RULEMAKING ISSUE
(Notation Vote)

March 27, 2006 SECY-06-0069

FOR: The Commissioners

FROM: Luis A. Reyes
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SUBJECT: PROPOSED RULE: REQUIREMENTS FOR EXPANDED DEFINITION OF BYPRODUCT MATERIAL (RIN: 3150-AH84)

PURPOSE:

To request Commission approval to publish a proposed 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 the proposed rule establishing the regulatory framework for regulating certain radium sources, accelerator-produced radioactive material, and certain discrete sources of naturally occurring radioactive material. 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 proposed rule would revise the definition for "byproduct material," add a definition for "discrete source," and amend existing regulations and add additional provisions in order to provide the regulatory framework for regulating the newly added byproduct material.

The resources necessary to complete this rulemaking are currently included in Fiscal Year (FY) 2006 and FY 2007 budget. The staff recommends that the Commission approves the staff regulatory approach and publication of the proposed rule.

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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;
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> (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
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> (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 issue final regulations within 18 months, to consult with States and other stakeholders in establishing requirements, and, to the maximum extent practicable, to cooperate with States and to use model State standards in developing the regulations. The staff has engaged 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. The staff has evaluated model State standards and considered potential impacts on the availability of radiopharmaceuticals in developing the requirements included in this proposed rule.

Section 651(e) of the EPAct became effective immediately upon signature by the President on August 8, 2005. Prior to enactment of the EPAct, the NRC did not have authority over this newly added byproduct material and does not currently have regulations in place that would specifically apply to this material. The EPAct provided a mechanism for the NRC to permit individuals to continue with their activities involving the newly added byproduct material and to permit States to continue to carry out their regulatory actions for the newly added byproduct material. Therefore, as provided in Section 651(e)(5) of the EPAct, the NRC issued a time-limited waiver (70 FR 51581; August 31, 2005) to those individuals and States from the requirements of Section 651(e) of the EPAct.

Although the NRC has not regulated this naturally occurring and accelerator-produced radioactive material (NARM) in the past, all Agreement States and most non-Agreement States have regulatory programs for such material. All Agreement States have regulated NARM by applying similar standards used to regulate other byproduct, source, and special nuclear material pursuant to agreement with the NRC.

There are currently 16 non-Agreement States plus U.S. Territories, Government agencies, and Federally recognized Indian Tribes, that would be affected by this rulemaking. Although most non-Agreement States and U.S. Territories have some type of program for NARM, the regulatory structures vary greatly from State to State. Four non-Agreement States (Idaho, Montana, South Dakota, and Wyoming) do not have any programs. At least two non-Agreement States (New Jersey and Pennsylvania) use a licensing approach similar to NRC regulations as their regulatory structure for managing NARM. The remaining non-Agreement States use registration as their regulatory structure. 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. In general, there is limited regulatory oversight where registration is used in non-Agreement States.

To enhance State cooperation 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. The staff formed a NARM Rulemaking Working Group, including participants from the States of Florida, Michigan, Oregon, and Texas, to develop a regulatory framework for the expanded definition of byproduct material and to draft this proposed rule. The staff also established a Nuclear Material Safety and Safeguards (NMSS) EPAct Task Force including participants from the States of North Carolina and Oregon as members and from the States of California and Illinois as resource members to focus on resolving implementation issues and to develop the transition plan required by Section 651(e) of the EPAct. The State representatives helped to gather State-specific data on the newly added byproduct material, develop technical bases, and formulate regulatory approaches for this proposed rule. The State representatives who participated in these various groups have played a key role in the development of this proposed rule and have provided valuable input to the rulemaking process. In addition, a Steering Committee was formed to provide oversight and management direction for both the NARM Rulemaking Working Group and the NMSS EPAct Task Force. The Steering Committee is comprised of NRC senior managers from the affected program offices, the Office of the General Counsel (OGC), Region I, and representatives of both the OAS and the CRCPD.

To ensure stakeholder involvement, the staff held a public meeting on November 9, 2005, to discuss rulemaking activities to incorporate the newly added byproduct material 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 regarding NRC regulating the newly added byproduct material. Representatives from other Federal agencies, States, medical communities, and a broad spectrum of interest groups were invited to participate in the "roundtable" discussion. Members of the public also offered comments and questions during the public meeting. After the meeting, the staff received five written comments from the Zirconium Environmental Committee, a member of the public, the State of Michigan, the Society of Nuclear Medicine, and the American Society of Nuclear Cardiology. The comments received at and following the public meeting were considered in the development of this proposed rule.

In addition to consultation with other Federal agencies regarding specific requirements, the staff also met separately with the Occupational Safety and Health Administration and the Food and Drug Administration to provide the staff with an additional opportunity to hear and understand their concerns. To keep other stakeholders informed, the staff made presentations on the status of this rulemaking at the Interagency Steering Committee of Radiation Standards (ISCORS) meeting and certain conferences of the nuclear medical communities. In November 2005, the staff created a NARM Web Page that can be easily accessed by the public via the ruleforum website to post documents related to this rulemaking. The staff continues to post additional documents as they become publicly available.

During the development of this proposed rule, considerable effort was made to interact with stakeholders, within the time constraints imposed by the EPAct (which mandates that the NRC issue final regulations by February 7, 2007). However, the fast paced rulemaking schedule did not allow for the interactive, iterative rulemaking process that some stakeholders sought. For example, in late January 2006, at an ISCORS briefing on the rulemaking, other Federal agencies pushed for coordination through the ISCORS NARM subcommittee and questioned what opportunity Federal agencies would have to provide input on the rule before the public comment period. Also, within the past month, the Council on Radionuclides and Radiopharmaceuticals, the Society of Nuclear Medicine, the American College of Radiology, and the American Association of Physicists in Medicine have all written to NRC and requested additional time for promulgating the proposed rule as well as additional stakeholder interactions. In all of these cases, the staff cannot both accommodate the requests and remain on schedule for the Congressionally imposed final rule date. Therefore, the staff has sought to balance efforts to obtain stakeholder input on the proposed rule issues and meet with stakeholder groups to the extent possible, while also achieving an aggressive schedule mandated in the EPAct. For example, the staff plans to hold, at least, one additional meeting with stakeholders before the final rule is submitted to the Commission. The staff will do this during the public comment period on the proposed rule. Such an interaction would allow the stakeholders to interact directly with the staff after stakeholders have had an opportunity to review the proposed rule package.

DISCUSSION:

The staff proposes to change the existing definition of “byproduct material” in NRC regulations to be consistent with amendments made to the definition of byproduct material in Section 11e. of the AEA by Section 651(e) of the EPAct that expanded the definition of byproduct material to include certain discrete sources of radium, certain accelerator-produced radioactive material (as discussed below), and certain discrete sources of naturally occurring radioactive material. This change would require amending the existing definitions contained in 10 CFR Parts 20, 30, 50, 72, 110, 150, 170, and 171. The draft proposed rule is provided in the proposed Federal Register notice (Enclosure 1). A draft environmental assessment (Enclosure 2) and draft regulatory analysis (Enclosure 3) accompany the draft proposed rule. The Office of International Programs is undertaking a separate rulemaking effort and plans to propose the same change for the definition of “byproduct material” in 10 CFR Part 110, Export and Import of Nuclear Equipment and Material.

As mandated by the EPAct and to minimize the need for changes to the State regulations, the staff is using to the maximum extent practicable the existing NRC regulations. The proposed rule also incorporates provisions from the model State standards to supplement certain requirements specific to the newly added byproduct material. In addition, the staff proposes to include provisions for "grandfathering" authorized individuals and certain provisions for the proposed rule to ensure minimal impact on the availability of radiopharmaceuticals. Because technical data are not available for many items containing radium-226, the staff proposes in the proposed rule to issue a general license while soliciting technical information and public comments on the proposal to issue a general license.

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 will now be 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. Rather, the term applies to naturally occurring radioactive material that the Commission determines presents a threat to public health and safety or to the common defense and security similar to the threat posed by discrete sources of radium-226.

In developing the definition of "discrete source," the staff worked closely with the States through the NARM Rulemaking Working Group and the NMSS EPAct Task Force. In addition, the definition of "discrete source" was one of the topics included in the November public meeting to solicit stakeholder input. Furthermore, the staff met with other Federal agency representatives regarding the definition of "discrete source." These representatives included personnel from: (1) the U.S. Department of Transportation; (2) the U.S. Department of Energy, including the National Nuclear Security Administration; (3) the U.S. Department of Defense; (4) the U.S. Department of Commerce; (5) the U.S. Environmental Protection Agency (EPA); and (6) the U.S. Department of Homeland Security/Customs and Border Protection.

The staff proposes 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."* This proposed definition of discrete source of radium-226 or discrete source of naturally occurring radioactive material may have the same radiological characteristics (type of radiation, half-life, etc.) as the radionuclides found in nature, but the radionuclides will have been concentrated and purposefully used for their radiological properties. This proposed definition would limit NRC's jurisdiction in that NRC would not regulate 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. However, NRC's authority over source material is not changed. Once a radioactive material, defined as a discrete source, becomes byproduct material, it will continue to be regulated as byproduct material, even if the discrete source is leaking or broken, or no longer has a physical boundary. As stated above,

Section 651(e)(1) of the EPAct expanded the definition of byproduct material in Section 11e. of the AEA to incorporate the additional byproduct material now under NRC jurisdiction. The staff proposes to incorporate the same definition of "byproduct material" into its regulations.

Naturally Occurring Radioactive Material as Byproduct Material

The EPAct places under NRC jurisdiction any discrete source of naturally occurring radioactive material, other than source material, that the Commission determines, in consultation with the EPA Administrator, the Secretary of Energy, the Secretary of Homeland Security, and the head of any other appropriate Federal agency, 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. In developing the definition of "discrete source," the staff solicited the views of other Federal agency representatives regarding the identification of other naturally occurring radioactive material posing a similar threat as radium-226. None were identified.

In Table 1 of its "Code of Conduct on the Safety and Security of Radioactive Sources" (Code of Conduct), the International Atomic Energy Agency (IAEA) identified certain quantities for 26 radionuclides that pose a significant risk to individuals, society, and the environment. The quantities for these radionuclides could be fatal or cause permanent injury to a person, who handles, or is otherwise in contact with such material for a short period of time, if not safely managed or securely protected. Of the 26 radionuclides, only two are naturally occurring radionuclides: radium-226 and polonium-210. The proposed rule addresses discrete sources of radium-226. Naturally occurring polonium-210 is scarce. Polonium-210 used for commercial purposes is usually produced in nuclear reactors and is already regulated by the NRC. Additionally, polonium-210 is unlikely to be commercially used in individual sources with activity levels within IAEA Category 1 or 2 sources. At this time, the staff has determined that no other discrete sources of naturally occurring radioactive material pose a threat similar to IAEA Code of Conduct Category 1 or 2 sources. Therefore, the proposed rule does not include regulating any other discrete sources of naturally occurring radioactive material, but it does leave open the possibility that sources could be identified at some later date.

Accelerator-Produced Radioactive Material as a Byproduct Material

The EPAct only gives the NRC authority over certain accelerator-produced radioactive material; it does not give the NRC authority to regulate the possession or use of particle accelerators. In evaluating the accelerator-produced radioactive material, the staff proposes to regulate the radioactive material both intentionally and incidentally produced by accelerators that are operated to intentionally produce a radioactive material for use for a commercial, medical, or research activity. The rationale for the staff's proposal is that the incidentally produced radioactive material is a direct result of producing the radioactive material for use for a commercial, medical, or research activity, and the NRC should consider all radioactive material to ensure public health and safety.

The staff does not propose regulating the radioactive material incidentally produced by accelerators that are operated to produce only particle beams and not radioactive materials. These accelerators are used primarily for industrial or medical purposes such as neutron radiography used for imaging and Stereotactic Radiosurgery used for radiation therapy. The

reasons for not regulating the incidentally produced radioactive material are that: (1) no radioactive material is produced for use for a commercial, medical, or research activity, and (2) the incidentally produced radioactive material resides within the accelerator or facility. In addition, the OAS indicated that linacs pose no real decommissioning issues because the induced radioactive material is usually short lived, and because machines are generally refurbished instead of decommissioned.

