussion for termination of the waiver for Government agencies and Federally recognized Indian Tribes, the Commission determined to terminate the waiver for these entities on the effective date of the final rule because there is currently limited regulatory oversight for the newly added byproduct material at these facilities. Options will be considered, on a case-by-case basis, to limit the impact of the transition of the authority on affected users of the new byproduct material in the State. Terminating the waiver for these entities at that time will provide for regulatory oversight of the newly added byproduct material.

Comment: A commenter stated that it holds Agreement State licenses and licenses from the NRC that authorize “radioactive material” for a broad range of radionuclides, i.e., any byproduct material with atomic numbers 1 through 83 or any byproduct material with atomic numbers 84 through 102. It also holds NRC licenses that authorize “byproduct material” for the same broad range of radionuclides. The commenter requested that the newly regulated byproduct materials be authorized under the current license authorizations until the licenses are renewed or amended. The commenter recommended that one way to accomplish this would

be to provide a general license for specific licensees containing broad scope authorizations. As an alternate approach, the commenter suggested that the rule could provide that licensees authorized for such activities as using, receiving, or possessing radionuclides with a range of atomic numbers are similarly authorized with respect to the newly regulated radionuclides. The commenter stated that these licensees already have the controls in place to allow for safe handling of the new radionuclides and that the blanket authorization will save the licensees and the NRC paperwork and expenses. The commenter suggested that the NRC could request information by letter on which licensees are handling the newly regulated radionuclides.

NRC Response: From the commenter's description of its NRC specific license authorization, it should already be authorized to use the newly regulated byproduct material. With the amended definition of *Byproduct material* in the NRC regulations via this rule, the use of *Byproduct material* in an existing license will be interpreted as authorizing all radioactive materials that fall under the newly expanded definition of *Byproduct material*. With the broad authorization in the specific license, a license amendment would only be needed if the quantity possessed for one or more particular radionuclides exceeds the individual limits specified in the existing license authorization. If an amendment is needed, the regulations provide that all licensees have 6 months from the effective date of this final rule or from the waiver termination date to submit an amendment request. In addition, the amended regulation would allow licensees to continue to use the newly regulated materials until the NRC takes final licensing action provided that the amendment request was submitted within the allotted time. The NRC believes that it has already provided adequate relief in its regulations to assure a smooth transition once the licensee's waiver is terminated, and that neither a general license nor a rule change is necessary for this purpose.

Comment: Two commenters requested that the NRC allow sufficient time for users to prepare for the regulatory change by simultaneously terminating all waivers August 7, 2009,

and not chance the supply disruption of PET radionuclides, drugs, and biologics. The commenter stated that there were many differing State regulations for NARM, and that a step-by-step approach to terminating State waivers could leave unintended voids in the regulations, thus disrupting supplies of PET radionuclides. Another commenter requested that the NRC terminate all waivers at the same time on August 7, 2009, to avoid disruption. The commenter stated that accelerator-production facilities, which were designed and built to meet less restrictive State regulations, may require significant time to be modified to meet the NRC's regulations, and older facilities may require special approvals from the NRC.

NRC Response: The EPAct requires that all waivers must be terminated no later than 4 years after the date of enactment of the EPAct. As explained in the discussion concerning the termination of the waiver, the NRC established a Transition Plan, as required by Section 651(e) of the EPAct, to facilitate an orderly transition of regulatory authority once the Commission had established a regulatory framework for regulating the newly added byproduct material. This regulatory framework has now been established through promulgation of this final rule.

The NRC recognizes the importance of minimizing disruption of PET radionuclides, drugs, and biologics and that many States have regulatory programs for NARM. While all of the waivers cannot be terminated in conjunction with the August 7, 2009, statutory deadline, the NRC is revising the proposed rule [10 CFR 30.3(c)(2) and (c)(3), 10 CFR 32.1(c)(2), 10 CFR 35.11(c)(2), and 10 CFR 35.13(a)(2)] to provide for some waivers to be terminated in conjunction with the expiration of the waiver on August 7, 2009. One aspect of the implementation approach in the proposed rule provided that requests for licensing actions (e.g., amendments or new applications) would need to be received by the NRC on or before August 7, 2009, or earlier, depending upon the date of the waiver termination. This would essentially mean waivers would need to be terminated in August 2008, in order to provide all

affected persons the same amount of time, as discussed in the draft Transition Plan, to submit licensing actions to the NRC. In response to the comment, the NRC is revising the proposed rule to provide for some waivers to be terminated in conjunction with the expiration of the waiver on August 7, 2009. The NRC plans to terminate waivers in stages starting from the effective date of this final rule and ending on August 7, 2009. When the waiver is terminated for persons in a State, all persons in that State have to comply with the NRC regulations for the newly defined byproduct material, regardless of whether a license has been issued by the NRC. If the waiver has not been terminated for the State, all persons in the State are still permitted under the waiver to continue to use the newly defined byproduct material.

The NRC does not agree that supplies of PET radionuclides will be disrupted. Under the waiver, PET radionuclide production facilities can continue to produce PET radionuclides. Once the waiver is terminated, a PET radionuclide production facility may continue to produce PET radionuclides while its license application or amendment request is under review, provided that a license application is submitted within 1 year or an amendment request within 6 months from the date of waiver termination. Medical use licensees can continue to receive PET radionuclides from these production facilities or PET radioactive drugs from drug manufacturers or commercial nuclear pharmacies either under the waiver or under the NRC's regulations allowing continued operation provided that the license application or amendment request was submitted within the allotted time.

Comments: Two commenters stated that the transition time created by the waiver was critical for the non-Agreement States so that patient care and research activities could continue without interruption. These commenters requested that the NRC maintain the waiver until the local medical and scientific communities become fully prepared for the new licensing costs and requirements.

NRC Response: The EPAct authorized the NRC to grant waivers for 4 years from the

date of enactment of the Act; it did not include any provisions that would allow the NRC to extend the waiver beyond the statutory deadline of August 8, 2009. The NRC recognizes the importance of continuing patient care and research activities without interruption and the need for local medical and scientific communities to have adequate time to become fully prepared for the new licensing costs and requirements.

The NRC has taken several steps to ensure a smooth transition of the NRC's regulatory authority over the newly defined byproduct material. In addition to preparing a Transition Plan, the NRC has, in this rulemaking, included regulatory provisions for persons or licensees in a non-Agreement State to continue using the newly defined byproduct material after the waiver is terminated for that State provided a license application or an amendment request is submitted within the allotted time frame. The NRC believes that its transitioning approach and the regulatory provisions will provide adequate time for licensees to transition to the new regulations without interrupting patient care or research for the following reasons: First, most medical and scientific communities in the non-Agreement States are already using both the traditional byproduct materials and the newly defined byproduct materials in similar uses; therefore, regulatory impact, including licensing fees and radiation safety programs, to these people should be minimal to none. Second, the NRC has made rulemaking-related documents and draft rules publicly available to keep stakeholders informed. Third, the NRC has allowed time for applicants to prepare new license applications or amendment requests in the regulations, during which they may continue to use the newly regulated byproduct material to provide for a smoother transition.

Comment: Two commenters were concerned that a "phased-in" approach for terminating the waivers issued in August 2005 had not been structured to allow for the transfer of PET radionuclides, drugs, and biologics to an NRC licensee from a radionuclide or drug production facility using accelerators that has not yet had the waiver terminated. One

commenter asked for clarification of potential impacts to the medical community due to early termination of the waiver to Federal facilities such as Veterans Hospitals (i.e., could Federal facilities still accept radioactive drugs from companies that are still covered under the waiver).

NRC Response: The NRC's phased waiver termination plan will not affect the transfer of PET radionuclides, drugs, and biologics to an NRC licensee from a PET radionuclide production facility that has not yet had the NRC waiver terminated. For example, a Government agency that is currently receiving PET radionuclides or drugs under the waiver may continue to be able to receive PET radionuclides or drugs from a PET radionuclide and drug producer or distributor when its waiver is terminated. Upon waiver termination, the Government agency's existing license or MML permit may already be authorized to receive PET drugs if the license or MML permit is for all *Byproduct material*. If the Government agency has used PET radionuclides and drugs under the waiver and the license (or MML permit) needs to be amended, the Government agency may continue to use the PET radionuclides and drugs while preparing the amendment and until the NRC (or the MML licensee) makes its final licensing decision, provided that an amendment request is submitted within 6 months from the date of waiver termination. If the Government agency used PET radionuclides and drugs under the waiver and did not have an NRC license (or MML permit), the Government agency may still continue to use the PET radionuclides and drugs while preparing a new license application and until the NRC (or the MML licensee) makes its final licensing decision, provided that a license application is submitted within 1 year from the date of waiver termination.

While all of the waivers cannot be terminated in conjunction with the August 7, 2009, statutory deadline, the NRC is revising the proposed rule [10 CFR 30.3(c)(2) and (c)(3), 10 CFR 32.1(c)(2), 10 CFR 35.11(c)(2), and 10 CFR 35.13(a)(2)] to provide for some waivers to be terminated in conjunction with the expiration of the waiver on August 7, 2009. The NRC plans to terminate waivers in stages starting from the effective date of this final rule and ending on

August 7, 2009.

These same principles would apply to the PET radionuclide and drug producers or distributors. After this rule becomes effective, the PET radionuclide and drug producers or distributors may continue to operate until the waiver is terminated for them. Once the waiver is terminated, they may continue to operate if the existing license authorizes all "byproduct material" or as authorized by this rule while preparing a new license application or an amendment request or while waiting for the NRC's final licensing decision, provided that the license application or amendment request is submitted within the allotted time as stated in this rule.

IV. Section-by-Section Analysis of Final Revisions.

PART 20 – STANDARDS FOR PROTECTION AGAINST RADIATION.

The authority citation for this part is revised to reflect the EPAct.

Section 20.1003 – Definitions.

The definition of *Byproduct material* is revised to reflect the new definition as mandated in Section 651(e) of the EPAct.

Definitions for *Accelerator-produced radioactive material*, *Discrete source*, and *Particle accelerator* are added.

A definition of *Waste* is added to clarify that, as mandated by the EPAct, byproduct material as defined in Sections 11e.(3) and 11e.(4) of the AEA is not low-level radioactive waste as defined in the LLRWPAA.

Section 20.1009 – Information collection requirements: OMB approval.

Reference to § 20.2008 is added.

Section 20.2001 – General requirements.

Paragraph (a)(4) is revised to include the new § 20.2008 which addresses disposal of waste.

Section 20.2006 – Transfer for disposal and manifests.

Paragraph (e) is added to require the use of uniform manifests for disposal of byproduct material as defined in Sections 11e.(3) and 11e.(4) of the AEA if intended for ultimate disposal at a land disposal facility licensed under 10 CFR Part 61.

Section 20.2008 – Disposal of certain byproduct material.

This section is added to part 20 to address disposal requirements for byproduct material as defined in Sections 11e.(3) and 11e.(4) of the AEA.

Appendix B to Part 20--Annual Limits on Intake (ALIs) and Derived Air Concentrations (DACs) of Radionuclides for Occupational Exposure; Effluent Concentrations; Concentrations for Release to Sewerage

The List of Elements table is revised to include the elements nitrogen and oxygen that are now considered byproduct material. Tables 1, 2, and 3 are revised to specifically include nitrogen-13 and oxygen-15 and their associated values.

PART 30 – RULES OF GENERAL APPLICABILITY TO DOMESTIC LICENSING OF BYPRODUCT MATERIAL.

The authority citation for this part is revised to reflect the EPAct.

Section 30.3 – Activities requiring license.

This section is revised to inform Government agencies, Federally recognized Indian Tribes, other licensees, and other persons who possessed and used byproduct material as defined in Section 11e.(3) of the AEA under the provisions of NRC's waiver (70 FR 51581; August 31, 2005) which sections of the regulations will apply to them when their waiver is terminated before issuance of an amendment or new license for byproduct material. For the Government agencies and Federally recognized Indian Tribes, requirements for the newly added byproduct material will apply to them on the effective date of the final rule.

This section is also revised to allow for transition for Government agencies, Federally recognized Indian Tribes, other persons, and other licensees, who possessed and used byproduct material as defined in Section 11e.(3) of the AEA under the waiver, to continue to use these materials while applying for and receiving licenses or amendments to existing licenses. This section revises the authority and responsibilities of persons or licensees that do not file for the license or amendment within the required time with respect to receipt, use, possession, and disposal of byproduct material and the decommissioning of facilities.

Section 30.4 – Definitions.

The definition of *Byproduct material* is revised to be consistent with the new definition in the AEA, with the exception that it does not include byproduct material as defined in Section 11e.(2) of the AEA.

The following definitions are added to this section: *Accelerator-produced radioactive material*, *Consortium, Cyclotron*, *Discrete source*, and *Particle accelerator*.

Section 30.15 – Certain items containing byproduct material.

This section is revised to add paragraph (a)(1)(viii) to authorize 0.037 MBq (1 μCi) of radium-226 per timepiece in intact timepieces manufactured before the effective date of the final rule.

Section 30.18 – Exempt quantities.

Paragraph (b) is revised to include byproduct material received or acquired before September 25, 1971, under a general license provided in 10 CFR 31.4 or by a State provision similar to 10 CFR 31.4.

Section 30.20 – Gas and aerosol detectors containing byproduct material.

Paragraph (a) is revised to apply to gas and aerosol detectors manufactured or distributed before the effective date of the final rule in accordance with a specific license issued by a State with comparable provisions to 10 CFR 32.26.

Section 30.32 – Application for specific licenses.

Paragraph (g) is revised to accept information from sealed source or device registrations with regard to NARM issued by the States under provisions comparable to 10 CFR 32.210 as a basis for licensing the use of sources and devices. The paragraph is also revised to allow a basis for licensing sources or devices containing NARM, that were manufactured before the effective date of the final rule, are not registered with the Commission under 10 CFR 32.210 or with an Agreement State, and for which all the information identified in 10 CFR 32.210 is unavailable.

Paragraph (j) is added to this section to inform an educational institution, a medical facility, or a Government facility applicant of the information required by the NRC to authorize

the production of PET radioactive drugs used for medical uses under 10 CFR part 35 for the noncommercial transfer to medical facilities in its consortium.

Section 30.34 – Terms and conditions of licenses.

Paragraph (g) is revised to require licensees to measure strontium-82 and strontium-85 contamination before use of the first eluate when eluding strontium-82/rubidium-82 generators.

Paragraph (j) is added to clarify that nothing in the authorization under 10 CFR 30.32(j) relieves the licensee from complying with FDA, other Federal, or State requirements for radioactive drugs, and to include requirements associated with the labeling and production of PET radioactive drugs by licensees authorized under the provisions of 10 CFR 30.32(j) to produce PET radioactive drugs for the noncommercial transfer to medical use licensees in their consortium. This section also requires licensees to use the notification process in 10 CFR 32.72 when permitting qualified authorized nuclear pharmacists to work as ANPs.

Section 30.71 – Schedule B.

Schedule B is revised to include 13 radionuclides that are now considered byproduct material and their associated exempt quantities.

Section 30.72 – Schedule C -- Quantities of radioactive materials requiring consideration of the need for an emergency plan for responding to a release.

The table in Schedule C is revised to specifically include radium-226 and its associated values.

PART 31 – GENERAL DOMESTIC LICENSES FOR BYPRODUCT MATERIAL.

The authority citation for this part is revised to reflect the EPAct.

Section 31.4 – Information collection requirements: OMB approval.

Reference to § 31.12 is added.

Section 31.5 – Certain detecting, measuring, gauging, or controlling devices and certain devices for producing light or an ionized atmosphere.

Paragraph (b)(1) is revised to add authority under the general license for byproduct material contained in devices which have been manufactured or initially transferred and labeled in accordance with the specifications contained in an equivalent specific license issued by a State with comparable provisions to 10 CFR 32.51.

Paragraph (c)(13)(i) is revised to add radium-226, with an activity of at least 3.7 MBq (0.1 mCi) to the criteria for devices requiring registration.

Section 31.8 – Americium-241 and radium-226 in the form of calibration or reference sources.

The section heading and paragraph (a) are revised to include radium-226 in a general license for calibration and reference sources.

Paragraph (b) is revised to recognize sources manufactured or initially transferred in accordance with the specifications contained in a specific license issued by a State with comparable provisions to 10 CFR 32.57.

Paragraph (c)(1) is revised to include an activity limit of 0.185 MBq (5 μCi) of radium-226.

Paragraph (c)(2) is revised to include radium-226 in the labeling requirement, with the provision added to footnote 1 that, for those sources manufactured before the effective date of the final rule, sources containing radium-226 shall be labeled in accordance with the applicable State regulations at the time of manufacture or import.

Paragraphs (c)(4), (d), and (e) are revised to include radium-226.

Section 31.11 – General license for use of byproduct material for certain in vitro clinical or laboratory testing.

Paragraphs (a) and (c) are revised to include cobalt-57 in the list of authorized byproduct material for use in in vitro clinical or laboratory testing.

Paragraph (d) is revised to allow receipt of prepackaged units that are labeled in accordance with a specific license issued by a State with comparable provisions to 10 CFR 32.71.

Sections 31.12, 31.13, and 31.14 are redesignated as §§ 31.21, 31.22, and 31.23, respectively.

Section 31.12 – General license for certain items and self-luminous products containing radium-226.

This section is added to the regulations to add a general license for certain items and self-luminous products containing radium-226 that were manufactured before the effective date of the final rule. The general license addresses radium-226 contained in products such as antiquities; timepieces; luminous items installed in air, marine, or land vehicles; all other luminous products; and small radium sources containing no more than 0.037 MBq (1 μCi) of radium-226.

The general license exempts persons from the provisions of 10 CFR parts 19, 20, and 21, and 10 CFR 30.50 and 10 CFR 30.51.

The general license includes requirements for notification, reporting, disposal, and certain prohibitions. However, the general license allows timepieces containing radium-226 to

be disassembled and repaired.

PART 32 – SPECIFIC DOMESTIC LICENSES TO MANUFACTURE OR TRANSFER CERTAIN ITEMS CONTAINING BYPRODUCT MATERIAL.

The authority citation for this part is revised to reflect the EPAct.

Section 32.1 – Purpose and scope.

A new paragraph (c) is added to inform Government agencies, Federally recognized Indian Tribes, other licensees, and other persons who manufacture or initially transfer items containing accelerator-produced radioactive material or discrete sources of radium-226 for sale or distribution to persons exempted from the licensing requirements of part 30 of this chapter, and persons generally licensed under part 31 or part 35 of this chapter, and radioactive drugs and sources and devices to medical use licensees, that the requirements in part 32 will apply to them when their waiver is terminated before issuance of an amendment or new license for such activities. The requirements will apply to Government agencies and Federally recognized Indian Tribes on the effective date of the final rule.

This paragraph allows Government agencies, Federally recognized Indian Tribes, other persons, and other licensees who manufacture or initially transfer items containing accelerator-produced radioactive material or discrete sources of radium-226 for sale or distribution to persons exempted from the licensing requirements of part 30 of this chapter, persons generally licensed under part 31 or part 35 of this chapter, and radioactive drugs and sources and devices to medical use licensees to continue to manufacture or initially transfer these items to such persons when their waiver is terminated before issuance of an amendment or new license for such activities.

Section 32.57 – Calibration or reference sources containing americium-241 or radium-226: Requirements for license to manufacture or initially transfer.

The heading and the section are revised to add radium-226.

Section 32.58 – Same: Labeling of devices.

This section is revised to include radium-226 in the example label.

Section 32.59 – Same: Leak testing of each source.

This section is revised to include radium-226.

Section 32.71 – Manufacture and distribution of byproduct material for certain in vitro clinical or laboratory testing under general license.

Paragraph (b)(8) is added to include cobalt-57, in units not exceeding 0.37 MBq (10 μCi) each, to the list of authorized byproduct material approved for distribution.

Paragraph (c)(1) is revised to include cobalt-57.

Section 32.72 – Manufacture, preparation, or transfer for commercial distribution of radioactive drugs containing byproduct material for medical use under part 35.

Paragraph (a) is revised to ensure that the NRC's regulation encompasses all drug manufacturers that are registered with the FDA or a State agency. The description of who is registered with the FDA was updated to conform with FDA regulations.

Paragraph (b) is revised to recognize nuclear pharmacists, who prepared only accelerator-produced radioactive drugs, before the effective date of the final rule and authorized nuclear pharmacists identified on permits issued by master material licensees or by a master material permittee of broad scope, to work as authorized nuclear pharmacists at a

commercial nuclear pharmacy under the notification process in 10 CFR 32.72.

Section 32.102 Schedule C – prototype tests for calibration or reference sources containing americium-241 or radium-226.

The heading and section are revised to include radium-226.

PART 33 – SPECIFIC DOMESTIC LICENSES OF BROAD SCOPE FOR BYPRODUCT MATERIAL.

The authority citation for this part is revised to reflect the EPAct.

Section 33.100 Schedule A.

This table is revised to add four additional radionuclides and their associated values.

PART 35 – MEDICAL USE OF BYPRODUCT MATERIAL.

The authority citation for this part is revised to reflect the EPAct.

Section 35.2 – Definitions.

The definitions of *Cyclotron* and *Positron Emission Tomography (PET) radionuclide production facility* are added.

Section 35.10 – Implementation.

Paragraph (a) is added to clarify that Government agencies and Federally recognized Indian Tribes possessing and using accelerator-produced radioactive material and discrete sources of radium-226 for medical use must comply with the requirements in this part on the effective date of the final rule. The paragraph also informs other persons using this material for

medical use when they must comply with the requirements of this part.

Section 35.11 – License required.

Paragraph (a) is revised, and paragraph (c) is added to allow Government agencies, Federally recognized Indian Tribes, and other persons who possessed and used accelerator-produced radioactive materials or discrete sources of radium-226, under the provisions of the NRC's waiver (70 FR 51581; August 31, 2005), to have time to apply for and receive a new medical use license and allow them to continue to use these materials, provided the new license was applied for in the time required. This section also provides the time period for applying for a new license.

Section 35.13 – License amendments.

Paragraph (a) is modified to allow Government agencies, Federally recognized Indian Tribes, and other licensees that possessed and used accelerator-produced radioactive materials or discrete sources of radium-226, under the provisions of the NRC's waiver (70 FR 51581; August 31, 2005), to continue to use this material provided that they submit an application to amend their licenses in the specified time required. This section also provides the time period for amending licenses.

A new paragraph (b)(5) is added to permit physicians and pharmacists who only used accelerator-produced radioactive materials or discrete sources of radium-226 during the NRC's waiver (70 FR 51581; August 31, 2005) to use the notification process.

Paragraph (e) is modified to require an amendment before a licensee adds to, or changes, areas of use identified in the application or on the license, including areas used in accordance with either 10 CFR 35.100 or 35.200 if the change includes the addition or relocation of either an area where PET radionuclides are produced or a PET radioactive drug

delivery line from the PET radionuclide/PET radioactive drug production area. Other areas of use where byproduct material is used only in accordance with either 10 CFR 35.100 or 10 CFR 35.200 continue to be excluded from this requirement.

Section 35.14 – Notifications.

Paragraph (a) is revised to address information needed for NRC notification of nuclear pharmacists and physicians who used only accelerator-produced radioactive materials and discrete sources of radium-226 who have not been identified on a license or permit during the NRC's waiver (70 FR 51581; August 31, 2005).

Paragraph (b) is revised to retain, in the notification requirements, any additions or changes in 10 CFR 35.100 or 10 CFR 35.200 areas of use, if the changes do not involve additions or relocations of either an area where PET radionuclides are produced or a PET radioactive drug delivery line from the PET radionuclide/PET radioactive drug production area.

Section 35.15 – Exemptions regarding Type A specific licenses of broad scope.

Paragraph (f) is revised to clarify that the broad scope licensee is exempted from making the notification of addition or changes in 10 CFR 35.100 or 10 CFR 35.200 areas of use.

Section 35.57 – Training for experienced Radiation Safety Officer, teletherapy or medical physicist, authorized medical physicist, authorized user, nuclear pharmacist, and authorized nuclear pharmacist.

A new paragraph (a)(3) is added to grandfather RSOs, medical physicists, or nuclear pharmacists who used only accelerator-produced radioactive materials or discrete sources of radium-226, or both, during the NRC's waiver (70 FR 51581; August 31, 2005) from training

requirements and to recognize them as RSOs, AMPs, or ANPs for those same materials and uses.

A new paragraph (b)(3) is added to grandfather physicians, dentists, or podiatrists who used only accelerator-produced radioactive materials or discrete sources of radium-226, or both, under the NRC's waiver (70 FR 51581; August 31, 2005) from training requirements and to recognize them as AUs for those same materials and uses.

Section 35.63 – Determination of dosages of unsealed byproduct material for medical use.

This section is revised to add a new provision in paragraphs (b)(2) and (c)(3) to include PET radioactive drug producers licensed under 10 CFR 30.32(j) for the production of PET radioactive drugs transferred noncommercially to members of their consortium.

Section 35.100 – Use of unsealed byproduct material for uptake, dilution, and excretion studies for which a written directive is not required.

Paragraph (a) is revised to permit medical use licensees to obtain PET drugs from PET radioactive drug producers licensed under 10 CFR 30.32(j) for the production of PET radioactive drugs transferred noncommercially to members of their consortium.

Paragraph (b) is revised to continue to clarify that 10 CFR 35.100 licensees are not allowed to produce PET radionuclides.

Section 35.200 – Use of unsealed byproduct material for imaging and localization studies for which a written directive is not required.

Paragraph (a) is revised to permit medical use licensees to obtain PET drugs from PET radioactive drug producers licensed under 10 CFR 30.32(j) for the production of PET

radioactive drugs transferred noncommercially to members of their consortium.

Paragraph (b) is revised to clarify that 10 CFR 35.200 licensees are not allowed to produce PET radionuclides.

Section 35.204 – Permissible molybdenum-99, strontium-82, and strontium-85 concentrations.

The section heading is revised to add strontium-82 and strontium-85.

Paragraph (a) is revised to address acceptable strontium-82 and strontium-85 concentrations when eluting strontium-82/rubidium-82 generators.

Paragraph (c) is revised and redesignated, and a new paragraph (c) is added to address measuring requirements for strontium-82 and strontium-85.

Section 35.300 – Use of unsealed byproduct material for which a written directive is required.

Paragraph (a) is revised to permit medical use licensees to obtain PET drugs from PET radioactive drug producers licensed under 10 CFR 30.32(j) for the production of PET radioactive drugs transferred noncommercially to members of their consortium.

Paragraph (b) is revised to clarify that 10 CFR 35.300 licensees are not allowed to produce PET radionuclides.

Section 35.2204 – Records of molybdenum-99, strontium-82, and strontium-85 concentrations.

The section heading is revised to add strontium-82 and strontium-85, and this section is revised to include a recordkeeping requirement of the strontium-82 and strontium-85 concentration tests required by 10 CFR 35.204(b) and (c).

PART 50 – DOMESTIC LICENSING OF PRODUCTION AND UTILIZATION FACILITIES.

The authority citation for this part is revised to reflect the EPAct.

Section 50.2 – Definitions.

The definition of *Byproduct material* is revised to be consistent with the new definition as mandated by the EPAct, with the exception that it will not include byproduct material as defined in Section 11e.(2) of the AEA.

PART 61 – LICENSING REQUIREMENTS FOR LAND DISPOSAL OF RADIOACTIVE WASTE.

The authority citation for this part is revised to reflect the EPAct.

Section 61.2 – Definitions.

The definition of *Waste* is revised to clarify that, as mandated by the EPAct, byproduct material, as defined in Sections 11e.(3) and 11e.(4) of the AEA, is not low-level radioactive waste as defined in the LLRWPAA.

PART 62 – CRITERIA AND PROCEDURES FOR EMERGENCY ACCESS TO NON-FEDERAL AND REGIONAL LOW-LEVEL WASTE DISPOSAL FACILITIES.

The authority citation for this part is revised to reflect the EPAct.

Section 62.2 – Definitions.

The definition of *Low-level radioactive waste (LLW)* is revised to clarify that byproduct material, as defined in Sections 11e.(3) and 11e.(4) of the AEA, is not considered low-level radioactive waste.

PART 72 – LICENSING REQUIREMENTS FOR THE INDEPENDENT STORAGE OF SPENT NUCLEAR FUEL, HIGH-LEVEL RADIOACTIVE WASTE, AND REACTOR-RELATED GREATER THAN CLASS C WASTE.

Section 72.3 – Definitions.

The definition of *Byproduct material* is revised to be consistent with the definition in 10 CFR 30.4. This definition is consistent with the definition of *Byproduct material* in the EPAct, with the exception that it will not include byproduct material as defined in Section 11e.(2) of the AEA.

PART 110 – EXPORT AND IMPORT OF NUCLEAR EQUIPMENT AND MATERIAL.

The authority citation for this part is revised to reflect the EPAct.

Section 110.2 – Definitions.

Definitions of *Accelerator-produced radioactive material*, *Discrete source*, and *Particle accelerator* are added.

PART 150 – EXEMPTIONS AND CONTINUED REGULATORY AUTHORITY IN AGREEMENT STATES AND IN OFFSHORE WATERS UNDER SECTION 274.

The authority citation for this part is revised to reflect the EPAct.

Section 150.3 – Definitions.

The definition of *Byproduct material* is revised to be consistent with the definition in the EPAct.

A definition of *Discrete source* is added.

PART 170 – FEES FOR FACILITIES, MATERIALS, IMPORT AND EXPORT LICENSES, AND OTHER REGULATORY SERVICES UNDER THE ATOMIC ENERGY ACT OF 1954, AS AMENDED.

The authority citation for this part is revised to reflect the EPAct.

Section 170.3 – Definitions.

The definition of *Byproduct material* is revised to be consistent with the new definition in the AEA, with the exception that it does not include byproduct material as defined in Section 11e.(2) of the AEA.

Section 170.31 – Schedule of fees for materials licenses and other regulatory services, including inspections, and import and export licenses.

This section is revised to include licenses that are not included in existing fee categories. Fee Category 3.B. is revised to include licenses for repair, assembly, and disassembly of products containing radium-226. Two new fee categories, 3.R. with additional subcategories and 3.S., are added to include fees for possession of items or products containing radium-226, which exceed the number of items or limits specified in 10 CFR 31.12, and for production of accelerator-produced radioactive material.

PART 171 – ANNUAL FEES FOR REACTOR 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 THE NRC.

The authority citation for this part is revised to reflect the EPAct.

Section 171.5 – Definitions.

The definition of *Byproduct material* is revised to be consistent with the new definition in the AEA, with the exception that it does not include byproduct material as defined in Section 11e.(2) of the AEA.

Section 171.16 – Annual fees: Materials licenses, holders of certificates of compliance, holders of sealed source and device registrations, holders of quality assurance program approvals, and government agencies licensed by the NRC.

This section is revised to include licenses that are not included in existing fee categories. Fee Category 3.B. is revised to include licenses for repair, assembly, and disassembly of products containing radium-226. Two new fee categories, 3.R. with additional subcategories and 3.S., are added to include fees for possession of items or products containing radium-226, which exceed the number of items or limits specified in 10 CFR 31.12, and for production of accelerator-produced radioactive material.

V. Criminal Penalties

For the purpose of Section 223 of the Atomic Energy Act (AEA), the Commission is amending 10 CFR Parts 20, 30, 31, 32, 33, 35, 50, 61, 62, 72, 110, 150, 170, and 171 under one or more of Sections 161b, 161i, or 161o of the AEA. Willful violations of the rule would be subject to criminal enforcement.

VI. Agreement State Compatibility

Under the “Policy Statement on Adequacy and Compatibility of Agreement State

Programs" approved by the Commission on June 30, 1997, and published in the Federal Register (62 FR 46517; September 3, 1997), this rule would be a matter of compatibility between the NRC and the Agreement States, thereby providing consistency among the Agreement States' and the NRC's requirements. The NRC staff analyzed the rule in accordance with the procedure established within Part III, "Categorization Process for NRC Program Elements," of Handbook 5.9 to Management Directive 5.9, "Adequacy and Compatibility of Agreement State Programs" (a copy of which may be viewed at http://www.nrc.gov/reading-rm/doc-collections/management-directives/).

The NRC program elements (including regulations) are placed into four compatibility categories (See the Compatibility Table in this section). In addition, the NRC program elements can also be identified as having particular health and safety significance or as being reserved solely to the NRC. Compatibility Category A are those program elements that are basic radiation protection standards and scientific terms and definitions that are necessary to understand radiation protection concepts. An Agreement State should adopt Category A program elements in an essentially identical manner to provide uniformity in the regulation of agreement material on a nationwide basis. Compatibility Category B are those program elements that apply to activities that have direct and significant effects in multiple jurisdictions. An Agreement State should adopt Category B program elements in an essentially identical manner. Compatibility Category C are those program elements that do not meet the criteria of Category A or B, but the essential objectives of which an Agreement State should adopt to avoid conflict, duplication, gaps, or other conditions that would jeopardize an orderly pattern in the regulation of agreement material on a nationwide basis. An Agreement State should adopt the essential objectives of the Category C program elements. Compatibility Category D are those program elements that do not meet any of the criteria of Category A, B, or C, above, and, thus, do not need to be adopted by Agreement States for purposes of compatibility.

Health and Safety (H&S) are program elements that are not required for compatibility but are identified as having a particular health and safety role (i.e., adequacy) in the regulation of agreement material within the State. Although not required for compatibility, the State should adopt program elements in this H&S category based on those of the NRC that embody the essential objectives of the NRC program elements because of particular health and safety considerations. Compatibility Category NRC are those program elements that address areas of regulation that cannot be relinquished to Agreement States under the AEA, as amended, or provisions of Title 10 of the Code of Federal Regulations. These program elements are not adopted by the Agreement States. The following table lists the parts and sections that would be revised and their corresponding categorization under the "Policy Statement on Adequacy and Compatibility of Agreement State Programs." A bracket around a category means that the section may have been adopted elsewhere, and it is not necessary to adopt it again.

The definition of *Byproduct material* in the AEA was expanded by Section 651(e) of the EPAct to incorporate certain discrete sources of radium-226 and certain accelerator-produced radioactive materials. The definition of *Byproduct material* in 10 CFR parts 20, 30, 50, 72, 150, 170, and 171 is amended to reflect the changes to the AEA. The definition of *Byproduct material* in parts 50, 72, 170, and 171 is reserved to the NRC. The definition of *Byproduct material* in 10 CFR parts 20, 30, and 150 are categorized as H&S. This designation is for regulatory program elements that have particular health and safety significance. The H&S designation indicates that the definition is needed for purposes of “adequacy.” If NARM is included in the Agreement between the NRC and the Agreement State, then NARM would be a necessary program element of the Agreement State program to adequately ensure public health and safety. The definition of *Discrete source* has also been identified in this rule as H&S because it is part of the definition of *Byproduct material*.

Compatibility Table

Section	Change	Subject	Compatibility	
			Existing	New
20.1003	Amend	Definition: *Byproduct Material* (add 11e.(3) & 11e.(4) material)	[A]	[H&S]
20.1003	Add	Definition: *Discrete Source*	-	H&S
20.1003	Add	Definition: *Particle Accelerator*	-	H&S
20.1003	Add	Definition: *Waste*	-	B
20.1009	Amend	List of OMB approved information collections	D	D
20.2001 (a)(4)	Amend	General requirements (add reference to new § 20.2008)	C	C
20.2006 (e)	Add	Transfer for disposal and manifests (add 11e.(3) and 11e.(4) byproduct material)	-	B
20.2008	Add	Disposal of 11e.(3) and 11e.(4) byproduct material (new section)	-	B
Appendix B to Part 20	Amend	Add limits for N-13 and O-15	A	A
30.3 (a)	Amend	Activities requiring license (add reference to paragraph (c))	C	C
30.3 (b)(1)	Add	Activities requiring license (requirements that apply to Government agencies and Federally recognized Indian Tribes at waiver termination)	-	NRC
30.3 (b)(2)	Add	Activities requiring license (authorization for Government agencies and Federally recognized Indian Tribes to possess and use 11e.(3) materials while applying for a license amendment)	-	NRC

Section	Change	Subject	Compatibility	
			Existing	New
30.3 (b)(3)	Add	Activities requiring license (authorization for Government agencies and Federally recognized Indian Tribes to possess and use 11e.(3) materials while applying for a new license)	-	NRC
30.3 (c)(1)	Add	Activities requiring license (requirements that apply to all other persons at waiver termination)	-	D
30.3 (c)(2)	Add	Activities requiring license (authorization for all other persons to possess and use 11e.(3) materials while applying for a license amendment)	-	D
30.3 (c)(3)	Add	Activities requiring license (authorization for all other persons to possess and use 11e.(3) materials while applying for a new license)	-	D
30.3 (d)	Add	Activities requiring license (continuation of authority for failure to submit amendment or license)	-	D
30.4	Add	Definition: *Accelerator-produced radioactive material*	-	H&S
30.4	Amend	Definition: *Byproduct material* (add 11e.(3) & 11e.(4) material)	[A]	[H&S]
30.4	Add	Definition: *Consortium*	-	C
30.4	Add	Definition: *Cyclotron*	-	D
30.4	Add	Definition: *Discrete source*	-	H&S
30.4	Add	Definition: *Particle accelerator*	-	H&S
30.15 (a)(1)(viii)	Add	Certain items containing byproduct material (add radium-226 intact timepieces and limited repairs)	B (all § 30.15)	B

Section	Change	Subject	Compatibility	
			Existing	New
30.18 (b)	Amend	Exempt quantities (add 11e.(3) material)	B (all § 30.18)	B
30.20 (a)	Amend	Gas and aerosol detectors containing byproduct material (grandfather 11e.(3) detectors)	B (all § 30.20)	B
30.32 (g)	Amend	Application for specific licenses	C	C
30.32 (j)	Add	Application for specific licenses (add noncommercial transfer of PET drugs)	-	B
30.34 (g)	Amend	Terms and conditions of licenses (add strontium-82/rubidium-82 generators)	D	H&S
30.34 (j)	Add	Terms and conditions of licenses (add noncommercial transfer of PET drugs)	-	B
30.71	Amend	Schedule B (add 11e.(3) material)	B	B
30.72	Amend	Schedule C - Quantities of radioactive materials requiring consideration of the need for an emergency plan for responding to a release (add radium-226)	H&S	H&S
31.4	Amend	List of OMB approved information collections	D	D
31.5 (b)(1) & (c)(13)	Amend	Certain detecting, measuring, gauging, or controlling devices and/or an ionizing atmosphere (add devices with NARM approved by States)	B (all § 31.5)	B
31.8	Amend	Americium-241 in the form of calibration or reference sources (add radium-226)	D	D
31.11	Amend	General license for use of byproduct material for certain in vitro clinical or laboratory testing (add cobalt-57)	D	D

Section	Change	Subject	Compatibility	
			Existing	New
31.12	Add	General license for certain items and self-luminous products containing radium-226 (new section)	-	C
32.1 (c)(1)	Add	Purpose and scope (requirements that apply to Government agencies and Federally recognized Indian Tribes at waiver termination and authorization to manufacture and distribute items with 11e.(3) material while applying for amendment or license)	-	NRC
32.1 (c)(2)	Add	Purpose and scope (requirements that apply to all other persons at waiver termination and authorization to manufacture and distribute items with 11e.(3) material while applying for amendment or license)	-	D
32.57	Amend	Calibration or reference sources containing americium-241: Requirements for license to manufacture or initially transfer (add radium-226)	B	B
32.58	Amend	Same: Labeling of devices (add radium-226)	B	B
32.59	Amend	Same: Leak testing of each source (add radium-226)	B	B
32.71 (b)(8) & (c)(1)	Add	Manufacture and distribution of byproduct material for certain in vitro clinical or laboratory testing under general license (add cobalt-57)	B	B

Section	Change	Subject	Compatibility	
			Existing	New
32.72 (a)(2)(i), (iii), (iv), (v), & (b)	Amend	Manufacture, preparation, or transfer for commercial distribution of radioactive drugs containing byproduct material for medical use under part 35 (recognize FDA and State registrations of PET facilities and pharmacist using 11e.(3) material)	B	B
32.102	Amend	Schedule C - prototype tests for calibration or reference sources containing americium-241 (add radium-226)	B	B
33.100	Amend	Schedule A (add beryllium-7, cobalt-57, radium-226, & sodium-22)	D	D
35.2	Add	Definition: *Cyclotron*	-	D
35.2	Add	Definition: *Positron Emission Tomography (PET) radionuclide production facility*	-	H&S
35.10 (a)	Add	Implementation (requirements that apply at waiver termination)	-	D
35.10 (g)	Redesignated	Implementation	-	D
35.11 (a)	Amend	License required (reference to § 35.11(c))	C	C
35.11 (c)(1)	Add	License required (authorize medical use of 11e.(3) materials by Government agencies and Federally recognized Indian Tribes while applying for license)	-	NRC
35.11 (c)(2)	Add	License required (authorize medical use of 11e.(3) materials by all other persons while applying for license)	-	D

Section	Change	Subject	Compatibility	
			Existing	New
35.13 (a)(1)	Amend	License amendments (authorize medical use of 11e.(3) materials by Government agencies and Federally recognized Indian Tribes while applying for amendment)	-	NRC
35.13 (a)(2)	Amend	License amendments (authorize medical use of 11e.(3) materials by all other licensees while applying for amendment)	-	D
35.13 (b)(5)	Add	License amendments (grandfather physicians and pharmacists that used 11e.(3) material)	D	D
35.13 (e)	Amend	License amendments (clarify amendment need)	D	D
35.14 (a) and (b)(4)	Amend	Notifications (using notification to allow continued operation for certain 11e.(3) material)	D	D
35.15 (f)	Amend	Exemptions regarding Type A specific licenses of broad scope (clarify the exemption)	D	D
35.57 (a)(3) & (b)(3)	Add	Training for experienced Radiation Safety Officer, teletherapy or medical physicist, authorized user, and nuclear pharmacist (grandfather RSO, AMP, ANP, and AU who used only 11e.(3) material)	-	D
35.63 (b)(2)(ii) & (c)(3)	Amend	Determination of dosages of unsealed byproduct material for medical use (recognize State licenses and State requirements)	H&S	H&S

Section	Change	Subject	Compatibility	
			Existing	New
35.63 (b)(2)(iii)	Add	Determination of dosages of unsealed byproduct material for medical use (recognize State licenses of PET facilities)	-	H&S
35.100 (a) & (b)	Amend	Use of unsealed byproduct material for uptake, dilution, and excretion studies for which a written directive is not required (allow use of PET radionuclides)	H&S	H&S
35.200 (a) & (b)	Amend	Use of unsealed byproduct material for imaging and localization studies for which a written directive is not required (allow use of PET radionuclides)	H&S	H&S
35.204 (a)	Amend	Permissible molybdenum-99 concentrations (add strontium-82 & strontium-85)	H&S	H&S
35.204 (c)	Add	Permissible molybdenum-99 concentrations (add strontium-82 & strontium-85	-	D
35.204 (d)	Redesignated	Permissible molybdenum-99 concentrations	D	D
35.300 (a) and (b)	Amend	Use of unsealed byproduct material for which a written directive is required (allow use of PET radionuclides)	H&S	H&S
35.2204	Amend	Records of molybdenum-99 concentrations (add strontium-82 & strontium-85)	D	D
50.2	Amend	Definition: *Byproduct material* (add 11e.(3) & 11e.(4) material)	NRC	NRC
61.2	Amend	Definition: *Waste* (clarify 11e.(3) & 11e.(4) material)	B	B
62.2	Amend	Definition: *Low-level radioactive waste* (clarify 11e.(3) & 11e.(4) material)	NRC	NRC

Section	Change	Subject	Compatibility	
			Existing	New
72.3	Amend	Definition: *Byproduct material* (add 11e.(3) & 11e.(4) material)	NRC	NRC
110.2	Add	Definition: *Accelerator-produced radioactive material*	-	NRC
110.2	Add	Definition*: Discrete source*	-	NRC
110.2	Add	Definition: *Particle accelerator*	-	NRC
150.3	Amend	Definition*: Byproduct material* (add 11e.(3) & 11e.(4) material)	A	H&S
150.3	Add	Definition*: Discrete source*	-	H&S
10 CFR Parts 170 and 171 address areas that generally are applicable only to the NRC's regulatory program; therefore, no compatibility designation is assigned.				