For those accelerators that are used to produce both radioactive material and particle beams, the staff proposes to regulate the intentionally produced radioactive material and all of the incidentally produced radioactive material when the accelerator is operated to produce radioactive material, as well as when it is operated to produce only particle beams. The incidental radioactive materials produced in these accelerators are indistinguishable from these two different modes of operation, so both the intentionally produced radioactive material and all of the incidentally produced radioactive material are covered by this proposed rule. There are high-energy accelerators, used for basic nuclear and particle research, that are capable of being used to produce radioactive material. To date, the staff is not aware of any accelerators that are currently operated in this manner.

Consideration of Model State Standards

As stated above, the EPAct mandates that the NRC use model State standards to the maximum extent practicable in promulgating regulations for the expanded definition of byproduct material. CRCPD published the "Suggested State Regulations for Control of Radiation" (SSRs) as the model regulations for radioactive materials. Most Agreement States have either adopted SSRs as the model regulations or have promulgated requirements similar to the SSRs. Non-Agreement States use the SSRs in varying degrees to regulate NARM. Therefore, SSRs provide a model for the basic regulatory framework for the NRC in regulating the newly added byproduct material. In addition, participants at the November 9, 2005, public meeting supported the recognition of SSRs as the model standards.

In developing the proposed rule, the staff considered various Parts of the SSRs. Although the SSRs include radiation safety requirements for particle accelerators and requirements for technologically enhanced naturally occurring radioactive material, only a few requirements in SSRs specifically address radium-226 or accelerator-produced radioactive material. Most Agreement States have regulated NARM under the same or similar requirements as reactor-produced radioactive material. There is also a general consensus among the States that NARM should be regulated under the same requirements as reactor-produced radioactive material and that the SSRs could be used as the model regulations. Therefore, the staff used a similar approach to regulate NARM using SSRs to the maximum extent practicable in developing this proposed rule. Specifically, the staff evaluated values included in the SSRs for exempt concentrations and exempt quantities for radionuclides of the newly added byproduct material. Consistent with the SSRs, no changes to the exempt concentrations were made in the proposed rule. Values from the SSRs for exempt quantities for the newly added byproduct material were incorporated in the proposed rule. 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 staff evaluated 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. Based on NUREG-1140, the staff proposes to add a value for radium-226 for which an emergency plan is required.

The staff also evaluated sections of the SSRs that are relevant to control of radium-226 and products containing radium-226. The staff proposes to use provisions in the SSRs regarding an exemption for previously distributed timepieces or other articles containing 37 kilobecquerels (kBq) (1 microcurie (μCi)) of radium-226 and the requirement to allow a specifically licensed person to possess up to 185 kBq (5 μCi) of radium-226 calibration sources under a general license. Although SSRs have a limit of up to 3.7 kBq (0.1 μCi) of radium-226 that may be used for smoke detectors distributed for use under an exemption from licensing, the Sealed Source and Device registry indicates that certain smoke detectors containing up to 74 kBq (2 μCi) had been approved for use under exemption from licensing. Therefore, the staff proposes to exempt the possession and use of radium smoke detectors distributed previously under a specific license issued by a State under comparable provisions to NRC regulations. The staff did not adopt the exemption for previously acquired self-luminous articles containing less than 3.7 kBq (0.1 μCi) of radium-226 because these products were not manufactured and distributed pursuant to a specific license. Instead of exempting these products, the staff proposes to generally license certain items and self-luminous products containing radium-226 that were manufactured prior to the EPAct. The staff also learned that some Agreement States include certain radium-226 exempt concentrations in their regulations, although the SSRs do not provide for this. In general, exempt concentrations are not acceptable for alpha emitters. Therefore, the staff did not include an exempt concentration for radium-226 in this proposed rule.

Regulatory Approach for Certain Discrete Sources of Radium-226

Based on public comment and State input, the staff learned that a large number of old consumer products (e.g., radium watch hands and antiquities) or items (radium needles) containing radium-226 are still in circulation, in storage, or in the public domain. Although the SSR does not have specific standards for products or items containing radium-226, the staff believes it is prudent to develop a graded regulatory approach based on risk associated with these products or items containing radium-226. Both the NRC staff and the State representatives desire to establish some type of exemptions for certain products and items containing radium-226. However, the staff was unable to develop the necessary technical basis to support an exemption due to insufficient technical data, such as type and number of products, activity levels, concentrations, doses, etc. Without the technical information to support exemptions, the staff recommends using a general license approach in regulating certain products or items containing radium-226. The general license would be granted to any person to acquire, receive, possess, use, or transfer radium-226 contained in antiquities, luminous items installed in aircraft, no more than 100 luminous items no longer installed in aircraft, or no more than 50 items of other luminous products including timepiece hands and dials, and small radium-226 sources containing no more than 37 kBq (1 μCi). The staff also has included, in the draft notice for the proposed rule, a specific request for public comments on the availability of technical information on products or items containing radium-226 in support of an exemption and on NRC's proposed general license approach in regulating products or items containing radium-226.

Other NRC actions to enhance the security and control of risk-significant radioactive materials will be updated to reflect the NRC's new authority to regulate radium-226. In a separate rulemaking, radium-226 is being added to 10 CFR Part 110, Appendix P, Table 1, "Import and Export Threshold Limits," and to 10 CFR Part 20, Appendix E, "Nationally Tracked Source Thresholds," for alignment with the IAEA Code of Conduct. The Increased Controls Orders and the Additional Security Measures Orders, for the transportation of radioactive materials in quantities of concern and for manufacturing and distribution licensees, did not include radium-226. Partly as a result of the U.S. Department of Health, Education and Welfare and the EPA effort to collect and dispose of radium-226 in the late 1970's through 1981, and as estimated in NUREG/CR-5962, there are no reported IAEA Category 1 or 2 radium-226 sources for industrial or medical use. The weighted average reported for the industrial radium-226 sources was about 0.17 terabecquerels (TBq) (0.46 curies (Ci)) or IAEA Category 4. The reported range of activity for these industrial sources did not exceed 0.053 TBq (1.4 Ci). Since the IAEA Category 3 threshold value is 0.04 TBq (1.1 Ci), the staff does not plan to revise the current Orders to material licensees to include radium-226. However, because there may be a slight potential for aggregated quantities of IAEA Category 3 sources to reach IAEA Category 2 threshold quantities, radium-226 will be included in the enhanced security and control rulemaking that incorporates the requirements from the Orders for materials licensees and transportation.

Regulatory Considerations for Accelerator-Produced Radioactive Material

The staff also evaluated the SSRs regarding accelerator-produced radioactive material. In general, requirements for accelerator-produced radioactive material are the same as for reactor-produced radioactive material. The SSRs do allow the use of cobalt-57 sources, in units not exceeding 370 kBq (10 µCi) each, under a certain general license. SSRs also include contamination levels for strontium-82/rubidium-82 generators for medical use. The staff evaluated the SSRs for specific information regarding NARM used in radiopharmaceuticals or positron emission tomography (PET) drugs, but no such information was found. In this proposed rule, the staff incorporated the general license for cobalt-57 and the contamination levels for strontium-82/rubidium-82 generators as stated in the SSRs. There were no additional regulatory requirements in the SSRs specific to accelerator-produced radioactive material.

The staff believes that the existing NRC regulatory framework is also applicable to the commercial production and manufacture (Part 30); distribution (Part 32); and medical use (Part 35) of radionuclides, radioactive drugs, and sealed sources and devices containing the newly added byproduct material of accelerator-produced radioactive material that is now under NRC authority. Using the existing regulatory framework would minimize the impact on the availability of radiopharmaceuticals to physicians and patients. Because of the extremely short half-life of PET radionuclides for medical use, a PET radionuclide production facility must be located near the medical use facility. This also increases the need for noncommercial distribution of PET radionuclides or PET drugs; however, the existing NRC regulations do not have a provision addressing this issue. In this proposed rule, the staff has included a provision to allow noncommercial distribution of medical use radioactive material between medical use licensees to increase the availability of radiopharmaceuticals to physicians and patients. Among other things, the staff also has included provisions to: (1) recognize existing PET production facilities; (2) grandfather certain individuals (such as an authorized user, authorized nuclear pharmacist, and authorized medical physicist) with regard to certain regulatory

requirements; and (3) permit individuals to continue to prepare and use radioactive drugs while applying for a new license or a license amendment.

Exempt Distribution Licensing Authority

For existing byproduct material, the NRC has retained the authority for authorizing distribution of products and materials where the end user is exempt from licensing and regulatory requirements and has not transferred this authority. With the expanded definition of byproduct material, the staff evaluated the potential impact on States that have issued an exempt distribution license for NARM. The staff learned that there are currently four Agreement States (California, Massachusetts, Maryland, and Tennessee) that have issued exempt distribution licenses for products and materials that contain discrete sources of radium-226 or accelerator-produced radioactive material to persons exempted from licensing and regulatory requirements. The staff also learned that these licensees have, in addition to the State-issued exempt distribution license, an exempt distribution license with the NRC for other existing byproduct material. The staff contacted these four Agreement States to obtain their views on NRC assuming responsibility for these exempt distribution licenses. The staff also contacted an additional five Agreement States that had expressed opinions on some aspects of exempt distribution licenses. All, except for Maryland, supported the idea of NRC assuming responsibility for these exempt distribution licenses for the newly added byproduct material to ensure consistency. The staff believes that NRC should assume responsibility over existing exempt distribution licenses issued by the Agreement States and that NRC should continue to assert authority over exempt distribution licensing, including the newly added byproduct material.

Clarification of Low-Level Radioactive Waste and Decommissioning Financial Assurance

Section 651(e)(3) of the EPAct mandates that the newly added byproduct material not be considered to be low-level radioactive waste for the purposes of the compact under the Low-Level Radioactive Waste Policy Amendment Act (42 U.S.C. 2021b) (LLRWPAA). The intent of this provision is for disposal of this newly added byproduct material not to be impacted by the compact process under the LLRWPAA and not to affect authority to dispose of the newly added byproduct material at a disposal facility in accordance with any Federal or State solid or hazardous waste law. This provision does not have an impact on NRC policy and only requires minor adjustments to NRC's existing regulations to clarify the intent and to make it clear that requirements for using the uniform manifest for disposal apply when disposing of the newly added byproduct material at a Part 61 disposal facility.

The NRC needs to ensure that there is adequate decommissioning funding to properly decontaminate and decommission facilities involving the newly added byproduct material. Radionuclides with a short half-life produced in accelerator facilities do not pose a concern with regard to decommissioning the facility. However, activated material residing within the accelerator facilities that is produced incidental to the production of accelerator-produced radioactive material would still pose a concern. These radionuclides with a longer half-life must be considered along with the accelerator-produced radioactive material to ensure adequate safety throughout the production operation and must be managed adequately at the time of decommissioning of the accelerator and the associated facility.

The staff believes that the financial assurance requirements, included in 10 CFR 30.35, are adequate to ensure that any individuals who will receive a specific license authorizing possession and use of byproduct material with, a half-life greater than 120 days and in sufficient quantities, will be required to have adequate financial assurance in place for decommissioning the facility.

Radium-226 is already included in Appendix B of 10 CFR Part 30 for purposes of determining the required level of financial assurance for holders of specific licenses. Therefore, applicants for specific licenses to possess discrete sources of radium-226 will need to ensure that adequate financial assurance is provided for the type and the total amount of sources they will possess. Financial assurance is not required under NRC's existing regulations for holders of a general license, which would include the general license for possession of discrete sources of radium-226 as presented in this proposed rule. The staff is cognizant of the potential existence of facilities and sites that may be, or have the potential to become, contaminated with significant amounts of radium-226 from past practices or operations. The staff believes that the existing regulatory framework for licensing and decommissioning, including a facility-specific decommissioning plan requirement in Part 30, is sufficient to address these situations. Although there are no financial assurances for decommissioning facilities that are currently contaminated from past practices with discrete sources of radium-226, the NRC has the authority to address these situations as they are identified in the future on a case-by-case basis.

Consideration of Fees

Persons applying for a specific license with NRC are required to pay a license application fee. Additionally, all persons who hold licenses issued by NRC are subject to annual fees. Existing fee categories and their related fees are provided in 10 CFR Parts 170 and 171. Section 170.12, "Payment of fees," provides the requirements for assessing application fees. Among other factors, the level of NRC's regulatory effort for actions such as licensing, inspections, and event response is considered when establishing the fees. A licensee that believes it is a small entity, as described in 10 CFR 171.16, may request consideration as such for the annual fees only, which would result in a reduced fee.

The staff believes that the majority of NRC licensees affected by this rulemaking could be accommodated within the existing fee categories because it is anticipated that these licensees are engaged in activities involving the newly added byproduct material that are very similar to activities involving the existing byproduct material. The staff is, however, proposing three new fee categories and one revision to an existing category for specific licenses engaged in activities involving items and products containing radium-226 and for specific licenses involved in production of accelerator-produced radioactive material.

The staff evaluated existing fee categories that require a similar level of regulatory effort as for regulating activities involving radium-226 and for regulating production of accelerator-produced radioactive material in determining the levels of licensing fees and annual fees. Most individuals collecting items containing radium-226 are expected to be under a general license and, therefore, would not be affected by the proposed fee requirements. When an individual collects a certain number of items that requires a specific license, the fee requirement will apply

to this individual. The staff is proposing a two-tiered fee level with a lower tier based on the number of items or limits specified in Part 31 for a general license, and a higher tier based on 10 times that number. The lower-tier fee level would be comparable to the fee category “8" of about $450 and $1,600, respectively, for the license application and annual fees. The higher-tier fee level would be comparable to the fee category “3.P.” of about $1,100 and $2,500, respectively, for the license application and annual fees. Persons who wish to disassemble, repair, or assemble products containing radium-226 would be required to obtain a specific license and would be subject to the license application and annual fees. The staff is proposing to include this use in the existing fee category “3.B.” for a license fee of about $3,500 and an annual fee of about $8,200. The staff is proposing to add a new fee category, “3.S.,” for the production of accelerator-produced radioactive materials because of the complexity of the production process and the radiation health and safety concerns when compared to activities that only involve use of existing radionuclides. The proposed fees would be comparable to fee category “3.C.” at about $4,700 for the application fee and $10,200 for the annual fee.

Strategy for Waiver Termination and Rule Implementation Periods

The staff is proposing an effective date that is 60 days from the date of publication of the final rule for those individuals whose waiver is terminated on the effective date. Individuals that continue to be under the time-limited waiver issued by the NRC (70 FR 51581; August 31, 2005) are not required to comply with the final rule until the waiver expires on August 8, 2009, or earlier if terminated by the NRC. The staff proposes to explicitly provide specific authority and conditions in Parts 30, 32, and 35 to allow activities involving the newly added byproduct material to continue upon expiration or termination of the waiver.

Waiver Termination for Government Agencies and Federally Recognized Indian Tribes
The purpose of the waiver is to allow NARM activities to continue while NRC develops regulations and to allow time for an orderly transition for the States on the regulatory authority for NARM. There is currently limited regulatory oversight for the newly added byproduct material at Government agencies and Federally recognized Indian Tribe facilities. Therefore, the staff recommends termination of the waiver for Government agencies and Federally recognized Indian Tribes on the effective date of the rule. Waiver termination is necessary in order to require these facilities to comply with the new requirements and for NRC to ensure protection of public health and safety for the newly added byproduct material. Although Government agencies and Federally recognized Indian Tribes are already being regulated by NRC for the AEA 11e.(1) and 11e.(2) byproduct material, the staff is proposing a transitional period for them to submit a license amendment or a new license application for the newly added byproduct material. The proposed rule would allow Government agencies and Federally recognized Indian Tribes an additional 6-month period of time from the effective date of the rule to apply for a license amendment, and an additional 12-month period from the effective date of the rule to apply for a new license. In addition, the proposed rule contains specific provisions that would give Government agencies and Federally recognized Indian Tribes authority to continue to use the newly added byproduct material after the waiver is terminated until the date of NRC’s final licensing determination. These entities would, however, be required to comply with all other aspects of the regulations (e.g., event reporting, personnel dosimetry) upon the effective date of the rule.

Waiver Termination for Other Individuals in Agreement States
Individuals located in an Agreement State would continue to comply with existing State regulations on NARM while the waiver was in effect, because the waiver allows the States to continue with their regulatory programs. Once an Agreement State certifies that its program is adequate to protect public health and safety, as determined by the NRC, the waiver would be terminated for the Agreement State and those individuals located within the State. Upon waiver termination, these individuals would continue to comply with State regulations for NARM under the agreement with the NRC.

Waiver Termination for Other Individuals in Non-Agreement States
Similarly, individuals located in non-Agreement States (including U.S. Territories which are not Agreement States) would continue to comply with any existing regulatory program of the State or U.S. Territory on NARM while the waiver was in effect. However, the waiver termination would depend on a number of factors such as the intent of a State or U.S. Territory to become an Agreement State, the status of the regulatory program, and the desire to have regulatory oversight early rather than late. The staff plans to address termination of the waivers for individuals in non-Agreement States, other than Government agencies and Federally recognized Indian Tribes, in the transition plan. Currently, the waivers are in place for such individuals and will remain in place until August 7, 2009, unless terminated earlier. Once a final rule and transition plan are issued by NRC, the staff intends to begin terminating the waivers for individuals in non-Agreement States, in groups of several States, beginning with States that have expressed no intent to move to Agreement State status and have limited regulatory programs for NARM material. Through such an approach, the staff will avoid a sudden rush in the summer of 2009 by NARM users in non-Agreement States to submit license amendment requests or new license applications, and the associated resource burden on NRC to evaluate the requests. Instead, for those States that do not take actions to become an Agreement State, NRC will phase in the waiver termination process between the time that the transition plan is published and the statutory end date for all waivers. Termination of the waivers will be accomplished by publishing a notice in the Federal Register. In the transition plan, the staff plans to explain that it will use the same approach as for Government agencies and Federally recognized Indian Tribes in the proposed rule regarding submittal of license applications; namely, that users are authorized to possess NARM material as long as they comply with the NRC's requirements and submit a license amendment request within 6 months or a new license application within 12 months.

Rule Implementation Strategy
In the enclosed proposed rule, the staff proposes a strategy for implementation that authorizes Government agencies or Federally recognized Indian Tribes to continue to use NARM following termination of their waiver for uses permitted under the applicable regulations until the date of NRC's final licensing determination, provided that the agency or tribe submits a license amendment request or new license application within the time periods specified in the proposed rule. The staff also plans to use this same regulatory approach in the transition plan (allowing 6 months for a license amendment, and 12 months for a new license application) for individuals in non-Agreement States. In the enclosed proposed rule, the staff also proposes a strategy for implementation for "all other persons" (i.e., everyone except for Government agencies and Federally recognized Indian Tribes, such as NARM users in non-Agreement States). The staff proposes an implementation strategy such that "all other persons" who possess and use NARM

material may, by rule, continue to use such material for uses permitted under the applicable regulations until the date of NRC's final licensing determination, provided that the individual submits a license amendment request or new license application by August 7, 2009, or earlier as noticed by the NRC (e.g., publishing a waiver termination notice in the *Federal Register* for a group of non-Agreement States).

The staff has also considered the issue of how to allow continued possession and use of NARM following termination of the waiver for each of these groups prior to the NRC's issuance of a license or license amendment. The proposed implementation strategy allows NARM users to possess and use material without a license, for a limited period of time (6 months or 12 months, depending on whether they need a license amendment or new license, respectively, followed by the time it takes the NRC staff to make a final licensing determination), after the waivers are terminated. However, individuals must comply with all other applicable regulations during this same time period (e.g., dose standards, reports of loss or theft, dosimetry requirements, security regulations). The proposed regulations would authorize the possession and use of licensed material prior to issuance of a license. This approach is not the only option for addressing this issue. Another option would be to allow the same time periods for submittal of new license applications or license amendments, but not authorize continued use of the newly added byproduct material after the date of the waiver termination. This would have the effect of putting NARM users into violation for possession of material without a license. NRC could then exercise enforcement discretion not to take enforcement action for violation of NRC regulations requiring use and possession of licensed material only under a license, provided that the NARM user meets the other conditions in the regulations and submits the license amendment or application within the specified time period. A third option would be to let all waivers run until the last possible date, August 7, 2009, and not terminate any in advance. Then NARM users in non-Agreement States would have to submit license amendments or applications well before their waiver terminated. However, the staff does not consider this final option to be realistic. Under this approach, the NRC could become inundated with a large number of licensing requests in the summer of 2009, should NARM users wait until the end of the waiver period to submit applications for a license or license amendment. This would result in a significant resource strain on the NRC staff, who would have to evaluate the requests, and could place many NARM users in noncompliance with NRC regulations as of August 8, 2009, if NRC had not yet acted on their requests. Therefore, the staff considers authorization by rule, or the option to exercise enforcement discretion, to be the only two viable options. The staff proposes the option of authorizing continued possession and use of the material by regulation, rather than the option of exercising enforcement discretion, and has prepared the enclosed draft Federal Register notice accordingly. One reason that the staff has decided to propose this approach is that NARM users in non-Agreement States are already in possession of the material, and authorizing continued possession and use by rule recognizes a pre-existing situation. Another advantage of the proposed approach is that it does not put large numbers of NARM users into noncompliance as they transition to NRC's regulations. However, the staff seeks Commission approval on this proposed approach. The staff also seeks the Commission's view as to whether a question should be asked in the proposed rule as to whether the proposed approach is the most appropriate means for resolving this issue.

Paperwork Reduction Impact

This rulemaking would have an increased burden on reporting and recordkeeping requirements because of the expanded definition of byproduct material, including discrete sources of radium-226, accelerator-produced radioactive materials, and discrete sources of naturally occurring radioactive material. Therefore, an Office of Management and Budget (OMB) review of the information collection requirements is needed, and an OMB clearance package is required to be forwarded to OMB.

NRC Strategic and Performance Goals

The proposed rule is consistent with NRC's strategic objectives and performance goals. Because the proposed 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 proposed rule would establish the regulatory structures 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 (reactor-produced radioactive 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-based 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. The staff held a public meeting on this rulemaking in early November 2005 to solicit public input and created a NARM Rulemaking Web Page to keep the stakeholders informed. The rulemaking will continue to be conducted in an open process. The staff plans to post the proposed notice on the NARM Rulemaking Web Page upon issuance of this Commission Paper. If approved by the Commission, the proposed rule will be published in the *Federal Register* for a 45-day public comment period. In early January 2006, a draft proposed rule was provided to the States (both Agreement States and non-Agreement States) and to the Advisory Committee on the Medical Uses of Isotopes (ACMUI) for an early opportunity for review. The staff also plans to hold a public meeting during the public comment period to obtain stakeholder input. The exact date, time, and location will be determined after the Commission provides direction on the proposed rule.

AGREEMENT STATE ISSUES:

On January 3, 2006, a copy of the draft proposed 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 NRC's proposal. Comments were received from the OAS and 10 Agreement States (Arkansas, Illinois, Iowa, Kansas, Nebraska, New York, North Carolina, Texas, Washington, and Wisconsin).

Initially, in a letter dated February 2, 2006, the OAS provided detailed comments on the draft proposed rule (Enclosure 4). The most significant concern, expressed throughout the OAS' comments, was NRC's method of implementing the requirements equivalent to States' regulations. Specifically, the OAS raised concerns regarding the proposed compatibility designations for portions of the draft proposed rule, especially the compatibility designations for definitions. The OAS suggested substantive improvements to the FRN and noted: "With the exception of the actions required of the Agreement States to be compatible with these rules, the

OAS Board finds the FRN for the proposed rule is extremely well written, clear and easy to understand and effective in communicating requirements." (Comment 33, Enclosure 4)

Following receipt of the OAS' comments, the rulemaking working group and then the Steering Committee addressed the appropriate compatibility level for the definition of the term "byproduct material" and attempted to resolve the issue. The rulemaking working group and Steering Committee also addressed the use of the terms "byproduct material" and "radioactive material" in the text of the Agreement State regulations. The staff applied the process in Management Directive 5.9, "Adequacy and Compatibility of Agreement State Programs," and the Office of State and Tribal Programs' Procedure SA-200 to assess the issue. There was a considerable range of views among individual NRC staff members involved in the process on whether Compatibility Category C, Compatibility Category D, or an identification of "Health and Safety" (H&S) should apply. After deliberating the issue, the staff concluded in a Steering Committee meeting that the proposed rule should identify the definition of "byproduct material" as H&S, and pose a question in the Federal Register notice about whether this is the correct designation or whether a different compatibility category should be assigned to the definition.