VII. Voluntary Consensus Standards

The National Technology Transfer and Advancement Act of 1995 (Pub. L. 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 law or otherwise impractical. In this final rule, the NRC is assuming regulation of certain discrete sources of naturally occurring radioactive material and accelerator-produced radioactive material in addition to those byproduct materials already under the NRC's jurisdiction. This action does not constitute the establishment of a standard that establishes generally applicable requirements.

The EPAct requires that the NRC use model State standards to the maximum extent practicable in developing and issuing regulations for the newly expanded definition of *Byproduct material*. In developing this final rule, the NRC has consulted with Agreement and non-Agreement States about their regulations. To the maximum extent practicable, the NRC has

incorporated the CRCPD's SSRs into this final rule.

VIII. Environmental Assessment and 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 not a major Federal action significantly affecting the quality of the human environment and therefore an environmental impact statement is not required. The Commission has prepared an environmental assessment for this final rule.

Amendments to the NRC's regulations incorporate new materials into the NRC's byproduct material regulatory program and establish new program elements where needed. Before the EPAct, the regulation of NARM, other than source material, was left primarily to the individual States. Although efforts were made by several States to provide a uniform regulatory environment, particularly for accelerator-produced radioactive material, there is currently no nationwide consistency to the regulation of NARM. The amendments to the NRC's regulations will provide a uniform regulatory environment for the acquisition, possession, use, transfer, and disposal of NARM. This uniform regulatory environment has been developed in cooperation with the States, using model State standards in existence to the maximum extent practicable. Because the approach for developing the generic NRC requirements started with the existing generic requirements for accelerator-produced radioactive material that had already been developed by the States for the SSRs, little change is expected to the byproduct material regulatory programs already in place for the Agreement States. Consequently, for Agreement States, the primary foreseeable impact of the regulatory changes applicable to accelerator-produced radioactive material is that the regulations will be uniformly applied by all Agreement

States. Therefore, for the regulation of accelerator-produced radioactive material by the Agreement States, these amendments to the NRC's regulations are not expected to have any adverse environmental impacts.

In non-Agreement States, these amendments to the NRC's regulations generally impose more restrictive requirements on the acquisition, possession, use, transfer, and disposal of accelerator-produced radioactive materials. In situations where the new NRC requirements are more restrictive than those already imposed by individual States' existing regulations, the result will likely be a positive impact on the environment. In situations where the NRC's requirements are less restrictive than the individual State's regulations, it is likely that the licensee will, in large part, continue with its current practices, and no substantial impact on the environment is anticipated. Therefore, it is expected that the overall environmental impacts of the regulation of accelerator-produced radioactive material in non-Agreement States will be positive.

The effects of the amendments to the NRC's regulations applicable to discrete sources of radium-226 and discrete sources of other naturally occurring radioactive material will be greater for the non-Agreement States than for the Agreement States because certain non-Agreement States do not have a regulatory program addressing this material. The imposition of regulations on the acquisition, possession, use, transfer, and disposal of these discrete sources of naturally occurring radioactive material will provide greater assurance that these activities are performed in a manner that is expected to be less harmful to the environment than would be assured without these regulations. Therefore, the effect of the NRC's regulations applicable to discrete sources of naturally occurring radioactive material is anticipated to be beneficial to the environment, and it is expected that the overall environmental impacts will be positive.

Therefore, the determination of the environmental assessment is that there will be no

significant impact to the human environment from this action.

The NRC sent a copy of the environmental assessment and the proposed rule to every State Liaison Officer and requested their comments on the environmental assessment. No significant comments were received that changed this conclusion.

IX. Paperwork Reduction Act Statement.

This final rule amends information collection requirements contained in 10 CFR Parts 19, 20, 30, 31, 32, and 35 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 3150-0044, -0014, -0017, -0016, -0001, -0010, and -0120. The changes to 10 CFR Parts 33, 50, 61, 62, 72, 110, 150, 170, and 171 do not contain new or amended information collection requirements.

The burden to the public for these information collections is estimated to average **XX hours** per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the information collection. Send comments on any aspect of these information collections, including suggestions for reducing the burden, to the Records and FOIA/Privacy Services Branch (T-5 F52), U.S. Nuclear Regulatory Commission, Washington, DC 20555-0001, or by Internet electronic mail to INFOCOLLECTS@NRC.GOV; and to the Desk Officer, Office of Information and Regulatory Affairs, NEOB-10202 (3150-0044, -0014, -0017, -0016, -0001, -0010, and -0120, Office of Management and Budget, Washington, DC 20503.

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.

X. Regulatory Analysis.

The Commission has prepared a regulatory analysis on this regulation. The regulatory analysis examines the costs and benefits of the alternatives considered by the Commission.

The regulatory analysis is available for inspection in the NRC Public Document Room, 11555 Rockville Pike, Rockville, MD, and may be downloaded from the rule forum website at http://ruleforum.llnl.gov. Single copies of the regulatory analysis are available from Lydia Chang, Office of Federal and State Materials and Environmental Management Programs, U.S. Nuclear Regulatory Commission, Washington, DC 20555-0001, telephone (301) 415-6319, e-mail lwc1@nrc.gov.

XI. Regulatory Flexibility Certification.

In accordance with the Regulatory Flexibility Act of 1980 (5 U.S.C. 605(b)), the Commission certifies that this rule will not have a significant economic impact on a substantial number of small entities. The majority of companies that own these businesses do not fall within the scope of the definition of "small entities" set forth in the Regulatory Flexibility Act or the Small Business Size Standards set out in regulations issued by the Small Business Administration at 13 CFR Part 121.

Section 651(e) of the EPAct expanded the definition of *Byproduct material* in

Section 11e. of the AEA to include any discrete source of radium-226, any material made radioactive by use of a particle accelerator, and any discrete source of naturally occurring radioactive material that would pose a similar threat to the public health and safety or the common defense and security as a discrete source of radium-226 that is extracted or converted after extraction for use in a commercial, medical, or research activity. This rulemaking amends the NRC's regulations to include this newly defined byproduct material. This amendment will potentially affect large numbers of individuals, businesses, or licensees engaged in activities involving discrete radium-226 sources or accelerator-produced radioactive material used for commercial, medical, or research activities. Many individuals, businesses, or licensees qualify as small business entities as defined by 10 CFR 2.810. However, the rule is not expected to have a significant economic impact on these individuals, businesses, or licensees because the NRC is using the existing regulatory framework to regulate these materials and is allowing sufficient time for individuals, businesses, and licensees to implement the requirements for this radioactive material. Based on the regulatory analysis, the NRC believes that the selected alternative reflected in the amendment is protective of public health and safety and is not overly burdensome to accomplish the NRC's regulatory objective. The NRC also notes that several Agreement States have imposed similar requirements on their licensees either by rule, order, or license condition.

XII. Backfit Analysis.

The NRC has determined that the backfit rule (10 CFR 50.109, 70.76, 72.62, or 76.76) does not apply to this rule because this amendment does not involve any provisions that would impose backfits as defined in 10 CFR Chapter 1. Therefore, a backfit analysis is not required.

XIII. Congressional Review Act.

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

List of Subject Terms

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, Source material, Special nuclear material, Waste treatment and disposal.

10 CFR Part 30

Byproduct material, Criminal penalties, Government contracts, Intergovernmental relations, Isotopes, Nuclear materials, Radiation protection, Reporting and recordkeeping requirements.

10 CFR Part 31

Byproduct material, Criminal penalties, Labeling, Nuclear materials, Packaging and containers, Radiation protection, Reporting and recordkeeping requirements, Scientific equipment.

10 CFR Part 32

Byproduct material, Criminal penalties, Labeling, Nuclear materials, Radiation protection, Reporting and recordkeeping requirements.

10 CFR Part 33

Byproduct material, Criminal penalties, Nuclear materials, Radiation protection, Reporting and recordkeeping requirements.

10 CFR Part 35

Byproduct material, Criminal penalties, Drugs, Health facilities, Health professions, Medical devices, Nuclear materials, Occupational safety and health, Radiation protection, Reporting and recordkeeping requirements.

10 CFR Part 50

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

10 CFR Part 61

Criminal penalties, Low-level waste, Nuclear materials, Reporting and recordkeeping requirements, Waste treatment and disposal.

10 CFR Part 62

Administrative practice and procedure, Denial of access, Emergency access to low-level waste disposal, Low-level radioactive waste, Low-level radioactive waste treatment and

disposal, Low-level waste policy amendments act of 1985, Nuclear materials, Reporting and recordkeeping requirements.

10 CFR Part 72

Administrative practice and procedure, Criminal penalties, Manpower training programs, Nuclear materials, Occupational safety and health, Penalties, Radiation protection, Reporting and recordkeeping requirements, Security measures, Spent fuel, Whistleblowing.

10 CFR Part 110

Administrative practice and procedure, Classified information, Criminal penalties, Export, Import, Intergovernmental relations, Nuclear materials, Nuclear power plants and reactors, Reporting and recordkeeping requirements, Scientific equipment.

10 CFR Part 150

Criminal penalties, Hazardous materials transportation, Intergovernmental relations, Nuclear materials, Reporting and recordkeeping requirements, Security measures, Source material, Special nuclear material.

10 CFR Part 170

Byproduct material, Import and export licenses, Intergovernmental relations, Nonpayment penalties, Nuclear materials, Nuclear power plants and reactors, Source material, Special nuclear material.

10 CFR Part 171

Annual charges, Byproduct material, Holders of certificates, registrations, approvals,

Intergovernmental relations, Nonpayment penalties, Nuclear materials, Nuclear power plants and reactors, Source material, Special nuclear material.

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, 30, 31, 32, 33, 35, 50, 61, 62, 72, 110, 150, 170, and 171.

PART 20 - STANDARDS FOR PROTECTION AGAINST RADIATION

1. The authority citation for part 20 is revised 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); sec. 1704, 112 Stat. 2750 (44 U.S.C. 3504 note); sec. 651(e), Pub. L. 109-58, 119 Stat. 806-810 (42 U.S.C. 2014, 2021, 2021b, 2111).

2. In § 20.1003, the definition of *Byproduct material* is revised, and definitions of *Accelerator-produced radioactive material*, *Discrete source, Particle accelerator,* and *Waste* are added alphabetically to read as follows:

§ 20.1003 Definitions.

* * * * *

Accelerator-produced radioactive material means any material made radioactive by a particle accelerator.

* * * * *

Byproduct material means--

(1) Any radioactive material (except special nuclear material) yielded in, or made radioactive by, exposure to the radiation incident to the process of producing or using special nuclear material;

(2) The tailings or wastes produced by the extraction or concentration of uranium or thorium from ore processed primarily for its source material content, including discrete surface wastes resulting from uranium solution extraction processes. Underground ore bodies depleted by these solution extraction operations do not constitute "byproduct material" within this definition;

(3)(i) Any discrete source of radium-226 that is produced, extracted, or converted after extraction, before, on, or after August 8, 2005, for use for a commercial, medical, or research activity; or

(ii) Any material that--

(A) Has been made radioactive by use of a particle accelerator; and

(B) Is produced, extracted, or converted after extraction, before, on, or after August 8, 2005, for use for a commercial, medical, or research activity; and

(4) Any discrete source of naturally occurring radioactive material, other than source material, that--

(i) The Commission, in consultation with the Administrator of the Environmental Protection Agency, the Secretary of Energy, the Secretary of Homeland Security, and the head of any other appropriate Federal agency, determines would pose a threat similar to the threat posed by a discrete source of radium-226 to the public health and safety or the common

defense and security; and

(ii) Before, on, or after August 8, 2005, is extracted or converted after extraction for use in a commercial, medical, or research activity.

* * * * *

Discrete source means a radionuclide that is distinct from the sources of radiation present in nature, and that has been processed so its concentration within a material has been purposely increased for use for commercial, medical, or research activities.

* * * * *

Particle accelerator means any machine capable of accelerating electrons, protons, deuterons, or other charged particles in a vacuum and of discharging the resultant particulate or other radiation into a medium at energies usually in excess of 1 megaelectron volt. For purposes of this definition, "accelerator" is an equivalent term.

* * * * *

Waste means those low-level radioactive wastes containing source, special nuclear, or byproduct material that are acceptable for disposal in a land disposal facility. For the purposes of this definition, low-level radioactive waste means radioactive waste not classified as high-level radioactive waste, transuranic waste, spent nuclear fuel, or byproduct material as defined in paragraphs (2), (3), and (4) of the definition of *Byproduct material* set forth in this section.

* * * * *

3. In § 20.1009, paragraph (b) is revised to read as follows:

§ 20.1009 Information collection requirements: OMB approval.

* * * * *

(b) The approved information collection requirements contained in this part appear in

§§ 20.1003, 20.1101, 20.1202, 20.1203, 20.1204, 20.1206, 20.1208, 20.1301, 20.1302, 20.1403, 20.1404, 20.1406, 20.1501, 20.1601, 20.1703, 20.1901, 20.1904, 20.1905, 20.1906, 20.2002, 20.2004, 20.2005, 20.2006, 20.2008, 20.2102, 20.2103, 20.2104, 20.2105, 20.2106, 20.2107, 20.2108, 20.2110, 20.2201, 20.2202, 20.2203, 20.2204, 20.2205, 20.2206, 20.2301, and appendix G to this part.

* * * * *

4. In § 20.2001, paragraph (a)(4) is revised to read as follows:

§ 20.2001 General requirements.

(a) * * *

(4) As authorized under §§ 20.2002, 20.2003, 20.2004, 20.2005, or 20.2008.

* * * * *

5. In § 20.2006, paragraph (e) is added to read as follows:

§ 20.2006 Transfer for disposal and manifests.

* * * * *

(e) Any licensee shipping byproduct material as defined in paragraphs (3) and (4) of the definition of *Byproduct material* set forth in § 20.1003 intended for ultimate disposal at a land disposal facility licensed under part 61 of this chapter must document the information required on the NRC's Uniform Low-Level Radioactive Waste Manifest and transfer this recorded manifest information to the intended consignee in accordance with appendix G to this part.

6. Section 20.2008 is added to Subpart K - Waste Disposal - to read as follows:

§ 20.2008 Disposal of certain byproduct material.

(a) Licensed material as defined in paragraphs (3) and (4) of the definition of *Byproduct material* set forth in § 20.1003 may be disposed of in accordance with part 61 of this chapter, even though it is not defined as low-level radioactive waste. Therefore, any licensed byproduct material being disposed of at a facility, or transferred for ultimate disposal at a facility licensed under part 61 of this chapter, must meet the requirements of § 20.2006.

(b) A licensee may dispose of byproduct material, as defined in paragraphs (3) and (4) of the definition of *Byproduct material* set forth in § 20.1003, at a disposal facility authorized to dispose of such material in accordance with any Federal or State solid or hazardous waste law, including the Solid Waste Disposal Act, as authorized under the Energy Policy Act of 2005.

7. In Appendix B to part 20, the List of Elements table is amended by adding Nitrogen and Oxygen in alphabetical order, and page 1 of Tables 1, 2, and 3 following the List of Elements is amended by adding Nitrogen and Oxygen by element to read as follows:

Appendix B to Part 20--Annual Limits on Intake (ALIs) and Derived Air Concentrations (DACs) of Radionuclides for Occupational Exposure; Effluent Concentrations; Concentrations for Release to Sewerage

* * * * *

List of Elements

Name	Atomic	
	Symbol	No.
* * *	* * *	* * *
Nitrogen	N	7
* * *	* * *	* * *
Oxygen	O	8
* * *	* * *	* * *

* * * * *

			Table 1 Occupational Values			Table 2 Effluent Concentration		Table 3 Releases to Sewers
			Col. 1	Col. 2	Col. 3	Col. 1	Col.2	
			Oral Ingestion	Inhalation				
Atomic No.	Radionuclide	Class	ALI (µCi)	ALI (µCi/ml)	DAC (µCi/ml)	Air (µCi/ml)	Water (µCi/ml)	Monthly Average Concentration (µCi/ml)
1	Hydrogen-3	Water, DAC includes skin absorption	8E+4	8E+4	2E-5	1E-7	1E-3	1E-2
		Gas (HT or T_2) Submersion[1]: Use above values as HT and T_2 oxidize in air and in the body to HTO						
4	Beryllium-7	W, all compounds except those given for Y	4E+4	2E+4	9E-6	3E-8	6E-4	6E-3
		Y, oxides, halides, and nitrates	-	2E+4	8E-6	3E-8	-	-
4	Beryllium-10	W, see 7Be	1E+3 LLI wall	2E+2	6E-8	2E-10	-	-
			(1E+3)	-	-	-	2E-5	2E-4
		Y, see 7Be	-	1E+1	6E-9	2E-11	-	-
6	Carbon-11[2]	Monoxide	-	1E+6	5E-4	2E-6	-	-

		Dioxide	-	6E+5	3E-4	9E-7	-	-
		Compounds	4E+5	4E+5	2E-4	6E-7	6E-3	6E-2
6	Carbon-14	Monoxide	-	2E+6	7E-4	2E-6	-	-
		Dioxide	-	2E+5	9E-5	3E-7	-	-
		Compounds	2E+3	2E+3	1E-6	3E-9	3E-5	3E-4
7	Nitrogen-13 [2]	Submersion[1]	-	4E-6	2E-8	-	-	-
8	Oxygen-15[2]	Submersion[1]	-	4E-6	2E-8	-	-	-
9	Fluorine-18[2]	D, fluorides of H, Li, Na, K, Rb, Cs, and Fr	5e+4 St wall (5E+4)	7E+4 -	3E-5 -	1E-7 -	- 7E-4	- 7E3
		W, fluorides of Be, Mg Ca, Sr, Ba, Ra, Al, Ga, In, Ti, As, Sb, Bi, Fe, Ru, Os, Co, Ni, Pd, Pt, Cu, Ag, Au, Zn, Cd, Hg, Sc, Y, Ti, Zr, V, Nb, Ta, Nm, Tc, and Re	-	9e+4	4e-5	1e-7	-	-
		y, LANTHANUM FLUORIDE	-	8e+4	3e-5	1e-7	-	-
11	Sodium-22	D, all compounds	4E+2	6E+2	3E-7	9E-10	6E-6	6E-5
11	Sodium-24	D, all compounds	4E+3	5E+3	2E-6	7E-9	5E-5	5E-4
12	Magnesium-28	D, all compounds except those given for W	7E+2	2E+3	7E-7	2E-9	9E-6	9E-5
		W, oxides, hydroxides, carbides, halides, and nitrates	-	1E+3	5E-7	2E-9	-	-
13	Aluminum-26	D, all compounds except those given for W	4E+2	6E+1	3E-8	9E-11	6E-6	6E-5
		W, oxides, hydroxides, carbides, halides, and nitrates	-	9E+1	4E-8	1E-10	-	-

FOOTNOTES:
[1] "Submersion" means that values given are for submersion in a hemispherical semi-infinite cloud of airborne material.

[2] These radionuclides have radiological half-lives of less than 2 hours. The total effective dose equivalent received during operations with these radionuclides might include a significant contribution from external exposure. The DAC values for all radionuclides, other than those designated Class "Submersion," are based upon the committed effective dose equivalent due to the intake of the radionuclide into the body and do not include potentially significant contributions to dose equivalent from external exposures. The licensee may substitute 1E-7 μCi/ml for the listed DAC to account for the submersion dose prospectively, but should use individual monitoring devices or other radiation measuring instruments that measure external exposure to demonstrate compliance with the limits. (See § 20.1203.)

* * * * *

PART 30 - RULES OF GENERAL APPLICABILITY TO DOMESTIC LICENSING OF BYPRODUCT MATERIAL

8. The authority citation for part 30 is revised to read as follows:

Authority: Secs. 81, 82, 161, 182, 183, 186, 68 Stat. 935, 948, 953, 954, 955, as amended, sec. 234, 83 Stat. 444, as amended (42 U.S.C. 2111, 2112, 2201, 2232, 2233, 2236, 2282); secs. 201, as amended, 202, 206, 88 Stat. 1242, as amended, 1244, 1246 (42 U.S.C. 5841, 5842, 5846); sec. 1704, 112 Stat. 2750 (44 U.S.C. 3504 note); sec. 651(e), Pub. L. 109-58, 119 Stat. 806-810 (42 U.S.C. 2014, 2021, 2021b, 2111).

Section 30.7 also issued under Pub. L. 95-601, sec. 10, 92 Stat. 2951 as amended by Pub. L. 102-486, sec. 2902, 106 Stat. 3123 (42 U.S.C. 5851). Section 30.34(b) also issued under sec. 184, 68 Stat. 954, as amended (42 U.S.C. 2234). Section 30.61 also issued under sec. 187, 68 Stat. 955 (42 U.S.C. 2237).

9. Section 30.3 is revised to read as follows:

§ 30.3 Activities requiring license.

(a) Except as provided in paragraphs (b)(2), (b)(3), (c)(2), and (c)(3) of this section and for persons exempt as provided in this part and part 150 of this chapter, no person shall

manufacture, produce, transfer, receive, acquire, own, possess, or use byproduct material except as authorized in a specific or general license issued in accordance with the regulations in this chapter.

(b)(1) The requirements, including provisions that are specific to licensees, in this part and parts 19, 20, 21, and 71 of this chapter, as well as the additional requirements for specific broad scope, industrial radiography, irradiator, or well logging uses in 10 CFR parts 33, 34, 36, or 39, respectively, shall apply to Government agencies or Federally recognized Indian Tribes on **[INSERT DATE 60 DAYS AFTER DATE OF PUBLICATION OF THIS FINAL RULE]**, when conducting activities under the authority provided by paragraphs (b)(2) and (b)(3) of this section.

(2) A specifically licensed Government agency or Federally recognized Indian Tribe that possesses and uses accelerator-produced radioactive material or discrete sources of radium-226 for which a license amendment is required to authorize the activities in paragraph (a) of this section, may continue to use these materials for uses permitted under this part until the date of the NRC's final licensing determination, provided that the licensee submits an amendment application on or before **[INSERT DATE 8 MONTHS AFTER DATE OF PUBLICATION OF THIS FINAL RULE]**.

(3) A Government agency or Federally recognized Indian Tribe that possesses and uses accelerator-produced radioactive material or discrete sources of radium-226 for which a specific license is required in paragraph (a) of this section, may continue to use such material for uses permitted under this part until the date of the NRC's final licensing determination provided that the agency or Indian Tribe submits an application for a license authorizing activities involving these materials on or before **[INSERT DATE 1 YEAR AND 2 MONTHS AFTER DATE OF PUBLICATION OF THIS FINAL RULE]**.

(c)(1) The requirements, including provisions that are specific to licensees in this part and parts 19, 20, 21, and 71 of this chapter, as well as the additional requirements for specific

broad scope, industrial radiography, irradiator, or well logging uses in 10 CFR parts 33, 34, 36, or 39, respectively, shall apply to all persons, other than those included in paragraph (b)(1) of this section, on August 8, 2009, or earlier as noticed by the NRC, when conducting activities under the authority provided by paragraphs (c)(2) and (c)(3) of this section.

(2) Except as provided in paragraph (b)(2) of this section, all other licensees, who possess and use accelerator-produced radioactive material or discrete sources of radium-226 for which a license amendment is required to authorize the activities in paragraph (a) of this section, may continue to use these materials for uses permitted under this part until the date of the NRC's final licensing determination, provided that the person submits an amendment application within 6 months from the waiver expiration date of August 7, 2009 (August 31, 2005; 70 FR 51581) or within 6 months from the date of an earlier termination of the waiver as noticed by the NRC, whichever date is earlier.

(3) Except as provided in paragraph (b)(3) of this section, all other persons, who possess and use accelerator-produced radioactive material or discrete sources of radium-226 for which a specific license is required in paragraph (a) of this section, may continue to use such material for uses permitted under this part until the date of the NRC's final licensing determination, provided that the person submits a license application within 12 months from the waiver expiration date of August 7, 2009 (August 31, 2005; 70 FR 51581) or within 12 months from the date of an earlier termination of the waiver as noticed by the NRC, whichever date is earlier.

(d) If a person or licensee is required to file an application for a license or amendment in accordance with paragraphs (b)(2), (b)(3), (c)(2), and (c)(3) of this section, but does not file for the license or amendment within the required time, the authority provided by paragraphs (b)(2), (b)(3), (c)(2), and (c)(3) of this section to receive or use the accelerator-produced radioactive material or discrete sources of radium-226 shall expire with respect to the person’s or licensee's

authority to receive and use such byproduct material. This authority shall not expire with respect to the responsibility of the person or licensee regarding the possession of such byproduct material, the decommissioning (including financial assurance) of facilities, or the disposal of such byproduct material.

10. In § 30.4, the definition of *Byproduct material* is revised, and the definitions of *Accelerator-produced radioactive material*, *Consortium, Cyclotron*, *Discrete source*, and *Particle accelerator* are added alphabetically to read as follows:

§ 30.4 Definitions.

* * * * *

Accelerator-produced radioactive material means any material made radioactive by a particle accelerator.

* * * * *

Byproduct material means–

(1) Any radioactive material (except special nuclear material) yielded in, or made radioactive by, exposure to the radiation incident to the process of producing or using special nuclear material;

(2)(i) Any discrete source of radium-226 that is produced, extracted, or converted after extraction, before, on, or after August 8, 2005, for use for a commercial, medical, or research activity; or

(ii) Any material that--

(A) Has been made radioactive by use of a particle accelerator; and

(B) Is produced, extracted, or converted after extraction, before, on, or after August 8, 2005, for use for a commercial, medical, or research activity; and

(3) Any discrete source of naturally occurring radioactive material, other than source material, that--

(i) The Commission, in consultation with the Administrator of the Environmental Protection Agency, the Secretary of Energy, the Secretary of Homeland Security, and the head of any other appropriate Federal agency, determines would pose a threat similar to the threat posed by a discrete source of radium-226 to the public health and safety or the common defense and security; and

(ii) Before, on, or after August 8, 2005, is extracted or converted after extraction for use in a commercial, medical, or research activity.

* * * * *

Consortium means an association of medical use licensees and a PET radionuclide production facility in the same geographical area that jointly own or share in the operation and maintenance cost of the PET radionuclide production facility that produces PET radionuclides for use in producing radioactive drugs within the consortium for noncommercial distributions among its associated members for medical use. The PET radionuclide production facility within the consortium must be located at an educational institution or a Federal facility or a medical facility.

* * * * *

Cyclotron means a particle accelerator in which the charged particles travel in an outward spiral or circular path. A cyclotron accelerates charged particles at energies usually in excess of 10 megaelectron volts and is commonly used for production of short half-life radionuclides for medical use.

* * * * *

Discrete source means a radionuclide that is distinct from the sources of radiation present in nature, and that has been processed so its concentration within a material has been

purposely increased for use for commercial, medical, or research activities.

* * * * *

Particle accelerator means any machine capable of accelerating electrons, protons, deuterons, or other charged particles in a vacuum and of discharging the resultant particulate or other radiation into a medium at energies usually in excess of 1 megaelectron volt. For purposes of this definition, *accelerator* is an equivalent term.

* * * * *

11. In § 30.15, paragraph (a)(1)(viii) is added to read as follows:

§ 30.15 Certain items containing byproduct material.

(a) * * *

(1) * * *

(viii) 0.037 megabecquerel (1 microcurie) of radium-226 per timepiece in intact timepieces manufactured prior to **[INSERT DATE 60 DAYS AFTER THE DATE OF PUBLICATION OF THIS FINAL RULE]**.

* * * * *

12. In § 30.18, paragraph (b) is revised to read as follows:

§ 30.18 Exempt quantities.

* * * * *

(b) Any person, who possesses byproduct material received or acquired before September 25, 1971, under the general license then provided in § 31.4 of this chapter or similar general license of a State, is exempt from the requirements for a license set forth in section 81

of the Act and from the regulations in parts 30 through 34, 36 and 39 of this chapter to the extent that this person possesses, uses, transfers, or owns byproduct material.

* * * * *

13. In § 30.20, paragraph (a) is revised to read as follows:

§ 30.20 Gas and aerosol detectors containing byproduct material.

(a) Except for persons who manufacture, process, produce, or initially transfer for sale or distribution gas and aerosol detectors containing byproduct material, any person is exempt from the requirements for a license set forth in section 81 of the Act and from the regulations in parts 19, 20, and 30 through 36, and 39 of this chapter to the extent that the person receives, possesses, uses, transfers, owns, or acquires byproduct material in gas and aerosol detectors designed to protect life or property from fires and airborne hazards, and manufactured, processed, produced, or initially transferred in accordance with a specific license issued under § 32.26 of this chapter, which license authorizes the initial transfer of the product for use under this section. This exemption also covers gas and aerosol detectors manufactured or distributed before **[INSERT DATE 60 DAYS AFTER THE DATE OF PUBLICATION OF THIS FINAL RULE]** in accordance with a specific license issued by a State under comparable provisions to § 32.26 of this chapter authorizing distribution to persons exempt from regulatory requirements.

* * * * *

14. In § 30.32, paragraphs (g)(1) and (g)(2) are revised and paragraphs (g)(3) and (j) are added to read as follows:

§ 30.32 Application for specific licenses.

* * * * *

(g) * * *

(1) Identify the source or device by manufacturer and model number as registered with the Commission under § 32.210 of this chapter, with an Agreement State, or for a source or a device containing radium-226 or accelerator-produced radioactive material with a State under provisions comparable to § 32.210 of this chapter; or

(2) Contain the information identified in § 32.210(c) of this chapter; or

(3) For sources or devices containing naturally occurring or accelerator-produced radioactive material manufactured prior to **[INSERT DATE 60 DAYS AFTER THE DATE OF PUBLICATION OF THIS FINAL RULE]** that are not registered with the Commission under § 32.210 of this chapter or with an Agreement State, and for which the applicant is unable to provide all categories of information specified in § 32.210(c) of this chapter, the applicant must provide:

(i) All available information identified in § 32.210(c) of this chapter concerning the source, and, if applicable, the device; and

(ii) Sufficient additional information to demonstrate that there is reasonable assurance that the radiation safety properties of the source or device are adequate to protect health and minimize danger to life and property. Such information must include a description of the source or device, a description of radiation safety features, the intended use and associated operating experience, and the results of recent leak test.

* * * * *

(j) An application from a medical facility, educational institution, or Federal facility to produce Positron Emission Tomography (PET) radioactive drugs for noncommercial transfer to licensees in its consortium authorized for medical use under part 35 of this chapter or equivalent Agreement State requirements shall include:

(1) A request for authorization for the production of PET radionuclides or evidence of an

existing license issued under part 30 of this chapter or Agreement State requirements for a PET radionuclide production facility within its consortium from which it receives PET radionuclides.

(2) Evidence that the applicant is qualified to produce radioactive drugs for medical use by meeting one of the criteria in § 32.72(a)(2) of this chapter.

(3) Identification of individual(s) authorized to prepare the PET radioactive drugs if the applicant is a pharmacy, and documentation that each individual meets the requirements of an authorized nuclear pharmacist as specified in § 32.72(b)(2) of this chapter.

(4) Information identified in § 32.72(a)(3) of this chapter on the PET drugs to be noncommercially transferred to members of its consortium.

15. In § 30.34, paragraph (g) is revised and paragraph (j) is added to read as follows:

§ 30.34 Terms and conditions of licenses.

* * * * *

(g) Each licensee preparing technetium-99m radiopharmaceuticals from molybdenum-99/technetium-99m generators or rubidium-82 from strontium-82/rubidium-82 generators shall test the generator eluates for molybdenum-99 breakthrough or strontium-82 and strontium-85 contamination, respectively, in accordance with § 35.204 of this chapter. The licensee shall record the results of each test and retain each record for 3 years after the record is made.

* * * * *

(j)(1) Authorization under § 30.32(j) to produce Positron Emission Tomography (PET) radioactive drugs for noncommercial transfer to medical use licensees in its consortium does not relieve the licensee from complying with applicable FDA, other Federal, and State requirements governing radioactive drugs.

(2) Each licensee authorized under § 30.32(j) to produce PET radioactive drugs for noncommercial transfer to medical use licensees in its consortium shall:

(i) Satisfy the labeling requirements in § 32.72(a)(4) of this chapter for each PET radioactive drug transport radiation shield and each syringe, vial, or other container used to hold a PET radioactive drug intended for noncommercial distribution to members of its consortium.

(ii) Possess and use instrumentation to measure the radioactivity of the PET radioactive drugs intended for noncommercial distribution to members of its consortium and meet the procedural, radioactivity measurement, instrument test, instrument check, and instrument adjustment requirements in § 32.72(c) of this chapter.

(3) A licensee that is a pharmacy authorized under § 30.32(j) to produce PET radioactive drugs for noncommercial transfer to medical use licensees in its consortium shall require that any individual that prepares PET radioactive drugs shall be:

(i) an authorized nuclear pharmacist that meets the requirements in § 32.72(b)(2) of this chapter, or

(ii) an individual under the supervision of an authorized nuclear pharmacist as specified in § 35.27 of this chapter.

(4) A pharmacy, authorized under § 30.32(j) to produce PET radioactive drugs for noncommercial transfer to medical use licensees in its consortium that allows an individual to work as an authorized nuclear pharmacist, shall meet the requirements of § 32.72(b)(5) of this chapter.

16. Section 30.71 is revised by adding Cesium 129 (Cs 129), Cobalt 57 (Co 57), Gallium 67 (Ga 67), Germanium 68 (Ge 68), Gold 195 (Au 195), Indium 111 (In 111), Iodine 123 (I 123), Iron 52 (Fe 52), Potassium 43 (K 43), Rubidium 81 (Rb 81), Sodium 22 (Na 22),

Yttrium 87 (Y 87), and Yttrium 88 (Y 88) in alphabetical order by element as follows:

§ 30.71 Schedule B.

Byproduct material	Microcuries
* * * * * * *	
Cesium 129 (Cs 129).....	100
* * * * * * *	
Cobalt 57 (Co 57).....	100
* * * * * * *	
Gallium 67 (Ga 67).....	100
* * * * * * *	
Germanium 68 (Ge 68).....	10
* * * * * * *	
Gold 195 (Au 195).....	10
* * * * * * *	
Indium 111 (In 111).....	100
* * * * * * *	
Iodine 123 (I 123).....	100
* * * * * * *	
Iron 52 (Fe 52).....	10
* * * * * * *	
Potassium 43 (K 43).....	10
* * * * * * *	
Rubidium 81 (Rb 81).....	10
* * * * * * *	
Sodium 22 (Na 22).....	10
* * * * * * *	
Yttrium 87 (Y 87).....	10

Yttrium 88 (Y 88).....	10
* * * * * * *	

17. Section 30.72 is revised by adding radium-226 in alphabetical order to read as follows:

§ 30.72 Schedule C--Quantities of radioactive materials requiring consideration of the need for an emergency plan for responding to a release.

Radioactive material[1]	Release fraction	Quantity (curies)
* * * * * * *		
Radium-226	0.001	100
* * * * * * *		

[1] For combinations of radioactive materials, consideration of the need for an emergency plan is required if the sum of the ratios of the quantity of each radioactive material authorized to the quantity listed for that material in Schedule C exceeds one.

* * * * *

PART 31 - GENERAL DOMESTIC LICENSES FOR BYPRODUCT MATERIAL

18. The authority citation for part 31 is revised to read as follows:

Authority: Secs. 81, 161, 183, 68 Stat. 935, 948, 954, as amended (42 U.S.C. 2111, 2201, 2233); secs. 201, as amended, 202, 88 Stat. 1242, as amended, 1244 (42 U.S.C. 5841,

5842); sec. 1704, 112 Stat. 2750 (44 U.S.C. 3504 note); sec. 651(e), P. Law 109-58, 119 Stat. 806-810 (42 U.S.C. 2014, 2021, 2021b, 2111).

19. In § 31.4, paragraph (b) is revised to read as follows:

§ 31.4 Information collection requirements: OMB approval.

* * * * *

(b) The approved information collection requirements contained in this part appear in §§ 31.5, 31.8, 31.11, and 31.12.

* * * * *

20. In § 31.5, paragraphs (b)(1)(i), (b)(1)(ii), and (c)(13)(i) are revised and paragraph (b)(1)(iii) is added to read as follows:

§ 31.5 Certain detecting, measuring, gauging, or controlling devices and certain devices for producing light or an ionized atmosphere.[2]

* * * * *

(b)(1) * * *

(i) A specific license issued under § 32.51 of this chapter; or

(ii) An equivalent specific license issued by an Agreement State; or

(iii) An equivalent specific license issued by a State with provisions comparable to § 32.51 of this chapter.

---

[2]Persons possessing byproduct material in devices under a general license in § 31.5 before January 15, 1975, may continue to possess, use, or transfer that material in accordance with the labeling requirements of § 31.5 in effect on January 14, 1975.