The staff has carefully reviewed and followed the process described in Management Directive 5.9, *"Adequacy and Compatibility of Agreement State Programs*," Handbook 5.9, Part III. A more detailed discussion, question by question, is included as Enclosure 5 to this paper. Based on applying M.D. 5.9, the staff concludes that the definition of "byproduct material" should be designated as "Health and Safety." Specifically:

(1) the definition should not be designated "NRC" (i.e., reserved to the NRC) because the AEA explicitly authorizes States to regulate byproduct material under Section 274b Agreements;

(2) the definition should not be designated "A" because it does not define a "basic radiation protection standard" that is necessary for a common understanding of radiation protection principles;

(3) the definition should not be designated "B" because, even if an Agreement State chose not to define 11e.(3) byproduct material in its regulations, a direct and significant transboundary implication would not exist. This result is because the newly added byproduct material does not require unique radiation safety handling or management (e.g., different training requirements, or different labeling requirements) and is currently addressed in existing NARM regulations;

(4) the definition should not be designated "C" because, if an Agreement State chose not to define 11e.(3) byproduct material, its absence would not create a gap, conflict, or duplication on a nationwide basis since this material is currently regulated by the States under existing State regulations. Furthermore, definitions specify the meaning of a term only as that term is used in the regulations in which it appears, and does not impose any regulatory requirement on a licensee;

(5) the definition should not be designated "D" because if the essential objectives of the definition were not incorporated somewhere within the State program (i.e., in statute or in regulations), it is possible that certain byproduct materials would not be subject to regulatory oversight, the result of which could be an exposure to an individual in excess of the Part 20 limits.

Therefore, while the definition does not meet the compatibility categories of “A,” “B,” “C, “D,” or “NRC,” the staff has determined the definition is needed for purposes of “adequacy” since if NARM is included in the Agreement with the NRC then NARM would be a necessary program element of the Agreement State program to adequately ensure public health and safety. Therefore, the proper categorization of the definition is “H&S.”

In implementing the Commission’s policy on Agreement States, a designation of “H&S” for the definition of byproduct material will require the staff to continue to assure that the essential objectives (i.e., that 11e.(3) and (4) byproduct materials are addressed in the State’s regulatory program) are met. This assurance is obtained by review of the complete set of regulations of a State requesting an Agreement, the review of newly adopted or amended Agreement State regulations, and the review of the status of an Agreement State’s regulations as part of the Integrated Materials Performance Evaluation Program. The staff notes that under a designation of “D” such assurance would not be obtained since program elements designated “D” are not a required part of an Agreement program (they could be dropped from or not included in the Agreement State program and the program could still be found adequate and compatible), and therefore not reviewed by the NRC staff.

The State members of the Steering Committee did not agree with the “H&S” identification. The State representatives indicated that the compatibility for the definition of "byproduct material" should be Compatibility Category “D”, prompting a series of discussions between the OAS and NRC management. The States strongly objected to any designation other than Compatibility Category “D,” and asked how their views could be represented to the Commission. The staff and the OAS' Chair agreed that the OAS should provide their views in writing, which could be attached to this Commission Paper. On February 27, 2006, Barbara L. Hamrick, Esq., Chair, OAS, submitted a letter to supplement and revise the OAS' earlier comments (see Enclosure 6). The OAS letter provides detailed justification for the States' position that Compatibility Category “D” is the correct designation, as well as State comments. The staff draws the Commission's attention to Enclosure 6 for a more thorough discussion of the OAS' and the States' views. The Commission should also note that the OAS' letter goes beyond just the compatibility category designation for the definition of "byproduct material" and addresses concerns of the State representatives, the language of the EPAct, and other definitions that arise from the EPAct. On March 1, 2006, Debra McBaugh, Chair, CRCPD, submitted a letter on behalf of the CRCPD membership and Board of Directors (Enclosure 7). The CRCPD letter strongly supports the comments of the OAS. The staff draws the Commission's attention to the CRCPD letter and notes that it, too, addresses other definitions included in the subject draft proposed rule. For transparency with the Commission, rather than summarize, paraphrase, or reference the letters, the staff has included the full text of the letters as enclosures to this paper so that the Commission has the benefit of the States’ views in their own words. In addition to the letters from the OAS and the CRCPD, the staff has also received letters from several States on the same subject.

In the proposed rule, the staff has indicated that the definitions of "byproduct material" and "discrete source" are identified as “H&S,” based on the staff's determination applying MD 5.9. The staff has also posed a question in the Federal Register notice about the compatibility category designation, will seek feedback from the public on this issue during the public comment period, and will report back to the Commission when the draft final rule is submitted.

The OAS also indicated that the NRC should consider including antique items containing radium-226 under an exemption. The OAS stated that most of these items are held in private collections, where many of the owners are likely unaware of the radioactive content. The OAS indicated that these items have been considered, as a matter of practice, exempt from regulation by the States, and the OAS is unaware of any data that suggest these items pose significant enough risk to warrant regulation. Since technical data are not available to support an exemption at this time, the staff did not revise its proposal of using the general license approach for radium-226 sources. The OAS also indicated that individuals involved in assembling, disassembling, and repairing products containing radium-226 have not been regulated in the past for radiation safety purposes; therefore, an outreach effort will be needed. The staff plans to seek OAS and CRCPD assistance in planning future public meetings or outreach programs. The staff has revised portions of the draft notice to address OAS comments, with the exception of referencing the US Pharmacopoeia as the source for the concentration limits for strontium-82/ rubidium-82 generator breakthrough because the reference is not in the SSRs.

With respect to individual State comments, in addition to supporting OAS comments dated February 2, 2006, and highlighting their own concerns regarding the proposed compatibility designations, the States raised specific comments of their own on the draft proposed rule. The State of Arkansas specifically expressed its concern on the general license approach for radium-226 sources, stating that an exemption should be granted for items previously manufactured and distributed, and would like NRC to determine the risk associated with radium-226 sources and reevaluate the proposal. The State of New York recommended that NRC update Part 20, Appendix B, to include the Annual Limits on Intake (ALI) and Derived Air Concentration (DAC) for nitrogen-13 and oxygen-15. Upon further evaluation and based on results of staff's preliminary calculation, the staff believes that it is not necessary to include in this proposed rulemaking specific ALIs and DACs for these two radionuclides for Part 20. The State of Washington agreed with the proposed compatibility designation and indicated if additional byproduct material is added at a later date, implementation expectation should be clearly stated in the proposed rule. The staff believes that a separate rulemaking would be required in the future to add other discrete sources of naturally occurring radioactive material that poses a threat similar to radium-226. Therefore, implementation expectation for adding other byproduct material in the future should be addressed in future rulemakings and not in this proposed rule.

The NRC staff has preliminarily analyzed the proposed rule in accordance with the procedures established within Part III of Handbook 5.9 to Management Directive 5.9, “Categorization Process for NRC Program Elements.” Since the proposed rule contains multiple amendments, the compatibility category varies for the specific changes. The staff is proposing a compatibility category for each proposed change and has included a summary table in Section V, “Agreement State Compatibility,” of the proposed notice. The compatibility categories included in the proposed rule include Compatibility Categories “B,” “C,” “D,” “NRC” and the identification “H&S.”

ACMUI COORDINATION:

A copy of the draft proposed rule was sent to the ACMUI for comment at the same time that it was sent to the Agreement States, and comments were received from the ACMUI on February 3,

2006. The ACMUI endorsed the regulatory approach of regulating NARM similarly to reactor-produced radioactive material. It strongly supported the accelerator groupings and NRC's intention to regulate only accelerators that are intentionally operated to produce a radioactive material. The ACMUI stated that it is important to incorporate the OAS and CRCPD position, but it is also important that NRC regulations and Agreement State programs be as compatible as possible. It indicated that some proposed compatibility levels are low, and that there will be a wide variation among Agreement States unless there is a high level of compatibility. The ACMUI also recommended a stronger regulatory strategy than general licensing for discrete radium-226 sources and discouraged an exemption strategy over a broad range of radium-226 sources.

The ACMUI indicated that it is critical that the regulatory burden does not limit access to patient care and availability of radioactive drugs. To minimize regulatory burden, the staff used the existing NRC regulatory framework and incorporated the SSRs to the maximum extent practicable in developing the proposed rule, and requested that the Federal Register notice solicit public input on a number of issues to ensure that concerns are raised and considered in finalizing the rulemaking. In addition, the staff included various grandfathering clauses and certain provisions to ensure availability of radiopharmaceuticals. The ACMUI stated that the proposed rule omitted updating the values in Part 20, Appendices B and C, and did not address all accelerator-produced radionuclides in Part 30 exempt quantities. The staff used the SSRs as the basis for adding radionuclides to Parts 20 and 30 for the proposed rule. As noted, the staff determined that it is inappropriate and unnecessary at this time to propose in this rulemaking any radionuclide- specific ALIs and DACs for Part 20. Since there are catch-all values for radionuclides that are not listed, it is not necessary to include every possible accelerator-produced radionuclide. Although some Agreement States have certain additional radionuclides included for exempt quantities in their State regulations that are not included in the SSRs, the staff determined not to include these radionuclides without additional information and further evaluation. The staff has revised portions of the draft notice to improve clarity in addressing the ACMUI comments.

RESOURCES:

To complete the rulemaking, NMSS will require three full-time equivalents (FTE) in FY 2006 and 2.4 FTE in FY 2007. All other offices will require a combined total of 2.5 FTE during those years. A total of $200K for contract support ($100K each year in FY 2006 and FY 2007) will be needed for the regulatory analysis, OMB supporting statement, and the regulatory flexibility evaluation. These resources are included in the FY 2006 and FY 2007 budgets. 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, this section of the paper may need to be revisited after issuance of the draft Staff Requirements Memorandum.

COMMITMENTS:

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

1. The staff will post the proposed notice on the NRC website once the Commission paper is issued.

2. The staff plans to hold a public meeting on the rule during the public comment period.

3. The staff plans to provide the Commission with a proposed approach for developing the transition plan in the summer of FY 2006.

RECOMMENDATIONS:

That the Commission:

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

2. Approve the staff's proposed implementation strategy, that would allow NARM users to possess and use material, without a license, for a limited period of time (i.e., authorization by rule), and specify whether or not the staff should include a question in the proposed rule regarding the staff's proposed implementation strategy versus the use of enforcement discretion.

3. Note:

   a. The proposed notice will provide 45 days for public comment.

   b. 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).

   c. A draft Environmental Assessment (Enclosure 2) and a draft Regulatory Analysis (Enclosure 3) have been prepared for this rulemaking.

   d. Appropriate Congressional committees will be informed of this action.

   e. A press release will be issued by the Office of Public Affairs when the proposed rulemaking is filed with the Office of the Federal Register.

   f. OMB review is required, and a clearance package will be forwarded to OMB no later than the date the proposed rule is submitted to the Office of the Federal Register for publication.

COORDINATION:

The OGC has no legal objection to the proposed rulemaking. The Office of the Chief Financial Officer has reviewed this Commission Paper for resource implications and has no objections. The rule suggests changes in information collection requirements that must be submitted to OMB no later than the date the proposed rule is forwarded to the Office of the Federal Register for publication.

/RA/

Luis A. Reyes
Executive Director
for Operations

Enclosures:
1. Federal Register Notice
2. Draft Environmental Assessment
3. Draft Regulatory Analysis
4. OAS comment letter dated February 2, 2006
5. Staff position on the compatibility category
6. OAS comment letter dated February 27, 2006
7. CRCPD comment letter dated March 1, 2006

[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: Proposed rule.

SUMMARY: The Nuclear Regulatory Commission (NRC) is proposing to amend its regulations to include jurisdiction over certain radium sources, accelerator-produced radioactive materials, and certain 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 States and other stakeholders, issue final regulations establishing requirements that the Commission determines necessary under the EPAct. This rulemaking effort is being

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., and the Conference of Radiation Control Program Directors, Inc. (CRCPD). In addition, this proposed rule was informed and guided by the CRCPD's applicable Suggested State Regulations for the Control of Radiation. Licensees and individuals who are engaged in activities involving the newly defined byproduct material in both Agreement States and non-Agreement States and United States Territories may be affected by this rulemaking.

DATES: Submit comments on the rule by **[insert 45 days from date of publication].** Submit comments specific to the information collections aspects of this rule by **[insert 30 days from date of publication]**. Comments received after the above dates will be considered if it is practical to do so, but assurance of consideration cannot be given to comments received after these dates. A copy of the draft proposed rule was made available on **(add the actual date of posting once the signed SECY paper is issued and released)** on the NRC's rulemaking website at http://ruleforum.llnl.gov.