* * * * *

(c) * * *

(13)(i) Shall register, in accordance with paragraphs (c)(13)(ii) and (iii) of this section, devices containing at least 370 megabecquerels (10 millicuries) of cesium-137, 3.7 megabecquerels (0.1 millicurie) of strontium-90, 37 megabecquerels (1 millicurie) of cobalt-60, 3.7 megabecquerels (0.1 millicurie) of radium-226, or 37 megabecquerels (1 millicurie) of americium-241 or any other transuranic (i.e., element with atomic number greater than uranium (92)), based on the activity indicated on the label. Each address for a location of use, as described under paragraph (c)(13)(iii)(D) of this section, represents a separate general licensee and requires a separate registration and fee.

* * * * *

21. Section 31.8 is revised to read as follows:

§ 31.8 Americium-241 and radium-226 in the form of calibration or reference sources.

(a) A general license is issued to those persons listed in this section to own, receive, acquire, possess, use, and transfer, in accordance with the provisions of paragraphs (b) and (c) of this section, americium-241 or radium-226 in the form of calibration or reference sources:

(1) Any person in a non-Agreement State who holds a specific license issued under this chapter which authorizes receipt, possession, use, and transfer of byproduct material, source material, or special nuclear material; and

(2) Any Government agency, as defined in § 30.4 of this chapter, which holds a specific license issued under this chapter which authorizes it to receive, possess, use, and transfer byproduct material, source material, or special nuclear material.

(b) The general license in paragraph (a) of this section applies only to calibration or

reference sources which have been manufactured or initially transferred in accordance with the specifications contained in a specific license issued under § 32.57 of this chapter or in accordance with the specifications contained in a specific license issued to the manufacturer by an Agreement State which authorizes manufacture of the sources for distribution to persons generally licensed by the Agreement State, or in accordance with a specific license issued by a State with comparable provisions to § 32.57.

(c) The general license in paragraph (a) of this section is subject to the provisions of §§ 30.14(d), 30.34 (a) to (e), and 30.50 to 30.63 of this chapter, and to the provisions of parts 19, 20, and 21, of this chapter. In addition, persons who own, receive, acquire, possess, use, and transfer one or more calibration or reference sources under this general license:

(1) Shall not possess at any one time, at any one location of storage or use, more than 0.185 megabecquerel (5 microcuries) of americium-241 or 0.185 megabecquerel (5 microcuries) of radium-226 in such sources;

(2) Shall not receive, possess, use, or transfer a source unless the source, or the storage container, bears a label which includes the following statement or a substantially similar statement which contains the information called for in the following statement:[1]

The receipt, possession, use, and transfer of this source, Model XX, Serial No. XX, are subject to a general license and the regulations of the United States Nuclear Regulatory Commission or of a State with which the Commission has entered into an agreement for the exercise of regulatory authority. Do not remove this label.

CAUTION--RADIOACTIVE MATERIAL--THIS SOURCE CONTAINS AMERICIUM-241 [or

---

[1]Sources generally licensed under this section before January 19, 1975, may bear labels authorized by the regulations in effect on January 1, 1975. Sources containing radium-226 generally licensed under this section and manufactured before **[INSERT DATE 60 DAYS AFTER THE DATE OF PUBLICATION OF THIS FINAL RULE]** shall be labeled in accordance with the applicable State regulations at the time of manufacture or import.

RADIUM-226, as appropriate]. DO NOT TOUCH RADIOACTIVE PORTION OF THIS SOURCE.

_____

(Name of manufacturer or initial transferor)

(3) Shall not transfer, abandon, or dispose of a source except by transfer to a person authorized by a license issued under this chapter or by an Agreement State to receive the source.

(4) Shall store a source, except when the source is being used, in a closed container adequately designed and constructed to contain americium-241 or radium-226 which might otherwise escape during storage.

(5) Shall not use a source for any purpose other than the calibration of radiation detectors or the standardization of other sources.

(d) This general license does not authorize the manufacture or import of calibration or reference sources containing americium-241 or radium-226.

(e) This general license does not authorize the export of calibration or reference sources containing americium-241 or radium-226.

22. In § 31.11, paragraph (a)(8) is added, and paragraphs (c)(1) and (d)(1) are revised to read as follows:

§ 31.11 General license for use of byproduct material for certain in vitro clinical or laboratory testing.

(a) * * *

(8) Cobalt-57, in units not exceeding 0.37 megabecquerel (10 microcuries) each for use

in in vitro clinical or laboratory tests not involving internal or external administration of byproduct material, or the radiation therefrom, to human beings or animals.

* * * * *

(c) * * *

(1) The general licensee shall not possess at any one time, under the general license in paragraph (a) of this section, at any one location of storage or use, a total amount of iodine-125, iodine-131, selenium-75, cobalt-57 and/or iron-59 in excess of 7.4 megabecquerels (200 microcuries).

* * * * *

(d) * * *

(1) Except as prepackaged units which are labeled in accordance with the provisions of a specific license issued under the provisions of § 32.71 of this chapter or in accordance with the provisions of a specific license issued by an Agreement State, or before **[INSERT DATE 60 DAYS AFTER THE DATE OF PUBLICATION OF THIS FINAL RULE]**, and the provisions of a specific license issued by a State with comparable provisions to § 32.71 that authorize manufacture and distribution of iodine-125, iodine-131, carbon-14, hydrogen-3 (tritium), selenium-75, iron-59, cobalt-57, or Mock Iodine-125 for distribution to persons generally licensed by the Agreement State or the State with comparable provisions to § 32.71.

* * * * *

§§ 31.12, 31.13, and 31.14 [Redesignated]

23. Sections 31.12, 31.13, and 31.14 are redesignated as § 31.21, § 31.22, and § 31.23, respectively, and new §§ 31.13 through 31.20 are added and reserved, and a new § 31.12 is added to read as follows:

§ 31.12 General license for certain items and self-luminous products containing radium-226.

(a) A general license is hereby issued to any person to acquire, receive, possess, use, or transfer, in accordance with the provisions of paragraphs (b), (c), and (d) of this section, radium-226 contained in the following products manufactured prior to **[INSERT DATE 60 DAYS AFTER DATE OF PUBLICATION OF THIS FINAL RULE]**:

(1) Antiquities originally intended for use by the general public. For the purposes of this paragraph, antiquities mean products originally intended for use by the general public and distributed in the late 19th and early 20th centuries, such as radium emanator jars, revigators, radium water jars, radon generators, refrigerator cards, radium bath salts, and healing pads.

(2) Intact timepieces containing greater than 0.037 megabecquerel (1 microcurie), nonintact timepieces, and timepiece hands and dials no longer installed in timepieces.

(3) Luminous items installed in air, marine, or land vehicles.

(4) All other luminous products, provided that no more than 100 items are used or stored at the same location at any one time.

(5) Small radium sources containing no more than 0.037 megabecquerel (1 microcurie) of radium-226. For the purposes of this paragraph, “small radium sources” means discrete survey instrument check sources, sources contained in radiation measuring instruments, sources used in educational demonstrations (such as cloud chambers and spinthariscopes), electron tubes, lightning rods, ionization sources, static eliminators, or as designated by the NRC.

(b) Persons who acquire, receive, possess, use, or transfer byproduct material under the general license issued in paragraph (a) of this section are exempt from the provisions of 10 CFR parts 19, 20, and 21, and §§ 30.50 and 30.51 of this chapter, to the extent that the receipt, possession, use, or transfer of byproduct material is within the terms of the general

license; provided, however, that this exemption shall not be deemed to apply to any such person specifically licensed under this chapter.

(c) Any person who acquires, receives, possesses, uses, or transfers byproduct material in accordance with the general license in paragraph (a) of this section:

(1) Shall notify the NRC should there be any indication of possible damage to the product so that it appears it could result in a loss of the radioactive material. A report containing a brief description of the event, and the remedial action taken, must be furnished to the Director of the Office of Federal and State Materials and Environmental Management Programs, U.S. Nuclear Regulatory Commission, Washington, DC 20555–0001 within 30 days.

(2) Shall not abandon the device containing radium-226. The product, and any radioactive material from the product, may only be disposed of according to § 20.2008 of this chapter or by transfer to a person authorized by a specific license to receive the radium-226 in the product or as otherwise approved by the NRC.

(3) Shall not export the device containing radium-226 except in accordance with part 110 of this chapter.

(4) Shall dispose of the product containing radium-226 by export only as provided by paragraph (c)(3) of this section, at a disposal facility authorized to dispose of radioactive material in accordance with any Federal or State solid or hazardous waste law, including the Solid Waste Disposal Act, as authorized under the Energy Policy Act of 2005, by transfer to a person authorized to receive radium-226 by a specific license issued under part 30 of this chapter, or equivalent regulations of an Agreement State, or as otherwise approved by the NRC.

(5) Shall respond to written requests from the NRC to provide information relating to the general license within 30 calendar days of the date of the request, or other time specified in the request. If the general licensee cannot provide the requested information within the allotted

time, it shall, within that same time period, request a longer period to supply the information by providing the Director of the Office of Federal and State Materials and Environmental Management Programs, by an appropriate method listed in § 30.6(a) of this chapter, a written justification for the request.

(d) The general license in paragraph (a) of this section does not authorize the manufacture, assembly, disassembly, repair, or import of products containing radium-226, except that timepieces may be disassembled and repaired.

PART 32 - SPECIFIC DOMESTIC LICENSES TO MANUFACTURE OR TRANSFER CERTAIN ITEMS CONTAINING BYPRODUCT MATERIAL

24. The authority citation for part 32 is revised to read as follows:

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); sec. 1704, 112 Stat. 2750 (44 U.S.C. 3504 note); sec. 651(e), Pub. L. 109-58, 119 Stat. 806-810 (42 U.S.C. 2014, 2021, 2021b, 2111).

25. In § 32.1, paragraph (c) is added to read as follows:

§ 32.1 Purpose and scope.

* * * * *

(c)(1) The requirements in this part, including provisions that are specific to licensees, shall apply to Government agencies and Federally recognized Indian Tribes with respect to accelerator-produced radioactive material or discrete sources of radium-226 on **[INSERT DATE 60 DAYS AFTER DATE OF PUBLICATION OF THIS FINAL RULE]** except that the agency or tribe may

continue to manufacture or initially transfer items containing accelerator-produced radioactive material or discrete sources of radium-226 for sale or distribution to persons exempted from the licensing requirements of part 30 of this chapter, and to persons generally licensed under part 31 of this chapter, and radioactive drugs and sources and devices to medical use licensees, until the date of the NRC's final licensing determination, provided that the agency or tribe submits a new license application for these activities on or before **[INSERT DATE 1 YEAR AND 2 MONTHS AFTER DATE OF PUBLICATION OF THIS FINAL RULE]** or an amendment application for these activities on or before **[INSERT DATE 8 MONTHS AFTER DATE OF PUBLICATION OF THIS FINAL RULE]**.

(2) The requirements in this part, including provisions that are specific to licensees, shall apply to all persons other than those included in paragraph (c)(1) of this section with respect to accelerator-produced radioactive material or discrete sources of radium-226 on August 8, 2009, or earlier as noticed by the NRC, except that these persons may continue to manufacture or initially transfer items containing accelerator-produced radioactive material or discrete sources of radium-226 for sale or distribution to persons exempted from the licensing requirements of part 30 of this chapter, and to persons generally licensed under part 31 of this chapter, and to sell or manufacture radioactive drugs and sources and devices to medical use licensees until the date of the NRC's final licensing determination, provided that the person submits a license application within 12 months from the waiver expiration date of August 7, 2009 (August 31, 2005; 70 FR 51581) or within 12 months from the date of an earlier termination of the waiver as noticed by the NRC, whichever is earlier; or that the person submits an amendment request within 6 months from the waiver expiration date of August 7, 2009 (August 31, 2005; 70 FR 51581) or within 6 months from the date of an earlier termination of the waiver as noticed by the NRC, whichever date is earlier.

26. In § 32.57, the heading and the introductory text are revised to read as follows:

§ 32.57 Calibration or reference sources containing americium-241 or radium-226: Requirements for license to manufacture or initially transfer.

An application for a specific license to manufacture or initially transfer calibration or reference sources containing americium-241 or radium-226, for distribution to persons generally licensed under § 31.8 of this chapter, will be approved if:

* * * * *

27. Section 32.58 is revised to read as follows:

§ 32.58 Same: Labeling of devices.

Each person licensed under § 32.57 shall affix to each source, or storage container for the source, a label which shall contain sufficient information relative to safe use and storage of the source and shall include the following statement or a substantially similar statement which contains the information called for in the following statement[1].

The receipt, possession, use, and transfer of this source, Model __, Serial No. __, are subject to a general license and the regulations of the United States Nuclear Regulatory Commission or of a State with which the Commission has entered into an agreement for the exercise of regulatory authority. Do not remove this label.

CAUTION--RADIOACTIVE MATERIAL--THIS SOURCE CONTAINS AMERICIUM-241 (or RADIUM-226). DO NOT TOUCH RADIOACTIVE PORTION OF THIS SOURCE.

---

[1]Sources licensed under § 32.57 before January 19, 1975, may bear labels authorized by the regulations in effect on January 1, 1975.

(Name of manufacturer or initial transferor)

28. Section 32.59 is revised to read as follows:

§ 32.59 Same: Leak testing of each source.

Each person licensed under § 32.57 shall perform a dry wipe test upon each source containing more than 3.7 kilobecquerels (0.1 microcurie) of americium-241 or radium-226 before transferring the source to a general licensee under § 31.8 of this chapter. This test shall be performed by wiping the entire radioactive surface of the source with a filter paper with the application of moderate finger pressure. The radioactivity on the paper shall be measured by using radiation detection instrumentation capable of detecting 0.185 kilobecquerel (0.005 microcurie) of americium-241 or radium-226. If this test discloses more than 0.185 kilobecquerel (0.005 microcurie) of radioactive material, the source shall be deemed to be leaking or losing americium-241 or radium-226 and shall not be transferred to a general licensee under § 31.8 of this chapter or equivalent regulations of an Agreement State.

29. In § 32.71, paragraph (b)(8) is added, and paragraph (c)(1) is revised to read as follows:

§ 32.71 Manufacture and distribution of byproduct material for certain in vitro clinical or laboratory testing under general license.

* * * * *

(b) * * *

(8) Cobalt-57 in units not exceeding 0.37 megabecquerel (10 microcuries) each.

(c) * * *

(1) Identifying the radioactive contents as to chemical form and radionuclide, and indicating that the amount of radioactivity does not exceed 0.37 megabecquerel (10 microcuries) of iodine-131, iodine-125, selenium-75, or carbon-14; 1.85 megabecquerels (50 microcuries) of hydrogen-3 (tritium); or 0.74 megabecquerel (20 microcuries) of iron-59; or Mock Iodine-125 in units not exceeding 1.85 kilobecquerels (0.05 microcurie) of iodine-129 and 0.185 kilobecquerel (0.005 microcurie) of americium-241 each; or cobalt-57 in units not exceeding 0.37 megabecquerel (10 microcuries); and

* * * * *

30. In § 32.72, paragraphs (a)(2)(i), (a)(2)(iii), (a)(2)(iv), (b)(2)(ii), (b)(4), and (b)(5) are revised, and a new paragraph (a)(2)(v) is added to read as follows:

§ 32.72 Manufacture, preparation, or transfer for commercial distribution of radioactive drugs containing byproduct material for medical use under part 35.

(a) * * *

(2) * * *

(i) Registered with the U.S. Food and Drug Administration (FDA) as the owner or operator of a drug establishment that engages in the manufacture, preparation, propagation, compounding, or processing of a drug under 21 CFR 207.20(a);

* * * * *

(iii) Licensed as a pharmacy by a State Board of Pharmacy;

(iv) Operating as a nuclear pharmacy within a Federal medical institution; or

(v) A Positron Emission Tomography (PET) drug production facility registered with a State agency.

* * * * *

(b) * * *

(2) * * *

(ii) This individual meets the requirements specified in §§ 35.55(b) and 35.59 of this chapter, and the licensee has received an approved license amendment identifying this individual as an authorized nuclear pharmacist; or

* * * * *

(4) May designate a pharmacist (as defined in § 35.2 of this chapter) as an authorized nuclear pharmacist if:

(i) The individual was a nuclear pharmacist preparing only radioactive drugs containing accelerator-produced radioactive material, and

(ii) The individual practiced at a pharmacy at a Government agency or Federally recognized Indian Tribe before **[INSERT DATE 60 DAYS AFTER DATE OF PUBLICATION OF THIS FINAL RULE]** or at all other pharmacies before August 8, 2009, or an earlier date as noticed by the NRC.

(5) Shall provide to the Commission:

(i) A copy of each individual's certification by the Board of Pharmaceutical Specialties; or

(ii) The Commission or Agreement State license, or

(iii) Commission master materials licensee permit, or

(iv) The permit issued by a licensee or Commission master materials permittee of broad scope or the authorization from a commercial nuclear pharmacy authorized to list its own authorized nuclear pharmacist, or

(v) Documentation that only accelerator-produced radioactive materials were used in the practice of nuclear pharmacy at a Government agency or Federally recognized Indian Tribe before **[INSERT DATE 60 DAYS AFTER DATE OF PUBLICATION OF THIS FINAL RULE]** or at all other

locations of use before August 8, 2009, or an earlier date as noticed by the NRC; and

(vi) A copy of the State pharmacy licensure or registration, no later than 30 days after the date that the licensee allows, under paragraphs (b)(2)(i) and (b)(2)(iii) of this section, the individual to work as an authorized nuclear pharmacist.

* * * * *

31. In § 32.102, the heading and the introductory paragraph are revised to read as follows:

§ 32.102 Schedule C--prototype tests for calibration or reference sources containing americium-241 or radium-226.

An applicant for a license under § 32.57 shall, for any type of source which is designed to contain more than 0.185 kilobecquerel (0.005 microcurie) of americium-241 or radium-226, conduct prototype tests, in the order listed, on each of five prototypes of the source, which contains more than 0.185 kilobecquerel (0.005 microcurie) of americium-241 or radium-226, as follows:

* * * * *

PART 33 - SPECIFIC DOMESTIC LICENSES OF BROAD SCOPE FOR BYPRODUCT MATERIAL

32. The authority citation for part 33 is revised to read as follows:

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); sec. 1704, 112 Stat. 2750 (44 U.S.C. 3504 note); sec. 651(e), Pub. L. 109-58, 119 Stat. 806-810

(42 U.S.C. 2014, 2021, 2021b, 2111).

33. Section 33.100 is revised by adding Beryllium-7, Cobalt-57, Radium-226, and Sodium-22 in alphabetical order to read as follows:

§ 33.100 Schedule A.

Byproduct material	Col. I curies	Col. II curies
* * * * * * *		
Beryllium-7	10	0.1
* * * * * * *		
Cobalt-57	10	0.1
* * * * * * *		
Radium-226	0.01	0.0001
* * * * * * *		
Sodium-22	0.1	0.001

* * * * *

PART 35 - MEDICAL USE OF BYPRODUCT MATERIAL

34. The authority citation for part 35 is revised to read as follows:

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); sec. 1704, 112 Stat. 2750 (44 U.S.C. 3504 note); sec. 651(e), Pub. L. 109-58, 119 Stat. 806-810 (42 U.S.C. 2014, 2021, 2021b, 2111).

35. In § 35.2, new definitions for *Cyclotron* and *Positron Emission Tomography (PET) radionuclide production facility* are added alphabetically to read as follows:

§ 35.2 Definitions.

* * * * *

Cyclotron means a particle accelerator in which the charged particles travel in an outward spiral or circular path. A cyclotron accelerates charged particles at energies usually in excess of 10 megaelectron volts and is commonly used for production of short half-life radionuclides for medical use.

* * * * *

Positron Emission Tomography (PET) radionuclide production facility is defined as a facility operating a cyclotron or accelerator for the purpose of producing PET radionuclides.

* * * * *

36. In § 35.10, paragraph (a) is added to read as follows:

§ 35.10 Implementation.

(a) A Government agency or a Federally recognized Indian Tribe that possesses and uses accelerator-produced radioactive material or discrete sources of radium-226 for which a specific medical use license is required by the Atomic Energy Act of 1954, as amended, must comply with the requirements of this part, including provisions that are specific to licensees, on **[INSERT DATE 60 DAYS AFTER DATE OF PUBLICATION OF THIS FINAL RULE]**. All other persons who possess and use accelerator-produced radioactive material or discrete sources of radium-226 for which a specific medical use license is required, must comply with the requirements of this part, including provisions that are specific to licensees, on August 8, 2009, or earlier as noticed

by the NRC.

* * * * *

37. In § 35.11, paragraph (a) is revised, and paragraph (c) is added to read as follows:

§ 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 paragraph (b) or (c) of this section.

* * * * *

(c)(1) A Government agency or a Federally recognized Indian Tribe, that possesses and uses accelerator-produced radioactive material or discrete sources of radium-226 for which a specific medical use license is required in paragraph (a) of this section, may continue to use such materials for medical uses until the date of the NRC's final licensing determination, provided that the person submits a medical use license application on or before **[INSERT DATE 1 YEAR AND 2 MONTHS AFTER DATE OF PUBLICATION OF THIS FINAL RULE]**.

(2) Except as provided in paragraph (c)(1) of this section, all other persons, who possess and use accelerator-produced radioactive material or discrete sources of radium-226 for which a specific medical use license is required in paragraph (a) of this section, may continue to use this type of material for medical uses permitted under this part until the date of the NRC's final licensing determination, provided that the person submits a medical use license application within 12 months from the waiver expiration date of August 7, 2009 (August 31, 2005; 70 FR 51581) or within 12 months from the date of an earlier termination of the waiver as noticed by the NRC, whichever date is earlier.

38. In § 35.13, paragraphs (a) and (e) are revised, and paragraph (b)(5) is added to read as follows:

§ 35.13 License amendments.

* * * * *

(a) Before it receives, prepares, or uses byproduct material for a type of use that is permitted under this part, but is not authorized on the licensee's current license issued under this part; except that--

(1) A Government agency or a Federally recognized Indian Tribe licensee who possesses and uses accelerator-produced radioactive material or discrete sources of radium-226 may continue to use such material for medical uses permitted under this part until the date of the NRC's final licensing determination, provided that the licensee submits an amendment application on or before **[INSERT DATE 8 MONTHS AFTER DATE OF PUBLICATION OF THIS FINAL RULE]**.

(2) Except as provided in paragraph (a)(1) of this section, all other licensees who possess and use accelerator-produced radioactive material or discrete sources of radium-226 may continue to use those materials for medical uses permitted under this part until the date of the NRC's final licensing determination, provided that the person submits a medical use license amendment request within 6 months from the waiver expiration date of August 7, 2009 (August 31, 2005; 70 FR 51581) or within 6 months from the date of an earlier termination of the waiver as noticed by the NRC, whichever date is earlier.

(b) * * *

(5) A physician, podiatrist, or dentist who used only accelerator-produced radioactive materials, discrete sources of radium-226, or both, for medical uses or a nuclear pharmacist who used only accelerator-produced radioactive materials in the practice of nuclear pharmacy

at a Government agency or Federally recognized Indian Tribe before **[INSERT DATE 60 DAYS AFTER DATE OF PUBLICATION OF THIS FINAL RULE]** or at all other locations of use before August 8, 2009, or an earlier date as noticed by the NRC, and for only those materials and uses performed before these dates.

* * * * *

(e) Before it adds to or changes the areas of use identified in the application or on the license, including areas used in accordance with either § 35.100 or § 35.200 if the change includes addition or relocation of either an area where PET radionuclides are produced or a PET radioactive drug delivery line from the PET radionuclide/PET radioactive drug production area. Other areas of use where byproduct material is used only in accordance with either § 35.100 or § 35.200 are exempt;

* * * * *

39. In § 35.14, the introductory text of paragraph (a) and paragraph (b)(4) are revised to read as follows:

§ 35.14 Notifications.

(a) A licensee shall provide the Commission a copy of the board certification and the written attestation(s), signed by a preceptor, 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, the permit issued by a Commission master material license broad scope permittee, or documentation that only accelerator-produced radioactive materials, discrete sources of radium-226, or both, were used for medical use or in the practice of nuclear pharmacy at a Government agency or Federally recognized Indian Tribe before **[INSERT DATE 60 DAYS AFTER DATE OF PUBLICATION OF THIS FINAL RULE]** or at all other locations of

use before August 8, 2009, or an earlier date as noticed by the NRC, and 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). For individuals permitted to work under § 35.13(b)(4), within the same 30-day time frame, the licensee shall also provide, as appropriate, verification of completion of;

* * * * *

(b) * * *

(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 if the change does not include addition or relocation of either an area where PET radionuclides are produced or a PET radioactive drug delivery line from the PET radionuclide/PET radioactive drug production area.

* * * * *

40. In § 35.15, paragraph (f) is revised to read as follows:

§ 35.15 Exemptions regarding Type A specific licenses of broad scope.

* * * * *

(f) The provisions of § 35.14(b)(4).

* * * * *

41. In § 35.57, paragraphs (a)(3) and (b)(3) are added to read as follows:

§ 35.57 Training for experienced Radiation Safety Officer, teletherapy or medical physicist, authorized medical physicist, authorized user, nuclear pharmacist, and

authorized nuclear pharmacist.

(a) * * *

(3) A Radiation Safety Officer, a medical physicist, or a nuclear pharmacist, who used only accelerator-produced radioactive materials, discrete sources of radium-226, or both, for medical uses or in the practice of nuclear pharmacy at a Government agency or Federally recognized Indian Tribe before **[INSERT DATE 60 DAYS AFTER DATE OF PUBLICATION OF THIS FINAL RULE]** or at all other locations of use before August 8, 2009, or an earlier date as noticed by the NRC, need not comply with the training requirements of § 35.50, § 35.51 or § 35.55, respectively, when performing the same uses. A nuclear pharmacist, who prepared only radioactive drugs containing accelerator-produced radioactive materials, or a medical physicist, who used only accelerator-produced radioactive materials, at the locations and time period identified in this paragraph, qualifies as an authorized nuclear pharmacist or an authorized medical physicist, respectively, for those materials and uses performed before these dates, for purposes of this chapter.

(b) * * *

(3) Physicians, dentists, or podiatrists who used only accelerator-produced radioactive materials, discrete sources of radium-226, or both, for medical uses performed at a Government agency or Federally recognized Indian Tribe before **[INSERT DATE 60 DAYS AFTER DATE OF PUBLICATION OF THIS FINAL RULE]** or at all other locations of use before August 8, 2009, or an earlier date as noticed by the NRC, need not comply with the training requirements of subparts D through H of this part when performing the same medical uses. A physician, dentist, or podiatrist, who used only accelerator-produced radioactive materials, discrete sources of radium-226, or both, for medical uses at the locations and time period identified in this paragraph, qualifies as an authorized user for those materials and uses performed before these dates, for purposes of this chapter.

42. In § 35.63, paragraphs (b)(2)(ii) and (c)(3) are revised, and paragraph (b)(2)(iii) is added to read as follows:

§ 35.63 Determination of dosages of unsealed byproduct material for medical use.

* * * * *

(b) * * *

(2) * * *

(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; or

(iii) A PET radioactive drug producer licensed under § 30.32(j) of this chapter or equivalent Agreement State requirements.

(c) * * *

(3) Combination of volumetric measurements and mathematical calculations, based on the measurement made by:

(i) A manufacturer or preparer licensed under § 32.72 of this chapter or equivalent Agreement State requirements; or

(ii) A PET radioactive drug producer licensed under § 30.32(j) of this chapter or equivalent Agreement State requirements.

* * * * *

43. In § 35.100, paragraph (a) and the introductory text of paragraph (b) are revised to read as follows:

§ 35.100 Use of unsealed byproduct material for uptake, dilution, and excretion studies

for which a written directive is not required.

* * * * *

(a) Obtained from:

(1) A manufacturer or preparer licensed under § 32.72 of this chapter or equivalent Agreement State requirements; or

(2) A PET radioactive drug producer licensed under § 30.32(j) of this chapter or equivalent Agreement State requirements; or

(b) Excluding production of PET radionuclides, prepared by:

* * * * *

44. In § 35.200, paragraph (a) and the introductory text of paragraph (b) are revised to read as follows:

§ 35.200 Use of unsealed byproduct material for imaging and localization studies for which a written directive is not required.

* * * * *

(a) Obtained from:

(1) A manufacturer or preparer licensed under § 32.72 of this chapter or equivalent Agreement State requirements; or

(2) A PET radioactive drug producer licensed under § 30.32(j) of this chapter or equivalent Agreement State requirements; or

(b) Excluding production of PET radionuclides, prepared by:

* * * * *

45. In § 35.204, the heading and paragraph (a) are revised, paragraph (c) is

redesignated as (d) and revised, and a new paragraph (c) is added to read as follows:

§ 35.204 Permissible molybdenum-99, strontium-82, and strontium-85 concentrations.

(a) A licensee may not administer to humans a radiopharmaceutical that contains:

(1) More than 0.15 kilobecquerel of molybdenum-99 per megabecquerel of technetium-99m (0.15 microcurie of molybdenum-99 per millicurie of technetium-99m); or

(2) More than 0.02 kilobecquerel of strontium-82 per megabecquerel of rubidium-82 chloride injection (0.02 microcurie of strontium-82 per millicurie of rubidium-82 chloride); or more than 0.2 kilobecquerel of strontium-85 per megabecquerel of rubidium-82 chloride injection (0.2 microcurie of strontium-85 per millicurie of rubidium-82).

* * * * *

(c) A licensee that uses a strontium-82/rubidium-82 generator for preparing a rubidium-82 radiopharmaceutical shall, before the first patient use of the day, measure the concentration of radionuclides strontium-82 and strontium-85 to demonstrate compliance with paragraph (a) of this section.

(d) If a licensee is required to measure the molybdenum-99 concentration or strontium-82 and strontium-85 concentrations, the licensee shall retain a record of each measurement in accordance with § 35.2204.

46. In § 35.300, paragraph (a) and the introductory text of paragraph (b) are revised to read as follows:

§ 35.300 Use of unsealed byproduct material for which a written directive is required.

* * * * *

(a) Obtained from:

(1) A manufacturer or preparer licensed under § 32.72 of this chapter or equivalent Agreement State requirements; or

(2) A PET radioactive drug producer licensed under § 30.32(j) of this chapter or equivalent Agreement State requirements; or

(b) Excluding production of PET radionuclides, prepared by:

* * * * *

47. Section 35.2204 is revised to read as follows:

§ 35.2204 Records of molybdenum-99, **strontium-82, and strontium-85 concentrations.**

A licensee shall maintain a record of the molybdenum-99 concentration or strontium-82 and strontium-85 concentration tests required by § 35.204(b) and (c) for 3 years. The record must include:

(a) 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; or

(b) For each measured elution of rubidium-82, the ratio of the measures expressed as kilobecquerel of strontium-82 per megabecquerel of rubidium-82 (or microcuries of strontium-82 per millicurie of rubidium), kilobecquerel of strontium-85 per megabecquerel of rubidium-82 (or microcuries of strontium-85 per millicurie of rubidium), the time and date of the measurement, and the name of the individual who made the measurement.

PART 50 - DOMESTIC LICENSING OF PRODUCTION AND UTILIZATION FACILITIES

48. The authority citation for part 50 is revised to read as follows:

Authority: Secs. 102, 103, 104, 161, 182, 183, 186, 189, 68 Stat. 936, 937, 938, 948, 953, 954, 955, 956, as amended, sec. 234, 83 Stat. 444, as amended (42 U.S.C. 2132, 2133, 2134, 2135, 2201, 2232, 2233, 2236, 2239, 2282); secs. 201, as amended, 202, 206, 88 Stat. 1242, as amended, 1244, 1246 (42 U.S.C. 5841, 5842, 5846); sec. 1704, 112 Stat. 2750 (44 U.S.C. 3504 note); sec. 651(e), Pub. L. 109-58, 119 Stat. 806-810 (42 U.S.C. 2014, 2021, 2021b, 2111). Section 50.7 also issued under Pub. L. 95-601, sec. 10, 92 Stat. 2951 (42 U.S.C. 5841). Section 50.10 also issued under secs. 101, 185, 68 Stat. 955, as amended (42 U.S.C. 2131, 2235); sec. 102, Pub. L. 91-190, 83 Stat. 853 (42 U.S.C. 4332). Sections 50.13, 50.54(dd), and 50.103 also issued under sec. 108, 68 Stat. 939, as amended (42 U.S.C. 2138).

Sections 50.23, 50.35, 50.55, and 50.56 also issued under sec. 185, 68 Stat. 955 (42 U.S.C. 2235). Sections 50.33a, 50.55a and Appendix Q also issued under sec. 102, Pub. L. 91-190, 83 Stat. 853 (42 U.S.C. 4332). Sections 50.34 and 50.54 also issued under sec. 204, 88 Stat. 1245 (42 U.S.C. 5844). Sections 50.58, 50.91, and 50.92 also issued under Pub. L. 97-415, 96 Stat. 2073 (42 U.S.C. 2239). Section 50.78 also issued under sec. 122, 68 Stat. 939 (42 U.S.C. 2152). Sections 50.80 - 50.81 also issued under sec. 184, 68 Stat. 954, as amended (42 U.S.C. 2234). Appendix F also issued under sec. 187, 68 Stat. 955 (42 U.S.C. 2237).

49. In § 50.2, the definition of *Byproduct material* is revised to read as follows:

§ 50.2 Definitions.

* * * * *

Byproduct material means–

(1) Any radioactive material (except special nuclear material) yielded in, or made radioactive by, exposure to the radiation incident to the process of producing or using special nuclear material;

(2)(i) Any discrete source of radium-226 that is produced, extracted, or converted after extraction, before, on, or after August 8, 2005, for use for a commercial, medical, or research activity; or

(ii) Any material that--

(A) Has been made radioactive by use of a particle accelerator; and

(B) Is produced, extracted, or converted after extraction, before, on, or after August 8, 2005, for use for a commercial, medical, or research activity; and

(3) Any discrete source of naturally occurring radioactive material, other than source material, that--

(i) The Commission, in consultation with the Administrator of the Environmental Protection Agency, the Secretary of Energy, the Secretary of Homeland Security, and the head of any other appropriate Federal agency, determines would pose a threat similar to the threat posed by a discrete source of radium-226 to the public health and safety or the common defense and security; and

(ii) Before, on, or after August 8, 2005, is extracted or converted after extraction for use in a commercial, medical, or research activity.

* * * * *

PART 61 - LICENSING REQUIREMENTS FOR LAND DISPOSAL OF RADIOACTIVE WASTE

50. The authority citation for part 61 is revised to read as follows:

Authority: Secs. 53, 57, 62, 63, 65, 81, 161, 182, 183, 68 Stat. 930, 932, 933, 935, 948, 953, 954, as amended (42 U.S.C. 2073, 2077, 2092, 2093, 2095, 2111, 2201, 2232, 2233); secs. 202, 206, 88 Stat. 1244, 1246 (42 U.S.C. 5842, 5846); secs. 10 and 14, Pub. L. 95-601, 92 Stat. 2951 (42 U.S.C. 2021a and 5851) and Pub. L. 102-486, sec. 2902, 106 Stat. 3123, (42 U.S.C. 5851); sec. 1704, 112 Stat. 2750 (44 U.S.C. 3504 note); sec. 651(e), Pub. L. 109-58, 119 Stat. 806-810 (42 U.S.C. 2014, 2021, 2021b, 2111).

51. In § 61.2, the definition for *Waste* is revised to read as follows:

§ 61.2 Definitions.

* * * * *

Waste means those low-level radioactive wastes containing source, special nuclear, or byproduct material that are acceptable for disposal in a land disposal facility. For the purposes of this definition, low-level radioactive waste means radioactive waste not classified as high-level radioactive waste, transuranic waste, spent nuclear fuel, or byproduct material as defined in paragraphs (2), (3), and (4) of the definition of *Byproduct material* set forth in § 20.1003 of this chapter.

PART 62 - CRITERIA AND PROCEDURES FOR EMERGENCY ACCESS TO NON-FEDERAL AND REGIONAL LOW-LEVEL WASTE DISPOSAL FACILITIES

52. The authority citation for part 62 is revised to read as follows:

Authority: Secs. 81, 161, as amended, 68 Stat. 935, 948, 950, 951, as amended (42 U.S.C. 211, 2201; secs. 201, 209, as amended, 88 Stat. 1242, 1248, as amended (42 U.S.C. 5841, 5849); secs. 3, 4, 5, 6, 99 Stat. 1843, 1844, 1845, 1846, 1847, 1848, 1849,

1850, 1851, 1852, 1853, 1854, 1855, 1856, 1857 (42 U.S.C. 2021c, 2021d, 2021e, 2021f; sec. 1704, 112 Stat. 2750 (44 U.S.C. 3504 note); sec. 651(e), Pub. L. 109-58, 119 Stat. 806-810 (42 U.S.C. 2014, 2021, 2021b, 2111).

53. In § 62.2, the definition for *Low-level radioactive waste (LLW)* is revised to read as follows:

§ 62.2 Definitions.

* * * * *

Low-level radioactive waste (LLW) means radioactive material that—

(1) Is not high-level radioactive waste, spent nuclear fuel, or byproduct material (as defined in paragraphs (2), (3), and (4) of the definition of *Byproduct Material* set forth in § 20.1003 of this chapter); and

(2) The NRC, consistent with existing law and in accordance with paragraph (1) of this definition, classifies as low-level radioactive waste.

* * * * *

PART 72 - LICENSING REQUIREMENTS FOR THE INDEPENDENT STORAGE OF SPENT NUCLEAR FUEL, HIGH-LEVEL RADIOACTIVE WASTE AND REACTOR-RELATED GREATER THAN CLASS C WASTE

54. The authority citation for part 72 continues to read as follows:

Authority: Secs. 51, 53, 57, 62, 63, 65, 69, 81, 161, 182, 183, 184, 186, 187, 189, 68 Stat. 929, 930, 932, 933, 934, 935, 948, 953, 954, 955, as amended, sec. 234, 83 Stat. 444, as amended (42 U.S.C. 2071, 2073, 2077, 2092, 2093, 2095, 2099, 2111, 2201, 2232, 2233,

2234, 2236, 2237, 2238, 2282); sec. 274, Pub. L. 86-373, 73 Stat. 688, as amended (42 U.S.C. 2021); sec. 201, as amended, 202, 206, 88 Stat. 1242, as amended, 1244, 1246 (42 U.S.C. 5841, 5842, 5846); Pub. L. 95-601, sec. 10, 92 Stat. 2951 as amended by Pub. L. 102-486, sec. 7902, 106 Stat. 3123 (42 U.S.C. 5851); sec. 102, Pub. L. 91-190, 83 Stat. 853 (42 U.S.C. 4332); secs. 131, 132, 133, 135, 137, 141, Pub. L. 97-425, 96 Stat. 2229, 2230, 2232, 2241, sec. 148, Pub. L. 100-203, 101 Stat. 1330-235 (42 U.S.C. 10151, 10152, 10153, 10155, 10157, 10161, 10168); sec. 1704, 112 Stat. 2750 (44 U.S.C. 3504 note); sec. 651(e), Pub. L. 109-58, 119 Stat. 806-810 (42 U.S.C. 2014, 2021, 2021b, 2111).

Section 72.44(g) also issued under secs. 142(b) and 148(c), (d), Pub. L. 100-203, 101 Stat. 1330-232, 1330-236 (42 U.S.C. 10162(b), 10168(c), (d)). Section 72.46 also issued under sec. 189, 68 Stat. 955 (42 U.S.C. 2239); sec. 134, Pub. L. 97-425, 96 Stat. 2230 (42 U.S.C. 10154). Section 72.96(d) also issued under sec. 145(g), Pub. L. 100-203, 101 Stat. 1330-235 (42 U.S.C. 10165(g)). Subpart J also issued under secs. 2(2), 2(15), 2(19), 117(a), 141(h), Pub. L. 97-425, 96 Stat. 2202, 2203, 2204, 2222, 2224 (42 U.S.C. 10101, 10137(a), 10161(h)). Subparts K and L are also issued under sec. 133, 98 Stat. 2230 (42 U.S.C. 10153) and sec. 218(a), 96 Stat. 2252 (42 U.S.C. 10198).

55. In § 72.3, the definition for *Byproduct material* is revised to read as follows:

§ 72.3 Definitions.