ADDRESSES: You may submit comments on the rule by any one of the following methods. Please include the following number (RIN 3150-AH84) in the subject line of your comments. Comments on rulemakings submitted in writing or in electronic form will be made available to the public in their entirety on the NRC rulemaking website. Personal information will not be removed from your comments.

Mail comments to: Secretary, U.S. Nuclear Regulatory Commission, Washington, DC 20555-0001, ATTN: Rulemakings and Adjudications Staff.

E-mail comments to: SECY@nrc.gov. If you do not receive a reply e-mail confirming that we have received your comments, contact us directly at (301) 415-1966. You may also submit comments via the NRC's rulemaking website at http://ruleforum.llnl.gov. Address questions about our rulemaking website to Carol Gallagher (301) 415-5905; email cag@nrc.gov. Comments can also be submitted via the Federal eRulemaking Portal http://www.regulations.gov.

Hand deliver comments to: 11555 Rockville Pike, Rockville, Maryland 20852, between 7:30 am and 4:15 pm Federal workdays (telephone (301) 415-1966).

Fax comments to: Secretary, U.S. Nuclear Regulatory Commission at (301) 415-1101.

You may submit comments on the information collections by the methods indicated in the Paperwork Reduction Act Statement.

Publicly available documents related to this rulemaking may be examined and copied for a fee at the NRC's Public Document Room (PDR), Public File Area O-1F21, One White Flint North, 11555 Rockville Pike, Rockville, Maryland. Selected documents, including comments, can be viewed and downloaded electronically via the NRC rulemaking website at http://ruleforum.llnl.gov.

Publicly available documents created or received at the NRC after November 1, 1999, are available electronically at the NRC's Electronic Reading Room at http://www.nrc.gov/NRC/ADAMS/index.html. From this site, the public can gain entry into the NRC's Agencywide Document Access and Management System (ADAMS), which provides text and image files of the NRC's public documents. If you do not have access to ADAMS or if there are problems in accessing the documents located in ADAMS, contact the NRC PDR Reference staff at 1-800-397-4209, 301-415-4737, or by e-mail to pdr@nrc.gov.

FOR FURTHER INFORMATION CONTACT: Lydia Chang, Office of Nuclear Material Safety and Safeguards, 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). However, the EPAct allowed the NRC 18 months from the date that the legislation was signed into law by the President to issue regulations to establish a national program for NARM. The EPAct also allowed the NRC to issue waivers to States and other entities while a regulatory framework for NARM was developed. A waiver was issued on August 31, 2005 (70 FR 51581).

Current Regulatory Structures for NARM.

The AEA authorizes States to assume regulatory control of radioactive materials produced in or by a nuclear reactor, 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, 33 States have assumed responsibility for regulating certain activities related to radioactive material by entering into agreements with the NRC. The State of Minnesota's Agreement will become effective March 31, 2006. 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 nor regulations for this type of material. Although the NRC has not regulated NARM in the past, all 33 Agreement States and certain non-Agreement States have regulatory programs for NARM. The NRC's current regulations do 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 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 NRC 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 NRC authority. In many respects, regulations applicable to NARM adopted by the Agreement States are compatible with the NRC regulations for the current materials program, or parallel to 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 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 has greater variation from Agreement State to Agreement State.

Other Federal Agencies' Regulatory Authority Over NARM.

Before the passage of the EPAct, NARM was regulated as a radioactive material and/or a hazardous substance but was not regulated by the NRC. 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 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 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 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 Department of Labor (DOL) has established regulations addressing the exposure of minors to radioactive material in the workplace. The Occupational Safety and Health Administration (OSHA) has the oversight for occupational health and safety for non-AEA materials. The Department of Commerce (DOC) has controlled the export of radioactive material. Prior to the enactment of the EPAct, the DOC regulated the export of all radium-226. With the enactment of the EPAct, 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 paragraphs 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.

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 turn of the 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. CRCPD has formed many working groups to develop a set of SSRs for radioactive material 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 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 and currently does not have 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. 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 this 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, 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.

Therefore, 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.

II. Discussion

A. *Initiating 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, e.g., the NRC met with OSHA on August 30, 2005. At the meeting, the participants discussed the NRC's role under the EPAct.

Forming Working Groups.

In October 2005, the NRC formed a NARM Rulemaking Working Group for developing a regulatory framework for the expanded definition of byproduct material and for drafting this proposed rule. In addition to the NRC staff, the NARM Working Group also included

participants from the State of Florida and the State of Oregon representing the CRCPD, the State of Texas representing the OAS, and the State of Michigan. Weekly meetings were held to take full use of the expert resources available within the NARM Working Group.

The NRC also established an Office of Nuclear Material Safety and Safeguards (NMSS) EPAct Task Force with members from the States of Oregon and North Carolina and with resource members from the States of Illinois and California. The State participants assisted the NARM rulemaking by gathering State-specific data, developing certain technical bases, and formulating certain regulatory approaches for the proposed rule. The State participants of the NMSS EPAct Task Force have performed key roles in the proposed rule development and have provided valuable input to the rulemaking process.

In addition, a Steering Committee was formed to provide oversight for both the NMSS 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 proposed rule development process, the Steering Committee met weekly to resolve issues and to provide management direction on the rulemaking. The Steering Committee plans to continue to meet on a regular basis until the rule is final.

Roundtable Public Meeting.

The NRC held a public meeting on November 9, 2005, to discuss rulemaking activities to incorporate 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 via the NRC rulemaking website at http://ruleforum.llnl.gov.

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 that was established to help implement the requirements of the EPAct. Other topics that were discussed included the role of State regulations, potential implications regarding production of radiopharmaceuticals and availability of radiopharmaceuticals to patients, definition of discrete source, the 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 via the NRC rulemaking website at http://ruleforum.llnl.gov and have been reviewed and considered by the NRC staff in the development of this proposed 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, 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 of the Positron Emission

Tomography (PET) drugs in PET centers registered with the FDA. In this proposed rule, the NRC proposes to 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 DOT, DOE, including the National Nuclear Security Administration, Department of Defense, 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 naturally occurring radioactive materials. 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.

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 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 nor qualitative technical information was identified during the development of the proposed rule that would support a broad exemption for these old discrete radium-226 sources. Because of the lack of specific health and safety information associated with many of the old radium-226 sources, the NRC is proposing a graded approach by using a general license to regulate different groups of radium-226 sources. In addition, in this proposed rule, the NRC is asking the public for any technical information that may be available to support an exemption, now or in the future.

B. *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 proposing a revision of 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 revised definition of *Byproduct material* will be promulgated in a separate rulemaking for 10 CFR Part 110. A different definition for the term *Byproduct material* is used in 10 CFR Part 40, and it remains unchanged by this proposed rule.

Radium-226.

Radium is a chemically reactive, silvery white, radioactive, metallic element with an atomic number of 88 and symbol of Ra. Radium is formed by the radioactive disintegration of thorium-230 in the decay series starting with uranium-238. Radium can be found in all uranium ores. Of the isotopes of radium, the most abundant and most stable is the isotope with a mass

number of 226. The half-life of radium-226 is 1599 years. Radium-226 emits alpha particles, 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. With advertisements proclaiming its special powers, 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. Radium was also used as a radiation source in needles or as plaques for cancer treatment. 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 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.

The two basic designs of particle accelerators are linear and circular. 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 also be bent into the circular shaped path. The process of accelerating, focusing, and bending (if necessary) 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. In some cases, targets consist of nuclides intended for activation and other nuclides that are also incidentally activated. Accelerators may also produce a neutron flux capable of activating materials. The production of incidental radioactive material is an inextricable part of any accelerator operation.

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 proposes to 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 does not propose to 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 proposes to 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 are covered

by this proposed rule. The NRC believes very few, if any, accelerators are operated in this way. NRC is seeking comments on the extent, if any, that accelerators are used to intentionally produce radioactive material and to provide beams for basic science research.

The EPAct does not give the NRC any authority to regulate the possession or use of particle accelerators, themselves. The NRC does not propose to adopt 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 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 is considering how 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. Comments are requested on the decommissioning of accelerator facilities, specifically addressing the extent to which accelerator components and facility building materials may become activated, the need to remove and properly dispose of the activated material during decommissioning to meet the radiation dose limits in 10 CFR Part 20 Subpart E--Radiological Criteria for License Termination, the costs of the decommissioning and disposal, if required, and the need for financial assurance by accelerator facilities to guarantee sufficient funding for proper decommissioning.

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 proposed regulatory approach for manufacturing

accelerator-produced radioactive material for industrial purposes is similar to the proposed 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 is now an important component of medical specialties for both diagnosis and therapy purposes. Today, the use of unsealed radioactive materials in nuclear medicine offers procedures that are essential in many medical specialties, from pediatrics to cardiology to psychiatry. Approximately 4,000 hospital-based nuclear medicine departments and many freestanding imaging centers in the U.S. perform millions of nuclear medicine imaging studies every year. Nuclear medicine is now an integral part of patient care and is extremely valuable in the early diagnosis and treatment of medical conditions. Nuclear medicine uses very small amounts of radioactive materials (radiopharmaceuticals) to diagnose and treat disease. In diagnosis, the radiopharmaceuticals are used and then detected by special cameras with the aid of computers in providing very precise images for the area of interest. In therapeutic nuclear medicine applications, the radiopharmaceuticals can be directed to the specific organ being treated. Radiation oncology uses larger amounts of radioactivity in sealed sources to deliver therapeutic or palliative radiation doses.

Radiopharmaceuticals could be made from radionuclides produced either in nuclear reactors or in particle accelerators. Currently, reactor-produced byproduct radionuclides for radioactive drugs are imported into the U.S. Although most reactor-produced radionuclides used in sealed sources are also imported, some are produced in an NRC-regulated nonpower reactor. Commercial manufacturers use these imported radionuclides to produce specific sealed sources, radioactive drugs, and biologics.

The most noteworthy radioactive drug source is the molybdenum-99/technetium-99m generator since technetium-99m is used in approximately 85 percent of all diagnostic studies in nuclear medicine. Commercial nuclear pharmacies subsequently use commercially produced radioactive drugs and drug sources, such as molybdenum-99/technetium-99m generators, to prepare unit dosages of other radioactive drugs such as technetium-99m sulfur colloid. The commercial nuclear pharmacy may also use radiochemicals to prepare radioactive drugs.

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 using fluorine-18, carbon-11, nitrogen-13, and even oxygen-15, also known as the PET drugs, have become popular. PET radionuclides and drugs are primarily produced in cyclotron facilities (often referred to as PET centers). PET drugs use radionuclides that decay by positron emission, which provides dual photons traveling in opposite directions that give a better spacial resolution of images for the area of diagnostic interest. Due to the relatively short half life (minutes to hours), PET radionuclides and drugs are produced at locations in close proximity to the patients (e.g., in hospitals or academic institutions) or at nearby locations.

Palladium-103 is the most common accelerator-produced medical use radionuclide contained in a sealed source. Palladium-103 manual brachytherapy sources were originally produced at reactor facilities, but currently all palladium-103 used in the U.S. is commercially produced by accelerators with a significant amount produced by U.S. accelerators. Other medical use radionuclides, used in 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 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 proposes to 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 amends 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 such discrete sources would pose a threat similar to the threat posed by a discrete source of radium-226. At this time, the proposed rule does not suggest any discrete sources of naturally occurring radioactive material for inclusion, and the proposed 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 levels 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. Since this proposed rule addresses discrete sources of radium-226, the only other naturally occurring radioactive material similar in hazard to radium-226 is polonium-210 when using the IAEA criteria. 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, polonium-210 used for commercial purposes is usually produced by bombarding bismuth-209 with neutrons in a nuclear reactor. Therefore, the polonium-210 used in commerce had been regulated by the NRC before the EPAct. Additionally, polonium-210 is very unlikely to be commercially used in individual radioactive sources with activity levels that would place them within IAEA Code of Conduct Category 1 or 2.

As noted previously, the NRC hosted an informal meeting with other Federal agency representatives on November 22, 2005, to discuss the development of a definition for discrete source to be added to the NRC regulations. At this meeting, in a general discussion, the participants briefly discussed the issue of other naturally occurring radioactive material that pose a threat similar to discrete sources of radium-226. Only polonium-210 was considered as a naturally occurring radionuclide that currently has any commercial importance to generating potentially significant quantities.

At this time, the NRC staff has determined that no other discrete sources of naturally occurring radioactive material pose a threat similar to radium-226-level or IAEA Code of Conduct Category 1 or 2 sources. In developing the proposed rule, and interacting with other Federal agencies and States, the NRC concluded that 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, this proposed rule does not propose to add any discrete sources of naturally occurring radioactive material to the definition of *Byproduct material*, other than radium-226 and polonium-210 covered elsewhere in the definition of *Byproduct material*. 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.

C. *The NRC's Regulatory Approach.*

Consideration of 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 regulations to the maximum extent practicable in issuing regulations for the expanded definition of byproduct material. CRCPD published SSRs which included the model regulations for radioactive materials. Because SSRs are the model regulations that most CRCPD member States have adopted, or States have issued requirements that are similar to the SSRs, then the SSRs provide the NRC a model for the basic regulatory framework for regulating the additional byproduct materials as defined by the EPAct. The SSRs are available on the CRCPD website at http://www.crcpd.org/free_docs.asp. The majority of stakeholders at the November 9, 2005, public meeting supported the recognition of SSRs as the model

regulations referred to in the EPAct. Although varying slightly from State to State, the majority of States regulating NARM have adopted the guidelines in SSRs.

The NRC considered the SSRs in developing the proposed rule. The NRC considered the SSRs in evaluating NARM radionuclides for potential inclusion in radionuclide-specific values listed in 10 CFR Part 20, Appendices B and C. The NRC found that there are no other radionuclides identified in comparable provisions in Part D of the SSRs that are not already included in 10 CFR Part 20. The NRC evaluated values in SSRs for exempt concentrations (Schedule A to 10 CFR Part 30) and exempt quantities (Schedule B to 10 CFR Part 30). These exemption values were carefully reviewed because of their potential impact on interstate commerce, reciprocity, and other commercial activities. The NRC determined that these values included in SSRs were consistent with the existing NRC approach and were derived using the same methodology. Hence, there is no change needed in the regulatory approach for exempt concentrations. With respect to the exempt quantities, the NRC is proposing to adopt the values included in SSRs into 10 CFR Part 30.

The NRC also evaluated pertinent sections of Part C of the SSRs that are relevant to control of radium and products containing radium. In Section C.4.b.ii, the SSRs indicate that the exempt quantity exemption applicable to radioactive material received under a former general license does not apply to radium-226. In Section C.4.c, the SSRs provide an exemption for timepieces or other articles containing not more than 37 kilobecquerels (kBq) (1 microcurie (μCi)) of radium-226, which were previously acquired. In Section C.22, the SSRs allow a general license, applicable to specifically licensed businesses and government agencies, to possess and use up to 185 kBq (5 μCi) of radium as calibration sources. The use of radium sources in industrial gauging devices may also be authorized under a general license specified in this section. In Section C.28, the SSRs allow up to 3.7 kBq (0.1 μCi) of radium-226 that may be incorporated into smoke detectors distributed under an exempt license. Some

Agreement States also include radium-226 in their exempt concentration and exempt quantities regulations.

The NRC evaluated certain sections of the SSRs regarding radioactive material used in medical activities. Section C.22(i) of the SSRs includes a general license for use of radioactive material for certain in vitro clinical or laboratory testing that is comparable to the requirements in 10 CFR 31.11 for the same type of general license. The SSRs indicated that cobalt-57, in units not exceeding 370 kBq (10 μCi) each, could be used under this general license. In this proposed rule, the use of cobalt-57 was added to the general license requirements in 10 CFR 31.11, and the cobalt-57 products included in the general license were added to 10 CFR 32.71 requirements, which provide the licensing criteria for the manufacturer and distributor of the products used under the general license. Section 32.71 of the NRC regulations is comparable with Section C.28(h) of the SSRs.

Paragraphs (j) and (k) of Section C.28 of the SSRs were reviewed for specific information on NARM radiopharmaceuticals or PET drugs, but no such information was found. Section G.48 of the SSRs includes contamination limits for strontium-82/rubidium-82 generators. The contamination limits from the SSRs are 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). In this proposed rule, the contamination limits and requirements to measure the contamination limits were added to 10 CFR 35.204 with corresponding recordkeeping requirements added to 10 CFR 35.2204. There were no additional regulatory requirements in the SSRs applicable to medical use licensees.

In developing this proposed rule, and as specifically discussed at the November 9, 2005, roundtable public meeting, the NRC learned that few SSRs specifically address accelerator-

produced radioactive material. Because most Agreement States have regulated accelerator-produced radioactive material in a manner similar to and under the same requirements as reactor-produced radioactive material, few SSRs exist solely to address accelerator-produced radioactive material. While SSRs do exist that address naturally occurring radioactive material issues, there appear to be few model State regulations specific to accelerator-produced radioactive material upon which the NRC can base this proposed rule. However, there is general agreement among the States, and reflected in the SSRs, that accelerator-produced radioactive material should be regulated under the same requirements as reactor-produced radioactive material. This proposed rule takes the same regulatory approach.

Common Defense and Security Considerations.

The NRC has supported efforts to establish international guidance for the safety and security of radioactive materials of concern. This effort has resulted in a major revision of the IAEA Code of Conduct. The revised Code of Conduct was approved by the IAEA Board of Governors in September 2003, and is available on the IAEA website at http://www-pub.iaea.org/MTCD/publications/PDF/Code-2004_web.pdf. Table 1 of the Code of Conduct lists those radionuclides that pose a significant risk to individuals, society, and the environment. While the Code of Conduct initially focused on sealed source management and control from a safety perspective, terrorist events have caused the scope to be broadened to include a security consideration. The Code of Conduct included 26 radionuclides with quantities that could be fatal or cause permanent injury to a person if not safely managed or securely protected. Of these 26 radionuclides, only two naturally occurring radionuclides are listed: radium-226 and polonium-210. With the passage of the EPAct, the NRC has regulatory authority over each of the radionuclides listed in Table 1 of the Code of Conduct. Radium-226

is one of the isotopes of concern for use in a radiological dispersal device, and it is on the list of radioactive sources in the IAEA Code of Conduct that could pose a significant risk.

The NRC has published a final rule relating to the export and import of radioactive materials for certain radionuclides listed in the Code of Conduct (70 FR 37985; July 1, 2005) and a proposed rule for national source tracking of sealed sources (70 FR 43646; July 28, 2005). In a separate rulemaking, the NRC will amend 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.

Definition of Discrete Sources.

The EPAct extended the definition of *Byproduct material* 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 gives the NRC authority over discrete sources of radium-226 but not over diffuse sources of radium-226. The result did not extend the NRC's authority over radium-226 as it occurs in nature, nor over other processes where radium-226 may be unintentionally concentrated. 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 as discrete sources; however, uranium and thorium within these materials may become licensable source material depending upon their concentration. To more clearly establish the limit of its authority regarding radium-226, the NRC was tasked with defining what constitutes a discrete source. The NRC is defining the term in this proposed rule.

The term *Discrete source* is not defined in the EPAct, and the EPAct specifically indicates that the final regulations, in establishing requirements necessary to carry out the

amendment, shall include a definition of the term *Discrete source*. This definition of *Discrete source* will be 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 NRC believes that this new authority over radium-226 and other naturally occurring radioactive material was not intended to extend to all naturally occurring radioactive material. 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. The authority does not extend to naturally occurring radioactive material that is found in nature in its original form and location, nor to naturally occurring radioactive material moved or concentrated inadvertently in some man-made process. The intent of the NRC in developing the definition of *Discrete source* for radium-226 and other naturally occurring radioactive material was to better define the materials covered by the new authority.

The NRC is proposing to define the term *Discrete source*, in defining radium-226 and other naturally occurring radioactive material, other than source material, as byproduct material, as "*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."* The discrete source will have the same radiological characteristics (type of radiation, half-life, etc.) as the radionuclide found in nature, but will have been concentrated and purposefully used for its radiological properties, after it has been removed from its original location in nature. This excludes the NRC jurisdiction over inadvertent movement or concentration of naturally occurring radioactive material. It does not change the NRC's authority, in any manner, over source material. This definition of *Discrete source* clarifies those

radium-226 sources and other naturally occurring radioactive material, other than source material, that will be delineated as byproduct material and will fall under the expanded definition of *Byproduct material* as mandated in the EPAct. This definition of *Discrete source* does not include material encapsulated or sealed only for disposal. However, it should be noted that once a radioactive material, as defined under this definition of *Discrete source*, becomes a byproduct material, it will continue to be regulated as a byproduct material even if the discrete radioactive source is leaking or broken, or no longer has a physical boundary.

D. *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 States for use under an exemption from licensing and under a general license. Generally, the NRC's intent in this proposed 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 proposed rule are only intended to accommodate items

manufactured in the past, which may still be in use or in storage. For example, radium-226 was used in timepieces and other self-luminous products, and in smoke detectors. Some time ago, promethium-147 and then tritium replaced radium-226 in self-luminous products. For many years, americium-241 has been the primary radionuclide used in smoke detectors; consequently, the use of radium-226 in the manufacture of smoke detectors stopped several years ago.

The bases of these proposed provisions are primarily the SSRs and also information in the 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 States. While this is not a complete database with respect to NARM, it includes detailed information about many products containing NARM previously evaluated by States. In addition to SSRs and the information in the SS&D registry, the specific provisions of the various States also have been considered in developing this proposed rule.

Exemptions from Licensing.

Part 30 of Title 10 of the Code of Federal Regulations 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. The two exemptions in 10 CFR 30.19 and 10 CFR 30.20, Self-luminous products and Gas and aerosol detectors, respectively, 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. Sections 30.14 and 30.18 of NRC's regulations, Exempt concentrations and Exempt quantities, respectively, 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 and have been made concerning how the product is distributed, used, and disposed of. The proposed rule would add some products and materials containing NARM to some of the current exemptions. The table of exempt concentrations in 10 CFR 30.70 already includes all of the radionuclides and associated limits contained in the equivalent section of the SSRs. Thus, the NRC is not proposing to revise the exempt concentration table in this proposed 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. The proposed rule would add these 13 radionuclides and their respective quantities, as currently 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 State's 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 proposing to add only the 13 radionuclides and values from the SSRs, and no further additions to 10 CFR 30.71 are included in the proposed 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 would apply to accelerator-produced radionuclides as well.

Timepieces containing radium-226.

The exemption in 10 CFR 30.15(a)(viii) would be revised to include timepieces that were previously manufactured prior to the effective date of the rule and containing no more than 37 kBq (1 μCi) of radium-226. This limit is consistent with the SSRs.

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 would not be 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. Instead, the possession, use, and transfer of these items would be subject to the general license for certain previously manufactured items and self-luminous products containing radium-226 established in 10 CFR Part 31. The NRC plans to further evaluate the health and safety implications of self-luminous products to determine if exemptions may be appropriate.

Smoke detectors.

Smoke detectors are included in the class exemption in 10 CFR 30.20 for gas and aerosol detectors. This exemption is revised in the proposed rule 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 in smoke detectors was, in fact, a past practice. The proposed provision added to 10 CFR 30.20 for detectors containing radium-226 would be 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 would have been used in approving distribution of these detectors for use under an exemption from licensing. This exemption would 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 continues to retain 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). The current 10 CFR 150.15(a)(6) 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 and regulatory requirements 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, States have only authorized a few distribution licensees for distribution to persons exempt from licensing requirements of exempt quantities of accelerator-produced radioactive material. These distribution licensees already have an NRC license under 10 CFR 32.18 authorizing the distribution of exempt quantities of pre-EPAct byproduct material. Thus, only a simple amendment of those NRC licenses will be required as a result of this aspect of this proposed 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: those "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 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 proposed rule would accommodate generally licensed devices meeting the restrictions of the general license that were previously approved by 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 changes in response to this proposed rule. 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) would be 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 is separate and quite different from the SS&D registration by the distributors. 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 would come under 10 CFR 31.5 include devices with 37 MBq (1 mCi) or more of radium-226. These devices would be subject to the registration requirement. Other certificates, which include devices with radium-226, allow only much smaller quantities. These devices would 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. At this time, 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. Information available from States will also be added. 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 would need to add devices containing radium-226 during the registration process.

Calibration and reference sources in 10 CFR 31.8.

Section 31.8 of 10 CFR Part 31 currently provides a general license for the use of up to 185 kBq (5 μCi) of americium-241 in calibration and reference sources. The SSRs and many State regulations also include radium-226 in their comparable provisions to the general license. This proposed rule would add 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.