* * * * *

Byproduct material means--

(1) Any radioactive material (except special nuclear material) yielded in, or made radioactive by, exposure to the radiation incident to the process of producing or using special nuclear material;

(2)(i) Any discrete source of radium-226 that is produced, extracted, or converted after extraction, before, on, or after August 8, 2005, for use for a commercial, medical, or research activity; or

(ii) Any material that--

(A) Has been made radioactive by use of a particle accelerator; and

(B) Is produced, extracted, or converted after extraction, before, on, or after August 8, 2005, for use for a commercial, medical, or research activity; and

(3) Any discrete source of naturally occurring radioactive material, other than source material, that--

(i) The Commission, in consultation with the Administrator of the Environmental Protection Agency, the Secretary of Energy, the Secretary of Homeland Security, and the head of any other appropriate Federal agency, determines would pose a threat similar to the threat posed by a discrete source of radium-226 to the public health and safety or the common defense and security; and

(ii) Before, on, or after August 8, 2005, is extracted or converted after extraction for use in a commercial, medical, or research activity.

* * * * *

PART 110 - EXPORT AND IMPORT OF NUCLEAR EQUIPMENT AND MATERIAL

56. The authority citation for part 110 is revised to read as follows:

Authority: Secs. 51, 53, 54, 57, 63, 64, 65, 81, 82, 103, 104, 109, 111, 126, 127, 128, 129, 161, 181, 182, 183, 187, 189, 68 Stat. 929, 930, 931, 932, 933, 936, 937, 948, 953, 954, 955, 956, as amended (42 U.S.C. 2071, 2073, 2074, 2077, 2092-2095, 2111, 2112, 2133,

2134, 2139, 2139a, 2141, 2154-2158, 2201, 2231-2233, 2237, 2239); sec. 201, 88 Stat. 1242, as amended (42 U.S.C. 5841; sec 5, Pub. L. 101-575, 104 Stat 2835 (42 U.S.C.2243); sec. 1704, 112 Stat. 2750 (44 U.S.C. 3504 note); Energy Policy Act of 2005; Pub. L. 109-58, 119 Stat. 594 (2005).

Sections 110.1(b)(2) and 110.1(b)(3) also issued under Pub. L. 96-92, 93 Stat. 710 (22 U.S.C. 2403). Section 110.11 also issued under sec. 122, 68 Stat. 939 (42 U.S.C. 2152) and secs. 54c and 57d., 88 Stat. 473, 475 (42 U.S.C. 2074). Section 110.27 also issued under sec. 309(a), Pub. L. 99-440. Section 110.50(b)(3) also issued under sec. 123, 92 Stat. 142 (42 U.S.C. 2153). Section 110.51 also issued under sec. 184, 68 Stat. 954, as amended (42 U.S.C. 2234). Section 110.52 also issued under sec. 186, 68 Stat. 955 (42 U.S.C. 2236). Sections 110.80-110.113 also issued under 5 U.S.C. 552, 554. Sections 110.130-110.135 also issued under 5 U.S.C. 553. Sections 110.2 and 110.42 (a)(9) also issued under sec. 903, Pub. L. 102-496 (42 U.S.C. 2151 et seq.).

57. In § 110.2, definitions of *Accelerator-produced radioactive material*, *Discrete source*, and *Particle accelerator* are added alphabetically to read as follows:

§ 110.2 Definitions.

* * * * *

Accelerator-produced radioactive material means any material made radioactive by a particle accelerator.

* * * * *

Discrete source means a radionuclide that is distinct from the sources of radiation present in nature, and that has been processed so its concentration within a material has been purposely increased for use for commercial, medical, or research activities.

* * * * *

Particle accelerator means any machine capable of accelerating electrons, protons, deuterons, or other charged particles in a vacuum and of discharging the resultant particulate or other radiation into a medium at energies usually in excess of 1 megaelectron volt. For purposes of this definition, "accelerator" is an equivalent term.

* * * * *

PART 150 - EXEMPTIONS AND CONTINUED REGULATORY AUTHORITY IN AGREEMENT STATES AND IN OFFSHORE WATERS UNDER SECTION 274

58. The authority citation for part 150 is revised to read as follows:

Authority: Sec. 161, 68 Stat. 948, as amended, sec. 274, 73 Stat. 688 (42 U.S.C. 2201, 2021); sec. 201, 88 Stat. 1242, as amended (42 U.S.C. 5841); sec. 1704, 112 Stat. 2750 (44 U.S.C. 3504 note); sec. 651(e), Pub. L. 109-58, 119 Stat. 806-810 (42 U.S.C. 2014, 2021, 2021b, 2111).

Sections 150.3, 150.15, 150.15a, 150.31, 150.32 also issued under secs. 11e(2), 81, 68 Stat. 923, 935, as amended, secs. 83, 84, 92 Stat. 3033, 3039 (42 U.S.C. 2014e(2), 2111, 2113, 2114). Section 150.14 also issued under sec. 53, 68 Stat. 930, as amended (42 U.S.C. 2073). Section 150.15 also issued under secs. 135, 141, Pub. L. 97-425, 96 Stat. 2232, 2241 (42 U.S.C. 10155, 10161). Section 150.17a also issued under sec. 122, 68 Stat. 939 (42 U.S.C. 2152). Section 150.30 also issued under sec. 234, 83 Stat. 444 (42 U.S.C. 2282).

59. In § 150.3, the definition of *Byproduct material* is revised, and a definition of *Discrete source* is added alphabetically to read as follows:

§ 150.3 Definitions.

* * * * *

Byproduct material means--

(1) Any radioactive material (except special nuclear material) yielded in, or made radioactive by, exposure to the radiation incident to the process of producing or using special nuclear material;

(2) The tailings or wastes produced by the extraction or concentration of uranium or thorium from ore processed primarily for its source material content, including discrete surface wastes resulting from uranium solution extraction processes. Underground ore bodies depleted by these solution extraction operations do not constitute "byproduct material" within this definition;

(3)(i) Any discrete source of radium-226 that is produced, extracted, or converted after extraction, before, on, or after August 8, 2005, for use for a commercial, medical, or research activity; or

(ii) Any material that--

(A) Has been made radioactive by use of a particle accelerator; and

(B) Is produced, extracted, or converted after extraction, before, on, or after August 8, 2005, for use for a commercial, medical, or research activity; and

(4) Any discrete source of naturally occurring radioactive material, other than source material, that--

(i) The Commission, in consultation with the Administrator of the Environmental Protection Agency, the Secretary of Energy, the Secretary of Homeland Security, and the head of any other appropriate Federal agency, determines would pose a threat similar to the threat posed by a discrete source of radium-226 to the public health and safety or the common defense and security; and

(ii) Before, on, or after August 8, 2005, is extracted or converted after extraction for use in a commercial, medical, or research activity.

* * * * *

Discrete source means a radionuclide that is distinct from the sources of radiation present in nature, and that has been processed so its concentration within a material has been purposely increased for use for commercial, medical, or research activities.

* * * * *

PART 170 - FEES FOR FACILITIES, MATERIALS, IMPORT AND EXPORT LICENSES, AND OTHER REGULATORY SERVICES UNDER THE ATOMIC ENERGY ACT OF 1954, AS AMENDED

60. The authority citation for part 170 is revised to read as follows:

Authority: Sec. 9701, Pub. L. 97-258, 96 Stat. 1051 (31 U.S.C. 9701); sec. 301, Pub. L. 92-314, 86 Stat. 227 (42 U.S.C. 2201w); sec. 201, Pub. L. 93-438, 88 Stat. 1242, as amended (42 U.S.C. 5841); sec. 205a, Pub. L. 101-576, 104 Stat. 2842, as amended (31 U.S. C. 901, 902); sec. 1704, 112 Stat. 2750 (44 U.S.C. 3504 note); sec. 623, Pub. L. 109-58, 119 Stat. 783 (42 U.S.C. 2201(w)); sec. 651(e), Pub. L. 109-58, 119 Stat. 806-810 (42 U.S.C. 2014, 2021, 2021(b), 2111).

61. In § 170.3, the definition of *Byproduct material* is revised to read as follows:

§ 170.3 Definitions.

* * * * *

Byproduct material means–

(1) Any radioactive material (except special nuclear material) yielded in, or made radioactive by, exposure to the radiation incident to the process of producing or using special nuclear material;

(2)(i) Any discrete source of radium-226 that is produced, extracted, or converted after extraction, before, on, or after August 8, 2005, for use for a commercial, medical, or research activity; or

(ii) Any material that--

(A) Has been made radioactive by use of a particle accelerator; and

(B) Is produced, extracted, or converted after extraction, before, on, or after August 8, 2005, for use for a commercial, medical, or research activity; and

(3) Any discrete source of naturally occurring radioactive material, other than source material, that--

(i) The Commission, in consultation with the Administrator of the Environmental Protection Agency, the Secretary of Energy, the Secretary of Homeland Security, and the head of any other appropriate Federal agency, determines would pose a threat similar to the threat posed by a discrete source of radium-226 to the public health and safety or the common defense and security; and

(ii) Before, on, or after August 8, 2005, is extracted or converted after extraction for use in a commercial, medical, or research activity.

* * * * *

62. In § 170.31, in the table, “Schedule of Materials Fees,” paragraph 3.B. is revised, and new categories 3.R. and 3.S. and corresponding fees are added to read as follows:

§ 170.31 Schedule of fees for materials licenses and other regulatory services, including

inspections, and import and export licenses.

* * * * *

SCHEDULE OF MATERIALS FEES

Category of materials licenses and type of fees[1]	Fee[2,3]
* * * * * * *	
3. Byproduct material:	
* * * * * * *	
B. Other licenses for possession and use of byproduct material issued under part 30 of this chapter for processing or manufacturing of items containing byproduct material for commercial distribution. This category also includes licenses for repair, assembly, and disassembly of products containing radium-226.	
Application	$4,500.
* * * * * * *	
R. Possession of items or products containing radium-226 identified in 10 CFR 31.12 which exceed the number of items or limits specified in that section.[6]	
1. Possession of quantities exceeding the number of items or limits in 10 CFR 31.12(a)(4), or (5) but less than or equal to 10 times the number of items or limits specified.	
Application	$590.
2. Possession of quantities exceeding 10 times the number of items or limits specified in 10 CFR 31.12(a) (4), or (5).	
Application	$1,400.
S. Licenses for production of accelerator-produced radionuclides.	
Application	$8,000.

* * * * * * *

[1] Types of fees - Separate charges, as shown in the schedule, will be assessed for pre-application consultations and reviews; applications for new licenses, approvals, or license terminations; possession only licenses; issuance of new licenses and approvals; certain amendments and renewals to existing licenses and approvals; safety evaluations of sealed sources and devices; generally licensed device registrations; and certain inspections. The following guidelines apply to these charges:

(a) Application and registration fees. Applications for new materials licenses and export and import licenses; applications to reinstate expired, terminated, or inactive licenses except those subject to fees assessed at full costs; applications filed by Agreement State licensees to register under the general license provisions of 10 CFR 150.20; and applications for amendments to materials licenses that would place the license in a higher fee category or add a new fee category must be accompanied by the prescribed application fee for each category.

(1) Applications for licenses covering more than one fee category of special nuclear material or source material must be accompanied by the prescribed application fee for the highest fee category.

(2) Applications for new licenses that cover both byproduct material and special nuclear material in sealed sources for use in gauging devices will pay the appropriate application fee for fee Category 1C only.

(b) Licensing fees. Fees for reviews of applications for new licenses and for renewals and amendments to existing licenses, for preapplication consultations and for reviews of other documents submitted to the NRC for review, and for project manager time for fee categories subject to full cost fees (fee Categories 1A, 1B, 1E, 2A, 4A, 5B, 10A, 11, 12, 13A, and 14) are due upon notification by the Commission in accordance with § 170.12(b).

(c) Amendment fees. Applications for amendments to export and import licenses must be accompanied by the prescribed amendment fee for each license affected. An application for an amendment to a license or approval classified in more than one fee category must be accompanied by the prescribed amendment fee for the category affected by the amendment unless the amendment is applicable to two or more fee categories, in which case the amendment fee for the highest fee category will apply.

(d) Inspection fees. Inspections resulting from investigations conducted by the Office of Investigations and nonroutine inspections that result from third-party allegations are not subject to fees. Inspection fees are due upon notification by the Commission in accordance with § 170.12(c).

(e) Generally licensed device registrations under 10 CFR 31.5. Submittals of registration information must be accompanied by the prescribed fee.

[2] Fees will not be charged for orders related to civil penalties or other civil sanctions issued by the Commission under 10 CFR 2.202 or for amendments resulting specifically from the requirements of these orders. For orders unrelated to civil penalties or other civil sanctions, fees will be charged for any resulting licensee-specific activities not otherwise exempted from fees under this chapter. Fees will be charged for approvals issued under a specific exemption provision of the Commission's regulations under Title 10 of the Code of Federal Regulations (e.g., 10 CFR 30.11, 40.14, 70.14, 73.5, and any other sections in effect now or in the future), regardless of whether the approval is in the form of a license amendment, letter of approval, safety evaluation report, or other form. In addition to the fee shown, an applicant may be assessed an additional fee for sealed source and device evaluations as shown in Categories 9A through 9D.

[3] Full cost fees will be determined based on the professional staff time multiplied by the appropriate professional hourly rate established in § 170.20 in effect at the time the service is provided, and the appropriate contractual support services expended. For applications currently on file for which review costs have reached an applicable fee ceiling established by the June 20, 1984, and July 2, 1990, rules, but are still pending completion of the review, the cost incurred after any applicable ceiling was reached through January 29, 1989, will not be billed to the applicant. Any professional staff-hours expended above those ceilings on or after January 30, 1989, will be assessed at the applicable rates established by § 170.20, as appropriate, except for topical reports whose costs exceed $50,000. Costs which exceed $50,000 for each topical report, amendment, revision, or supplement to a topical report completed or under review from January 30, 1989, through August 8, 1991, will not be billed to the applicant. Any professional hours expended on or after August 9, 1991, will be assessed at the applicable rate established in § 70.20.

* * * * *

[6] Persons who possess radium sources that are used for operational purposes in another fee category are not also subject to the fees in this category. (This exception does not apply if the radium sources are possessed for storage only.)

* * * * *

PART 171--ANNUAL FEES FOR REACTOR 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 THE NRC

63. The authority citation for part 171 is revised to read as follows:

Authority: Sec. 7601, Pub. L. 99-272, 100 Stat. 146, as amended by sec. 5601, Pub. L. 100-203, 101 Stat. 1330 as amended by sec. 3201, Pub. L. 101-239, 103 Stat. 2132, as amended by sec. 6101, Pub. L. 101-508, 104 Stat. 1388, as amended by sec. 2903a, Pub. L. 102-486, 106 Stat. 3125 (42 U.S.C. 2213, 2214); and as amended by Title IV, Pub. L. 109-103, 119 Stat. 2283 (42 U.S.C. 2214; sec. 301, Pub. L. 92-314, 86 Stat. 227 (42 U.S.C. 2201w); sec. 201, Pub. L. 93-438, 88 Stat. 1242, as amended (42 U.S.C. 5841); sec. 1704, 112 Stat. 2750 (44 U.S.C. 3504 note); sec 651(e), Pub. L. 109-58, 119 Stat. 806-810 (42 U.S.C. 2014, 2021,

2021(b), 2111).

64. In § 171.5, the definition of *Byproduct material* is revised to read as follows:

§ 171.5 Definitions.

* * * * *

Byproduct material means–

(1) Any radioactive material (except special nuclear material) yielded in, or made radioactive by, exposure to the radiation incident to the process of producing or using special nuclear material;

(2)(i) Any discrete source of radium-226 that is produced, extracted, or converted after extraction, before, on, or after August 8, 2005, for use for a commercial, medical, or research activity; or

(ii) Any material that--

(A) Has been made radioactive by use of a particle accelerator; and

(B) Is produced, extracted, or converted after extraction, before, on, or after August 8, 2005, for use for a commercial, medical, or research activity; and

(3) Any discrete source of naturally occurring radioactive material, other than source material, that--

(i) The Commission, in consultation with the Administrator of the Environmental Protection Agency, the Secretary of Energy, the Secretary of Homeland Security, and the head of any other appropriate Federal agency, determines would pose a threat similar to the threat posed by a discrete source of radium-226 to the public health and safety or the common defense and security; and

(ii) Before, on, or after August 8, 2005, is extracted or converted after extraction for use

in a commercial, medical, or research activity.

* * * * *

65. In § 171.16, paragraph (d), in the table, Schedule of Materials Annual Fees and Fees for Government Agencies Licensed by the NRC, paragraph 3.B. is revised, and new categories 3.R. and 3.S. and corresponding fees are added to read as follows:

§ 171.16 Annual Fees: Materials licensees, holders of certificates of compliance, holders of sealed source and device registrations, holders of quality assurance program approvals, and government agencies licensed by the NRC.

* * * * *

SCHEDULE OF MATERIALS ANNUAL FEES AND FEES FOR GOVERNMENT AGENCIES LICENSED BY THE NRC

Category of materials licenses		Annual fees[1,2,3]
* * * * * * *		
3. Byproduct material.		
* * * * * * *		
	B. Other licenses for possession and use of byproduct material issued under part 30 of this chapter for processing or manufacturing of items containing byproduct material for commercial distribution. This category also includes licenses for repair, assembly, and disassembly of products containing radium-226.	$8,300
* * * * * * *		
	R. Possession of items or products containing radium-226 identified in 10 CFR 31.12 which exceed the number of items or limits specified in that section.[14]	

		1. Possession of quantities exceeding the number of items or limits in 10 CFR 31.12(a) (4), or (5) but less than or equal to 10 times the number of items or limits specified.	$2,100
		2. Possession of quantities exceeding 10 times the number of items or limits specified in 10 CFR 31.12(a) (4), or (5).	$2,700
	S. Licenses for production of accelerator-produced radionuclides.		$11,800
* * * * * * *			

* * * * *

[1] Annual fees will be assessed based on whether a licensee held a valid license with the NRC authorizing possession and use of radioactive material during the current fiscal year. However, the annual fee is waived for those materials licensees and holders of certificates, registrations, and approvals who either filed for termination of their licenses or approvals or filed for possession only/storage licenses before October 1, 2004, and permanently ceased licensed activities entirely by September 30, 2004. Annual fees for licensees who filed for termination of a license, downgrade of a license, or for a possession only license during the fiscal year and for new licenses issued during the fiscal year will be prorated in accordance with the provisions of § 171.17. If a person holds more than one license, certificate, registration, or approval, the annual fee(s) will be assessed for each license, certificate, registration, or approval held by that person. For licenses that authorize more than one activity on a single license (e.g., human use and irradiator activities), annual fees will be assessed for each category applicable to the license. Licensees paying annual fees under Category 1A(1) are not subject to the annual fees for Category 1C and 1D for sealed sources authorized in the license.

[2] Payment of the prescribed annual fee does not automatically renew the license, certificate, registration, or approval for which the fee is paid. Renewal applications must be filed in accordance with the requirements of parts 30, 40, 70, 71, 72, or 76 of this chapter.

[3] Each fiscal year, fees for these materials licenses will be calculated and assessed in accordance with § 171.13 and will be published in the Federal Register for notice and comment.

* * * * *

[14] Persons who possess radium sources that are used for operational purposes in another fee category are not also subject to the fees in this category. (This exception does not apply if the radium sources are possessed for storage only.)

* * * * *

Dated at Rockville, Maryland, this _____ day of _____, 2007.

For the Nuclear Regulatory Commission.

_____

Annette L. Vietti-Cook,
Secretary of the Commission.

Environmental Assessment for Final Rulemaking - Expanded Definition of Byproduct Material Established by Section 651(e) of the Energy Policy Act of 2005

U.S. Nuclear Regulatory Commission

Table of Contents

ACRONYMS/ABBREVIATIONS

AEA	Atomic Energy Act of 1954, as amended
AEC	U.S. Atomic Energy Commission
ALARA	as low as reasonably achievable
ARM	Accelerator-produced radioactive material
CFR	Code of Federal Regulations
CRCPD	Conference of Radiation Control Program Directors, Inc.
DOE	Department of Energy
DOT	Department of Transportation
EPA	Environmental Protection Agency
EPAct	Energy Policy Act of 2005
FONSI	Finding of No Significant Impact
FR	Federal Register
IAEA	International Atomic Energy Agency
LLRWPAA	Low-Level Radioactive Waste Policy Amendments Act
NARM	naturally occurring and accelerator-produced radioactive material (in this document, limited to that made byproduct material by the EPAct)
NMSS	Office of Nuclear Materials Safety and Safeguards
NORM	naturally occurring radioactive material
NRC	U.S. Nuclear Regulatory Commission
OAS	Organization of Agreement States, Inc.
OSHA	Occupational Safety and Health Administration
Pub. L.	Public Law
RCRA	Resource Conservation and Recovery Act
SS&D	Sealed Source and Device
SSRs	Suggested State Regulations for the Control of Radiation
U.S.C.	United States Code

1.0 INTRODUCTION

The U.S. Nuclear Regulatory Commission (NRC) is amending its regulations to include certain radium sources, certain naturally occurring radioactive material, and accelerator-produced radioactive materials as required by Section 651(e) of the Energy Policy Act of 2005 (EPAct), which was signed into law on August 8, 2005. The EPAct expanded the definition of byproduct material in Section 11e. of the Atomic Energy Act of 1954 (AEA) to include certain naturally occurring and accelerator-produced radioactive materials (NARM), placing these byproduct materials under NRC authority. The EPAct also required the NRC to provide a regulatory framework for licensing and regulating this NARM. The NRC prepared this environmental assessment to determine whether adopting these regulations, which provide the required regulatory framework, will have any significant environmental impact.

Background

Radioactive materials may be divided into two general groups: naturally occurring radioactive material (NORM), which would exist in nature even in the absence of human activity, and radioactive materials that are produced by the technological activities of humankind. The second group, which makes up the vast majority of radioactive material used in human activity, includes products of nuclear reactors and accelerator-produced radioactive material (ARM).

Collectively, “naturally occurring and accelerator-produced radioactive material,” other than source material, is referred to as NARM. The significance of the distinction between source material and the products of nuclear fission reactors and NARM is that prior to the passage of the EPAct in 2005, the NRC had no regulatory authority over NARM. Since the passage of the AEA, the NRC and its predecessor agency, the Atomic Energy Commission (AEC), have regulated the acquisition, possession, use, transfer, and disposal of byproduct material, as well as source material and special nuclear material. Byproduct material was originally defined to include only materials made radioactive in the production or utilization of special nuclear material; i.e., radioactive material produced in a fission reactor, and later to also include tailings and waste produced by the extraction or concentration of uranium or thorium from any ore processed primarily for its source material content. The regulation of NORM other than source material (and that in the tailings and waste produced by the extraction or concentration of uranium or thorium from any ore processed primarily for its source material content), and accelerator-produced radioactive material was left primarily to the individual States. Although efforts were made by several States to provide a uniform regulatory environment, there was no nationwide consistency to the regulation of NARM. Other Federal agencies exercised limited regulatory authority over activities involving NARM consistent with their primary missions, but again there was no overall, consistent regulation as in the case of byproduct, source, and special nuclear material.

The Energy Policy Act of 2005

On August 8, 2005, the President signed into law the Energy Policy Act of 2005. Among other provisions, Section 651(e) of the EPAct expanded the definition of byproduct material in Section 11 e. of the AEA and required the Commission to provide a regulatory framework for licensing and regulating this NARM in accordance with the expanded definition of byproduct material.

Specifically, as stated in Section 651(e) of the EPAct, the definition of byproduct material, as provided in Section 11 e.(1) and (2) of the AEA, is expanded to include:

> "(3)(A) any discrete source of radium-226 that is produced, extracted, or converted after extraction, before, on, or after the date of enactment of this paragraph for use for a commercial, medical, or research activity; or
>
> (B) any material that —
>
> (i) has been made radioactive by use of a particle accelerator; and
>
> (ii) is produced, extracted, or converted after extraction, before, on, or after the date of enactment of this paragraph for use for a commercial, medical, or research activity; and
>
> (4) any discrete source of naturally occurring radioactive material, other than source material, that —
>
> (A) the Commission, in consultation with the Administrator of the Environmental Protection Agency, the Secretary of Department of Energy, the Secretary of the Department of Homeland Security, and the head of any other appropriate Federal agency, determines would pose a threat similar to the threat posed by a discrete source of radium-226 to the public health and safety or the common defense and security; and
>
> (B) before, on, or after the date of enactment of this paragraph is extracted or converted after extraction for use in a commercial, medical, or research activity."

The EPAct's expanded byproduct material definition introduces the term, "discrete source," as applied to radium-226 and certain other sources of NORM. Section 651(e) also requires the NRC to define this term by rulemaking. Finally, the EPAct clarifies that NARM, as included in the expanded byproduct material definition, shall not be considered low-level radioactive waste for disposal for the purposes of meeting the provisions of the Low-Level Radioactive Waste Policy Amendments Act (LLRWPAA).

Prior to enactment of the EPAct, the NRC had neither authority over NARM nor regulations for such material. The current regulatory structure for the control of radioactive materials was established by the AEA, as amended. The AEA authorizes States to assume regulatory control over radioactive materials produced in or by a nuclear reactor, provided the State has an adequate, NRC-compatible program to protect the public health and safety and enters into an agreement with the NRC. The activities regulated by these "Agreement States" include the use of byproduct, source, and limited quantities of special nuclear material. Each Agreement State issues licenses to persons who use these materials in that State. The NRC issues licenses to persons using these materials in non-Agreement States, plus certain categories of entities and activities nationwide. Currently, there are 34 Agreement States and 16 non-Agreement States, plus U. S. territories, Government agencies, and Federally recognized Indian tribes. (Note: Minnesota's agreement, effective as of March 31, 2006, is included in this summation.)

Although the NRC has not regulated most NARM in the past, all Agreement States and certain non-Agreement States have established regulatory programs for NARM. Some States have different regulations for other, typically diffuse types of NORM. Some Government agencies have developed "self-regulating" programs internally applying NRC radiation safety requirements to NARM uses. For years, Agreement States have regulated NARM use in a fairly uniform and consistent manner. This was accomplished by using the same standards to regulate NARM as those used to regulate other byproduct, source, and special nuclear material. In many respects, regulations adopted by the Agreement States are compatible with

the NRC regulations in Title 10 of the Code of Federal Regulations (10 CFR) for the current materials program, or the Suggested State Regulations for the Control of Radiation (SSRs) developed by the Conference of Radiation Control Program Directors, Inc. (CRCPD). The regulatory structure for control of NARM in non-Agreement States varies greatly from State to State. While some non-Agreement States have established NARM regulatory structures similar to those established by the Agreement States, other non-Agreement States have elected to use facility and/or device registration as their regulatory structure for managing NARM users. It was, in part, due to this lack of national consistency, that the EPAct added these materials to the AEA definition of byproduct material.

Need for the Preferred Action

The EPAct became effective on August 8, 2005. The EPAct requires the NRC to provide a regulatory framework for licensing and regulating the naturally occurring and accelerator-produced radioactive materials that are included in the expanded byproduct material definition in Section 651(e) of the Act. The EPAct directed the NRC to promulgate regulations to establish a national program for NARM.

The Preferred Action

The Commission's regulations in Part 30 (in Title 10 of the Code of Federal Regulations) set out the basic requirements for domestic licensing of byproduct material. The NRC is incorporating NARM into the byproduct material definition under §§ 20.1003, 30.4, 50.2, 72.3, 150.3, 170.3, and 171.5 to agree with the expanded byproduct material definition provided in Section 651(e) of the EPAct. In addition, the NRC is amending its regulations governing the receipt, possession, use, storage, transfer, and disposal of byproduct material to conform with this expanded byproduct material definition. The preferred action is to amend the Commission's regulations in 10 CFR Parts 20, 30, 31, 32, 33, 35, 50, 61, 62, 72, 110, 150, 170, and 171.

The major features of the final amendments address:

- revising the byproduct material definition to reflect the expanded definition provided in Section 651(e) of the EPAct;
- defining or redefining the terms: accelerator-produced radioactive material, consortium, cyclotron, discrete source, low-level radioactive waste, particle accelerator, positron emission tomography (PET) radionuclide production facility, and waste;
- delineating licensing provisions for manufacture, possession, use, transfer, ownership, and disposal of NARM and products containing NARM, including provisions for exemptions from licensing requirements;
- specifying exempt quantity limits applicable to ARM;
- specifying NARM packaging and labeling requirements;
- specifying requirements for manufacture, preparation, and transfer of radioactive drugs containing ARM;
- delineating licensing requirements for persons who manufacture, produce, acquire, receive, possess, prepare, use, or transfer NARM-containing medical products; including provisions for obtaining licenses and license amendments;
- specifying requirements for medical professionals who are experienced users of NARM; and
- specifying testing requirements for sources containing NARM.

2.0 PREFERRED ACTION AND ALTERNATIVES

To define the alternatives considered in the implementation of the EPAct, the NRC staff differentiated between the actions specifically required by the Act and areas where the Act allows flexibility in the degree of regulatory authority to be applied in the rule. Based on this review, the staff developed alternatives to the regulatory framework with regard to areas where the EPAct allows flexibility. The alternatives include a no-action alternative; a second alternative which would implement the requirements specifically mandated by the Act and the highest degree of regulatory authority and control included within the bounds allowed by the flexibility within the EPAct; and the preferred alternative, which reflects the staff's approach for accomplishing the EPAct's requirements, described as a graded approach.

Requirements of the EPAct

Section 651(e)(4)(B) of the EPAct requires the Commission to use model State standards, to the "maximum extent practicable," in developing the regulations. The NARM regulations for most Agreement States are based on model regulations, known as the Suggested State Regulations for the Control of Radiation (SSRs). The SSRs for radioactive materials are compatible in many respects with the NRC regulations.

Section 651(e) of the EPAct mandates that NARM not be considered low-level radioactive waste for the purposes of the Low-Level Radioactive Waste Policy Amendments Act (42 U.S.C. 2021b) (LLRWPAA). This provision is consistent with current NRC policy, under which NARM would be classified as "radioactive waste" for disposal purposes and may be disposed of according to Federal and State hazardous waste laws. This provision would be included in all of the alternatives.

Areas Where EPAct Allows Flexibility

During the process of developing a regulatory framework for licensing and regulating NARM, the staff identified several areas where the Act allows some degree of flexibility. As discussed below, the EPAct does not specifically address the type of license to be required for NARM licensed activities or whether incidentally irradiated material should be regulated. Furthermore, the EPAct delegated, to the NRC, the responsibility for defining the term "discrete source," as it applies to radium-226 and certain other NORM.

Section 651(e) of the EPAct requires the Commission to develop regulations to establish the regulatory requirements necessary to carry out this section of the Act. While the requirement to maintain consistency with current State regulations strongly suggests using a similar regulatory framework of specific and general licenses and exemptions, the EPAct does not mandate which license type (i.e., general or specific) would be required for NARM, nor does the Act specify whether allowances for exemptions from byproduct material regulations should be provided in the final regulations. Under the AEA, the Commission has authority to issue both general and specific licenses for the use of byproduct material and also to exempt byproduct material from regulatory control under the AEA. Because of the flexibility allowed by current regulations and Section 651(e) of the EPAct, it is reasonable to consider more than one alternative specifying different license types and exemption allowances, depending upon whether or not there exist model State regulations upon which the rule could be based.

Section 651(e) of the EPAct requires the Commission to include, as byproduct material, certain accelerator-produced radioactive material (ARM). This expanded byproduct material definition

only includes material that is produced, extracted, or converted specifically for use in a commercial, medical, or research activity. The radioactive material intentionally produced by activation of the target is commonly referred to as "product ARM." The EPAct does not specifically address whether material that is incidentally irradiated during operation of an accelerator (referred to as "incidental ARM") should be regulated. Because of the flexibility allowed by the EPAct in this respect, it is reasonable to consider more than one alternative with differing regulatory approaches for incidental ARM.

Section 651(e)(4)(A)(ii) of the EPAct requires the Commission to define the term "discrete source" as applied to radium-226 and certain other NORM in the expanded definition of byproduct material. A discrete source would be defined to include a concentrated radioactive material that is distinct from the radiation present in nature. The flexibility allowed by this requirement relates to whether or not the radionuclide or radioactive material specifically has been concentrated on purpose for use for commercial, medical, or research activity. A broad "discrete source" definition could include any concentrated radium-226 or other NORM, regardless of whether it was concentrated specifically for its radiological properties or incidentally from a process that extracts or produces products, such as fertilizer, fly ash, or residue from the purification of water. A more limited "discrete source" definition would only include radioactive material in which the radionuclide was concentrated with the intent of using its properties, thereby excluding NRC jurisdiction over inadvertent movement or concentration of NORM. Because of the flexibility in allowing the Commission to provide this definition, it is reasonable to consider more than one alternative, each with a different discrete source definition.

Section 651(e)(4)(D) of the EPAct requires the Commission to consider the impact on the availability of pharmaceuticals to physicians and patients in promulgating these regulations. This requirement does not prescribe how to consider the potential impact of the regulations on the medical community or patients; nor the approach to be taken to address potential impacts. This requirement allows flexibility in the regulatory framework that is applied to ARM products generated for medical activities, as well as the implementation aspects for the regulations. Although the EPAct allows flexibility in considering the regulation's potential impacts on the medical community or patient, and it is reasonable to consider more than one alternative with differing medical ARM product licensing requirements and implementation plans, there are no discernable differences between the environmental impacts of the alternative approaches to addressing pharmaceutical availability. Therefore, both the preferred action and Alternative 2 would establish a similar set of regulations and an implementation process to minimize the regulatory impact on the availability of accelerator-produced radioactive drugs. The key points associated with this area of the final regulations are summarized later in this section, under the discussion of Alternative 3.

Based on the staff's review of the actions specifically mandated by the EPAct and areas where the EPAct allows flexibility in the degree of regulatory authority and control, the staff identified three alternatives: (1) to take no action; (2) to establish regulations that apply the greatest extent of regulatory authority and control allowed by the EPAct; and (3) to establish regulations that apply a graded, risk-informed approach to exercising the regulatory authority provided by the EPAct. The following provides a more detailed discussion of each alternative. The discussion under the Alternative 3 description and in Section 4.0 provides the basis for choosing Alternative 3 as the preferred alternative.

Alternative 1: The No-Action Alternative

The no-action alternative is to maintain the status quo. Under the no-action alternative, the Commission would neither adopt the expanded definition of byproduct material provided in Section 651(e) of the EPAct, nor provide a regulatory framework for licensing and regulating NARM. The staff understands that the no-action alternative is not acceptable, as this rulemaking activity is Congressionally mandated; however, this alternative provides the baseline against which the other alternatives are assessed.

Alternative 2: Revise Regulations to Maximize NRC's Regulatory Authority and Control

This alternative would establish regulations to implement the requirements specifically required by the EPAct and the highest degree of regulatory authority and control included within the bounds allowed by the flexibility within the EPAct. In accordance with EPAct Section 651(e)(4)(B), the NARM regulatory framework would be based, to the maximum extent practicable, on the SSRs.

This alternative is to establish regulations and an implementation process that would minimize the regulatory impact on the availability of accelerator-produced radioactive drugs by taking the following actions: (1) applying NRC's established regulatory framework to the commercial distribution of these drugs; (2) expanding the regulations to permit noncommercial distribution of PET drugs within a consortium; (3) "grandfathering" current users of accelerator-produced drugs; and (4) permitting individuals and other entities to continue to prepare and use radioactive drugs while they are applying for new licenses or amendments.

Under this alternative, the revised regulations would require more specific licenses for the production, use, transfer, and distribution of NARM material and products containing NARM. In areas where the SSRs do not specifically address material within the scope of the new byproduct material definition or where there are few model State regulations at the national consensus level upon which the NRC can base its regulations, this alternative would require specific licenses. Part N of the SSRs address NORM; however, this is generally applicable to diffuse sources of NORM, which have not been produced for the purpose of using the radioactive material within for commercial, medical, or research activities.

SSR requirements for ARM and discrete sources of radium are the same as for reactor-produced radioactive material as they are all covered under provisions for "radioactive material." Only a few provisions in the model State regulations are specific to discrete sources of radium and accelerator-produced radioactive material. Specific provisions concerning ARM radionuclides include: (1) a general license and associated requirements for cobalt-57 *in vitro* clinical or laboratory tests, (2) contamination levels for strontium-82/rubidium-82 generators for medical use, (3) exempt quantity limits for certain accelerator-produced radionuclides. With respect to radium, the SSRs include: (1) an exemption for previously acquired timepieces containing up to 37 kilobecquerels (kBq) (1 microcurie (μCi)) of radium-226, (2) an exemption for other previously acquired self-luminous products containing up to 3.7 kBq (0.1 μCi) of radium-226, (3) a provision to allow a specifically licensed person to possess up to 185 kBq (5 μCi) of radium-226 in calibration and reference sources under a general license, and (4) an exemption for gas and aerosol detectors containing NARM, with a limit of 3.7 kBq (0.1 μCi) of radium-226 that may be incorporated into smoke detectors distributed for use under exemption from licensing. Under this alternative, these specific requirements would be included in the regulations.

However, the SSRs do not specifically address certain categories of products and discrete sources containing radium-226 which are in the public domain but may not be otherwise covered under a license. Therefore, under this alternative, the regulations would require specific licenses for discrete sources of radium-226 that may not be otherwise covered under a general license or an exemption in the SSRs. For NARM material and products containing NARM that are addressed in the SSRs, such as those discussed above, this alternative would include a regulatory framework similar to the SSRs.

Section 651(e)(4)(A)(ii) of the EPAct requires the Commission to define the term "discrete source" as applied to radium-226 and other NORM in the expanded definition of byproduct material. Under this alternative, discrete source would be defined broadly to include any concentrated radium-226 or other NORM, regardless of whether it was intentionally concentrated or incidentally concentrated from a process that extracts or produces products not intended to be radioactive. This definition would not limit the NRC's jurisdiction to only include radionuclides that are concentrated and used purposefully for their properties. This broader definition would divert the NRC's regulatory efforts away from those materials that pose the greatest health and security risk by including an array of NORM sources, including sources that were created through inadvertent movement or concentration of naturally occurring radioactive material, such as that found in scaling on pipes from the fossil fuel industry, in fly ash from coal burning, or in fertilizers.

Under this alternative, any material rendered radioactive by a particle accelerator, including incidental radioactive materials, would be covered by the Commission's regulations from the time at which it is initially irradiated. Byproduct material would include product ARM and all incidental ARM, including irradiated target material, accelerator internal structures, and facility building materials, regardless of the accelerator type or use.

In accordance with Section 651(e)(3), for disposal purposes, this newly defined byproduct material would be classified only as radioactive waste, and would not be considered to be low-level radioactive waste for the purposes of the LLRWPAA.

Alternative 3: Revise Regulations to Apply a Graded, Risk-Informed Approach for Regulatory Authority over NARM

The NRC proposed and is now finalizing an alternative that revises its regulations by applying a graded approach to exercising regulatory authority over NARM in order to focus the staff's regulatory efforts on those activities that pose the greatest risk to protection of the public health and safety and promotion of the common defense and security. Beyond implementing the requirements specifically mandated by the EPAct, this alternative addresses the flexibility within the EPAct by establishing regulations that are commensurate with the potential health and safety consequences applicable to each NARM-containing product type. As required by the EPAct, the NARM regulatory framework has been based, to the maximum extent practicable, on the SSRs.

This preferred alternative includes general licensing provisions for certain products and discrete sources containing radium-226 that are apparently in the public domain but may not be otherwise covered under a license and are not specifically addressed in the SSRs. This alternative also accommodates generally licensed devices meeting the restrictions of the general licenses that were previously approved by States under existing regulations. This alternative is to regulate NARM under most of the same requirements as reactor-produced radioactive material. Additionally, this alternative adds certain products and materials

containing NARM to some of the current exemptions, thereby allowing these NARM-containing products to be used without any regulatory requirements imposed on the user. This alternative does not require any changes be made to the exempt concentrations for radionuclides included in the SSRs, and adopts appropriate values for exempt quantities for the newly defined byproduct material consistent with the SSRs. The preferred alternative also adopts an exemption for timepieces containing 37 kBq (1 μCi) or less of radium-226 and adopts the requirement to allow a specifically licensed person to possess up to 185 kBq (5 μCi) of radium-226 in calibration and reference sources under a general license.