General license for in vitro test kits in 10 CFR 31.11.

The general license for in vitro test kits in 10 CFR 31.11 would also be revised. In vitro test kits are discussed later under “Regulatory Framework for Accelerator-Produced Radioactive Material Used in Medical Activities.”

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

A new section would be added to 10 CFR Part 31 to provide a general license to any person for other products and discrete sources containing radium-226 which are apparently in the public domain but may not be otherwise covered under a license and are not specifically addressed in the SSRs. The general license would include: (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, healing pads, etc.; (2) luminous hands and dials not contained in timepieces and other luminous items, provided that no more than 50 are used or stored at the same location at any one time; (3) luminous gauges and other aircraft safety items containing radium-226 installed in aircraft; (4) luminous aircraft gauges and other aircraft safety items containing radium-226 no longer installed in aircraft, 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, spinthariscopes, etc.), electron tubes, lightning rods, ionization sources, and static eliminators.

The general license would allow any person to acquire, receive, possess, use, or transfer radium-226 contained in the aforementioned products. Persons who receive, possess, use, or transfer the radium-226 items under the general license would be exempt from the provisions of 10 CFR Parts 19, 20, and 21 to the extent that the receipt, possession, use, or transfer is within the terms of the general license.

The proposed general license would prohibit the manufacture, assembly, disassembly, repair, or import of products containing radium-226; prohibit export under the general license; and require that the product is only to 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 proposed general license would also prohibit abandonment of the product. The general license would require notifying the NRC or the Agreement State 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 would require persons possessing these devices under a general license to respond to written requests for information from the NRC or the appropriate Agreement States.

The Commission intends to conduct an evaluation to better understand the products, determine the extent to which radium may have been used in the products, the activities or quantities of radium-226 that might have been used or remain in the products, and determine any health and safety or environmental impacts that the products pose. It is anticipated, based on the information developed from this evaluation, that the Commission may determine that it is appropriate to exempt additional products from further regulatory control, or modify the general license. Meanwhile, it is the NRC's intent, to a large extent, to maintain the existing "status quo" with Agreement State regulation of NARM through the imposition of minor restrictions on transfer and possession, except when larger numbers of products may be involved or significant contamination of property has resulted.

The Commission specifically requests comments to provide information that may assist the NRC to more fully evaluate potential impact to public health and safety and the environment due to activities involving radium-226 sources. In particular, the Commission requests input on any quantitative or qualitative health and safety information regarding radium-226 sources that may be used to support a regulatory framework other than general licensing, such as an

exemption. The Commission also requests comments regarding its general license approach for certain items and self-luminous products containing radium-226 that were manufactured prior to the effective date of the rule, regarding whether an exemption is a more effective and viable approach, and requests additional information for the technical basis supporting an exemption in lieu of a general license. In particular, the Commission would appreciate input on whether this general license approach, and its allowances and restrictions, is reasonable while the Commission evaluates the products; whether the general license should allow possession of radium-226 luminous items, such as individual watch hands, dials, gauge indicators and faces, which are not contained in an intact finished product regardless of number; whether commercial transfers should be restricted and require a specific license; or whether data are available to justify an exemption for certain types of radium-226 sources, now or in the future.

Regulatory Framework for Accelerator-Produced Radioactive Material Used in Medical Activities.

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. The NRC has a well established regulatory framework for the commercial production, distribution, and use of in vitro test kits, radioactive drugs, biologics, and SS&Ds for medical activities involving byproduct material yielded in, or made radioactive by, exposure to the radiation incident to the process of producing or using special nuclear material. The NRC believes this existing regulatory framework is also applicable to the commercial producers, distributors, and medical users of in vitro test kits, radionuclides, radioactive drugs, biologics, and SS&Ds containing NARM that are now included in the EPAct's expanded definition of byproduct material. The NRC also believes this framework will minimize the impact of its regulations on the availability of radioactive drugs

containing accelerator-produced radionuclides.

This regulatory framework for the commercial radioactive drug manufacturer and the commercial nuclear pharmacy consists of licenses (or authorizations) issued under 10 CFR Part 30 to possess and use the radioactive materials, 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 license issued under 10 CFR 32.72 to distribute radioactive drugs to medical use licensees. While the medical SS&D manufacturers also have licenses (or authorizations) issued under 10 CFR Part 30, their medical distribution licenses are issued under 10 CFR 32.74. The medical distribution licenses (or authorizations) issued under 10 CFR 32.72 and 10 CFR 32.74 authorize distribution to medical use licensees, but do not authorize the possession and use of byproduct material.

This regulatory framework is directly applicable to longer half-life NARM radionuclides, e.g., thallium-201, cobalt-57, and palladium-103, that are produced in a few accelerator facilities for import by, or transfer to, drug manufacturers, in vitro kit manufacturers, commercial nuclear pharmacies, and sealed source producers. It is also applicable to the commercial production and distribution of PET radionuclides, e.g., fluorine-18, oxygen-15, and carbon-11, which are a special subset of NARM radionuclides. The NARM (including PET) radionuclide producers will be licensed for the production and subsequent possession and use of the NARM (or PET) radionuclides under 10 CFR Part 30. The NARM (including PET) radionuclide producer can transfer these radionuclides to other licensees under the provisions of 10 CFR 30.41. This includes distribution of NARM (or PET) radionuclides to individuals, including universities and research laboratories, for basic research but not medical use. If the NARM (including PET) radionuclide producer also uses these radionuclides to make radioactive drugs (including PET drugs) or medical sealed sources that are distributed directly to medical use licensees, then the NARM radionuclide producer also needs a 10 CFR 32.72 or 10 CFR 32.74 medical distribution

license for this purpose. These medical use licensees are authorized to use these materials on patients or human research subjects. The commercial NARM (including PET) radioactive drug or biologic manufacturer and commercial nuclear pharmacy preparing NARM (including PET) radioactive drugs and biologics will need a license (or authorization) issued under 10 CFR Part 30 and another issued under 10 CFR 32.72.

PET drugs are a special subset of NARM drugs that are characterized by the radiation they emit and usually have very short half lives. Individual hospitals and academic institutions, in addition to the commercial drug manufacturers and commercial nuclear pharmacies, may also have cyclotrons that are used to produce PET radionuclides and may prepare PET drugs from these nuclides. Although PET drugs have very short half lives, certain PET radionuclides with longer half lives can be transported from the production facility to the user's site. This permits the commercial distribution of some PET drugs (e.g., fluorine-18 glucose) to medical users that do not have a cyclotron. Even medical users with cyclotrons may purchase widely used PET drugs from commercial manufacturers or nuclear pharmacies so their cyclotrons can be used to produce other PET radionuclides. The longer half-life PET radionuclides may also be combined with nonradioactive chemicals and biologics to produce new PET drugs and biologics.

The extremely short half-life radionuclides used for medical use have to be administered immediately after production and would essentially necessitate that the cyclotron be located in the medical facility. Some hospitals form "consortiums" with adjacent or nearby hospitals to make PET radionuclides and drugs available to these associated facilities through noncommercial distributions. While the NRC's existing regulatory framework works for the commercial production and distribution of PET radionuclides and drugs, it was not developed to handle the noncommercial distribution between medical use licensees. Failure to address noncommercial distribution would impact the availability of these radioactive 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 radionuclides, drugs, and biologics among medical use licensees. In accordance with this process, a medical use facility, which uses its own cyclotron to produce PET radionuclides for use under its own medical use license, would not need a medical distribution license, but it would need to have either a separate 10 CFR Part 30 license for the PET radionuclide production facility or a 10 CFR Part 30 authorization for this production facility on its medical use license. As with other radionuclide production facilities, the radiation safety program will be reviewed in accordance with the criteria in 10 CFR 30.33. If the licensee has a broad scope authorization for 10 CFR Part 30 uses, then the program also will be reviewed in accordance with 10 CFR Part 33.

Under the new regulatory framework, if the medical use facility does not intend to commercially distribute the PET radionuclides, drugs, or biologics, but intends to transfer them to other medical facilities in its consortium, a medical distribution license is not needed, but an authorization for the noncommercial transfer of the radionuclides, drugs, and biologics to other medical use licensees is needed. With minor revisions to 10 CFR Part 35, the consortium medical use facilities would be authorized by regulation to receive these PET drugs.

The NRC is distinguishing between the “production” of PET radionuclides which requires the presence of the cyclotron and the “preparation” of PET drugs which may occur at another location. To ensure the continued availability of PET drugs, all PET centers (i.e., facilities with cyclotrons used to produce PET radionuclides), including commercial nuclear pharmacies, that are registered with FDA or a State will be authorized to produce PET radionuclides under their 10 CFR Part 30 license or 10 CFR Part 30 authorization. The NRC will review the radiation safety programs of these facilities in accordance with the criteria in 10 CFR 30.33.

To ensure availability of PET drugs from commercial nuclear pharmacy PET centers

that are not registered with the FDA or a State, these pharmacies will be authorized for PET radionuclide production if their radiation safety programs meet the criteria in 10 CFR 30.33, which includes individuals with training and experience in the production of PET radionuclides, i.e., the processes from insertion of targets in the accelerator/cyclotron beam to radiochemical isolation, purification, and testing, so that the requirements in 10 CFR 30.33(a)(3) are met. Individuals, such as radiochemists, physicists, engineers, and others with appropriate training and experience, will be recognized as authorized users under the pharmacy's 10 CFR Part 30 authorization for the production of PET radionuclides and other radionuclides using cyclotrons and other types of accelerators. This training and experience will be evaluated by the NRC through reviewing and processing of a license application on a case-by-case basis.

Authorized nuclear pharmacists will continue to be authorized to use already produced reactor-produced radionuclides, PET radionuclides, and other accelerator-produced radionuclides to prepare PET drugs and other radioactive drugs, i.e., compound PET drugs and other radioactive drugs, under the practice of pharmacy. Medical use licensees that receive PET radionuclides that are added to "cold kits" may 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.

Further, to ensure the availability of NARM (which includes PET) radioactive drugs and biologics, individuals who may include nuclear pharmacists among others, responsible for the production of PET radionuclides at the cyclotron facilities under the NRC waiver issued on August 31, 2005, will be "grandfathered" and will not be required to meet new training and experience requirements as long as their duties and responsibilities under the new license do not significantly change. When adding these individuals to a license, the applicant will be required to document that these individuals were responsible for the production of PET radionuclides using a cyclotron or accelerator during the period the waiver was in effect.

To ensure a smooth transition and availability of NARM (which includes PET) radioactive drugs, biologics, and sealed source use in medical facilities, those individuals that used only NARM byproduct materials for medical uses under the NRC's August 31, 2005, waiver will be "grandfathered" in the regulations with appropriate changes to 10 CFR Part 35.

The radiation safety knowledge needed to safely use the newly added byproduct material radionuclides for medical uses is similar to that for the existing byproduct radionuclides used in medicine. Individuals already authorized to use byproduct material in 10 CFR Part 35 are therefore authorized to use the newly added byproduct material for medical use. Further, no changes were made to the training and experience criteria in 10 CFR Part 35 for any authorized individual.

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 noncommercial distribution of these drugs by medical use licensees; (3) expanding the authorization for commercial nuclear pharmacies to produce PET radionuclides; (4) "grandfathering" current users of accelerator-produced radioactive drugs; (5) retaining the existing training and experience criteria in 10 CFR Part 35 for authorized individuals; and (6) permitting individuals to continue to prepare and use radioactive drugs while they are applying for new licenses or amendments.

The medical use of extremely short half-life radionuclides, e.g., oxygen-15, requires the radionuclide to be administered in the imaging and localization medical use area (10 CFR 35.200) immediately after the radionuclide is produced by the cyclotron. This necessitates the medical use area to be co-located with the cyclotron or to have a radionuclide delivery line from the PET radionuclide production area. This introduces the potential for a high radiation area in a medical use area that is normally considered a low radiation area. This is a unique situation

and was not envisioned when 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. These requirements are found in 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 proposed rule clarifies that an amendment would be required in the unique situation described previously if the changes involved movement of the cyclotron or a radionuclide delivery line from the PET radionuclide production area. Changes to the typical 10 CFR 35.100 and 10 CFR 35.200 medical use areas are not affected.

Consideration of NARM in 10 CFR Part 20, Appendix B.