Under this preferred alternative, *discrete source* is defined to include only radionuclides that were concentrated with the intent of using the radionuclides for commercial, medical, or research activities. *Discrete source* is defined in the final rule as "a radionuclide that is distinct from the sources of radiation present in nature, and that has been processed so that its concentration within a material has been purposely increased for use in commercial, medical, or research activities." Under this definition, discrete sources of radium-226 or discrete sources of naturally occurring radioactive material may have the same radiological characteristics (i.e., type of radiation, half-life, etc.) as the radionuclides found in nature, but the radionuclides will have been purposely concentrated for use of the radionuclides specifically. This definition limits NRC's jurisdiction, by excluding inadvertent movement or concentration of naturally occurring radioactive material, such as that found in scaling on pipes from the fossil industry, in fly ash from coal burning, or in fertilizers. NRC's authority over source material will not be changed by this definition. This definition is revised from that proposed for clarification purposes. Under the revised definition, once a radioactive material, defined as a discrete source, becomes byproduct material, it continues to be byproduct material, even if no longer "discrete" in the usual sense. Contamination resulting from the use of discrete sources of radium-226, or other radionuclide identified under Section 11e.(4) of the AEA, is still byproduct material.

Under this preferred alternative, the NRC will regulate the radioactive material (product and incidental ARM) produced by all accelerators that intentionally produce a radioactive material for its radioactive properties (e.g., PET production facilities). The rationale for this approach is that this incidentally produced radioactive material is a direct result of producing the radioactive material for use for a commercial, medical, or research activity. In addition, it is necessary for the NRC to consider all radioactive material in its regulatory evaluation to ensure health and safety of the radioactive material production. This preferred alternative will not regulate incidental ARM that results from the operation of accelerators that only produce particle beams and do not intentionally produce radioactive materials for use for a commercial, medical, or research activity (e.g., electron microscopes and medical therapy linear accelerators). The reasons for not regulating this incidentally produced radioactive material are: (1) no radioactive material is produced for use for a commercial, medical, or research activity from such operation, and (2) the incidentally produced radioactive material resides within the accelerator or facility. For those accelerators that are used to produce both radioactive material and particle beams, the preferred alternative will apply NRC regulations to the incidental ARM, as well as the product ARM, produced by the accelerator. The incidental ARM produced in such accelerators during the production of radioactive material for use for a commercial, medical, or research activity is indistinguishable from that produced when the same accelerator is operated to produce only particle beams, so both are covered by this final rule.

The regulatory framework and implementation process associated with radiopharmaceuticals under this preferred alternative will be the same as that described previously for Alternative 2. This preferred alternative will establish regulations and an implementation process that will minimize the regulatory impact on the availability of accelerator-produced radioactive drugs by

taking the following actions: (1) applying its established regulatory framework to the commercial distribution of these drugs; (2) expanding the regulations to permit noncommercial distribution of PET drugs within a consortium; (3) "grandfathering" current users of accelerator-produced drugs; and (4) permitting individuals and other entities to continue to prepare and use radioactive drugs while they are applying for new licenses or amendments.

Under the preferred alternative, as required by Section 651(e)(3), NARM-containing byproduct material will be classified only as radioactive waste, and will not be considered to be low-level radioactive waste for the purposes of the LLRWPAA.

3.0 AFFECTED ENVIRONMENT AND CURRENT REGULATORY STRUCTURE

The alternatives evaluated in this environmental assessment involve establishing and promulgating changes to the Commission's regulations in order to implement the Commission's regulatory authority over certain radium sources, certain naturally occurring radioactive material, and accelerator-produced radioactive materials as provided by Section 651(e) of the EPAct. The human environment affected by this activity includes the physical environment in which the NARM is produced, received, possessed, used, transferred, distributed, and disposed and the regulatory environment that defines the rules and regulations governing activities associated with NARM. Ultimately, the impact on the human environment will be dependent on changes to the current regulatory environment and the resultant impacts on the physical environment.

3.1 Affected Physical Environment

Radium-226 and Other NORM with Similar Risk as Radium-226

Under the previous regulatory framework, NRC did not directly regulate NORM radionuclides (except source material and those in mill tailings and waste), including radium-226 and other NORM that would pose a similar threat to that posed by a discrete source of radium-226. Radium-226 is a NORM radionuclide that can be found in all uranium ores. Since its discovery in 1898 until the early 1900's, the dangers of radium were not fully understood. Because of its ability to stimulate luminescence, industries manufactured many consumer products containing radium. Manufacture of most of these products was discontinued for health and safety reasons, but the wide use of radium in luminescent paints for items such as watch hands and faces and aircraft instruments, dials, and gauges continued until after World War II. Many of these early products, such as radium emanator jars, radium bath salts, and healing pads, still remain in the possession of museums and individual collectors. More recently, radium sources were used in industrial radiography, industrial smoke detectors, and some industrial products, such as gauges. Because of its radiological properties, radium-226 poses a potential threat to public health and safety if not managed safely and securely.

The International Atomic Energy Agency (IAEA) identified a list of sources that are considered to pose a high risk to human health and safety if not managed safely and securely. Of the 33 radionuclides identified by the IAEA Code of Conduct to cause deterministic detrimental effects at reference doses, only two that are not source material are naturally occurring radionuclides: radium-226 and polonium-210. Therefore, using the IAEA criteria, the only other NORM similar in hazard to radium-226 is polonium-210. However, naturally occurring polonium that has been extracted or concentrated for use is scarce. Commercially used polonium-210 is produced in a nuclear reactor. Consequently, polonium-210 is already regulated by the NRC as

byproduct material. At this time, no other discrete sources of NORM were identified that would pose a hazard similar to radium-226.

Accelerator-Produced Radioactive Material

Particle accelerators produce radioactive material by directing a beam of high-speed particles at a target composed of a specifically selected element, which is usually not radioactive. When the nuclei in the target are struck by the high-speed particles, they undergo a nuclear transformation and a new nuclide is formed. The nuclide produced during this activation process is usually radioactive and is useful because of its radiological properties. Most of the accelerator-produced radioactive material today is created for use in medicine.

Particle Accelerators

A particle accelerator is a device that imparts kinetic energy to subatomic particles by increasing their speed through electromagnetic interactions. Particle accelerators are used to produce radioactive material by directing a beam of high-speed particles at a target composed of a specifically selected element, which is usually not radioactive. The target element is activated when its nuclei are struck by high-speed particles and undergo a nuclear transformation. Usually, the nuclide produced is radioactive and is useful because of its radiological properties.

Particle accelerators may be separated into three functional groupings:
(1) those that are operated exclusively to intentionally produce radioactive materials in quantities useful for their radiological properties for a commercial, medical, or research activity (e.g., PET production facilities and other accelerators that produce radioactive material for use in medical activities);
(2) those that are intended to only produce particle beams and not radioactive materials (e.g., electron microscopes, linear accelerators used for the medical treatment of cancer); or
(3) those that intentionally produce both radioactive materials and particle beams (few, if any, accelerators are in this grouping).

In addition to the radioactive material intentionally produced by particle accelerators, the production of incidental ARM is an inextricable part of any accelerator operation. Incidental ARM may include accelerator internals and materials in the structure of the building and facilities housing the accelerator. For those accelerators that are used to intentionally produce radioactive material (i.e., functional groups (1) and (3), above), the incidental ARM that results during the production of product ARM is indistinguishable from that which would be produced from the particle beam alone. For accelerators that are used to produce particle beams only (i.e., functional group (2), above), no radioactive material is produced for use for a commercial, medical, or research activity from such operation, and the incidental ARM that results from operation resides within the accelerator or facility.

Accelerator-Produced Radioactive Material Used in Medical Activities

The majority of accelerator-produced radioactive material is created for use in medicine. Approximately 4,000 hospital-based nuclear medicine departments and many freestanding imaging centers in the U.S. perform a large number of nuclear medicine imaging studies every year. Nuclear medicine is an integral part of patient care and is valuable in the early diagnosis and treatment of many medical conditions. Nuclear medicine uses radioactive materials (radiopharmaceuticals) to diagnose and treat disease. In diagnosis, the radiopharmaceuticals

are introduced into the body through injection or ingestion, then detected by special "cameras" with the aid of computers to provide images of the area of interest. In treatment, the radiopharmaceuticals can be directed to a specific organ being treated.

Radiopharmaceuticals can be made from radionuclides produced in nuclear reactors or in particle accelerators. Currently, most reactor-produced byproduct material radionuclides are imported into the U.S., where they are used to produce specific radioactive drugs (including biologics). There are a limited number of commercial manufacturers in the U.S. that produce radiopharmaceuticals using radionuclides such as thallium-201, iodine-123, indium-111, and gallium-67 that are produced in particle accelerators. In recent years, radiopharmaceuticals known as PET drugs have been produced in cyclotron facilities (known as PET centers). PET imaging devices produce diagnostic images with better spacial resolution than other traditional diagnostic imaging techniques. Due to their short half-lives, PET radionuclides and drugs are produced at locations in close proximity to the patients, such as hospitals. Manual brachytherapy sources containing accelerator-produced palladium-103 also represent a significant medical use of ARM material in therapy treatments.

Radiation Dose from NARM

The principal public health and safety consideration associated with the expanded byproduct material definition pertains to the occupational dose resulting from the regulation of this material. The source of the radiation exposure may be the radioactive material itself (i.e., NARM and NARM-containing products), or structures or equipment that have become irradiated by a particle beam. The NRC's standards for the protection of radiation workers and members of the public from the hazardous effects of radiation are provided in 10 CFR Part 20. These regulations specify provisions for radiation protection programs (including requirements to use procedures and controls to achieve doses that are as low as is reasonably achievable (ALARA)), occupational and public dose limits, engineering and administrative controls to reduce exposure, respiratory protection requirements, and material storage and control requirements. Occupational dose is defined to include dose received in the course of employment as a result of exposure to licensed (regulated) and unlicensed (unregulated) sources. Licensees are not required to differentiate between dose contributed from NARM and dose contributed from other byproduct, source, or special nuclear material. Although 10 CFR Part 20 does not differentiate between dose obtained from regulated or unregulated sources of radiation, Part 20 is only applicable to activities conducted under NRC-issued licenses. As a result, industrial and private activities that only involve products containing NARM, and not any other previously licensed radioactive material, would not have been provided the protection afforded by Part 20 prior to implementation of the EPAct requirements.

Disposal of NARM-Containing Radioactive Waste

Under the current practices, radioactive wastes containing NARM and NARM-containing products, including decommissioning waste containing incidental ARM, are disposed of at State-permitted hazardous and solid waste disposal facilities and at the regional radioactive waste disposal facilities located in Barnwell, South Carolina, and Richland, Washington. The authority to permit disposal of NARM is provided by Federal or State hazardous waste laws and State radioactive waste laws, including the Solid Waste Disposal Act, which are not affected by the provisions of the EPAct.

Decommissioning Issues

In addition to the radioactive material intentionally produced by particle accelerators, the production of incidental ARM is an inextricable part of any accelerator operation. Incidental ARM may include accelerator internals and materials in the structure of the building and facilities housing the accelerator. In its radiological criteria for license termination, the NRC already requires licensees to consider sources other than AEA material, including radium, during decommissioning activities at NRC-licensed sites contaminated with source material, such as rare-earth processing facilities. The primary effect of the EPAct with respect to decommissioning is that regulations governing decommissioning will be applied to additional facilities.

3.2 Current Regulatory Environment

Because a well-established regulatory framework for control of NARM already exists in many Agreement States, the EPAct requirements to expand the byproduct material definition to include NARM and establish the necessary regulatory framework will have little, if any, direct impact on the physical environment. This section discusses the NRC's current regulatory structure and the regulatory structures established by Agreement States for control over NARM, including both NORM (i.e., radium-226 and other NORM) and the material produced by particle accelerators.

Current NRC Regulatory Framework for Byproduct Material

Under the AEA, the Commission has authority to issue both general and specific licenses for the use of byproduct material and also to exempt byproduct material from regulatory control. A specific license is issued by the Commission to grant authority to a person who has filed a license application with the Commission. These are issued under Part 30, with additional specific licensing requirements for certain activities contained in Parts 32, 33, 34, 35, 36, and 39.

A general license grants authority to unnamed persons for certain activities involving byproduct material, and is effective without the filing of an application with the Commission or the issuance of a licensing document to a particular person, although certain general licenses require registration with the Commission. 10 CFR Part 31 establishes general licenses for the possession and use of byproduct material and a general license for ownership of byproduct material. Many provisions in Part 30 are also applicable to general licenses established by Part 31. The EPAct provisions allow accommodation of generally licensed sources and devices meeting the restrictions of the general licenses that were previously approved by States under comparable provisions to 10 CFR Part 32.

10 CFR Part 30 includes a number of exemptions from licensing requirements. These exemptions allow for certain products and materials containing byproduct material to be used without any regulatory requirements imposed on the user. Class exemptions are provided that cover a broad class of products, such as gas and aerosol detectors and self-luminous products. Under class exemption provisions, new products can be approved for use through the licensing process if an applicant demonstrates that the specific product is within the class and meets certain radiation dose criteria. This contrasts with materials exemptions, for which the level of safety is controlled for a large number of radionuclides through such means as specification of radionuclide types and quantities. The remaining exemptions from licensing are product-specific, for which many assumptions can be and have been made concerning how the product

is distributed, used, and disposed. The NRC retains the authority for authorizing distribution of products and materials where the end user is exempt from licensing and regulatory requirements.

Regulation of NARM in Agreement States and Non-Agreement States

As established by the AEA, the previous regulatory structure provides the NRC control of materials as byproduct material only if it is produced in a nuclear reactor or included in mill tailings or waste. The AEA authorizes States to assume regulatory control of radioactive materials produced in or by a nuclear reactor, provided the State has an adequate NRC-compatible program to protect the public health and safety and enters into an agreement with the NRC. The activities regulated by these "Agreement States" include the use of byproduct, source, and limited quantities of special nuclear material. Except for activities that are regulated solely by the NRC, each Agreement State issues licenses to persons who use these materials in that State. The NRC issues licenses to persons using these materials in non-Agreement States. Currently, there are 34 Agreement States and 16 non-Agreement States plus U.S. territories.

Although the NRC has not regulated most NARM in the past, all Agreement States and certain non-Agreement States have established regulatory programs for NARM. For years, Agreement States have regulated NARM use in a fairly uniform and consistent manner. The regulatory structure used by Agreement States generally does not distinguish between NARM and other radioactive material. NARM users in Agreement States are expected to implement all aspects of standards for their radiation protection programs with respect to NARM, including those aspects relating to receipt, possession, use, storage, transfer, transportation, and disposal of NARM. This regulatory structure also subjects NARM users in the Agreement States to the same licensing, inspection, and enforcement policies as those using other byproduct material, or source or special nuclear material. In addition, this regulatory structure allows for both specific and general licensing of various products and the distribution of certain NARM items to end users that are exempt from regulation, and, in many cases, includes provisions to review and approve proposals for sealed sources and devices containing NARM.

Nearly all of the Agreement States have based their NARM regulation in large part on model regulations, known as the SSRs. The SSRs are compatible in many respects to the NRC regulations. Under the SSRs' regulatory framework, NARM is a regulated radioactive material comparable to other byproduct material. Adoption of the SSR regulations for NARM by most of the Agreement States accounts for the relatively high degree of uniformity and consistency in the Agreement States' regulations. Note, there is also a separate part of the SSR's for Technologically Enhanced Naturally Occurring Radioactive Material (TENORM). This covers NORM that was not redefined as byproduct material by the EPAct.

The regulatory structure for control of NARM in non-Agreement States varies greatly from State to State. While some non-Agreement States have established a NARM regulatory structure similar to those established by the Agreement States, other non-Agreement States have elected to use facility and/or device registration as their regulatory structure for managing NARM users, and a few non-Agreement States have neither structure in place.

Other Federal Agencies' Regulatory Authority over NARM

Prior to the passage of the EPAct, many States regulated NARM as a radioactive material and/or a hazardous substance, but the NRC generally had no corresponding regulations.

Although States had the primary responsibility for regulating the use of these materials, certain Federal regulations did and will continue to apply, under some circumstances, such as environmental protection, workplace safety, drug and medical device safety, transportation, and disposal. With the passage of the EPAct, the NRC will have primary responsibility for radiation safety and the regulation of use of these materials in cooperation with the States, with the exception of activities that are self-regulated by the Department of Energy (DOE).

Other Federal agencies have established programs in regulating certain aspects of activities involving NARM. The Department of Transportation (DOT) regulates interstate transport of NARM. In cooperation with DOT, the NRC approves Type B packages through regulations in 10 CFR Part 71. The Environmental Protection Agency (EPA) has established controls for certain NARM through several authorities, including the Clean Air Act, the Safe Drinking Water Act, the Toxic Substances Control Act, the Comprehensive Environmental Response, Compensation, and Liability Act, and the Solid Waste Disposal Act, also known as the Resource Conservation and Recovery Act (RCRA). The Occupational Safety and Health Administration (OSHA) of the Department of Labor has the oversight for occupational health and safety including for radiation protection. It has regulations governing radiation protection in the workplace, including provisions addressing exposure of minors to radioactive material in the workplace, but defers to NRC on AEA materials. The Department of Commerce has controlled the export of radioactive material. The Consumer Product Safety Commission regulations have addressed hazardous substances other than byproduct, source, and special nuclear materials currently regulated by the NRC. The Food and Drug Administration (FDA) regulates all drugs and medical devices (including drugs and medical devices containing radioactive materials) by requiring accepted manufacturing practices to assure the purity and potency of drugs, and consistency of finished drugs and medical devices in establishing the safety and effectiveness of these drugs and medical devices.

4.0 ENVIRONMENTAL IMPACTS

The final amendments will have no significant impacts on the public or the environment.

In general, the Commission's regulatory philosophy is to develop regulations that focus the staff's regulatory responsibilities on those activities that pose the greatest risk to protection of public health and safety and promotion of common defense and security. The Commission believes that, through the development of risk-informed and performance-based regulations, greater flexibility can be provided, while continuing to provide adequate protection of public health and safety. Consistent with this philosophy, the preferred alternative will apply a graded licensing approach to the NARM regulatory framework by including provisions for general licenses and regulatory exemptions for NARM and products containing NARM that represent a low level of risk to public health and safety and common defense and security, and specific licenses for NARM and products containing NARM that pose a higher level of risk. In considering the expansion of the definition of byproduct material to include discrete sources of radium-226 and accelerator-produced radioactive material, the NRC evaluated products and materials previously approved by States for use under an exemption from licensing and under a general license. Under the preferred alternative, the NRC's intent is to accommodate existing products and materials that were previously regulated by the States under similar provisions if the potential doses are similar to those expected from other currently regulated products and materials.

The final amendments will provide a national regulatory structure for NARM under which persons in non-Agreement States will be governed by regulations that are generally consistent with those applicable in Agreement States. The regulatory structure is based in large part on the regulations currently used by most Agreement States. These regulations have been found to be adequate to protect the public health and safety. The regulatory structure used by Agreement States generally does not distinguish between NARM and other radioactive material. NARM users in Agreement States are expected to implement all aspects of standards for their radiation protection programs with respect to NARM, including those aspects relating to receipt, possession, use, storage, transfer, transportation, and disposal of NARM. This regulatory structure also subjects NARM users in Agreement States to the same licensing, inspection, and enforcement policies as those using other byproduct, source, or special nuclear material. In addition, this regulatory structure allows for both specific and general licensing of various NARM products and the distribution of certain NARM items to end users that are exempt from regulation, and, in many cases, includes provisions to review and approve proposals for sealed sources and devices containing NARM. The promulgation of regulations that are consistent with the Agreement States' current regulatory structure will benefit the environment by allowing the continuation of regulatory and compliance practices that have already proven to be protective of the environment and the public health and safety.

Exemptions

The exemptions included in this final rule cover products and materials previously allowed to be used under exemption from licensing by States. Exemptions from licensing requirements allow for uncontrolled disposal, such that products and materials covered by such exemptions are normally disposed of in landfills and municipal incinerators. Thus, such provisions have potential for resulting in environmental impacts.

Two are for products containing radium-226, a very long-lived alpha-emitter. These are § 30.15(a)(1)(viii) for intact timepieces with no more than 37 kBq (1 μCi) of radium-226 and § 30.20 for gas and aerosol detectors, if approved by a State under provisions comparable to § 32.26. However, both of these exemptions are limited to previously manufactured products. Thus, they will allow for the continued use, without regulatory controls, of a dwindling supply of products produced some time ago. They do not allow for future manufacture and distribution, greatly minimizing any environmental impacts from uncontrolled disposal. The NRC also conducted a screening level dose assessment of timepieces containing radium-226 to further support the exemption.

The one other exemption from licensing included in the final rule is the expansion of the list of exempt quantities in § 30.71 used under the exemption from licensing in § 30.18. None of the 13 radionuclides being added are alpha-emitters. (As alpha-emitters present a relatively high internal hazard, they generally have more potential for presenting environmental impacts.) All of these radionuclides are relatively short-lived. Only one, sodium-22, has a half-life greater than a year: 2.6 years. Also, none of these materials are expected to be distributed in large quantities. Primarily as a result of the short half-lives, this provision has little potential for resulting in any adverse environmental impacts.

General Licenses

There are four general licenses in the final rule. Three of these are existing general licenses being revised to accommodate products previously approved for distribution for use by general licensees under provisions of State regulations similar to NRC's existing regulations. All four of

these general licenses require controlled disposal of the covered products. However, general licensees are typically less reliable than specific licensees in meeting all regulatory requirements. Thus, there may exist a higher probability of products becoming "orphaned" or being incorrectly disposed.

The general license in § 31.8, to which radium-226 will be added, is only applicable to specific licensees that have calibration and reference sources, and simply eliminates certain administrative requirements that would exist if these sources were under the specific license.

The general license in § 31.11 will be revised to add 370 kBq (10 μCi) of cobalt-57 used in in vitro kits. Persons using this general license must be specifically licensed or preregistered with the NRC. These materials have a low probability of being disposed of improperly in significant quantities and very limited potential for causing environmental impacts.

The general license in § 31.5 will be revised to accommodate devices approved by States under provisions comparable to § 32.51. Thus, these devices will have been reviewed by States as meeting the same safety criteria as other devices used under § 31.5. The registration requirement in the general license in § 31.5 is intended to reduce the probability of loss of control of devices by the general licensee. It is being revised to include a criterion for registration for radium-226. Devices containing radium-226 were mostly distributed some time ago and few remain in use. Those with more than 3.7 MBq (0.1 mCi) will come under the registration requirement. The only accelerator-produced radionuclides approved by States for use under comparable provisions of State regulations are cobalt-57 and sodium-22; these are generally used in relatively small quantities. This limited expansion of this general license is not projected to have a significant potential for adverse environmental impacts.

One new general license provision is being added. It is for certain previously manufactured items and self-luminous products containing radium-226. Except for the disassembly and repair of timepieces, it does not authorize manufacture, assembly, disassembly, repair, or import of these products, which were generally manufactured some time ago. As noted, intact timepieces with no more than 37 kBq (1 μCi) of radium-226 are being exempted from licensing requirements under this final rule. Timepieces with larger quantities of radium and repairs of any timepieces are covered by this general license. Although not specifically exempted under State regulations, these products have usually not come under regulatory controls. The requirements in this provision are limited, but intended to improve the likelihood of proper disposal and identification of significant instances of contamination. General licensees will be required to notify NRC concerning damage to products and potential contamination incidents, so that appropriate regulatory actions can be taken to ensure proper cleanup. These provisions, though limited, should be beneficial to the environment.

Impacts on Other Federal Agencies

Other Federal agencies have established programs in regulating certain aspects of activities involving NARM. The regulatory structure was developed with the support and coordination of other Federal agencies to ensure that the NRC's regulations complement the other Federal agencies' regulatory missions without duplicating their regulations. Certain Federal regulations, such as those applicable to environmental protection, workplace safety, drug safety, transportation, and disposal, will continue to apply under some circumstances, but the NRC will have primary responsibility for radiation safety and in regulating the use of NARM in cooperation with the States. Implementation of regulations that are consistent with the NRC's regulatory mission and complement the other Federal agencies' regulatory missions, maximizes

each agency's regulatory effectiveness by allowing the agencies to continue to perform the functions for which they are most qualified, thereby maintaining the appropriate focus on protection of the public health and safety.

Waste Impacts

Section 651(e)(3) of the EPAct mandates that the newly added byproduct materials (i.e., NARM): (1) are not considered to be a low-level radioactive waste for the purposes of the Low-Level Radioactive Waste Policy Amendments Act (LLRWPAA); and (2) may only be disposed of in a facility that is adequate to protect public health and safety and is either licensed by the Commission or by an Agreement State or is permitted under a Federal or State hazardous or solid waste disposal law. The intent of this provision is that the process of developing compacts as implemented in accordance with the LLRWPAA is not to be affected by the addition of NARM into the definition of byproduct material. The preferred action will implement this requirement by adding a definition of waste in 10 CFR 20.1003 to ensure that the term "low-level radioactive waste," when used in the NRC requirements, does not include NARM. This change will ensure that the health and safety of the public is protected by requiring disposal of this material in NRC-regulated disposal facilities or disposal facilities permitted under Federal or State solid or hazardous waste laws, including the Solid Waste Disposal Act.

Decommissioning

The preferred action does not change the NRC's criteria for decommissioning licensed facilities, although it may result in additional facilities being subject to the decommissioning criteria. The regulations will be applied to incidental ARM, such as that in the structures of buildings and structures housing the accelerators, resulting from the operation of particle accelerators that intentionally produce radioactive material. Consequently, the NRC considered whether additional regulatory actions might be needed to provide for the safe decommissioning of particle accelerator buildings and facilities, including the removal and disposal of activated building materials, in order to assure that the dose limits to workers and members of the public are not exceeded. Comments were requested on the decommissioning of accelerator facilities, specifically addressing: (1) the extent to which accelerator components and facility building materials may become activated; (2) the need to remove and properly dispose of such activated material during decommissioning in order to meet the radiation dose limits in 10 CFR Part 20 Subpart E--Radiological Criteria for License Termination; (3) the costs of the decommissioning and disposal, if required; and (4) the need for financial assurance by accelerator facilities to guarantee sufficient funding for proper decommissioning. Only limited technical information was submitted. At this time, the Commission believes that the existing requirements in this area are appropriate and adequate for their application to accelerator facilities. No unique problems are expected that would result in significant impacts to the environment from the application of existing regulations governing decommissioning to these newly regulated sites.

5.0 AGENCIES AND PERSONS CONSULTED

The program for revising the Commission's regulations and the associated guidance documents has involved extensive interactions and consultations with potentially affected parties (primarily representatives from the other Federal agencies, States, the medical community, and the public).

Initiating the Rulemaking Process

The NRC took several initiatives in an effort to enhance stakeholder involvement and to improve efficiency during this rulemaking process. With assistance from the Organization of Agreement States (OAS) and CRCPD, the NRC was able to obtain participation of several State representatives in various working groups in the development of the rule. Principals from OAS and CRCPD, representing interests for both Agreement States and non-Agreement States, also participated in the steering committee by forming a partnership with the NRC in making rulemaking decisions. In an effort to keep stakeholders informed, the NRC held a public roundtable meeting in early November 2005 and established the "Expanded Definition of Byproduct Material (NARM Rulemaking)" web page via the rulemaking website http://ruleforum.llnl.gov for posting rulemaking-related documents. In addition, the NRC met with other Federal agencies to ensure coordination regarding this rulemaking. For example, on August 30, 2005, NRC staff met with OSHA staff to discuss the NRC's role under the EPAct.

Forming Working Groups

In October 2005, the NRC formed a NARM Rulemaking Working Group to develop a regulatory framework for the expanded definition of byproduct material and to draft this rule. In addition to the NRC staff, the NARM Rulemaking Working Group included participants from the State of Florida and the State of Oregon, representing the CRCPD, and from the State of Texas, representing the OAS. Weekly meetings were held to fully utilize the expert resources available within the NARM Rulemaking Working Group.

The NRC also established an Office of Nuclear Materials Safety and Safeguards (NMSS) EPAct Task Force to help implement the various requirements of the EPAct, including the requirements in Section 651(e). The EPAct Task Force included members from the State of Illinois and the State of Oregon representing CRCPD and from the State of North Carolina representing OAS. The State representatives assisted the NARM Rulemaking Working Group by gathering State specific data, developing certain technical bases, and formulating certain regulatory approaches for the rule. The State members of the EPAct Task Force assisted in the rule development, and provided input to the rulemaking process.

In addition, a Steering Committee was formed to provide oversight for both the EPAct Task Force and NARM Rulemaking Working Group. The Steering Committee is comprised of managers from the affected NRC program offices and principals from OAS and CRCPD. During the early rule development process, the Steering Committee met weekly, and later less frequently, to resolve issues and to provide management direction on the rulemaking.

Roundtable Public Meeting

The NRC held a public meeting on November 9, 2005, to discuss rulemaking activities to accommodate NARM into its regulatory framework as mandated by the EPAct. The public meeting was in a "roundtable" format to allow stakeholders an opportunity to discuss concerns and to enhance interaction among all interested parties on the subject of the NRC regulating NARM. Representatives from other Federal agencies, States, and a broad spectrum of interest groups were invited to participate in the "roundtable" discussion. A transcript of this meeting is available on the NRC's rulemaking website.

During the public meeting, the NRC provided an overview of the EPAct and discussed the rulemaking process and the role of the NMSS EPAct Task Force. Other topics that were

discussed included the role of State regulations, potential implications regarding production of radiopharmaceuticals and availability of radiopharmaceuticals to patients, the definition of discrete source, NRC jurisdiction over accelerator-produced radioactive material, and waste and transportation issues.

Following the public meeting, the NRC received five written comments from interested parties related to the discussion at the meeting and the rulemaking activities. These comment letters are available on the NRC's rulemaking website and were reviewed and considered by the NRC staff in the development of this rule.

Interface With Other Federal Agencies and States

In addition to the public meeting, the NRC interacted and met with FDA staff to exchange information regarding the NRC's NARM rulemaking efforts and the FDA's regulations for accelerator-produced drugs. The primary objective of the FDA's regulations is to ensure medical safety, purity, potency, and effectiveness of the drugs, whereas that of the NRC's regulations is to ensure radiation safety. During the meeting, areas of potential dual regulation were discussed. Since the NRC and the FDA have different missions, the associated regulations are complementary, rather than duplicative. FDA has published a proposed rule, "Current Good Manufacturing Practice for Positron Emission Tomography Drugs," and expects to finalize the rule soon. The FDA's final rule will establish criteria for the production and process/quality controls of the Positron Emission Tomography (PET) drugs in PET centers registered with the FDA. In accordance with this final rule, the NRC will recognize the FDA registration in the NRC's regulations.

The NRC hosted a meeting of Federal agency representatives on November 22, 2005, to discuss the development of a definition of *Discrete source* to be added to the NRC regulations. The meeting consisted of members of the NRC's Interagency Coordinating Committee that had already been established for development of the National Source Tracking System. Agencies represented at this meeting were from DOT, DOE, including the National Nuclear Security Administration, DOD, DOC, EPA, and the U.S. Customs and Border Protection. The participants briefly discussed their agency's jurisdiction over, and involvement with, radium-226 and other NORM. At the conclusion of the meeting, a draft definition was formulated. This definition formed the basis for the definition in the proposed rule, with only minor changes and text rearrangement for clarity. As a result of public comment, the definition has been further clarified in the final rule.

An ad hoc focus group was formed to specifically address issues related to the broad spectrum of old radium-226 sources and to formulate a regulatory strategy. The focus group included individuals from both the NRC Headquarters and Regions and representatives from the States of Florida, North Carolina, Illinois, Michigan, Oregon, and Texas. Although many of the old discrete radium-226 sources have been used for decades, no specific quantitative or qualitative technical information was identified during the development of the rule that would support a broad exemption for these old discrete radium-226 sources. Due to lack of specific health and safety information associated with many of the old radium-226 sources, the NRC developed the preferred alternative, which provides a graded approach by using a general license to regulate different groups of radium-226 sources. In addition, in the proposed rule, the NRC asked for the public to provide any technical information that may be available to support exemptions, now or in the future. Limited information was provided as a result of public comment.

The NRC staff determined that the preferred alternative is not a type of action that has the potential to directly cause effects on historic properties, because it is a procedural action that revises the Commission's regulations, and does not directly involve changes to any specific site, area, or region. Therefore, no consultation is required under Section 106 of the National Historic Preservation Act. Additionally, the NRC staff determined that Section 7 consultation with the U.S. Fish and Wildlife Service is not required because the preferred alternative is procedural in nature and will not affect listed species or critical habitat.

6.0 CONCLUSION

The NRC is amending its regulations to address certain radium sources, certain naturally occurring radioactive material, and accelerator-produced radioactive materials as required by Section 651(e) of the Energy Policy Act of 2005. This document was prepared so that the environmental impacts would be considered as part of the decision-making process. Based on currently available information, as described in this document, 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 these amendments are a major Federal action but will not significantly affect the quality of the human environment, and therefore that an environmental impact statement is not required.

7.0 LIST OF PREPARERS

Neil Haggerty, Project Manager, All Sections
Derek Widmayer, Project Manager, Waste Management

8.0 LIST OF REFERENCES

Atomic Energy Act of 1954, as Amended, Pub. L. 83-703 (1954).

Energy Policy Act of 2005, Pub. L.109-58 (2005).
Code of Federal Regulations, Title 10, Energy, Part 20, "Standards for protection against radiation."

Code of Federal Regulations, Title 10, Energy, Part 30, "Rules of general applicability to domestic licensing of byproduct material."

Code of Federal Regulations, Title 10, Energy, Part 31, "General domestic licenses for byproduct material."

Code of Federal Regulations, Title 10, Energy, Part 32, "Specific domestic licenses to manufacture or transfer certain items containing byproduct material."

Code of Federal Regulations, Title 10, Energy, Part 33, "Specific domestic licenses of broad scope for byproduct material."

Code of Federal Regulations, Title 10, Energy, Part 35, "Medical use of byproduct material."

Code of Federal Regulations, Title 10, Energy, Part 50, “Domestic licensing of production and utilization facilities.”

Code of Federal Regulations, Title 10, Energy, Part 51, “Environmental protection regulations for domestic licensing and related regulatory functions.”

Code of Federal Regulations, Title 10, Energy, Part 61, “Licensing requirements for land disposal of radioactive waste.”

Code of Federal Regulations, Title 10, Energy, Part 62, “Criteria and procedures for emergency access to non-Federal and regional low-level waste disposal facilities.”

Code of Federal Regulations, Title 10, Energy, Part 72, “Licensing requirements for the independent storage of spent nuclear fuel, high-level radioactive waste, and reactor-related greater than Class C waste.”

Code of Federal Regulations, Title 10, Energy, Part 150, “Exemptions and continued regulatory authority in Agreement States and in offshore waters under Section 274.”

Code of Federal Regulations, Title 10, Energy, Part 170, “Fees for facilities, materials, import and export licenses, and other regulatory services under the Atomic Energy Act of 1954, as amended.”

Code of Federal Regulations, Title 10, Energy, Part 171, “Annual fees for reactor 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 the NRC.”

Low-Level Radioactive Waste Policy Amendments Act of 1985, Pub. L. 99-240 (1986).

National Environmental Policy Act of 1969, as amended, 42 U.S.C. §4231 et seq. (1970).

Regulatory Analysis for Final Rulemaking - Expanded Definition of Byproduct Material Established by Section 651(e) of the Energy Policy Act of 2005

U.S. Nuclear Regulatory Commission

March 2007

Enclosure

TABLE OF CONTENTS

ACRONYMS

AEA	Atomic Energy Act of 1954
AEC	U.S. Atomic Energy Commission
ARM	accelerator-produced radioactive material
CFR	Code of Federal Regulations
CRCPD	Conference of Radiation Control Program Directors, Inc.
DHS	U.S. Department of Homeland Security
DOE	U.S. Department of Energy
DOT	U.S. Department of Transportation
EPA	U.S. Environmental Protection Agency
EPAct	Energy Policy Act of 2005
FR	Federal Register
IAEA	International Atomic Energy Agency
LLWPA	Low-Level Radioactive Waste Policy Act
NARM	naturally occurring and accelerator-produced radioactive material
NORM	naturally occurring radioactive material
NRC	U.S. Nuclear Regulatory Commission
OAS	Organization of Agreement States, Inc.
OSHA	Occupational Safety and Health Administration
PET	positron emission tomography
RCRA	Resource Conservation and Recovery Act
SS&D	sealed source and device
SSRs	Suggested State Regulations for the Control of Radiation
U.S.C.	United States Code

1.0 Introduction

The U.S. Nuclear Regulatory Commission (NRC) is amending its regulations to include certain radium sources, certain naturally occurring radioactive material, and accelerator-produced radioactive materials as required by Section 651(e) of the Energy Policy Act of 2005 (EPAct), which was signed into law on August 8, 2005. The EPAct expanded the definition of byproduct material in Section 11e. of the Atomic Energy Act of 1954 (AEA) to include certain "naturally occurring and accelerator-produced radioactive materials" (NARM), placing these byproduct materials under NRC authority. The EPAct also required the NRC to provide a regulatory framework for licensing and regulating this NARM.

The purpose of this regulatory analysis is to evaluate the costs and benefits associated with the rule. The rule (Reference 1) amends 10 CFR Parts 20, 30, 31, 32, 33, 35, 50, 61, 62, 72, 110, 150, 170 and 171. This document presents background material, rulemaking objectives, rulemaking alternatives, and analysis results for each alternative in terms of constant 2005 dollars. Public comments were requested for the proposed rule text and this regulatory analysis.

1.1 Background

Radioactive materials may be divided into two general groups: naturally occurring radioactive material (NORM), which would exist in nature even in the absence of human activity, and radioactive materials that are produced by the technological activities of humankind. The second group, which makes up the vast majority of radioactive material used in human activity, includes products of nuclear reactors and accelerator-produced radioactive material (ARM).

Collectively, "naturally occurring and accelerator-produced radioactive material," other than source material, is referred to as NARM. The significance of the distinction between source material and the products of nuclear fission reactors and NARM is that prior to the passage of the EPAct in 2005, the NRC had no regulatory authority over NARM. Since the passage of the AEA, the NRC and its predecessor agency, the Atomic Energy Commission (AEC), have regulated the acquisition, possession, use, transfer, and disposal of byproduct material, as well as source material and special nuclear material. Byproduct material was originally defined to include only materials made radioactive in the production or utilization of special nuclear material, i.e., radioactive material produced in a fission reactor, and later to also include tailings and waste produced by the extraction or concentration of uranium or thorium from any ore processed primarily for its source material content.

The regulation of NORM other than source material (and that in the tailings and waste produced by the extraction or concentration of uranium or thorium from any ore processed primarily for its source material content), and accelerator-produced radioactive material was left primarily to the individual States. Although efforts were made by several States to provide a uniform regulatory environment, there was no nationwide consistency to the regulation of NARM. Other federal agencies exercised limited external regulatory authority over activities involving NARM consistent with their primary missions, but again there was no overall, consistent external regulation as in the case of byproduct, source, and special nuclear material.

1.1.1 The Energy Policy Act of 2005

On August 8, 2005, the President signed into law the EPAct. Among other provisions, Section 651(e) of the EPAct expanded the definition of byproduct material, as defined in Section 11e. of the AEA. It also required the Commission to provide a regulatory framework for licensing and regulating byproduct material in accordance with this new, expanded definition.

Specifically, Section 651(e) of the EPAct expanded the definition of byproduct material to include certain naturally occurring and accelerator-produced radioactive materials as defined below, and hereafter referred to as NARM:

(1) any discrete source of radium-226 that is produced, extracted, or converted after extraction, before, on, or after the date of enactment of this paragraph for use for a commercial, medical, or research activity;

(2) any material that has been made radioactive by use of a particle accelerator and is produced, extracted, or converted after extraction, before, on, or after the date of enactment of this paragraph for use for a commercial, medical, or research activity; and

(3) any discrete source of naturally occurring radioactive material, other than source material, that the Commission, in consultation with the Administrator of the Environmental Protection Agency (EPA), the Secretary of Department of Energy (DOE), the Secretary of the Department of Homeland Security (DHS), and the head of any other appropriate Federal agency, determines would pose a threat similar to the threat posed by a discrete source of radium-226 to the public health and safety or the common defense and security, and that is extracted or converted after extraction before, on, or after the date of enactment of this paragraph for use in a commercial, medical, or research activity.

The EPAct's expanded byproduct material definition introduces a new term, "discrete source," as applied to radium-226 and certain other sources of NORM. Section 651(e) also requires the NRC to define this term by rulemaking.

Finally, the EPAct clarifies that NARM, as included in the expanded byproduct material definition, shall not be considered low-level radioactive waste for disposal for the purposes of meeting the provisions of the Low-Level Radioactive Waste Policy Amendments Act (LLRWPAA).

1.1.2 Current Status of NRC Requirements

The AEA authorizes States to assume regulatory control over radioactive materials produced in or by a nuclear reactor, provided the State has an adequate, NRC-compatible program to protect the public health and safety and enters into an agreement with the NRC. As authorized by Section 274b. of the AEA and as of April 2006, 34 States have assumed responsibility for regulating certain activities related to radioactive material by entering into agreements with the NRC. The activities regulated by these "Agreement States" include the use of byproduct, source, and some uses of special nuclear material. Each Agreement State issues licenses to persons who use these materials in that State, except for DOE, Federal facilities, Federally recognized Indian tribes, and for certain activities. The NRC issues licenses to persons using these materials in Federal facilities, Federally recognized Indian tribes, and non-Agreement States.

Prior to enactment of the EPAct, the NRC did not have authority over NARM nor did it have regulations for such material. Although the NRC has not regulated NARM, all 34 Agreement States and certain non-Agreement States have regulatory programs for NARM. Nonetheless, the NRC's current regulations do require licensees to account for occupational dose contributed from NARM, as well as dose contributed from byproduct material, because the definition of occupational dose encompasses both licensed material and nonlicensed material. In addition, the NRC requires, in its radiological criteria for license termination, that licensees consider other sources including radium during decommissioning activities at sites contaminated with source material.

Non-Agreement States

Most non-Agreement States and territories have some type of program for NARM, but the regulatory structures vary greatly. A few non-Agreement States have no regulatory programs for NARM. Certain other non-Agreement States have established a *licensing structure* for regulating their NARM users. For these, the regulatory structure could:

- parallel the NRC regulations applicable to the current materials program, or
- parallel the Suggested State Regulations for the Control of Radiation (SSRs) developed by the Council of Radiation Control Program Directors, Inc. (CRCPD).

The remaining non-Agreement States or territories have elected to use *registration* as their regulatory structure for managing the NARM users. Some register facilities; others register both facilities and devices. Some use registration information to conduct inspections; others use registration to identify facility locations for security purposes. In general, there is limited regulatory oversight where registration is used in non-Agreement States. It was, in part, due to this lack of national consistency in NARM regulatory structure, that the EPAct placed these materials under the NRC jurisdiction.

Agreement States

For many years, the Agreement States have regulated NARM use in a fairly uniform and consistent manner. The Agreement States have accomplished this essentially by regulating NARM the same way that they regulate other radioactive material under NRC authority. In many respects, regulations applicable to NARM adopted by the Agreement States are compatible to the NRC regulations for the current materials program, or parallel to the CRCPD's SSRs.

For the most part, the regulatory structure used by Agreement States does not distinguish between NARM, as defined above, and other radioactive material. NARM users in Agreement States are expected to implement all aspects of standards for their radiation protection programs with respect to NARM, including those aspects relating to receipt, possession, use, storage, transfer, transportation, and disposal. This regulatory structure also subjects NARM users in the Agreement States to the same licensing, inspection, and enforcement policies as those using other radioactive materials. In addition, this regulatory structure allows for both specific and general licensing of various NARM products, the distribution of certain NARM items to persons exempt from regulation, and, in most cases, includes provisions to review and approve proposals for NARM sealed sources and devices.

Finally, the Agreement States have regulated a vast array of NARM produced for medical, industrial, research and development, commercial, and consumer purposes. In many Agreement States, this regulatory structure also captures some types of nondiscrete sources found in the oil, gas and mining industries; moreover, it also captures inadvertently produced activation products from the use of proton beams for medical radiation therapy. However, the regulation of these nondiscrete sources and activation products has greater variation from Agreement State to Agreement State.

1.1.3 Other Federal Agencies' Regulatory Authority Over NARM

Prior to the passage of the EPAct, NARM was regulated as a radioactive material, or as a hazardous substance, but was not regulated by the NRC. Although States had the primary responsibility for regulating the use of NARM, certain Federal regulations applied under some circumstances, including:

- transportation,
- environmental protection and waste disposal,
- workplace radiation exposure and safety,
- export controls,
- consumer products, and
- radioactive drug and medical device safety.

With passage of the EPAct, the NRC has primary responsibility for radiation safety and in regulating the use of these radioactive materials in cooperation with the States, with the exception of activities that are self-regulated by the DOE. Other Federal regulatory agencies have established programs in regulating certain aspects of activities involving NARM (Table 1-1).

Table 1-1. Federal Agencies with Regulatory Responsibility for NARM

Agency	Responsibilities for NARM Regulation
Department of Transportation	Regulates interstate transport of radioactive material. In cooperation with DOT, NRC approves Type B packages through 10 CFR Part 71 regulations.
Environmental Protection Agency	Has established controls for certain radioactive material through several authorities, including the Clean Air Act, the Safe Drinking Water Act, the Toxic Substances Control Act, the Resource Conservation and Recovery Act, and the Comprehensive Environmental Response, Compensation, and Liability Act.
Occupational Safety and Health Administration of the Department of Labor	Oversight for occupational health and safety; has established regulations addressing the exposure to radioactive material in the workplace; in general, defers its authority to NRC with respect to AEA materials.
Department of Commerce	Has controlled the export of radioactive material.
Consumer Product Safety Commission	Regulations have addressed hazardous substances other than byproduct, source, and special nuclear materials currently regulated by the NRC.
Food and Drug Administration	Regulates all drugs (including drugs containing radioactive materials) by requiring good manufacturing practices to assure the purity, potency, and consistency of finished drugs with their labeling in establishing the safety and effectiveness of these drugs. Regulates all medical devices (including medical devices containing radioactive materials) by requiring good manufacturing practices to assure medical devices are not adulterated or miss-branded and safe and effective when used in accordance with the labeling.

Section 651(e)(3) of the EPAct provides that byproduct material, as defined by sections 11e.(3) or 11e.(4) of the AEA, may only be transferred to and disposed of in a disposal facility that is licensed by either the NRC, or a State that has entered into an agreement with the Commission under Section 274b. of the AEA, or at a disposal facility in accordance with any Federal or State solid or hazardous waste law, including the Solid Waste Disposal Act.

1.1.4 Development of the Suggested State Regulations

Since enactment of the AEA in 1954, scientists have continued to develop new technologies to produce radionuclides, for example particle accelerators. At the beginning of the twentieth century, naturally occurring radioactive material, including radium-226, was routinely used in consumer products and in cancer treatment (Reference 2). With no Federal mandate to regulate these materials, most States established regulatory structures for both accelerator-produced radioactive materials and naturally occurring radioactive material, including radium-226.

In 1968, CRCPD was chartered as a nonprofit organization to provide a forum for enhancing communication among States and Federal agencies regarding radiation regulations and to promote a uniform radiation protection environment for all radioactive material. Throughout the years, CRCPD developed policies and guidance for its member States. In addition, CRCPD is responsible for the development of model regulations, known as the SSRs. CRCPD has formed many working groups to develop, for radioactive materials, a set of SSRs that are compatible in many respects to the NRC regulations. Under the SSRs' regulatory framework, NARM is a regulated radioactive material comparable to byproduct material. Nearly all of the Agreement States have based their regulations on this model for NARM.

For NARM regulation only, CRCPD also established "Licensing States" similar to the Agreement State Program under Section 274 of the AEA. Licensing States recognized by CRCPD pursuant to criteria found in Publication 94-8 "CRCPD Recognition of Licensing States for the Regulation and Control of NARM" are those States that have demonstrated an adequate and consistent regulatory control program for NARM. Licensing State designation assures comparable regulatory structures with respect to NARM, and other States may grant reciprocal recognition of their licenses or acceptance of their licensees' manufactured products.

1.1.5 Issuance of Waiver on August 31, 2005

Section 651(e) of the EPAct became effective upon signature by the President on August 8, 2005. Prior to enactment of the EPAct, the NRC did not have authority over NARM, and did not have regulations in place that would specifically apply to this material. Nonetheless, persons carrying on activities involving NARM could be, and States seeking to continue regulation of NARM would be, in technical violation of the AEA. Therefore, the NRC determined that it would be prudent to establish a mechanism to permit individuals currently engaged in activities involving NARM to continue with their activities. Although the Commission could have proceeded through issuing orders on a case-by-case basis to oversee activities involving NARM while establishing the regulatory framework for regulating this material, the Commission determined that this would be inefficient and resource intensive.

Section 651(e)(5) of the EPAct authorizes the Commission to issue a waiver of the requirements of Section 651(e) to any entity with respect to NARM for specified periods of time if the Commission determines that the waiver is in accordance with the protection of the public

health and safety and the promotion of the common defense and security. The Commission determined that such a waiver could be granted to entities that engaged in activities involving NARM. The Commission determined that there was no basis to conclude that these materials would not continue to be used in a manner that is protective of public health and safety while the waiver is in effect. The Commission also determined that it would be in the best interests of the public to allow continued use of NARM, especially for medical purposes, and to allow the States to continue to regulate NARM until the Commission could codify new regulations for these materials.

The Commission believed that granting the waiver would allow the States to continue with their regulatory programs, would allow persons engaged in activities involving NARM to continue their operations in a safe manner, and would allow continued access to medical radiopharmaceuticals. In addition, it would enable the Commission to work with the States to develop appropriate regulations for NARM and to formulate a sound transition plan for implementation of such regulations. It would also provide an opportunity for non-Agreement States to consider entering into an agreement with the NRC. The Commission determined that issuance of the waiver would be in accordance with the protection of public health and safety and the promotion of the common defense and security.

The Commission granted a waiver (70 FR 51581; August 31, 2005) from the requirements of Section 651(e) of the EPAct to: (1) all persons engaged in export from or import into the United States of byproduct material through August 7, 2006, unless terminated sooner if the Commission determined that an earlier termination was warranted and except with regard to the requirements of the Department of Commerce relating to export of such material; (2) all persons acquiring, delivering, receiving, possessing, owning, using, or transferring byproduct material through August 7, 2009, unless terminated sooner if the Commission determined that an earlier termination was warranted; and (3) all States that had entered into an agreement with the Commission under Section 274b of the AEA and States that had not entered into such an Agreement, through August 7, 2009, unless terminated sooner by the Commission.

1.1.6 Related Rulemakings

Byproduct Material in Specifically Licensed Portable Gauges

The NRC published a final rule amending its regulations governing the use of byproduct material in specifically licensed portable gauges (70 FR 2001; January 12, 2005). Specific licenses for portable gauges are governed by NRC regulations in 10 CFR Part 30. The final rule requires a portable gauge licensee to use a minimum of two independent physical controls that form tangible barriers to secure portable gauges from unauthorized removal whenever the portable gauges are not under the control and constant surveillance of the licensee. The primary intent of this rulemaking is to increase licensees' control of portable gauges to reduce the opportunity for unauthorized removal or theft.

Export and Import of Radioactive Materials

The NRC published a final rule amending its regulations relating to the export and import of radioactive materials for certain radionuclides listed in the Code of Conduct (70 FR 37985; July 1, 2005). General and specific licenses for export and import of nuclear equipment or material are governed by NRC regulations in 10 CFR Part 110. In an effort separate from this rulemaking, the NRC amended its regulations in 10 CFR Part 110 on export and import of

radioactive material to address discrete sources of radium-226 in a manner consistent with the Code of Conduct.

National Source Tracking System

The NRC published a final rule related to implementing a National Source Tracking System for certain sealed sources (71 FR 65686; November 8, 2006). The amendments require licensees to report certain transactions involving these sealed sources to the National Source Tracking System. These transactions include manufacture, transfer, receipt, disassembly, or disposal of nationally tracked sources. The amendments also require each licensee to provide its initial inventory of nationally tracked sources to the National Source Tracking System and annually reconcile the information in the system with the licensee's actual inventory. In addition, the amendments require manufacturers to assign a unique serial number to each nationally tracked source.

Exemptions from Licensing, General Licenses, and Distribution of Byproduct Material

The NRC published a proposed rule related to exemptions from licensing, general licenses, and distribution of byproduct material (71 FR 275; January 4, 2006). Exemptions from licensing of byproduct material are governed by NRC regulations in 10 CFR Part 30. The NRC is proposing to amend its regulations governing the use of byproduct material to revise requirements for reporting transfers to persons exempt from licensing, simplify the licensing of smoke detector distribution, remove obsolete provisions, and clarify certain regulatory provisions. These changes would affect licensees who distribute byproduct material to exempt persons, users of some generally licensed devices, and some exempt persons.

1.2 Objectives of the Rule

The EPAct requires the NRC to provide a regulatory framework for licensing and regulating the naturally occurring and accelerator-produced radioactive materials that are included in the expanded byproduct material definition in Section 651(e) of the Act. The EPAct directed the NRC to develop regulations to establish a national program for NARM. These regulations are the subject of this rule. The NRC is amending its regulations to include certain radium sources, accelerator-produced radioactive materials, and certain naturally occurring radioactive material, as required by Section 651(e) of the Energy Policy Act of 2005.

The EPAct mandated that the NRC use model State regulations to the maximum extent practical in developing regulations for the expanded definition of byproduct material. CRCPD publishes SSRs as the model regulations for radioactive materials. Since SSRs are the model regulations that most CRCPD member States have adopted, or States have developed requirements that are similar to the SSRs, then the SSRs can provide the NRC a model for the basic regulatory framework for regulating the additional byproduct materials as defined by the EPAct.

This rule is not intended to impose unnecessary regulatory burden beyond what is necessary and sufficient for providing reasonable assurance that public health and safety is protected. This purpose is consistent with NRC's policy, as discussed in NUREG-1614, Vol. 3 entitled "U.S. Nuclear Regulatory Commission Strategic Plan, Fiscal Year 2004-2009," to assure that the nation's use of radioactive material is conducted in a manner that protects public health and safety and the environment. In addition, the EPAct directs the Commission to develop regulations that address threats to common defense and security. This final rule is designed to

provide maximum flexibility in its implementation and impose the minimum regulatory burden while achieving these and other objectives identified in the EPAct.

2.0 Identification of Alternative Approaches

NRC identified three alternatives for providing a regulatory framework to license and regulate NARM consistent with the expanded byproduct material definition in the EPAct. These alternatives were developed using input from a public process, and are the same as those considered in the Environmental Assessment for the rule (Reference 3).

The NRC took several initiatives to enhance stakeholder involvement and to improve efficiency during the rulemaking process. With assistance from OAS and CRCPD, the NRC was able to obtain participation of several State representatives in the development of the rule. Principals from OAS and CRCPD, representing interests for both Agreement States and non-Agreement States, participated in the steering committee, forming a partnership with the NRC in rulemaking decisions. In an effort to keep stakeholders informed, the NRC held a public roundtable meeting in early November 2005 and established the "Expanded Definition of Byproduct Material (NARM Rulemaking)" Web page via the rulemaking website, http://ruleforum.llnl.gov, for posting rulemaking-related documents. The NRC met with other Federal agencies to ensure coordination regarding this rulemaking. The NRC met with OSHA on August 30, 2005, and with FDA on November 17, 2005. At both meetings, the participants discussed the NRC's new role under the EPAct. In addition, the NRC conducted a public meeting with stakeholders in August 2006 to discuss the rule.

2.1 Comparison of Alternatives

NRC identified the following three alternatives for this regulatory analysis:

1. take no action, which provides a baseline to assess the other two alternatives;

2. revise regulations to maximize NRC regulatory authority and control allowed by the EPAct; and

3. revise regulations to apply a graded risk informed approach to exercising regulatory authority over NARM.

In defining the alternatives, the NRC staff reviewed the EPAct to differentiate between the actions specifically mandated by the EPAct and actions in the EPAct that have some flexibility in the degree of regulatory authority or control that may be applied in the rule. Alternative 3 represents the best balance with regard to this degree of flexibility by adopting a “graded approach,” and is the preferred alternative to implement the new regulations.

2.1.1 Actions Mandated by the EPAct

Section 651(e)(4)(B) of the EPAct requires the Commission to use model State standards, to the “maximum extent practicable,” in developing the regulations. The NARM regulations for most Agreement States are based on model regulations, known as Suggested State Regulations for the Control of Radiation, or SSRs. The SSRs for radioactive materials are compatible in many respects to the NRC regulations.

Section 651(e) of the EPAct mandates that NARM not be considered low-level radioactive waste for the purposes of the Low-Level Radioactive Waste Policy Amendments Act (42 U.S.C. 2021b) (LLRWPAA). This provision is consistent with current NRC policy, under which NARM would be classified as "radioactive waste" for disposal purposes and may be disposed of according to Federal and State hazardous waste laws. This provision is included in all of the alternatives.

2.1.2 Issues Where EPAct Allows Flexibility

During the process of developing a regulatory framework for licensing and regulating NARM, the staff identified several areas where the Act allows some degree of flexibility. As discussed below, the EPAct does not specifically address the type of license to be required for NARM licensed activities or whether incidentally irradiated material should be regulated. Furthermore, the EPAct delegated, to the NRC, the responsibility for defining the term "discrete source," as it applies to radium-226 and certain other NORM.

Section 651(e) of the EPAct requires the Commission to develop regulations to establish the regulatory requirements necessary to carry out this section of the Act. While the requirement to maintain consistency with current State regulations strongly suggests using a similar regulatory framework of specific and general licenses and exemptions, the EPAct does not mandate which license type (i.e., general or specific) would be required for NARM, nor does the Act specify whether allowances for exemptions from byproduct material regulations should be provided in the final regulations. Under the AEA, the Commission has authority to issue both general and specific licenses for the use of byproduct material and also to exempt byproduct material from regulatory control under the AEA. Because of the flexibility allowed by current regulations and Section 651(e) of the EPAct, it is reasonable to consider more than one alternative specifying different license types and exemption allowances, depending upon whether or not there exist model State regulations upon which the rule could be based.

Section 651(e) of the EPAct requires the Commission to include, as byproduct material, certain accelerator-produced radioactive material (ARM). This expanded byproduct material definition only includes material that is produced, extracted, or converted specifically for use in a commercial, medical, or research activity. The radioactive material intentionally produced by activation of the target is commonly referred to as "product ARM." The EPAct does not specifically address whether material that is incidentally irradiated during operation of an accelerator (referred to as "incidental ARM") should be regulated. Because of the flexibility allowed by the EPAct in this respect, it is reasonable to consider more than one alternative with differing regulatory approaches for incidental ARM.

Section 651(e)(4)(A)(ii) of the EPAct requires the Commission to define the term "discrete source" as applied to radium-226 and certain other NORM in the expanded definition of byproduct material. A discrete source would be defined to include a concentrated radioactive material that is distinct from the radiation present in nature. The flexibility allowed by this requirement relates to whether the radionuclide or radioactive material specifically has been concentrated on purpose for use for commercial, medical, or research activity. A broad "discrete source" definition could include any concentrated radium-226 or other NORM, regardless of whether it was concentrated specifically for commercial, medical, or research use or incidentally from a process that extracts or produces products, such as fertilizer, fly ash, or residue from the purification of water. A more limited "discrete source" definition would only include radioactive material in which the radionuclide was concentrated with the intent of using its properties, thereby excluding NRC jurisdiction over inadvertent movement or concentration

of NORM. Because of the flexibility in allowing the Commission to provide this definition, it is reasonable to consider more than one alternative, each with a different discrete source definition.

Section 651(e)(4)(D) of the EPAct requires the Commission to consider the impact on the availability of pharmaceuticals to physicians and patients in promulgating these regulations. This requirement does not prescribe how to consider the potential impact of the regulations on the medical community or patients; nor the approach to be taken to address potential impacts. This requirement allows flexibility in the regulatory framework that is applied to ARM products generated for medical activities, as well as the implementation aspects for the regulations. Although the EPAct allows flexibility in considering the regulation's potential impacts on the medical community or patient, and it is reasonable to consider more than one alternative with differing medical ARM product licensing requirements and implementation plans, there are no discernable differences between the environmental and economic impacts of the alternative approaches to addressing pharmaceutical availability. Therefore, both the preferred action and Alternative 2 would establish a similar set of regulations and an implementation process to minimize the regulatory impact on the availability of accelerator-produced radioactive drugs. The key points associated with this area of the final regulations are summarized later in this section, under the discussion of Alternative 3.

Based on the staff's review of the actions specifically mandated by the EPAct and areas where the EPAct allows flexibility in the degree of regulatory authority, the staff identified three alternatives: (1) to take no action; (2) to establish regulations that apply the greatest extent of regulatory authority and control allowed by the EPAct; and (3) to establish regulations that apply a graded, risk-informed approach to exercising the regulatory authority provided by the EPAct. The following provides a more detailed discussion of each alternative. Section 3.0 shows input assumptions used to analyze the alternatives, and Section 4.0 presents results and the economic basis for choosing Alternative 3 as the preferred alternative. Section 5 provides a summary of the decision rationale.

2.2 Alternative 1: The No-Action Alternative

The No-Action alternative is to maintain the status quo, with no costs incurred and no benefits realized. Under the No-Action alternative, the Commission would neither adopt the expanded definition of byproduct material provided in Section 651(e) of the EPAct, nor provide a regulatory framework for licensing and regulating NARM.

The staff understands that the No-Action alternative is not acceptable, as this rulemaking activity is Congressionally mandated. However, this alternative provides a baseline condition from which the other alternatives will be assessed (Reference 4).

2.3 Alternative 2: Revise Regulations to Maximize NRC's Regulatory Authority

This alternative would establish regulations to implement the requirements specifically required by the EPAct and the highest degree of regulatory authority and control included within the bounds allowed by the flexibility within the EPAct. In accordance with EPAct Section 651(e)(4)(B), the NARM regulatory framework would be based, to the maximum extent practicable, on the SSRs.

This alternative is to establish regulations and an implementation process that would minimize the regulatory impact on the availability of accelerator-produced radioactive drugs by taking the

following actions: (1) applying NRC's established regulatory framework to the commercial distribution of these drugs; (2) expanding the regulations to permit noncommercial distribution of PET drugs within a consortium; (3) "grandfathering" current users of accelerator-produced drugs; and (4) permitting individuals and other entities to continue to prepare and use radioactive drugs while they are applying for new licenses or amendments.

Under this alternative, the revised regulations would require more specific licenses for the production, use, transfer, and distribution of NARM and products containing NARM. In areas where the SSRs do not specifically address material within the scope of the new byproduct material definition or where there are few model State regulations at the national consensus level upon which the NRC can base its regulations, this alternative would require specific licenses. Part N of the SSRs address NORM; however, this is generally applicable to diffuse sources of NORM, which have not been produced for the purpose of using the radioactive material within for commercial, medical, or research activities.

SSR requirements for ARM and discrete sources of radium are the same as for reactor-produced radioactive material as they are all covered under provisions for "radioactive material." Only a few provisions in the model State regulations are specific to discrete sources of radium and accelerator-produced radioactive material. Specific provisions concerning ARM radionuclides include: (1) a general license and associated requirements for cobalt-57 *in vitro* clinical or laboratory tests , (2) concentration ratios for strontium-82/rubidium-82 generators for medical use, (3) exempt quantity limits for certain accelerator-produced radionuclides. With respect to radium, the SSRs include: (1) an exemption for previously acquired timepieces containing up to 37 kilobecquerels (kBq) (1 microcurie (μCi)) of radium-226, (2) an exemption for other previously acquired self-luminous products containing up to 3.7 kBq (0.1 μCi) of radium-226, (3) a provision to allow a specifically licensed person to possess up to 185 kBq (5 μCi) of radium-226 in calibration and reference sources under a general license, and (4) an exemption for gas and aerosol detectors containing NARM, with a limit of 3.7 kBq (0.1 μCi) of radium-226 that may be incorporated into smoke detectors distributed for use under exemption from licensing. Under this alternative, these specific requirements would be included in the regulations.

However, the SSRs do not specifically address certain categories of products and discrete sources containing radium-226 which are in the public domain but may not be otherwise covered under a license. Therefore, under this alternative, the regulations would require specific licenses for discrete sources of radium-226 that may not be otherwise covered under a general license or an exemption in the SSRs. For NARM and products containing NARM that are addressed in the SSRs, such as those discussed above, this alternative would include a regulatory framework similar to the SSRs.

Section 651(e)(4)(A)(ii) of the EPAct requires the Commission to define the term "discrete source" as applied to radium-226 and other NORM in the expanded definition of byproduct material. Under this alternative, "discrete source" would be defined broadly to include any concentrated radium-226 or other NORM, regardless of whether it was intentionally concentrated or incidentally concentrated from a process that extracts or produces products not intended to be radioactive. This definition would not limit the NRC's jurisdiction to only include radionuclides that are concentrated and used purposefully for their properties. This broader definition would divert the staff's regulatory efforts away from those materials that pose the greatest health and security risk by including an array of NORM sources, including sources that were created through inadvertent movement or concentration of naturally occurring radioactive

material, such as that found in scaling on pipes from the fossil fuel industry, in fly ash from coal burning, or in fertilizers.

Under this alternative, any material rendered radioactive by a particle accelerator, including incidental radioactive materials, would be covered by the Commission's regulations from the time at which it is initially irradiated. Byproduct material would include product ARM and incidental ARM, including irradiated target material, accelerator internal structures, and facility building materials, regardless of the accelerator type or use.

In accordance with Section 651(e)(3), for disposal purposes, this newly defined byproduct material would be classified only as radioactive waste, and would not be considered to be low-level radioactive waste for the purposes of the LLRWPAA.

2.4 Alternative 3: Revise Regulations to Apply a Graded Regulatory Authority

The NRC proposed and is now finalizing an alternative that revises its regulations by applying a graded regulatory authority and control over NARM in order to focus the staff's regulatory efforts on those activities that pose the greatest risk to protection of the public health and safety and promotion of the common defense and security. Beyond implementing the requirements specifically mandated by the EPAct, this alternative addresses the flexibility within the EPAct by establishing regulations that are commensurate with the potential health and safety consequences applicable to each NARM-containing product type. As required by the EPAct, the NARM regulatory framework has been based, to the maximum extent practicable, on the SSRs.

This preferred alternative includes general licensing provisions for certain products and discrete sources containing radium-226 that are apparently in the public domain but may not be otherwise covered under a license and are not specifically addressed in the SSRs. This alternative also accommodates generally licensed devices meeting the restrictions of the general licenses that were previously approved by States under existing regulations. This alternative is to regulate NARM under most of the same requirements as reactor-produced radioactive material. Additionally, this alternative adds certain products and materials containing NARM to some of the current exemptions, thereby allowing these NARM-containing products to be used without any regulatory requirements imposed on the user. This alternative does not require any changes be made to the exempt concentrations for radionuclides included in the SSRs, and adopts appropriate values for exempt quantities for the newly defined byproduct material consistent with the SSRs. The preferred alternative also adopts an exemption for timepieces containing 37 kBq (1 µCi) or less of radium-226 and adopts the requirement to allow a specifically licensed person to possess up to 185 kBq (5 µCi) of radium-226 in calibration and reference sources under a general license.

Under this preferred alternative, "discrete source" is defined to include only radionuclides that were concentrated with the intent of using the radionuclides for commercial, medical, or research activities. *Discrete source* is defined in the final rule as "a radionuclide that is distinct from the sources of radiation present in nature, and that has been processed so that its concentration within a material has been purposely increased for use in commercial, medical, or research activities." Under this definition, discrete sources of radium-226 or discrete sources of naturally occurring radioactive material, may have the same radiological characteristics (i.e., type of radiation, half-life, etc.) as the radionuclides found in nature, but the radionuclides will have been purposely concentrated for use of the radionuclides specifically. This definition limits NRC's jurisdiction, by excluding inadvertent movement or concentration of naturally occurring

radioactive material, such as that found in scaling on pipes from the fossil industry, in fly ash from coal burning, or in fertilizers. NRC's authority over source material would not be changed by this definition. This definition is revised from that proposed for clarification purposes. Under the revised definition, once a radioactive material, defined as a discrete source, becomes byproduct material, it continues to be byproduct material, even if no longer "discrete" in the usual sense. Contamination resulting from the use of discrete sources of radium-226, or other radionuclide identified under section 11e.(4) of the AEA, is still byproduct material.

Under this preferred alternative, the NRC will regulate the radioactive material (product and incidental ARM) produced by all accelerators that intentionally produce a radioactive material for its radiological properties (e.g., PET production facilities). The rationale for this approach is that this incidentally produced radioactive material is a direct result of producing the radioactive material for use for a commercial, medical, or research activity. In addition, it is necessary for the NRC to consider all radioactive material in its regulatory evaluation to ensure health and safety of the radioactive material production. This preferred alternative would not regulate incidental ARM that results from the operation of accelerators that only produce particle beams and do not intentionally produce radioactive materials for use for a commercial, medical, or research activity (e.g., electron microscopes and medical therapy linear accelerators). The reasons for not regulating this incidentally produced radioactive material are: (1) no radioactive material is produced for use for a commercial, medical, or research activity from such operation, and (2) the incidentally produced radioactive material resides within the accelerator or facility. For those accelerators that are used to produce both radioactive material and particle beams, the preferred alternative would establish regulations for the incidental ARM, as well as the product ARM, produced by the accelerator. The incidental ARM produced in such accelerators during the production of radioactive material for use for a commercial, medical, or research activity is indistinguishable from that produced when the same accelerator is operated to produce only particle beams, so both are covered by this final rule.

The regulatory framework and implementation process associated with radiopharmaceuticals under this preferred alternative would be the same as that described previously for Alternative 2. This preferred alternative would establish regulations and an implementation process that would minimize the regulatory impact on the availability of accelerator-produced radioactive drugs by taking the following actions: (1) applying its established regulatory framework to the commercial distribution of these drugs; (2) expanding the regulations to permit noncommercial distribution of PET drugs within a consortium; (3) "grandfathering" current users of accelerator-produced drugs; and (4) permitting individuals and other entities to continue to prepare and use radioactive drugs while they are applying for new licenses or amendments.

Under the preferred alternative, as required by Section 651(e)(3), NARM-containing byproduct material would be classified only as radioactive waste, and would not be considered to be low-level radioactive waste for the purposes of the LLRWPAA.

The next section describes the methodology to analyze benefits and costs of implementing the rule based on the assumptions in Alternatives 2 and 3.

3.0 Analysis of Values and Impacts

This chapter examines the values (benefits) and impacts (costs) expected to result from NRC's rule. The benefits and costs are analyzed for implementation of the rule under Alternative 2, Maximum Regulation, and Alternative 3, Graded Approach. Alternative 1 is described below as the "baseline" for the analysis.

Section 3.1 lists the affected attributes. Section 3.2 describes the methodology for calculating benefits and costs associated with each attribute. The analysis is done over a ten-year time period. General assumptions are presented, as are the specific assumptions for each alternative. Appendix A shows the input and results for Alternative 2. Appendix B shows the input and results for Alternative 3. Appendix C presents a list of references.

The results are shown in Section 4.0, in constant 2005 dollars. The results are presented for the one-time costs and the annual operating expense to implement the rule. The total cost of the rule over the 10-year implementation period is estimated using 7 percent and 3 percent real discount rates. Under the preferred Graded Approach, Alternative 3, the estimated total costs are $33 million and $39 million, discounted at 7 percent and 3 percent, respectively. Under the Maximum Regulation alternative, the estimated costs are about $90 million and $102 million at 7 percent and 3 percent real discount rates, respectively.

3.1 Identification of Affected Attributes

This section identifies characteristics in the public and private sectors that will be affected by the rule. These are called "attributes," using the list of potential attributes provided by NRC in Chapter 5 of its *Regulatory Analysis Technical Evaluation Handbook* (Reference 5). The affected attributes for the rule include the following:

1. ***Industry Implementation***. Under Alternatives 2 and 3, industry would incur one-time costs, both capital and labor, to implement the rule. These costs are associated with activities to prepare license amendments and applications, to make necessary capital improvements to facilities, to prepare new procedures for recordkeeping and reporting, and to develop safety programs among other activities.

2. ***Industry Operation***. Under Alternatives 2 and 3, industry would incur an increase in annual labor-related operating expense to implement the rule, such as conducting routine surveys, updating records and procedures, inspecting and testing equipment, training personnel, and other operating and maintenance activities.

3. ***NRC Implementation.*** NRC will incur one-time costs to prepare guidance documentation during this implementation time period, and will process license applications and amendments during the initial period of implementation.

4. ***NRC Operation***. NRC will incur an increase in annual operating expense due to staff time to review license amendments and applications, and to conduct inspections.

5. ***Other Government***. The identified alternatives may impose a small cost to Agreement State governments with respect to additional reporting requirements for products that contain radium-226. This cost is insignificant and is not included in the analysis.

6. ***Public Health (Routine)***. No costs are anticipated for this attribute. NRC anticipates a slight benefit since some additional byproduct material will fall within the NRC regulatory framework under the rule. The number of affected particle accelerators that fall within the regulatory framework is well known and under adequate control in Agreement States and many of the non-Agreement States. The number of affected persons who come in contact with discrete sources containing radium-226 is not known, and is a contributor to uncertainty in this analysis.

   NRC anticipates a small number of specific licenses will be issued to persons who repair, assemble and disassemble products containing radium-226, or who possess items or products containing radium-226 that exceed those specified in the rule under 10 CFR 31.12. There also is a general license category in 10 CFR 31.12 that includes notification requirements, should a discrete source containing radium-226 show any indication of damage such that it could result in a loss of radioactive material. 10 CFR 31.12 also specifies disposal requirements for products or items that contain radium-226. Specific licenses are expected for gauges containing radium-226. The public and occupational health concern includes the following types of sources: a) radium needles, thought primarily to be at hospitals and research centers as a sealed source but with a safety concern if the source has leaked; b) gauging devices that contain a radium-226 source that have a safety concern if the source is not secure; c) intact luminescent devices, such as those found in older aircraft gauges; d) collections of intact collectible antiquities that contain radium-226 and could pose a radon or a contamination hazard; and e) other luminous antique products such as watch hands and dials. NRC anticipates a slight benefit in public health due to improved radiological control of these discrete sources containing radium-226.

7. ***Occupational Health (Routine)***. No costs are anticipated for this attribute. NRC anticipates a slight benefit from the rule due to increased regulation of radioactive material used in medical applications and radium-226 in gauges.

   In January 2000, NRC released an evaluation of radiological occupational health risk for 40 different types of byproduct material licensed activities and devices ("*Risk Analysis and Evaluation of Regulatory Options for Nuclear Byproduct Material Systems*", see Reference 6). The risk results were derived for workers at licensee facilities and the maximally exposed member of the public, who in most cases was another worker at the facility but who was not directly involved in the licensed activity. The results were derived based on both "normal operations" and "accident" risk. In the relative risk rankings, field radiography, shielded room radiography, and three medical applications were ranked "high" in risk. The medical applications were therapeutic nuclear medicine, medical brachytherapy with manual afterloading, and medical teletherapy with a single source. The radiation safety practices are considered adequate at facilities that provide these medical procedures.

8. ***Public Health (Accidental)***. No costs are anticipated for this attribute. NRC anticipates a slight benefit due to increased regulation of byproduct material.

9. ***Occupational Health (Accidental)***. No costs are anticipated for this attribute. NRC anticipates a slight benefit due to increased regulation of byproduct material.

10. ***Regulatory Efficiency***. The alternatives to no action under consideration would result in a small benefit due to more consistent regulations among Agreement States and the NRC.

11. ***Environmental Considerations***. No costs are anticipated for this attribute. NRC anticipates a slight benefit due to increased regulation of byproduct material. Reference 3, the Environmental Assessment, contains more information.

12. ***Safeguards and Security Considerations***. The identified alternatives to no action are expected to provide a slight benefit in terms of prevention of radiological sabotage.

13. ***Improvements in Knowledge***. A benefit may occur for NRC as a result of the rulemaking. NRC may gain valuable information about previously unregulated entities, such as those possessing certain radium-226 sources.

14. ***Other Considerations***. Public confidence in NRC may be affected positively by the rule. The public may have more confidence in NRC's program for protection of human health and safety, and the environment, through the regulatory framework to ensure proper management and safe use of the newly defined byproduct material (discrete sources of radium-226 and product ARM in conjunction with the existing byproduct material (reactor-produced radioactive material). This is done while providing a general license for persons who have small numbers of discrete radium-226 sources and radium-226 used in collectible items or antiques.

The following attributes are not expected to be affected:

15. ***Offsite Property***. No impacts are anticipated to affect offsite property because no changes are anticipated in accident frequency. A slight reduction in property consequences is possible due to regulation, and remediation of sites with radium-226 contamination.

16. ***Onsite Property***. No impacts are anticipated to affect onsite property for the same reasons provided above for offsite property, with a slight benefit from site remediation efforts.

17. ***General Public***. No impacts are anticipated for the general public.

18. ***Antitrust Considerations***. There are no costs associated with this attribute because there are no antitrust considerations applicable to this rulemaking.

3.2 Analytical Methodology

This section describes the process used to evaluate values and impacts associated with the affected attributes discussed above for the alternative methods to implement the rule. The *values* (benefits) include any desirable changes in affected attributes. As described earlier, only slight benefits are expected due to improved public and occupational health. These benefits are not quantified because of the perceived small numbers of radium-226 sources in the general population, and the effectiveness of existing regulations in the Agreement States and many non-Agreement States to monitor radioactive material. The *impacts* (costs) include any undesirable changes in affected attributes, such as increased costs for different segments of industry to conduct their business in accordance with new regulations. These attributes have quantifiable values and impacts due to implementing the rule:

– Industry Implementation
– Industry Operation
– NRC Implementation
– NRC Operation

Costs are calculated for Alternative 2, Maximum Regulation, and Alternative 3, Graded Approach, to implement the rule. This requires input assumptions for the following:

- Number of existing and new licensees that may be affected by the rule;
- Industry costs to prepare and submit license amendments and license applications;
- NRC costs to review license amendments and license applications;
- Industry costs for recordkeeping and reporting to comply with new regulations; and
- Industry capital costs to comply with new regulations.

NRC collected the input assumptions using data and information obtained from the following sources: Public Meetings; Public Comments; NRC Workgroups and NRC Staff experience; Reports and documents (e.g., OMB burden statements); and Independent Research. Both Agreement and non-Agreement States participated in public meetings and in the NRC workgroup meetings. The number of affected entities for this rule was estimated using NRC information on existing licensees, NRC staff best professional judgement, and consultation with Agreement State and non-Agreement States.

3.2.1 General Assumptions

The general input assumptions for the analysis are discussed below.

- NRC wage rate: $87.00/hour. This is NRC's incremental labor rate which includes only the variable costs associated with implementation and operation costs of the rule; this labor rate is consistent with Section 5.2 of NUREG/CR-4627, Generic Cost Estimates (Reference 7).

- Industry wage rate: $87.00/hour.

- No incremental costs or benefits are expected to occur for this rule under the regulations in 10 CFR Parts 33, 50, 61, 62, 72, 150, 170 and 171, although there are rule text changes in these regulations resulting from the definition of byproduct material.

- NRC will have additional licensees due to the new definition of byproduct material. For Alternative 2, Maximum Regulation, NRC estimates an increase of 3985 licensees. About 3500 licensees are expected to have particle accelerators, 40 licensees in the industrial sector, 45 medical users, and 400 that have gauges or other items containing radium. Medical use licensees with accelerators are counted within these approximations. Fees collected by NRC for license applications and annual license fees are assumed to be a transfer payment and are not included in the analysis. For Alternative 3, the Graded Approach, NRC estimates an increase of 335 licensees. About 100 licensees are expected to have radium products, 45 are expected to be from the industrial sector, 60 from medical, 45 PET accelerators, and 85 independent accelerators. None from the industrial sector are expected to be in well-logging or radiography applications. Although flyash and pipescale could have been included in this analysis, these licensees were not included because of a lack of data.

- The time period for the analysis is 10 years. We estimate both first year, one-time implementation costs and an increase in annual operating expense to support implementation of the rule. The values for annual operating expense are identical for each of the 10 years in the analysis, and are based primarily on labor hours contained in current OMB submission statements for the affected regulations. The annuity formula used to discount the annual expense values is on page B.3 of Reference 5.

3.2.2 Specific Assumptions for Alternative 1

Under the No-Action alternative (Alternative 1), NRC would maintain the current requirements for byproduct material and NARM. Thus, relative to existing requirements, no values or impacts would result from Alternative 1. The costs (impacts) and benefits (values) to be derived from the other alternatives would not be realized.

3.2.3 Specific Assumptions for Alternative 2

The specific assumptions are shown below for Alternative 2, Maximum Regulation. The primary difference between Alternative 2 and Alternative 3, Graded Approach, is the number of licensees that fall under this regulatory framework. Alternative 2 assumes 3985 new licensees while Alternative 3 assumes 335.

The NRC also has made assumptions for the number of specific licenses for persons with products and materials containing radium-226. For these licensees, under Alternative 3, we have added 300 licensees for possession of radium products, that would be generally licensed, in addition to the 100 assumed in both Alternatives 2 and 3. Appendix A shows the line item assumptions for the implementation and annual operating expense for Alternative 2.

10 CFR Part 19, Notices, Instructions and Reports to Workers: Inspection and Investigations

- We assumed 3585 new licensees, all of which have one-time set-up costs to comply with 10 CFR 19.12 regarding radiation exposure reports and instructions to workers. This is 3350 more licensees than Alternative 3, the Graded Approach.
- All of the 3585 licensees would be affected by annual reporting requirements regarding notifications and reports to workers under 10 CFR 19.12, 19.13(a), and 19.13(b), and about 10 percent of the licensees would be affected by the requirements in 10 CFR 19.13(c) and 19.13(e).

10 CFR Part 20, Standards for Protection Against Radiation

- We assumed about 5 percent of a total of 3985 licensees, or 199 licensees, would have one-time set-up costs to comply with 10 CFR 20.1101 regarding development, documentation and implementation of a radiation safety program. The 3985 total includes all 3585 licensees with implementation costs for 10 CFR Part 19 and the 400 licensees for possession of radium products. A $10,000 one-time capital expense is assumed for each of the 199 licensees to construct new facilities or to renovate existing facilities to comply with this part. All 3985 licensees also would have one-time labor expense to comply with 10 CFR 20.1406 regarding design and operating procedures for minimization of contamination and 10 CFR 20.2102 regarding ALARA records retention.
- We assume about 15 percent of the 3985 licensees, or 598 licensees, would have an annual labor expense for other reporting and recordkeeping requirements primarily in 10 CFR 20.1906, 20.2102 and 20.2103.
- All 3985 licensees are assumed to be correctly filling-out the manifests, currently, for waste disposal, so there is no additional cost for this activity under Appendix G.

10 CFR Part 30, Rules of General Applicability to Domestic Licensing of Byproduct Material

- We assume 3985 new licensees would have one-time labor costs for license application under 10 CFR 30.32.
- We assume 15 authorizations for production of PET drugs for non-commercial distribution to consortium members under 10 CFR 30.32(j) which is a one-time labor expense. We assume for the same 15 licensees an annual expense of 390 hours each for labeling of vials and syringes under 10 CFR 30.34(j); this assumption is the same as under Alternative 3.
- Only 5 new licensees, the same as under Alternative 3, are assumed to have one-time and annual labor expense to comply with financial assurance requirements for decommissioning under 10 CFR 30.35(a) and 30.35(b).
- Of the total 3985 new licensees, only 8 are assumed to have quantities of material that would require a one time expense to calculate whether an emergency plan was needed, and 3 would have to prepare an emergency plan for compliance with the emergency planning regulations in 10 CFR 30.32.

10 CFR Part 31, General Domestic Licenses for Byproduct Material

- We assume that 100 General Licenses in Alternative 2, the same as Alternative 3, would have an annual labor expense to comply with the regulations in 10 CFR 31.5.
- The provisions for a general license in 10 CFR 31.12 do not apply to Alternative 2. The general license for products containing radium-226 are only in Alternative 3.

10 CFR Part 32, Specific Licenses for Manufacture or Transfer

- No differences are modeled in Alternative 2 compared to Alternative 3. The specific assumptions for 10 CFR Part 32 are listed in Section 3.2.4.

10 CFR Part 35, Medical Use of Byproduct Material

- There will be one-time implementation costs under 10 CFR Part 35, but only minor incremental changes compared to the Alternative 3 assumptions. About one-half of the extra one-time implementation cost is due to an estimated 80 licensees with review and approval requirements from NRC for the protection of human subjects (under 10 CFR 35.6).
- The assumptions for annual operating expense burden are based on regulatory requirements in certain sections of 10 CFR Part 35. The specific assumptions for most of these line items are moderately higher than the assumptions used to represent Alternative 2.
- The most significant change in annual operating expense for Alternative 2 is an estimated 160 licensees that have an approximate 42 hour labor burden to record dosages of unsealed byproduct material for medical use, per 10 CFR 35.2063.

Additional Cost to NRC

- We assume 3985 new license applications with a one-time implementation effort of 40 hours staff time to process each new license. 3500 are for particle accelerators; 40 are in the industrial sector, 45 are medical users, and 400 are for gauges and other items containing radium-226. Medical uses and the non-commercial distribution of PET drugs to consortium members are included in these totals.
- We assume annual labor expense to process 150 new license amendments per year and 50 inspections per year for Alternative 2.

Waste and Decommissioning

- Of the 3500 particle accelerators, we assume that 150 of these facilities have large enough amounts of radioactive waste for modeling waste costs. The other 3350 accelerators are non-producing ARM with minimal radioactive waste. We assume the 45 particle accelerators producing significant waste under Alternative 3 produce on average two-thirds of the tonnage in the waste stream produced by the 150 accelerators in Alternative 2.

- No costs were assumed for waste disposal and decommissioning for the 40 industrial sector licensees and the 400 licensees with gauges and other items containing radium-226. This is the same assumption used for Alternative 3; additional information regarding the basis for this assumption is presented in the specific assumptions for Waste and Decommissioning for Alternative 3.

3.2.4 Specific Assumptions for Alternative 3

The specific assumptions are described below for Alternative 3, Graded Approach, which is the NRC preferred alternative. Appendix B shows the assumptions used for the number of licensees affected, assumed capital and labor implementation costs, and the labor hours associated with annual operating expense activities for each line item in the cost analysis.

10 CFR Part 19, Notices, Instructions and Reports to Workers: Inspection and Investigations

- We assume 235 licensees would have one-time set-up costs to comply with 10 CFR 19.12 regarding worker radiation exposure reporting. This includes 25 manufacturing and distribution licensees, of which 5 have accelerators and 20 are users; 20 are large medical licensees, of which 15 have accelerators and 5 are users; 40 are small medical users; 20 are industrial users; 45 are PET accelerators; and 85 are independent accelerators.
- All of the 235 licensees would be affected by annual reporting requirements regarding notifications and reports to workers under 10 CFR 19.12, 19.13(a), and 19.13(b), and about 10 percent of the licensees would be affected by the requirements in 10 CFR 19.13(c) and 19.13(e).

10 CFR Part 20, Standards for Protection Against Radiation

- We assume 5 percent of a total of 335 licensees would have one-time set-up costs to comply with 10 CFR 20.1101 regarding development, documentation and implementation of a radiation safety program. A $10,000 one-time capital expense is assumed for each licensee to construct new facilities or to renovate existing facilities to comply with this regulation. The 335 total includes the 235 new licensees described above and an additional 100 licensees with specific licensed gauges.
- All 335 licensees would have one-time labor expense to comply with 10 CFR 20.1406. The assumption is 20 hours per licensee.
- We assume all 335 licensees would have an annual labor expense for other reporting and recordkeeping requirements primarily in 10 CFR 20.1906, 20.2102 and 20.2103.

10 CFR Part 30, Rules of General Applicability to Domestic Licensing of Byproduct Material

- We assume that all 335 licensees would have one-time labor costs for license application under 10 CFR 30.32.
- We assume 15 authorizations for production of PET drugs for non-commercial distribution to consortium members under 10 CFR 30.32(j) and a one-time labor expense and annual expense for these 15 licensees for labeling of vials and syringes under 10 CFR 30.34(j).
- A subset of the particle accelerator licensees, estimated at 5, also would have one-time labor expense to comply with financial assurance requirements for decommissioning under 10 CFR 30.35 (unsealed byproduct material with a half-life greater than 120 days and in quantities exceeding 100,000 times Appendix B to 10 CFR Part 30). The amount of decommissioning funding assurance is specified in 10 CFR 30.35(d) and is based on the possession limit of material at the licensed site. The range is from $113,000 to $1,125,000 unless the quantity upper bound is exceeded, in which case a decommissioning funding plan must be submitted per 10 CFR 30.35(e).
- Most of the annual burden hours is in the licensee's labeling requirements and procedures of use of instrumentation in 10 CFR 30.34(j)(2).

10 CFR Part 31, General Domestic Licenses for Byproduct Material

- We assume that 100 General Licenses would have an annual labor expense to comply with the regulations in 10 CFR 31.5.
- We assume 300 persons, who possess certain items containing radium-226, are eligible for a general license under the new section 10 CFR 31.12. Of these, we assume that 1 percent (3) would have annual labor expense to comply with notification and reporting conditions. This is a new labor burden, estimated at 4 hours per affected licensee.

10 CFR Part 32, Specific Licenses for Manufacture or Transfer

- The assumptions for part 32 are the same in Alternative 2 compared to Alternative 3. We assume that 22 new accelerator facilities, that manufacture and distribute radioactive drugs for medical purposes, would have a one-time labor expense of 2 hours each to prepare instrumentation procedures consistent with the requirements of 10 CFR 32.72(c). We assume the three licensees under 10 CFR 32.74 do not require implementation activities.
- We assume the 22 new accelerator facilities would have an annual labor burden of 390 hours each for labeling requirements under 10 CFR 32.72(a) and an equivalent annual labor burden associated with procedures for use of instrumentation under the requirements under 10 CFR 32.72(c).

10 CFR Part 35, Medical Use of Byproduct Material

- There will be one-time implementation costs under 10 CFR Part 35. Most of the one-time implementation cost is due to requirements under 10 CFR 35.6, 35.24 and 35.26.
- The most significant change in annual operating expense for Alternative 3 is an estimated 80 licensees that have an approximate 42 hour labor burden to record dosages of unsealed byproduct material for medical use, per 10 CFR 35.2063, and an estimated 200 licensees that have an approximate 13 hour labor burden to prepare written directives before the administration of I-131 sodium iodide or any therapeutic dosage of unsealed byproduct material, per 10 CFR 35.40(a).

Additional Cost to NRC

- We assume 335 new license applications with a one-time effort of 40 hours staff time to process each new license.
- We assume the one-time effort to develop a new guidance document in the first year of implementation, with 300 staff hours required to prepare the document.
- For annual operating costs, we assume that 75 license amendments and 25 additional inspections are required each year over the 10-year analysis. Each license amendment requires 20 staff hours and each inspection requires 24 hours staff time.

Waste and Decommissioning

- Of the particle accelerators, we assume that 45 of these facilities have material amounts of radioactive waste for estimation of waste processing costs. We assume these 45 accelerators have 0.25 tons per year of waste, with a disposal cost of $22 per ton and a transport cost to an authorized solid waste facility of $40 per ton. Few if any of the facilities are expected to be decommissioned during the 10-year analysis period. We

assume a $10,000 annual sinking fund expense for decommissioning these particle accelerators.

- No costs were assumed for waste disposal and decommissioning the 50 industrial sector licensees and 100 licensees with gauges and other items containing radium-226 or the small number of sites where there are people who have large collections of products containing radium-226. The gauges are believed to be owned by companies with larger numbers of gauges containing other radioactive material, and the waste and decommissioning related to radium-226 gauges is low compared to other obligations.

4.0 Results

This section presents results of values and impacts that are expected to be derived from the rule. The results are shown for each affected part in Title 10 of the Code of Federal Regulations and by the following four attributes as discussed in section 3.2:

– Industry Implementation
– Industry Operation
– NRC Implementation
– NRC Operation

The rule is expected to provide values in other attributes, such as Public Health, Occupational Health, and Safeguards and Security Considerations, but these values are not quantified because they are expected to be small and there is no verifiable input available at this time to support input assumptions. For health attributes, the benefits in terms of avoided radiological exposure are expected to be small. As a result, the quantifiable results in this analysis are entirely on the impacts (i.e., costs) expected from implementation of the rule as required by Section 651(e) of the EPAct. The costs are presented in constant 2005 dollars, for both implementation and annual operating expense. The impact of the rule over a 10-year analysis period is estimated using 7 percent and 3 percent real discount rates to show an overall effect in terms of constant 2005 dollars.

Alternative 3 is the Graded Regulatory approach, which is the preferred approach. Alternative 2 would revise the regulations to maximize NRC's regulatory authority. Alternative 1 is the "No-Action" alternative that provides a baseline against which the other two alternatives are assessed.

4.1 Summary of Results

Table 4-1 presents the net impact of the rule for each of the three alternatives, at 7 percent and 3 percent real discount rates, including all benefits and costs over the 10-year analysis period.

Table 4-1: Net Impact of Alternatives 1, 2 and 3

Regulatory Alternative	10-Year Total 7% discount rate (2005$)	10-Year Total 3% discount rate (2005$)
1. No-Action	0	0
2. Maximum Regulatory Authority	(90,108,228)	(101,774,070)
3. Graded Regulatory Authority	(32,534,759)	(38,820,088)

Note: Costs in all tables are represented by negative numbers.

Table 4-2 provides the estimated costs, by attribute, over the 10-year analysis period. The Industry Implementation and NRC implementation costs are all one-time capital and labor expense, in 2005 dollars, and are thus not discounted. The other two categories have annual expense, so the discounted expenses are different under 7 percent and 3 percent discount rates. Industry Operation costs are a large part of total estimated cost over the 10-year period.

Table 4-2. Values and Impacts by Attribute

Attribute	Alternative 2 10-Year Total Cost (2005$)		Alternative 3 10-Year Total Cost (2005$)	
	7 percent discount	3 percent discount	7 percent discount	3 percent discount
Industry Implementation	(24,257,346)	(24,257,346)	(2,245,864)	(2,245,864)
Industry Operation	(49,390,565)	(60,505,888)	(27,813,787)	(33,823,857)
NRC Implementation	(13,893,900)	(13,893,900)	(1,191,900)	(1,191,900)
NRC Operation	(2,566,417)	(3,116,936)	(1,283,208)	(1,558,468)
Total	(90,108,228)	(101,774,070)	(32,534,759)	(38,820,088)

The Industry Implementation and NRC Implementation attributes represent projected costs that would be incurred by affected licensees and the NRC to install or implement changes as required in the rule, or to process new license applications. Alternative 2, Maximum Regulation, has substantially higher implementation costs than Alternative 3.

The Industry Operation attribute represents the additional annual operating expense projected to be incurred by the affected licensees as required by the regulations in the rule. For Alternative 2, the Industry Operation costs are about 60 percent of the total costs because the implementation costs are so high. For Alternative 3, where there are less implementation costs, the Industry Operation costs are about 85 percent of the total costs.

The NRC Operation attribute represents additional annual expense to process license amendments and to conduct inspections for the rule.

Table 4-3 shows the results for estimated implementation costs and annual operating expense to comply with the rule, by affected 10 CFR Part. For Alternative 3, the largest *one-time* cost to industry is to comply with 10 CFR Part 20 regulations, followed by the requirements in 10 CFR Part 30. The largest *annual cost* to industry for Alternative 3 is to comply with 10 CFR Part 32 regulations, followed by the requirements in 10 CFR Part 30 and 10 CFR Part 35.

An “impact per entity” for one-time costs to comply with the rule is about $6,700 for each of the estimated 335 licensees who are affected by the new regulations under 10 CFR Part 19, 20, 30, 32, and 35 for the preferred Alternative 3. In general, this cost would be applied to renovate an existing facility and expand the radiation safety program in order to comply with radiation protection safety functions that the licensee may not have fully implemented before the effective date of the rule.

Table 4-3. Summary of One-Time Costs and Annual Labor Expense

10 CFR Part	Alternative 2		Alternative 3	
	One-time Cost ($)	Annual Cost ($)	One-time Cost ($)	Annual Cost ($)
19	(5,614,110)	(2,875,791)	(368,010)	(188,681)
20	(15,858,583)	(697,566)	(1,336,583)	(429,345)
30	(2,683,298)	(1,112,360)	(460,448)	(1,096,004)
31	0	(5,525)	0	(6,569)
32	(3,828)	(1,494,608)	(3,828)	(1,494,608)
35	(97,527)	(1,181,021)	(76,995)	(755,543)
NRC Operation	0	(365,400)	0	(182,700)
NRC Implementation	(13,893,900)	0	(1,191,900)	0
Waste and Decommissioning	0	(28,200)	0	(19,900)
Total	(38,151,246)	(7,760,470)	(3,437,764)	(4,173,349)

Note: Costs are represented by negative numbers.

There is a margin of error in the operating expense assumptions when applied to the working experience of individual facilities. Most of the labor expense assumptions to derive the costs shown above were obtained from OMB submission statements that have information of burden for regulated recordkeeping and reporting activities. These burden statements that were used for the input assumptions have not, to date, included production accelerators or persons who possess or repair products that contain radium-226. The costs in this analysis are based on best available data to support the rulemaking.

The greatest uncertainty in the cost estimates is with the input assumptions for waste and decommissioning activities, which fall within the Industry Operation attribute. The input data to represent these activities are based on independent research and staff experience for waste transportation and disposal. Reference 8, "Economic Risk of Contamination Cleanup Costs Resulting from Large Nonreactor Nuclear Material Licensee Operations," provides information about decontamination costs following several types of hypothetical accidents, including separately a waste warehouse fire and a tornado, at a large facility that manufactures a variety of radiological products. The upper bound of economic risk for this large facility was estimated to be $31,000/year in 1990 dollars. Reference 9, "Radiological Assessments for Clearance of Materials from Nuclear Facilities," has an estimate of total amount of steel scrap cleared from U.S. hospitals with rooms under radiological regulatory control. Decommissioning information for a variety of radioactive material sites is available for review at the following NRC website, www.nrc.gov/info-finder/decommissioning/complex. Among these sites, one had operated a Co-60 irradiator and was reporting decommissioning costs to date of about $25 million, with an additional $2 million to $3 million needed to complete decommissioning. Other smaller byproduct material sites have significantly lower estimated decommissioning costs.

5.0 Decision Rationale

The assessment of costs and benefits discussed above, quantitatively when possible and qualitatively otherwise, leads the NRC to the conclusion that the rulemaking would:

- Use the model State regulations to the maximum extent practicable to regulate certain radium sources, accelerator-produced radioactive materials, and certain naturally occurring radioactive material, as required by EPAct;

- Minimize the impact on the availability of radioactive drugs to physicians and patients while assuring the protection of public health and safety in the future; and

- Minimize the regulatory burden on regulated entities while protecting the public health and safety and the common defense and security.

Because the regulation is mandated by the U.S. Congress, adoption of the No-Action Alternative is not feasible. In order to meet the Congressional mandate to promulgate regulations, while minimizing burden on stakeholders, NRC developed Alternative 3, a Graded Approach for exercising regulatory authority over NARM. In so doing, NRC took advantage of opportunities in the EPAct to consider alternatives in developing its regulations. Alternative 2 would not allow such discretion, and the impacts associated with this Alternative would be much higher than NRC's preferred approach (Alternative 3). Because both Alternatives are believed to be equally protective of public health and safety and the common defense and security, NRC has determined that Alternative 3, providing regulatory discretion, is the most appropriate alternative.

6.0 Implementation

Specific provisions are included in this rule, and several actions are planned in conjunction with, or following, the issuance of this final rule covering the newly added byproduct material, including:

1. Issuance and publication of a Transition Plan for the orderly transition of regulatory authority for the newly added byproduct material;

2. Termination of the waiver issued by the NRC (70 FR 51581; August 31, 2005) for the States and users of the newly added byproduct material; and

3. Inclusion of specific provisions allowing users of the newly added byproduct material to continue with their activities for a period of time while coming into compliance with the newly issued regulations.

With respect to a Backfit Analysis, the alternatives examined in this regulatory analysis do not involve any provisions that would require backfits as defined in 10 CFR Part 50.109(a)(1). Consequently, a backfit analysis is not necessary.

6.1 Transition Plan

Section 651(e) of the EPAct requires the NRC, in issuing new regulations for the newly added byproduct material, to prepare and publish a transition plan for regulatory authority over the newly added byproduct material in Agreement and non-Agreement States. The transition plan must describe the conditions under which a State may exercise authority over the newly added byproduct material. The transition plan also must include a statement of the Commission that any agreement between the Commission and a State, under Section 274b. of the Atomic Energy Act of 1954, as amended, covering byproduct material and entered into before the date of publication of the transition plan, must be considered to include the newly added byproduct material, providing that the Governor of the Agreement State certifies to the Commission on the date of publication of the transition plan that: (1) the State has a program for licensing the newly covered byproduct material that is adequate to protect the public health and safety, as determined by the Commission; and (2) the State intends to continue to implement the regulatory responsibility of the State with respect to the newly defined byproduct material.

7.0 Implications for Other Federal Agencies

Promulgation of this rule would have no significant adverse effects on other Federal regulatory agencies.

8.0 Effect on Small Entities

This rule may have a minor economic impact on some small entities in non-Agreement States. A small number of businesses that may be impacted by the rule fall within the scope of the definition of "small entities" set forth in the Regulatory Flexibility Act or the Small Business Size Standards set out in regulations issued by the Small Business Administration at 13 CFR Part 121.

Section 651(e) of the EPAct expanded the definition of byproduct material in Section 11e. of the AEA to include any discrete source of radium-226, any material made radioactive by use of a particle accelerator, and any discrete source of naturally occurring radioactive material that would pose a similar threat to the public health and safety or the common defense and security as a discrete source of radium-226 that is extracted or converted after extraction for use in a commercial, medical, or research activity. This rulemaking would amend the NRC regulations to include this newly defined byproduct material. This amendment would potentially affect large numbers of individuals, businesses, or licensees engaged in activities involving discrete radium-226 sources or accelerator-produced radioactive material used for commercial, medical, or research activities.

Many individuals, businesses, or licensees would qualify as small business entities as defined by 10 CFR 2.810. Because the NRC is using the existing regulatory framework to regulate these materials and is allowing sufficient time for individuals, businesses, and licensees to implement the requirements for this radioactive material, the impact on small entities is believed to be acceptable.

Based on the analysis provided in Section 3 of this Regulatory Analysis, the NRC believes that the selected alternative is protective of public health and safety and is not overly burdensome in order to accomplish the NRC's regulatory objective. The NRC also notes that several Agreement States have similar regulations already implemented either by rule, order, or license condition.

APPENDIX A Input and Results for Alternative 2

This appendix provides details of the line-by-line input and results for Alternative 2, the Maximum Regulation. The following pages show input and results for 10 CFR Part 19, 20, 30, 31, 32, 35, NRC Costs, and Waste and Decommissioning.

10 CFR Part 19
Alternative 2

Section #	Total # Licensees	One Time			Annual			Total One Time Cost	Total Annual Cost
		% licensees affected	# of Licensees	Hours of labor per Licensee	% licensees affected	# of Licensees	Hours of labor per Licensee		
19.12	3585	100%	3585	18	100%	3585	0.2	$ (5,614,110)	$ (62,379)
19.13(a)	3585	0%	0	0	100%	3585	0.2	$ -	$ (62,379)
19.13(b)	3585	0%	0	0	100%	3585	8.4	$ -	$ (2,620,542)
19.13(c)	3585	0%	0	0	10%	359	3.3	$ -	$ (102,569)
19.13(e)	3585	0%	0	0	10%	359	0.9	$ -	$ (27,922)
							Total	**$ (5,614,110)**	**$ (2,875,791)**

Notes: as of 8-Feb-2006:

Annual hours of labor per licensee reduced by 80 percent compared to OMB Final Supporting Statement for 10 CFR Part 19 (OMB Clearance No. 3150-0044)

19.12 Requires licensees to provide radiation exposure reports to workers
19.13(a) Notification and report to individuals
19.13(b) Advise workers annually of dose
19.13(c) At request of worker formerly engaged in activities at the facility, exposure report for each year.
19.13(e) At request of worker terminating employment at the facility, exposure report for year and current quarter.

10 CFR Part 20
Alternative 2

Section #	Total # Licensees	One Time				Annual			Total One Time Cost	Total Annual Cost
		% licensees affected	# of Licensees	Capital Cost per Licensee	Hours of labor per Licensee	% licensees affected	# of Licensees	Hours of labor per Licensee		
20.1101 *	3985	5%	199	$ (10,000)	0	0%	0	0	$ (1,990,000)	$ -
20.1406	3985	100%	3985	$ -	20	0%	0	0	$ (6,933,900)	$ -
20.1601(c)	1	100%	1	$ -	8	0%	0	0	$ (696)	$ -
20.1906(d)	1	100%	1	$ -	1	0%	0	0	$ (87)	$ -
20.1906(e)	3985	0%	0	$ -	0	15%	598	1	$ -	$ (52,026)
20.2102(a)&(b)	3985	100%	3985	$ -	20	15%	598	4	$ (6,933,900)	$ (208,104)
20.2103(a)&(b)	3985	0%	0	$ -	0	15%	598	8	$ -	$ (416,208)
20.2107(a)	25	0%	0	$ -	0	100%	25	5	$ -	$ (10,875)
20.2108(a)	50	0%	0	$ -	0	15%	8	8	$ -	$ (5,568)
20.2201(a)	1	0%	0	$ -	0	100%	1	3	$ -	$ (261)
20.2201(b)	1	0%	0	$ -	0	100%	1	3	$ -	$ (261)
20.2201(d)	1	0%	0	$ -	0	100%	1	3	$ -	$ (261)
20.2202(b)	1	0%	0	$ -	0	100%	1	40	$ -	$ (3,480)
20.2203(a)	1	0%	0	$ -	0	100%	1	6	$ -	$ (522)
								Total	**$ (15,858,583)**	**$ (697,566)**

Notes: as of 8-Feb-2006:

Source of hours of labor per licensee is Draft OMB Supporting Statement for 10 CFR Part 20 (OMB Clearance No. 3150-0014)

* A $10,000 capital expense is assumed for each affected licensee to construct or renovate facilities.

20.1101 Requires licensees to develop, document and implement radiation protection programs, establish procedures, and perform program review.
20.1406 Requires applicants for licenses to describe how facility design and procedures for operation will minimize contamination of the facility and environment, facilitate eventual decommissioning, and minimize generation of radioactive waste.
20.1601(c) Allows licensees to apply to the Commission for approval of alternate methods for control of access to high radiation areas.
20.1906(e) Requires licensees to develop and maintain procedures regarding radioactive material shipment.
20.2102(a)&(b) (a) Requires licensees to maintain records of the radiation protection program, including ALARA; (b) requires licensees to retain records of radiation programs until the Commission terminates the license.
20.2103(a)&(b) (a) Requires licensees to maintain records showing the results of surveys and calibrations; (b) requires licensees to maintain records for 3 years, unless they form the basis of dose estimates in which case they must be maintained through license termination.
20.2107(a) Requires information on the identity and quality of the radionuclides released by licensee in effluents to unrestricted areas.
20.2108(a) Requires records of waste disposal to permit routine inspection for compliance, and inspection against constraints on the kinds and quantities of licensed material.
20.2201(a) Requires licensees to report any theft or loss of licensed material by telephone immediately or in writing within 30 days, dependent upon the potential risk to the health and safety of the public.
20.2201(b) Requires licensees to follow up telephone reports with written reports of the incident within 30 days of the telephone report.
20.2201(d) Requires additional information relevant to the loss of radioactive material, discovered after the written report, be submitted within 30 days of discovery.
20.2202(b) Requires that the licensee notify the NRC within 24 hours upon becoming aware of specific incidents involving licensed material.
20.2203(a) Contains the requirements for the content of the reports required by Paragraph 20.2203(a).

10 CFR Part 30
Alternative 2

Section	Total # Licensees	One Time			Annual			Total One Time Cost	Total Annual Cost
		% licensees affected	# of Licensees	Hours of labor per Licensee	% licensees affected	# of Licensees	Hours of labor per Licensee		
30.9(b)	1	0%	0	0	100%	1	1.0	$ -	$ (87)
30.32	3985	100%	3985	7	5%	199	1.0	$ (2,426,865)	$ (17,335)
30.32 (i) - EP	3	100%	3	10	100%	3	10.0	$ (2,610)	$ (2,610)
30.32 (i) - Calculation	5	100%	5	1	0%	0	0.0	$ (435)	$ -
30.32 (j)	15	100%	15	42.5	0%	0	0.0	$ (55,463)	$ -
30.32 (g)	20	100%	20	3	0%	0	0.0	$ (5,220)	$ -
30.34(e)(4) - Orders	1	0%	0	0	100%	1	3.0	$ -	$ (261)
30.34(e)(4) - Sfguards	5	0%	0	0	100%	5	0.5	$ -	$ (218)
30.34(h)	5	0%	0	0	1%	2	0.5	$ -	$ (87)
30.34(j)(2)(i)	15	100%	15	2	100%	15	390.0	$ (2,610)	$ (508,950)
30.34(j)(2)(ii)	15	0%	0	0	100%	15	390.0	$ -	$ (508,950)
30.34(j)(4)	15	0%	0	0	20%	3	0.5	$ -	$ (131)
30.35(a)&(b) - Certific	5	100%	5	100	100%	5	10.0	$ (43,500)	$ (4,350)
30.35(a)&(b) - F Plan	5	100%	5	300	100%	5	10.0	$ (130,500)	$ (4,350)
30.35(g)	14	100%	14	10	100%	14	10.0	$ (12,180)	$ (12,180)
30.36(d)	1	0%	0	0	100%	1	1.0	$ -	$ (87)
30.36(g)	1	0%	0	0	100%	1	336.0	$ -	$ (29,232)
30.41(c)&(d)	60	0%	0	0	100%	60	4.0	$ -	$ (20,880)
30.50(a),(b),&(c)	2	0%	0	0	100%	2	4.0	$ -	$ (696)
Appendix D	25	100%	25	1	50%	13	1.0	$ (2,175)	$ (1,088)
Appendix E	20	100%	20	1	50%	10	1.0	$ (1,740)	$ (870)
							Total	**$ (2,683,298)**	**$ (1,112,360)**

Notes: as of 8-Feb-2006:

Source of hours of labor per licensee is OMB Final Supporting Statement for 10 CFR Part 30 (OMB Clearance No. 3150-0017).

30.9(b)	Requires applicant or licensee to notify the Commission of information which has significant implications for public health and safety or the common defense and security.
30.32	License application process for entities with gauges containing radium-226 products, accelerators and other NARM use.
30.32 (i) - EP	Requires applicants that will posses amounts of materials requiring an emergency plan to either submit an evaluation demonstrating an emergency plan is not needed or to provide the emergency plan.
30.32 (j)	License appliction process for authorization for production of PET drugs for non-commercial distribution to consortium members.
30.34(e)(4) - Orders	The authority for Commission issuance of orders for the modification of licenses.
30.34(e)(4) - Sfguards	Certain licensees are required to take compensatory actions against threats, requiring safeguards plans and other safeguard requirements.
30.34(h)	Requires immediate notification to the appropriate NRC regional administrator, in writing, following the filing of bankruptcy petition.
30.34(j)(2)(i)	Applicants must satisfy labeling requirements for each transport radiation shield and each syringe, vial, or other container used to hold radioactive drug to be transferred for commercial distribution.
30.34(j)(2)(ii)	Requires licensee to have procedures for use of instrumentation used to measure radioactivity of radioactive drugs.
30.34(j)(4)	Requires licensees, licensed as a pharmacy by a State Board of Pharmacy or are operating as a nuclear pharmacy within a Federal medical institution, to provide certification information to NRC.
30.35(a)&(b) - Certific	Specifies licensees required to submit a decommissioning funding plan or a certification of financial assurance for decommissioning.
30.35(a)&(b) - F Plan	Specifies licensees required to submit a decommissioning funding plan or a certification of financial assurance for decommissioning.
30.35(g)	Requires records retention, regarding decommissioning of the facility, until the license is terminated by the Commission.
30.41(c)&(d)	Requires verification informaton, prior to transfer and receipt of byproduct material; and (d) specifies acceptable methods for verification.
30.50(a),(b),&(c)	Notification of events or conditions that threaten the health and safety of individuals using or potentially exposed to licensed material.
Appendix D	Criteria for companies to pass the financial test when they furnish their own funds guarantee for decommissioning cost.
Appendix E	Criteria for nonprofit colleges, universities and hospitals to pass the financial test when they furnish their own funds guarantee for

10 CFR Part 31
Alternate 2

Section #	Total # Licensees	One Time			Annual			Total One Time Cost	Total Annual Cost
		% licensees affected	# of Licensees	Hours of labor per Licensee	% licensees affected	# of Licensees	Hours of labor per Licensee		
31.5(c)(4)	100	0%	0	0.0	100%	100	0.3	$ -	$ (2,175)
31.5(c)(8)	5	0%	0	0.0	100%	5	0.6	$ -	$ (261)
31.5(c)(9)	1	0%	0	0.0	100%	1	1.0	$ -	$ (87)
31.5(c)(11)	100	0%	0	0.0	100%	100	0.3	$ -	$ (2,958)
31.5(c)(14)	5	0%	0	0.0	100%	5	0.1	$ -	$ (44)
31.12	0	0%	0	4.0	0%	0	4.0	$ -	$ -
							Total	**$ -**	**$ (5,525)**

Notes: as of 8-Feb-2006:

Source of hours of labor per licensee is OMB Final Supporting Statement for 10 CFR Part 31 (OMB Clearance No. 3150-0016).

31.5(c)(4) General licensee must maintain records showing that tests for leakage of radioactive materials, proper operation of on-off mechanism, and/or other specified tests have been performed.

31.5(c)(8) General licensees may transfer or dispose of devices containing byproduct material only by approved methods.

31.5(c)(9) General licensees wishing to transfer a devise to another general licensee may do so under certain conditions.

31.5(c)(11) General licensees must respond to written requests from NRC within certain time constraints.

31.5(c)(14) General licensees must notify NRC within 30 days of changes of address for the location of use of devices.

10 CFR Part 32
Alternative 2

Section	Total # Licensees	One Time			Annual			Total One Time Cost	Total Annual Cost
		% licensees affected	# of Licensees	Hours of labor per Licensee	% licensees affected	# of Licensees	Hours of labor per Licensee		
32.72(a)(4)	22	0%	0	0	100%	22	390	$ -	$ (746,460)
32.72(b)(5)	22	0%	0	0	100%	22	0.5	$ -	$ (957)
32.72(c)	22	100%	22	2	100%	22	390	$ (3,828)	$ (746,460)
32.74(a)(2)(viii)	3	0%	0	0	100%	3	2.8	$ -	$ (731)
							Total	**$ (3,828)**	**$ (1,494,608)**

Notes: as of 8-Feb-2006:

Source of hours of labor per licensee is OMB Final Supporting Statement for 10 CFR Part 32 (OMB Clearance No. 3150-0001).

32.72(a)(4) Applicants must satisfy labeling requirements for each transport radiation shield and each syringe, vial, or other container used to hold radioactive drug to be transferred for commercial distribution.

32.72(b)(5) Requires licensees, licensed as a pharmacy by a State Board of Pharmacy or are operating as a nuclear pharmacy within a Federal medical institution, to provide information on authorized nuclear pharmacist status to NRC.

32.72(c) Requires licensee to have procedures for use of instrumentation used to measure radioactivity of radioactive drugs.

32.74(a)(2)(viii) Requires labeling instructions for handling and storing radioactive sources or devices, from the radiation safety standpoint.

10 CFR Part 35
Alternative 2

Section	Total # Licensees	One Time			Annual			Total One Time Cost	Total Annual Cost
		% licensees affected	# of Licensees	Hours of labor per Licensee	% licensees affected	# of Licensees	Hours of labor per Licensee		
35.6	80	100%	80	4.0	25%	20	4.0	$ (27,840)	$ (6,960)
35.14	195	100%	195	0.5	15%	28	0.5	$ (8,483)	$ (1,218)
35.19	2	0%	0	0.0	100%	2	1.0	$ -	$ (174)
35.24 (a)	410	100%	410	0.5	2%	8	2.5	$ (17,835)	$ (1,740)
35.24 (b)	62	100%	62	0.5	10%	6	0.5	$ (2,697)	$ (261)
35.24 (f)	21	100%	21	0.5	0%	0	0.0	$ (914)	$ -
35.26	410	100%	410	0.5	2%	8	0.5	$ (17,835)	$ (348)
35.27	120	100%	120	1.0	1%	1	1.0	$ (10,440)	$ (87)
35.40 (a)	240	0%	0	0.0	100%	240	13.0	$ -	$ (271,440)
35.40 (a)(1)	21	0%	0	0.0	100%	21	1.8	$ -	$ (3,197)
35.40 (c)(1)	105	0%	0	0.0	100%	105	2.5	$ -	$ (22,838)
35.41	240	100%	240	0.5	1%	2	0.5	$ (10,440)	$ (87)
35.2060	49	0%	0	0.0	100%	49	5.1	$ -	$ (21,741)
35.61	120	0%	0	0.0	100%	120	0.0	$ -	$ (313)
35.2063	160	0%	0	0.0	100%	160	42.5	$ -	$ (591,878)
35.2067(a)	176	0%	0	0.0	100%	176	0.2	$ -	$ (2,756)
35.2067(b)	176	0%	0	0.0	100%	176	0.1	$ -	$ (1,837)
35.2070	55	0%	0	0.0	100%	55	1.1	$ -	$ (5,264)
35.80(a)(1)	4	0%	0	0.0	100%	4	20.0	$ -	$ (6,960)
35.2080 (a)	5	0%	0	0.0	100%	5	0.6	$ -	$ (261)
35.2080 (b)	5	0%	0	0.0	100%	5	26.0	$ -	$ (11,310)
35.2092	120	0%	0	0.0	100%	120	1.0	$ -	$ (10,858)
35.2204	9	0%	0	0.0	100%	9	20.8	$ -	$ (16,286)
35.310	70	0%	0	0.0	100%	70	1.0	$ -	$ (6,090)
35.2310	58	0%	0	0.0	100%	58	0.1	$ -	$ (505)
35.315(b)	1	0%	0	0.0	100%	1	1.0	$ -	$ (87)
35.315(a)	70	0%	0	0.0	100%	70	1.8	$ -	$ (10,962)
35.2404	150	0%	0	0.0	100%	150	1.2	$ -	$ (15,921)
35.2406	150	0%	0	0.0	100%	150	3.0	$ -	$ (39,150)
35.410	39	0%	0	0.0	100%	39	1.0	$ -	$ (3,393)
35.415(c)	7	0%	0	0.0	100%	7	1.0	$ -	$ (609)
35.415(a)(1)	28	0%	0	0.0	100%	28	0.5	$ -	$ (1,218)
35.2432	40	0%	0	0.0	100%	40	3.0	$ -	$ (10,440)
35.2024 (a)	410	0%	0	0.0	100%	410	1.3	$ -	$ (44,588)
35.2024 (b)	62	0%	0	0.0	100%	62	0.1	$ -	$ (539)
35.2026	410	0%	0	0.0	100%	410	0.3	$ -	$ (8,918)
35.2040	210	0%	0	0.0	100%	210	2.6	$ -	$ (47,502)
35.2041	240	100%	240	0.1	1%	2	0.1	$ (1,044)	$ (9)
35.2061	120	0%	0	0.0	100%	120	0.4	$ -	$ (3,915)
35.2075 (a)	56	0%	0	0.0	100%	56	1.5	$ -	$ (7,308)
35.2075 (b)	4	0%	0	0.0	100%	4	0.4	$ -	$ (139)
35.3045(c)	2	0%	0	0.0	100%	2	0.5	$ -	$ (87)
35.3045(d)	2	0%	0	0.0	100%	2	8.0	$ -	$ (1,392)
35.3045(e)	2	0%	0	0.0	100%	2	2.0	$ -	$ (348)
35.3045(g)	2	0%	0	0.0	100%	2	0.5	$ -	$ (87)
35.3047(c)	0	0%	0	0.0	0%	0	0.0	$ -	$ -
35.3047(d)	0	0%	0	0.0	0%	0	0.0	$ -	$ -
35.3047(e)	0	0%	0	0.0	0%	0	0.0	$ -	$ -
35.3047(f)	0	0%	0	0.0	0%	0	0.0	$ -	$ -
35.3067	0	0%	0	0.0	0%	0	0.0	$ -	$ -
							Total	**$ (97,527)**	**$ (1,181,021)**

Notes: as of 8-Feb-2006:

Source of hours of labor per licensee is OMB Final Supporting Statement for 10 CFR Part 35 (OMB Clearance No. 3150-0010).
Section descriptions on following page.

10 CFR Part 35
Alternative 2 (continued)

35.6	Licensee must receive review and approval for compliance with the requirements for the protection of human subjects.
35.14	Licensees must provide training and experience documentation after the licensee permits an individual to work as an authorized user (AU), as an authorized nuclear pharmacist (ANP), or as an authorized medical physicist (AMP).
35.19	Allows NRC to grant exemptions to take into account special circumstances.
35.24 (a)	Licensee management must approve license submittals and radiation protection program changes.
35.24 (b)	Licensee management must approve Radiation Safety Officer who accepts all responsibility of the post.
35.24 (f)	Licensees, who work with two or more types of uses of byproduct material, must establish a Radiation Safety Committee.
35.26	Allows a licensee to make certain changes in their radiation safety program.
35.27	Licensees must instruct each supervised individual, who contacts byproduct material for medical use, in the radiation protection procedures.
35.40 (a)(1)	Complete record documentation of the administration of byproduct material or radiation from byproduct material.
35.40 (c)(1)	Permits a written revision to an existing written directive.
35.41	Licensees must develop, implement and maintain written procedures to verify human research subject's identity.
35.2060	Licensees must possess and use instrumentation to measure the activity of unsealed byproduct material before it is administered to each patient or human research subject; licensee must keep these records for three years.
35.61	Licensees must perform and retain calibration information of survey instruments.
35.2063	Licensees must determine and record the activity of each dosage before medical use, and retain records for three years.
35.2067(a)	Licensees, in possession of any sealed source or brachytherapy source, must test the source for leakage, take inventory at certain intervals, and retain relevant leak test and inventory records.
35.2067(b)	Licensees must retain records of the semi-annual physical inventory for three years.
35.69(b)	Labeling requirements for each syringe and vial that contains unsealed byproduct material.
35.2070	Licensees must survey ambient radiation exposure rate each day for all areas where unsealed byproduct material was prepared for use or administered; records retention of these surveys is 3 years.
35.80(a)(1)	Licensees that provide mobile service must obtain a letter signed by the management of each client to permit the use of byproduct material at the client's address.
35.2080 (a)	Licensees that provide mobile medical services must to retain letter for three years.
35.2080 (b)	Licensees must maintain a record of each survey (all areas of use before leaving a client's address) for three years.
35.2092	Licensees must retain records of the disposal of licensed materials for three years.
35.2204	Licensees must maintain records of molybdenum-99 concentration tests for three years.
35.310	Licensees must provide safety instruction to personnel caring for patients or human research subjects that have received therapy with unsealed byproduct material, and cannot be released.
35.2310	Licensees must maintain records of safety instruction training, in caring for patients and human research subjects, for three years.
35.315(b)	Licensee must notify the Radiation Safety Officer and the authorized user as soon as possible if a patient or human research subject who cannot be released has a medical emergency or dies.
35.315(a)	Licensee must post information indicating where and how long visitors may stay in the patient's room.
35.2404	Licensees must maintain a record of patient or human research subject surveys for three years.
35.2406	Licensees must maintain records of brachytherapy source accountability for three years.
35.410	Licensees must provide safety instruction to personnel caring for patients or human research subjects that are receiving brachytherapy and cannot be released.
35.415(c)	Licensee must promptly notify the Radiation Safety Officer and the authorized user as soon as possible if a patient or human research subject who cannot be released has a medical emergency or dies.
35.415(a)(1)	Licensee must post information indicating where and how long visitors may stay in the patient's room.
35.2432	Licensees must maintain a record of calibrations of brachytherapy sources for three years.
35.2630	Licensees must have a calibrated domisetry system available for use and calibrated at specified intervals; the records retention for each calibration, intercomparison, and comparison is for the duration of the license.
35.2024 (a)	Licensees must retain a record of actions, taken by the licensee's management, for five years.
35.2024 (b)	Licensees must retain Radiation Safety Officer documentation for the duration of the license.
35.2026	Licensees must retain a record of each radiation protection program change for five years.
35.2040	Licensees must retain a copy of each written directive for three years.
35.2041	Licensees must retain a copy of procedures for administrations requiring a written directive for the duration of the license.
35.2061	Licensees must calibrate the survey instruments used to show compliance with 10 CFR Part 20 before first use, annually, and following a repair affecting calibration; records retention is for three years.
35.2075 (a)	Licensees must retain a record documenting the basis for releasing individuals, containing radiopharmaceuticals or implants, into situations where they could expose members of the general public.
35.2075 (b)	Licensees must retain a record of the instructions provided to a breast-feeding female (if exposed to a radiation dose) showing necessary information was given for the protection of the infant or child.
35.3045(c)	Licensees must notify NRC by telephone no later than the next calendar day after discovery of a medical event.
35.3045(d)	Licensees must submit a written report within 15 days of the discovery of a medical event.
35.3045(e)	Licensees must notify the referring physician and the individual who is the subject of the medical event no later than 24 hours after its discovery.
35.3045(g)	Licensees must provide an annotated copy of the medical event report with identifying information no later than 15 days after the discovery of an event.
35.3047(c)	Licensee must notify by telephone the NRC Operation Center no later than the next calendar day after discovery of a dose to the embryo/fetus or nursing child.
35.3047(d)	Licensee must submit a written report to the appropriate NRC Regional Office no later than 15 days after the discovery of a dose to an embryo/fetus or nursing child.
35.3047(e)	Licensee must notify the referring physician and also notify the pregnant individual or mother no later than 24 hours after discovery of an event.
35.3047(f)	Licensee must provide an annotated copy of the report to NRC and the referring physician, no later than 15 days after the discovery of dose to an embryo/fetus or a nursing child.
35.3067	Licensees must report detection of a leaking source within 5 days after a leakage test reveals removable contamination.

NRC Costs
Alternative 2

NRC	Units	Staff time per	One Time	Annual
New licenses applications	3985	40 hours	$ (13,867,800)	
New license amendments annually	150	20 hours		$ (261,000)
Inspections of licensee facilities	50 / year	24 hours		$ (104,400)
			$ -	$ (365,400)

NRC		2005	2006
Guidance	300 hours		$ (26,100)
New licenses applications			$ (13,867,800)
Total one-time implementation			$ (13,893,900)

Waste and Decommissioning
Alternative 2

Waste		One-time	Annual
		0	$ (28,200)
Number accelerators	150		
Waste/yr/fac (tons)	0.1		
Disposal cost/ton ($)	22		
Transport cost/ton ($)	40		
Decommissioning			
			$ (15,000)

APPENDIX B Input and Results for Alternative 3

This appendix provides details of the line-by-line input and results for Alternative 3, the Graded Approach. The following pages show input and results for 10 CFR Part 19, 20, 30, 31, 32, 35, NRC Costs, and Waste and Decommissioning.

10 CFR Part 19
Alternative 3

Section #	Total # Licensees	One Time			Annual			Total One Time Cost	Total Annual Cost
		% licensees affected	# of Licensees	Hours of labor per Licensee	% licensees affected	# of Licensees	Hours of labor per Licensee		
19.12	235	100%	235	18	100%	235	0.2	$ (368,010)	$ (4,089)
19.13(a)	235	0%	0	0	100%	235	0.2	$ -	$ (4,089)
19.13(b)	235	0%	0	0	100%	235	8.4	$ -	$ (171,779)
19.13(c)	235	0%	0	0	10%	24	3.3	$ -	$ (6,857)
19.13(e)	235	0%	0	0	10%	24	0.9	$ -	$ (1,867)
							Total	**$ (368,010)**	**$ (188,681)**

Notes: as of 8-Feb-2006:

Annual hours of labor per licensee reduced by 80 percent compared to OMB Final Supporting Statement for 10 CFR Part 19 (OMB Clearance No. 3150-0044)

19.12 Requires licensees to provide radiation exposure reports to workers
19.13(a) Notification and report to individuals
19.13(b) Advise workers annually of dose
19.13(c) At request of worker formerly engaged in activities at the facility, exposure report for each year.
19.13(e) At request of worker terminating employment at the facility, exposure report for year and current quarter.

10 CFR Part 20
Alternative 3

Section #	Total # Licensees	One Time				Annual			Total One Time Cost	Total Annual Cost
		% licensees affected	# of Licensees	Capital Cost per Licensee	Hours of labor per Licensee	% licensees affected	# of Licensees	Hours of labor per Licensee		
20.1101 *	335	5%	17	$ (10,000)	0	0%	0	0	$ (170,000)	$ -
20.1406	335	100%	335	$ -	20	0%	0	0	$ (582,900)	$ -
20.1601(c)	1	100%	1	$ -	8	0%	0	0	$ (696)	$ -
20.1906(d)	1	100%	1	$ -	1	0%	0	0	$ (87)	$ -
20.1906(e)	335	0%	0	$ -	0	100%	335	1	$ -	$ (29,145)
20.2102(a)&(b)	335	100%	335	$ -	20	100%	335	4	$ (582,900)	$ (116,580)
20.2103(a)&(b)	335	0%	0	$ -	0	100%	335	8	$ -	$ (233,160)
20.2107(a)	25	0%	0	$ -	0	100%	25	5	$ -	$ (10,875)
20.2108(a)	50	0%	0	$ -	0	100%	50	8	$ -	$ (34,800)
20.2201(a)	1	0%	0	$ -	0	100%	1	3	$ -	$ (261)
20.2201(b)	1	0%	0	$ -	0	100%	1	3	$ -	$ (261)
20.2201(d)	1	0%	0	$ -	0	100%	1	3	$ -	$ (261)
20.2202(b)	1	0%	0	$ -	0	100%	1	40	$ -	$ (3,480)
20.2203(a)	1	0%	0	$ -	0	100%	1	6	$ -	$ (522)
								Total	**$ (1,336,583)**	**$ (429,345)**

Notes: as of 8-Feb-2006:

Source of hours of labor per licensee is Draft OMB Supporting Statement for 10 CFR Part 20 (OMB Clearance No. 3150-0014)

* A $10,000 capital expense is assumed for each affected licensee to construct or renovate facilities.

20.1101 Requires licensees to develop, document and implement radiation protection programs, establish procedures, and perform program review.
20.1406 Requires applicants for licenses to describe how facility design and procedures for operation will minimize contamination of the facility and environment, facilitate eventual decommissioning, and minimize generation of radioactive waste.
20.1601(c) Allows licensees to apply to the Commission for approval of alternate methods for control of access to high radiation areas.
20.1906(e) Requires licensees to develop and maintain procedures regarding radioactive material shipment.
20.2102(a)&(b) (a) Requires licensees to maintain records of the radiation protection program, including ALARA; (b) requires licensees to retain records of radiation programs until the Commission terminates the license.
20.2103(a)&(b) (a) Requires licensees to maintain records showing the results of surveys and calibrations; (b) requires licensees to maintain records for 3 years, unless they form the basis of dose estimates in which case they must be maintained through license termination.
20.2107(a) Requires information on the identity and quality of the radionuclides released by licensee in effluents to unrestricted areas.
20.2108(a) Requires records of waste disposal to permit routine inspection for compliance, and inspection against constraints on the kinds and quantities of licensed material.
20.2201(a) Requires licensees to report any theft or loss of licensed material by telephone immediately or in writing within 30 days, dependent upon the potential risk to the health and safety of the public.
20.2201(b) Requires licensees to follow up telephone reports with written reports of the incident within 30 days of the telephone report.
20.2201(d) Requires additional information relevant to the loss of radioactive material, discovered after the written report, be submitted within 30 days of discovery.
20.2202(b) Requires that the licensee notify the NRC within 24 hours upon becoming aware of specific incidents involving licensed material.
20.2203(a) Contains the requirements for the content of the reports required by Paragraph 20.2203(a).

10 CFR Part 30
Alternative 3

Section	Total # Licensees	One Time			Annual			Total One Time Cost	Total Annual Cost
		% licensees affected	# of Licensees	Hours of labor per Licensee	% licensees affected	# of Licensees	Hours of labor per Licensee		
30.9(b)	1	0%	0	0	100%	1	1.0	$ -	$ (87)
30.32	335	100%	335	7	5%	16.75	1.0	$ (204,015)	$ (1,457)
30.32 (i) - EP	3	100%	3	10	0%	0	10.0	$ (2,610)	$ -
30.32 (i) - Calculation	5	100%	5	1	0%	0	0.0	$ (435)	$ -
30.32 (g)	20	100%	20	3	0%	0	0.0	$ (5,220)	$ -
30.32 (j)	15	100%	15	42.5	0%	0	0.0	$ (55,463)	$ -
30.34(e)(4) - Orders	1	0%	0	0	100%	1	3.0	$ -	$ (261)
30.34(e)(4) - Sfguards	5	0%	0	0	100%	5	0.5	$ -	$ (218)
30.34(h)	1	0%	0	0	1%	2	0.5	$ -	$ (87)
30.34(j)(2)(i)	15	0%	0	2	100%	15	390.0	$ -	$ (508,950)
30.34(j)(2)(ii)	15	100%	15	2	100%	15	390.0	$ (2,610)	$ (508,950)
30.34(j)(4)	15	0%	0	0	20%	3	0.5	$ -	$ (131)
30.35(a)&(b) - Certific	5	100%	5	100	100%	5	10.0	$ (43,500)	$ (4,350)
30.35(a)&(b) - F Plan	5	100%	5	300	100%	5	10.0	$ (130,500)	$ (4,350)
30.35(g)	14	100%	14	10	100%	14	10.0	$ (12,180)	$ (12,180)
30.36(d)	1	0%	0	0	100%	1	1.0	$ -	$ (87)
30.36(g)	1	0%	0	0	100%	1	360.0	$ -	$ (31,320)
30.41(c)&(d)	60	0%	0	0	100%	60	4.0	$ -	$ (20,880)
30.50(a),(b),&(c)	2	0%	0	0	100%	2	4.0	$ -	$ (696)
Appendix D	25	100%	25	1	50%	13	1.0	$ (2,175)	$ (1,131)
Appendix E	20	100%	20	1	50%	10	1.0	$ (1,740)	$ (870)
							Total	**$ (460,448)**	**$ (1,096,004)**

Notes: as of 8-Feb-2006:

Source of hours of labor per licensee is OMB Final Supporting Statement for 10 CFR Part 30 (OMB Clearance No. 3150-0017).

30.9(b)	Requires applicant or licensee to notify the Commission of information which has significant implications for public health and safety or the common defense and security.
30.32	License application process for entities with gauges containing radium-226 products, accelerators and other NARM use.
30.32(i) -EP	Requires applicants that will posses amounts of materials requiring an emergency plan to to provide the emergency plan.
30.32(i) - Calc	Requires applicants with certain materials to calculate dose to the public to determine if an emergency plan is needed.
30.32 (j)	License appliction process for authorization for production of PET drugs for non-commercial distribution to consortium members.
30.34(e)(4) - Orders	The authority for Commission issuance of orders for the modification of licenses.
30.34(e)(4) - Sfguards	Certain licensees are required to take compensatory actions against threats, requiring safeguards plans and other safeguard requirements.
30.34(h)	Requires immediate notification to the appropriate NRC regional administrator, in writing, following the filing of bankruptcy petition.
30.34(j)(2)(i)	Applicants must satisfy labeling requirements for each transport radiation shield and each syringe, vial, or other container used to hold radioactive drug to be transferred for commercial distribution.
30.34(j)(2)(ii)	Requires licensee to have procedures for use of instrumentation used to measure radioactivity of radioactive drugs.
30.34(j)(4)	Requires licensees, licensed as a pharmacy by a State Board of Pharmacy or are operating as a nuclear pharmacy within a Federal medical institution, to provide certification information to NRC.
30.35(a)&(b) - Certific	Specifies licensees required to submit a decommissioning funding plan or a certification of financial assurance for decommissioning.
30.35(a)&(b) - F Plan	Specifies licensees required to submit a decommissioning funding plan or a certification of financial assurance for decommissioning.
30.35(g)	Requires records retention, regarding decommissioning of the facility, until the license is terminated by the Commission.
30.41(c)&(d)	Requires verification informaton, prior to transfer and receipt of byproduct material; and (d) specifies acceptable methods for verification.
30.50(a),(b),&(c)	Notification of events or conditions that threaten the health and safety of individuals using or potentially exposed to licensed material.
Appendix D	Criteria for companies to pass the financial test when they furnish their own funds guarantee for decommissioning cost.
Appendix E	Criteria for nonprofit colleges, universities and hospitals to pass the financial test when they furnish their own funds guarantee for

10 CFR Part 31
Alternative 3

Section #	Total # Licensees	One Time			Annual			Total One Time Cost	Total Annual Cost
		% licensees affected	# of Licensees	Hours of labor per Licensee	% licensees affected	# of Licensees	Hours of labor per Licensee		
31.5(c)(4)	100	0%	0	0.0	100%	100	0.3	$ -	$ (2,175)
31.5(c)(8)	5	0%	0	0.0	100%	5	0.6	$ -	$ (261)
31.5(c)(9)	1	0%	0	0.0	100%	1	1.0	$ -	$ (87)
31.5(c)(11)	100	0%	0	0.0	100%	100	0.3	$ -	$ (2,958)
31.5(c)(14)	5	0%	0	0.0	100%	5	0.1	$ -	$ (44)
31.12	300	0%	0	0.0	1%	3	4.0	$ -	$ (1,044)
							Total	**$ -**	**$ (6,569)**

Notes: as of 8-Feb-2006:

Source of hours of labor per licensee is OMB Final Supporting Statement for 10 CFR Part 31 (OMB Clearance No. 3150-0016).

31.5(c)(4)	General licensee must maintain records showing that tests for leakage of radioactive materials, proper operation of on-off mechanism, and/or other specified tests have been performed.
31.5(c)(8)	General licensees may transfer or dispose of devices containing byproduct material only by approved methods.
31.5(c)(9)	General licensees wishing to transfer a devise to another general licensee may do so under certain conditions.
31.5(c)(11)	General licensees must respond to written requests from NRC within certain time constraints.
31.5(c)(14)	General licensees must notify NRC within 30 days of changes of address for the location of use of devices.
31.12	New section of regulations specifying general license conditions for products containing Radium-226.

10 CFR Part 32
Alternative 3

Section	Total # Licensees	One Time			Annual			Total One Time Cost	Total Annual Cost
		% licensees affected	# of Licensees	Hours of labor per Licensee	% licensees affected	# of Licensees	Hours of labor per Licensee		
32.72(a)(4)	22	0%	0	0	100%	22	390	$ -	$ (746,460)
32.72(b)(5)	22	0%	0	0	100%	22	0.5	$ -	$ (957)
32.72(c)	22	100%	22	2	100%	22	390	$ (3,828)	$ (746,460)
32.74(a)(2)(viii)	3	0%	0	0	100%	3	2.8	$ -	$ (731)
							Total	**$ (3,828)**	**$ (1,494,608)**

Notes: as of 8-Feb-2006:

Source of hours of labor per licensee is OMB Final Supporting Statement for 10 CFR Part 32 (OMB Clearance No. 3150-0001).

32.72(a)(4)	Applicants must satisfy labeling requirements for each transport radiation shield and each syringe, vial, or other container used to hold radioactive drug to be transferred for commercial distribution.
32.72(b)(5)	Requires licensees, licensed as a pharmacy by a State Board of Pharmacy or are operating as a nuclear pharmacy within a Federal medical institution, to provide information on authorized nuclear pharmacist status to NRC.
32.72(c)	Requires licensee to have procedures for use of instrumentation used to measure radioactivity of radioactive drugs.
32.74(a)(2)(viii)	Requires labeling instructions for handling and storing radioactive sources or devices, from the radiation safety standpoint.

10 CFR Part 35
Alternative 3

Section	Total # Licensees	One Time			Annual			Total One Time Cost	Total Annual Cost
		% licensees affected	# of Licensees	Hours of labor per Licensee	% licensees affected	# of Licensees	Hours of labor per Licensee		
35.6	40	100%	40	4.0	25%	10	4.0	$ (13,920)	$ (3,480)
35.14	180	100%	180	0.5	15%	28	0.5	$ (7,830)	$ (1,218)
35.19	1	0%	0	1.0	100%	1	1.0	$ -	$ (87)
35.24 (a)	370	100%	370	0.5	2%	6	2.5	$ (16,095)	$ (1,305)
35.24 (b)	60	100%	60	0.5	10%	6	0.5	$ (2,610)	$ (261)
35.24 (f)	20	100%	20	0.5	0%	0	0.0	$ (870)	$ -
35.26	370	100%	370	0.5	2%	6	0.5	$ (16,095)	$ (261)
35.27	115	100%	115	1.0	1%	1	1.0	$ (10,005)	$ (87)
35.40 (a)	200	0%	0	0.0	100%	200	13.0	$ -	$ (226,200)
35.40 (a)(1)	20	0%	0	0.0	100%	20	0.7	$ -	$ (1,218)
35.40 (c)(1)	100	0%	0	0.0	100%	100	1.0	$ -	$ (8,700)
35.41	200	100%	200	0.5	1%	2	0.5	$ (8,700)	$ (87)
35.2060	25	0%	0	0.0	100%	25	5.1	$ -	$ (11,093)
35.61	60	0%	0	0.0	100%	60	3.0	$ -	$ (15,660)
35.2063	80	0%	0	0.0	100%	80	42.5	$ -	$ (295,939)
35.2067(a)	88	0%	0	0.0	100%	88	0.2	$ -	$ (1,378)
35.2067(b)	88	0%	0	0.0	100%	88	0.1	$ -	$ (919)
35.2070	28	0%	0	0.0	100%	28	1.1	$ -	$ (2,680)
35.80(a)(1)	2	0%	0	0.0	100%	2	20.0	$ -	$ (3,480)
35.2080 (a)	2	0%	0	0.0	100%	2	0.6	$ -	$ (104)
35.2080 (b)	2	0%	0	0.0	100%	2	26.0	$ -	$ (4,524)
35.2092	60	0%	0	0.0	100%	60	1.0	$ -	$ (5,429)
35.2204	9	0%	0	0.0	100%	9	20.8	$ -	$ (16,286)
35.310	35	0%	0	0.0	100%	35	1.0	$ -	$ (3,045)
35.2310	29	0%	0	0.0	100%	29	0.1	$ -	$ (252)
35.315(b)	1	0%	0	0.0	100%	1	1.0	$ -	$ (87)
35.315(a)	35	0%	0	0.0	100%	35	1.8	$ -	$ (5,481)
35.2404	100	0%	0	0.0	100%	100	1.2	$ -	$ (10,614)
35.2406	100	0%	0	0.0	100%	100	3.0	$ -	$ (26,100)
35.410	20	0%	0	0.0	100%	20	1.0	$ -	$ (1,740)
35.415(c)	4	0%	0	0.0	100%	4	1.0	$ -	$ (348)
35.415(a)(1)	14	0%	0	0.0	100%	14	0.5	$ -	$ (609)
35.2432	20	0%	0	0.0	100%	20	3.0	$ -	$ (5,220)
35.2024 (a)	370	0%	0	0.0	100%	370	1.3	$ -	$ (40,238)
35.2024 (b)	60	0%	0	0.0	100%	60	0.1	$ -	$ (522)
35.2026	370	0%	0	0.0	100%	370	0.3	$ -	$ (8,048)
35.2040	200	0%	0	0.0	100%	200	2.6	$ -	$ (45,240)
35.2041	200	100%	200	0.1	1%	2	0.1	$ (870)	$ (9)
35.2061	60	0%	0	0.0	100%	60	0.4	$ -	$ (1,958)
35.2075 (a)	28	0%	0	0.0	100%	28	1.5	$ -	$ (3,654)
35.2075 (b)	2	0%	0	0.0	100%	2	0.4	$ -	$ (70)
35.3045(c)	2	0%	0	0.0	100%	2	0.5	$ -	$ (87)
35.3045(d)	2	0%	0	0.0	100%	2	8.0	$ -	$ (1,392)
35.3045(e)	2	0%	0	0.0	100%	2	2.0	$ -	$ (348)
35.3045(g)	2	0%	0	0.0	100%	2	0.5	$ -	$ (87)
35.3047(c)	0	0%	0	0.0	0%	0	0.0	$ -	$ -
35.3047(d)	0	0%	0	0.0	0%	0	0.0	$ -	$ -
35.3047(e)	0	0%	0	0.0	0%	0	0.0	$ -	$ -
35.3047(f)	0	0%	0	0.0	0%	0	0.0	$ -	$ -
35.3067	0	0%	0	0.0	0%	0	0.0	$ -	$ -
							Total	**$ (76,995)**	**$ (755,543)**

Notes: as of 8-Feb-2006:

Source of hours of labor per licensee is OMB Final Supporting Statement for 10 CFR Part 35 (OMB Clearance No. 3150-0010).
Section descriptions on following page.

10 CFR Part 35
Alternative 3 (continued)

35.6	Licensee must receive review and approval for compliance with the requirements for the protection of human subjects.
35.14	Licensees must provide training and experience documentation after the licensee permits an individual to work as an authorized user (AU), as an authorized nuclear pharmacist (ANP), or as an authorized medical physicist (AMP).
35.19	Allows NRC to grant exemptions to take into account special circumstances.
35.24 (a)	Licensee management must approve license submittals and radiation protection program changes.
35.24 (b)	Licensee management must approve Radiation Safety Officer who accepts all responsibility of the post.
35.24 (f)	Licensees, who work with two or more types of uses of byproduct material, must establish a Radiation Safety Committee.
35.26	Allows a licensee to make certain changes in their radiation safety program.
35.27	Licensees must instruct each supervised individual, who contacts byproduct material for medical use, in the radiation protection procedures.
35.40 (a)(1)	Complete record documentation of the administration of byproduct material or radiation from byproduct material.
35.40 (c)(1)	Permits a written revision to an existing written directive.
35.41	Licensees must develop, implement and maintain written procedures to verify human research subject's identity.
35.2060	Licensees must possess and use instrumentation to measure the activity of unsealed byproduct material before it is administered to each patient or human research subject; licensee must keep these records for three years.
35.61	Licensees must perform and retain calibration information of survey instruments.
35.2063	Licensees must determine and record the activity of each dosage before medical use, and retain records for three years.
35.2067(a)	Licensees, in possession of any sealed source or brachytherapy source, must test the source for leakage, take inventory at certain intervals, and retain relevant leak test and inventory records.
35.2067(b)	Licensees must retain records of the semi-annual physical inventory for three years.
35.69(b)	Labeling requirements for each syringe and vial that contains unsealed byproduct material.
35.2070	Licensees must survey ambient radiation exposure rate each day for all areas where unsealed byproduct material was prepared for use or administered; records retention of these surveys is 3 years.
35.80(a)(1)	Licensees that provide mobile service must obtain a letter signed by the management of each client to permit the use of byproduct material at the client's address.
35.2080 (a)	Licensees that provide mobile medical services must to retain letter for three years.
35.2080 (b)	Licensees must maintain a record of each survey (all areas of use before leaving a client's address) for three years.
35.2092	Licensees must retain records of the disposal of licensed materials for three years.
35.2204	Licensees must maintain records of molybdenum-99 concentration tests for three years.
35.310	Licensees must provide safety instruction to personnel caring for patients or human research subjects that have received therapy with unsealed byproduct material, and cannot be released.
35.2310	Licensees must maintain records of safety instruction training, in caring for patients and human research subjects, for three years.
35.315(b)	Licensee must notify the Radiation Safety Officer and the authorized user as soon as possible if a patient or human research subject who cannot be released has a medical emergency or dies.
35.315(a)	Licensee must post information indicating where and how long visitors may stay in the patient's room.
35.2404	Licensees must maintain a record of patient or human research subject surveys for three years.
35.2406	Licensees must maintain records of brachytherapy source accountability for three years.
35.410	Licensees must provide safety instruction to personnel caring for patients or human research subjects that are receiving brachytherapy and cannot be released.
35.415(c)	Licensee must promptly notify the Radiation Safety Officer and the authorized user as soon as possible if a patient or human research subject who cannot be released has a medical emergency or dies.
35.415(a)(1)	Licensee must post information indicating where and how long visitors may stay in the patient's room.
35.2432	Licensees must maintain a record of calibrations of brachytherapy sources for three years.
35.2630	Licensees must have a calibrated domisetry system available for use and calibrated at specified intervals; the records retention for each calibration, intercomparison, and comparison is for the duration of the license.
35.2024 (a)	Licensees must retain a record of actions, taken by the licensee's management, for five years.
35.2024 (b)	Licensees must retain Radiation Safety Officer documentation for the duration of the license.
35.2026	Licensees must retain a record of each radiation protection program change for five years.
35.2040	Licensees must retain a copy of each written directive for three years.
35.2041	Licensees must retain a copy of procedures for administrations requiring a written directive for the duration of the license.
35.2061	Licensees must calibrate the survey instruments used to show compliance with 10 CFR Part 20 before first use, annually, and following a repair affecting calibration; records retention is for three years.
35.2075 (a)	Licensees must retain a record documenting the basis for releasing individuals, containing radiopharmaceuticals or implants, into situations where they could expose members of the general public.
35.2075 (b)	Licensees must retain a record of the instructions provided to a breast-feeding female (if exposed to a radiation dose) showing necessary information was given for the protection of the infant or child.
35.3045(c)	Licensees must notify NRC by telephone no later than the next calendar day after discovery of a medical event.
35.3045(d)	Licensees must submit a written report within 15 days of the discovery of a medical event.
35.3045(e)	Licensees must notify the referring physician and the individual who is the subject of the medical event no later than 24 hours after its discovery.
35.3045(g)	Licensees must provide an annotated copy of the medical event report with identifying information no later than 15 days after the discovery of an event.
35.3047(c)	Licensee must notify by telephone the NRC Operation Center no later than the next calendar day after discovery of a dose to the embryo/fetus or nursing child.
35.3047(d)	Licensee must submit a written report to the appropriate NRC Regional Office no later than 15 days after the discovery of a dose to an embryo/fetus or nursing child.
35.3047(e)	Licensee must notify the referring physician and also notify the pregnant individual or mother no later than 24 hours after discovery of an event.
35.3047(f)	Licensee must provide an annotated copy of the report to NRC and the referring physician, no later than 15 days after the discovery of dose to an embryo/fetus or a nursing child.
35.3067	Licensees must report detection of a leaking source within 5 days after a leakage test reveals removable contamination.

RC Costs
Alternative 3

NRC	Units	Staff time per	One Time	Annual
New licenses applications	335	40 hours	$ (1,165,800)	
New license amendments annually	75	20 hours		$ (130,500)
Inspections of licensee facilities	25 / year	24 hours		$ (52,200)
			$ -	$ (182,700)

NRC		2005	2006
Guidance	300 hours		$ (26,100)
New licenses applications			$ (1,165,800)
Total one-time implementation			$ (1,191,900)

Waste and Decommissioning
Alternative 3

Waste		One-time	Annual
		0	$ (19,900)
Number accelerators	45		
Waste/yr/fac (tons)	0.25		
Disposal cost/ton ($)	22		
Transport cost/ton ($)	40		
Decommissioning			
			$ (10,000)

APPENDIX C

References

1. Proposed Rule: Requirements for Expanded Definition of Byproduct Material (RIN: 3150-AH84).
2. "The First Nuclear Industry," *Scientific American*, v247, November 1982, pages 180-193.
3. Environmental Assessment for Final Rulemaking - Expanded Definition of Byproduct Material Established by Section 651(e) of the Energy Policy Act of 2005.
4. Nuclear Regulatory Commission (U.S.), "Regulatory Analysis Guidelines of the U.S. Nuclear Regulatory Commission," NUREG/BR-0058, Revision 4, September 2004.
5. Nuclear Regulatory Commission (U.S.), "Regulatory Analysis Technical Evaluation Handbook, Final Report," NUREG/BR-0184, January 1997.
6. Nuclear Regulatory Commission (U.S.), "Risk Analysis and Evaluation of Regulatory Options for Nuclear Byproduct Material Systems," NUREG/CR-6642, Volume 1, January 2000.
7. Nuclear Regulatory Commission (U.S.), "Generic Cost Estimates," NUREG/CR-4627, Revision 1 & 2, January 1992.
8. Nuclear Regulatory Commission (U.S.), "Economic Risk of Contamination Cleanup Costs Resulting from Large Nonreactor Nuclear Material Licensee Operations," NUREG/CR-5381, March 1990.
9. Nuclear Regulatory Commission (U.S.), "Radiological Assessments for Clearance of Materials from Nuclear Facilities," NUREG-1640, Volume 2, October 2004.

24722

Submission of Federal Rules Under the Congressional Review Act

☑ President of the Senate ☐ Speaker of the House of Representatives ☐ GAO

Please fill the circles electronically or with black pen or #2 pencil.

1. Name of Department or Agency
U.S. Nuclear Regulatory Commission

2. Subdivision or Office
Office of FSME

3. Rule Title
10 CFR Parts 20, 30, 31 et al.: Requirements for Expanded Definition of Byproduct Material

4. Regulation Identifier Number (RIN) or Other Unique Identifier (if applicable)
RIN 3150-AH84

5. Major Rule ○ Non-major Rule ◉

6. Final Rule ◉ Other ○ _____

7. With respect to this rule, did your agency solicit public comments? Yes ◉ No ○ N/A ○

8. Priority of Regulation (fill in one)
◉ Economically Significant; or Significant; or Substantive, Non Significant
○ Routine and Frequent or Informational/Administrative/Other (Do not complete the other side of this form if filled in above.)

9. Effective Date (if applicable) **60 days from date of publication**

10. Concise Summary of Rule (fill in one or both) attached ○ stated in rule ◉

Submitted by: _____ (signature)

Name: **Rebecca L. Schmidt**

Title: **Director, Office of Congressional Affairs**

For Congressional Use Only:

Date Received: _____

Committee of Jurisdiction: _____

3/23/99

	Yes	No	N/A
A. With respect to this rule, did your agency prepare an analysis of costs and benefits?	◉	○	○
B. With respect to this rule, by the final rulemaking stage, did your agency			
1. certify that the rule would not have a significant economic impact on a substantial number of small entities under 5 U.S.C.§ 605(b)?	◉	○	○
2. prepare a final Regulatory Flexibility Analysis under 5 U.S.C. § 604(a)?	○	◉	○
C. With respect to this rule, did your agency prepare a written statement under § 202 of the Unfunded Mandates Reform Act of 1995?	○	◉	○
D. With respect to this rule, did your agency prepare an Environmental Assessment or an Environmental Impact Statement under the National Environmental Policy Actg (NEPA)?	◉	○	○
E. Does this rule contain a collection of information requiring OMB approval under the Paperwork Reduction Act of 1995?	◉	○	○
F. Did you discuss any of the following in the preamble to the rule?	○	◉	○
• E.O. 12612, Federalism	○	◉	○
• E.O. 126630, Government Actions and Interference with Constitutionally Protected Property Rights	○	◉	○
• E.O. 12866, Regulatory Planning and Review	○	◉	○
• E.O. 12875, Enhancing the Intergovernmental Partnership	○	◉	○
• E.O. 12988, Civil Justice Reform	○	◉	○
• E.O. 13045, Protection of Children from Environmental Health Risks and Safety Risks	○	◉	○
• Other statutes or executive orders discussed in the preamble concerning the rulemaking process (please specify)			

24722

Submission of Federal Rules Under the Congressional Review Act

☐ President of the Senate ☑ Speaker of the House of Representatives ☐ GAO

Please fill the circles electronically or with black pen or #2 pencil.

1. Name of Department or Agency	2. Subdivision or Office
U.S. Nuclear Regulatory Commission	Office of FSME

3. Rule Title

10 CFR Parts 20, 30, 31 et al.: Requirements for Expanded Definition of Byproduct Material

4. Regulation Identifier Number (RIN) or Other Unique Identifier (if applicable)

RIN 3150-AH84

5. Major Rule ○ Non-major Rule ◉

6. Final Rule ◉ Other ○ _____

7. With respect to this rule, did your agency solicit public comments? Yes ◉ No ○ N/A ○

8. Priority of Regulation (fill in one)

◉ Economically Significant; or Significant; or Substantive, Non Significant

○ Routine and Frequent or Informational/Administrative/Other (Do not complete the other side of this form if filled in above.)

9. Effective Date (if applicable) **60 days from date of publication**

10. Concise Summary of Rule (fill in one or both) attached ○ stated in rule ◉

Submitted by: _____ (signature)

Name: **Rebecca L. Schmidt**

Title: **Director, Office of Congressional Affairs**

For Congressional Use Only:

Date Received: _____

Committee of Jurisdiction: _____

3/23/99

	Yes	No	N/A
A. With respect to this rule, did your agency prepare an analysis of costs and benefits?	◉	○	○
B. With respect to this rule, by the final rulemaking stage, did your agency			
1. certify that the rule would not have a significant economic impact on a substantial number of small entities under 5 U.S.C.§ 605(b)?	◉	○	○
2. prepare a final Regulatory Flexibility Analysis under 5 U.S.C. § 604(a)?	○	◉	○
C. With respect to this rule, did your agency prepare a written statement under § 202 of the Unfunded Mandates Reform Act of 1995?	○	◉	○
D. With respect to this rule, did your agency prepare an Environmental Assessment or an Environmental Impact Statement under the National Environmental Policy Actg (NEPA)?	◉	○	○
E. Does this rule contain a collection of information requiring OMB approval under the Paperwork Reduction Act of 1995?	◉	○	○
F. Did you discuss any of the following in the preamble to the rule?	○	◉	○
• E.O. 12612, Federalism	○	◉	○
• E.O. 126630, Government Actions and Interference with Constitutionally Protected Property Rights	○	◉	○
• E.O. 12866, Regulatory Planning and Review	○	◉	○
• E.O. 12875, Enhancing the Intergovernmental Partnership	○	◉	○
• E.O. 12988, Civil Justice Reform	○	◉	○
• E.O. 13045, Protection of Children from Environmental Health Risks and Safety Risks	○	◉	○
• Other statutes or executive orders discussed in the preamble concerning the rulemaking process (please specify)			

_____

_____

_____

24722

Submission of Federal Rules Under the Congressional Review Act

☐ President of the Senate ☐ Speaker of the House of Representatives ☑ GAO

Please fill the circles electronically or with black pen or #2 pencil.

1. Name of Department or Agency
U.S. Nuclear Regulatory Commission

2. Subdivision or Office
Office of FSME

3. Rule Title
10 CFR Parts 20, 30, 31 et al.: Requirements for Expanded Definition of Byproduct Material

4. Regulation Identifier Number (RIN) or Other Unique Identifier (if applicable)
RIN 3150-AH84

5. Major Rule ○ Non-major Rule ◉

6. Final Rule ◉ Other ○ _____

7. With respect to this rule, did your agency solicit public comments? Yes ◉ No ○ N/A ○

8. Priority of Regulation (fill in one)
◉ Economically Significant; or Significant; or Substantive, Non Significant
○ Routine and Frequent or Informational/Administrative/Other (Do not complete the other side of this form if filled in above.)

9. Effective Date (if applicable) **60 days from date of publication**

10. Concise Summary of Rule (fill in one or both) attached ○ stated in rule ◉

Submitted by: _____ (signature)

Name: **Rebecca L. Schmidt**

Title: **Director, Office of Congressional Affairs**

For Congressional Use Only:

Date Received: _____

Committee of Jurisdiction: _____

3/23/99

	Yes	No	N/A
A. With respect to this rule, did your agency prepare an analysis of costs and benefits?	◉	○	○
B. With respect to this rule, by the final rulemaking stage, did your agency			
1. certify that the rule would not have a significant economic impact on a substantial number of small entities under 5 U.S.C.§ 605(b)?	◉	○	○
2. prepare a final Regulatory Flexibility Analysis under 5 U.S.C. § 604(a)?	○	◉	○
C. With respect to this rule, did your agency prepare a written statement under § 202 of the Unfunded Mandates Reform Act of 1995?	○	◉	○
D. With respect to this rule, did your agency prepare an Environmental Assessment or an Environmental Impact Statement under the National Environmental Policy Actg (NEPA)?	◉	○	○
E. Does this rule contain a collection of information requiring OMB approval under the Paperwork Reduction Act of 1995?	◉	○	○
F. Did you discuss any of the following in the preamble to the rule?	○	◉	○
• E.O. 12612, Federalism	○	◉	○
• E.O. 126630, Government Actions and Interference with Constitutionally Protected Property Rights	○	◉	○
• E.O. 12866, Regulatory Planning and Review	○	◉	○
• E.O. 12875, Enhancing the Intergovernmental Partnership	○	◉	○
• E.O. 12988, Civil Justice Reform	○	◉	○
• E.O. 13045, Protection of Children from Environmental Health Risks and Safety Risks	○	◉	○
• Other statutes or executive orders discussed in the preamble concerning the rulemaking process (please specify)			