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. Since 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. Certain dose conversion factors were not readily available. This necessitated using an alternative approach to calculate these values for nitrogen-13 and oxygen-15. 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 4×10^{-6} microcurie per milliliter (1.48×10^{-2} becquerels per milliliter) for occupational exposure and a corresponding effluent concentration of 2×10^{-8} microcurie per milliliter (7.4×10^{-4} becquerels per milliliter) for exposure of members of the public. The above calculated values are relatively close to the default values for DAC and effluent concentration and different only 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, and because the NRC's preliminary calculated DAC and effluent concentration values for both nitrogen-13 and oxygen-15 are relatively close to the default values in 10 CFR Part 20, Appendix B, the NRC is not proposing to add specific values for these radionuclides in this rulemaking.

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 (1 rem) effective dose equivalent or 0.05 sievert (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 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 proposed rule would add 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. Although 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, the requirement includes the use of the "rule of ratios" (See Footnote 1 to 10 CFR 30.72), so that licenses authorizing other byproduct material, in quantities approaching values that would require emergency planning 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 policy and requires only a minor change to the regulations to ensure that the term "low-level radioactive waste," when

used in the NRC 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 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 proposing any changes to 10 CFR Part 61 at this time, 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.

Section 651(e)(3) of the EPAct also allows that, notwithstanding the previously mentioned provisions that require the NRC licensing of the disposal of the newly added byproduct material, 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, is not affected. 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 proposing a change to its regulations in 10 CFR Part 20 that would 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.

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. 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 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 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 to cause a public health and safety concern, need to be addressed for the purposes of establishing adequate financial assurances for decommissioning leading to license termination.

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 proposed by the NRC, a general licensee may become subject to specific licensing if a large number of discrete sources of radium-226 are accumulated (e.g., more than 50 luminous products in one location). 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 individuals 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 proposing any changes in the financial assurance of the decommissioning regulation.

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 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. 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). There is not enough known about the breadth or depth of these potential radium-226 contamination situations, and how many of them exist at facilities that will apply for specific licenses, to propose any additional requirements to address them at this time. Therefore, the NRC proposes to address these situations on a case-by-case basis as they are identified following issuance of the new requirements for the newly added byproduct material.

E. *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 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 (currently $197). An application fee must generally be paid for each applicable fee category.

Additionally, all persons who hold licenses issued by NRC are subject to annual fees under 10 CFR Part 171, unless exempt under the provisions of 10 CFR 171.11. The 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 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 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), which is indicative of the safety risk and resulting regulatory costs associated with these categories of licenses. The annual fees for a materials users license (other than a master materials license) currently range from $750 for fee category 2.B (shielding) to $27,300 for fee category 7.B (broad-scope medical).

The license application fees schedule is in 10 CFR 170.31. The annual fees schedule is in 10 CFR 171.16. The fee amounts noted in this section are the FY 2005 fees which may change in July 2006, once the FY 2006 Fee Rule becomes effective.

The NRC believes that the majority of NRC licensees affected by this 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 proposing three new fee categories for activities that are currently not covered by its regulations, but are covered under this proposed rule. The new fee categories would apply to certain previously manufactured items 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 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 collecting items containing radium-226 are expected to be eligible for a general license under the proposed 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 31.12 (e.g. proper disposal of the radioactive material). However, if an individual collects more than the number of items or limits specified in this section, that individual would be required to obtain a specific license and be subject to the regulations regarding license application and annual fees. The NRC is proposing a new fee category, 3.R., with a two-tiered fee level, for those individuals 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)(3), (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 proposed 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 proposed new fee category, 3.R.1., is for individuals possessing quantities greater than the number of items or limits in 10 CFR 31.12(a)(3), (4), or (5), but less than or equal to 10 times these quantities. Since 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. would be $450 and $1,600, respectively. The second proposed new fee category, 3.R.2., is for individuals possessing quantities greater than 10 times the number of items or limits in 10 CFR 31.12(a)(3), (4), or (5). The license application and annual fees for this new category, 3.R.2., would be $1,100 and $2,500, 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 would be required to obtain a specific license and would be subject to the applicable license application and annual fees. The NRC is proposing to include 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 fee for this category is currently $3,500, and the annual fee is currently $8,200.

The NRC is proposing to add a new fee category, 3.S., for the production of accelerator-produced radioactive materials. The NRC is proposing this new fee category because these production activities need to be distinguished from those activities that only involve use of already prepared radionuclides. The estimated regulatory effort for the proposed new fee category, 3.S., would be comparable to that for fee category 3.C. The license application and annual fees for this new category would be $4,700 for the application fee and $10,200 for the annual fee.

The NRC is specifically requesting comments on the proposed fee categories and amounts. The NRC is requesting these comments based upon its assumption that the majority of existing NRC licensees covered by this rulemaking will not be impacted because the existing fee categories remain sufficient to cover all regulated activities. The NRC would like to receive comments from current NRC licensees who believe they will need to amend their licenses. Some amendments will be needed to add the new fee categories, with the attendant Parts 170 and 171 fees as a result of this rulemaking. The NRC is currently assuming that approximately 75 requests for a new license or an amendment will contain one of the new fee categories.

Additionally, the NRC requests comments from potential licensees currently not regulated by the NRC, but who may be required to obtain an NRC license as a result of this rulemaking. The NRC is interested in information on whether these licenses would fall under

the current fee categories, and/or the new fee categories proposed in this rulemaking.

Regarding the regulation of radium-226, the NRC is specifically requesting comments from private collectors of items or products containing radium-226 as to whether private collectors believe that they will remain within the boundaries of the proposed general license in 10 CFR 31.12 and whether there are private collectors who believe that they will be required to obtain a specific license.

The NRC would also like to receive comments on the proposed two-tiered fee level under fee category 3.R. Currently, the NRC estimates receiving approximately 20 new applications for tier one fee category and one new application for the tier two fee category.

The NRC would like to receive comments on the proposed new fee category, 3.S., for the production of accelerator-produced radioactive materials. The NRC is currently assuming that approximately 25 new applications will be received for this fee category. Specifically, the NRC requests comments on whether operators of production facilities agree that a new category is needed or believe that they fall into existing categories.

F. *Implementation Strategy.*

Several actions are planned or must occur coincident with, or following, the NRC issuance of final rules 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 for Agreement and non-Agreement States;

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

(3) An implementation period for users of the newly added byproduct material to come 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 intends to 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 effective through 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 States to continue to regulate this material during the applicable waiver period. All individuals 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 NRC regulatory authority for the material on August 8, 2009. The waiver may also be terminated earlier than August 8, 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 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 such an 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 three or more years to complete. If a State requests an agreement with the Commission, but the agreement cannot be established while the waiver is in effect, i.e., through August 7, 2009, a special arrangement would need to be made with the Commission for the State to continue its regulatory program over the newly added byproduct material. Without an agreement or special arrangement, regulatory authority over the newly added byproduct material will automatically remain with the Commission on the date the waiver expires, or is terminated earlier by the Commission.

If an Agreement or non-Agreement State notifies the Commission, during the waiver period, that it does not intend to continue with its regulatory program with respect to the newly added byproduct material, the NRC, in coordination with the State, will determine an appropriate date to terminate the waiver for the State. Users of the material in the State will be subject to NRC regulatory authority on the termination date of the waiver. Specific actions for users in the State to comply with the new requirements of the rule will be noticed in the Federal Register (Notification of Waiver Termination and Implementation Dates of Rule). 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 Commission intends to terminate the waiver for Government agencies and Federally recognized Indian Tribes on the effective date of the final rule because there is currently limited regulatory oversight for the newly added byproduct material at these facilities. Waiver termination is necessary in order to require Government agencies and Federally recognized Indian Tribes to comply with the new requirements and for NRC to ensure protection of public health and safety for the newly added byproduct material.

The purpose of the waiver is to allow time for the States and individuals to have an orderly transition of the regulatory authority for NARM. Terminating the waiver for the

Government agencies and Federally recognized Indian Tribes on the effective date of the final rule provides for regulatory oversight of the newly added byproduct material. A "Notification of Waiver Termination and Implementation Dates of Rule" applicable to Government agencies and Federally recognized Indian Tribes will be included with the publication of the final rule.

Implementation Period.

Although Government agencies and Federally recognized Indian Tribes are already being regulated by NRC for the AEA 11e.(1) and 11e.(2) byproduct material, the NRC is proposing a transitional period for them to submit a license amendment or a new license application for the newly added byproduct material. The proposed rule would allow 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 proposed rule contains specific provisions that would give Governmental agencies and Federally recognized Indian Tribes authority to continue to use the newly added byproduct material during the period when the waiver is terminated until the date of 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 the final rule.

For individuals owning, using, and otherwise engaging in activities involving the newly added byproduct material, the date on which compliance with the rule will be required will depend on the date of waiver termination. For certain States and individuals, 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. The NRC plans to terminate the waiver for Government agencies and Federally recognized Indian Tribes on the effective date of the final rule, and these users will be subject to the new requirements on that date. The effective date of the rule will be 60 days after the date of publication of the final rule to give the Government agencies and Federally recognized Indian Tribes time to comply with the requirements. The NRC is proposing to provide Government agencies and Federally recognized Indian Tribes 6 months from the effective date (or 8 months from the date of publication of the final rule) to apply for a license amendment for the newly added byproduct material if they hold an NRC specific byproduct materials license, and 12 months from the effective date of the final rule to submit a new license application for the newly added byproduct material if a new NRC specific byproduct materials license is needed. 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.

The NRC plans to separately solicit information from the States on their intentions concerning continuing with, or establishing new, regulatory programs for the newly added byproduct material. Users will be subject to NRC regulatory authority upon expiration or termination of the waiver if they are located either in an Agreement State that does not intend to continue its regulatory program with respect to the newly added byproduct material or in a non-Agreement State that does not enter into an agreement with the Commission under section 274b. of the AEA that covers the newly added byproduct material. For these users, the waiver termination process, specific authority, and condition to continue activities involving the newly added byproduct material will be described in the Commission's transition plan, required by Section 651(e) of the EPAct. Specific actions for these users to comply with the new

requirements of the rule will be noticed in the Federal Register (Notification of Waiver Termination and Implementation Dates of Rule). For users of the material who transition from a State regulatory program to NRC's regulatory program, the NRC expects to provide, in the notification, a similar provision allowing a 6-month period for submitting an amendment and a 12-month period for submitting a new license application provided that a license amendment or license application is submitted on or before August 7, 2009. At this time, the NRC is not aware of any Agreement State that does not intend to continue its regulatory program with respect to the newly added byproduct material. The NRC requests comments on the proposed effective date for the final rule and other implementation periods, to ensure that the affected individuals have sufficient time to come into compliance with the new requirements.

G. *Summary of Issues for Public Comment.*

The NRC is requesting additional information or comments on multiple topics. The issues and sections of this document where these issues are explained are as follows:

(1) Technical information that may be available to support an exemption for old discrete radium-226 sources. (See Section II, Item A, "Interface With Other Federal Agencies and States.")

(2) The extent that accelerators are used to intentionally produce radioactive material and provide beams for basic science research. (See Section II, Item B, subsection "Particle Accelerators.")

(3) The decommissioning of accelerator facilities including accelerator components and facility building materials that may become activated. (See Section II, Item B, subsection "Particle Accelerators.")

(4) The health and safety impact from activities involving radium-226 sources, in

particular, an alternative to the general licensing approach, such as an exemption. A technical basis supporting an exemption. (See Section II, Item D, "New General License for Certain Items and Self-Luminous Products Containing Radium-226.")

(5) Whether the majority of licensees believe they will remain in their existing fee categories. Whether potential licensees currently not regulated by NRC, but who may be required to obtain an NRC license as a result of this rulemaking, believe their licenses would fall under the current fee categories and/or the proposed fee categories. (See Section II, Item E, "License Application and Annual Fees.")

(6) Whether private collectors of items or products containing radium-226 believe these items or products will remain within the boundaries of the proposed general license and whether private collectors believe they will be required to obtain a specific license. (See Section II, Item E, "License Application and Annual Fees.")

(7) Proposed fee categories and amounts and the two-tiered fee level. (See Section II, Item E, "License Application and Annual Fees.")

(8) The proposed effective date for the final rule and other implementation periods. (See Section II, Item F, subsection "Implementation Period.")

(9) The compatibility category designations and, in particular, on the compatibility designation of the definition of *Discrete source*. (See Section V.)

(10) The environmental assessment. (See Section VIII.)

(11) Information collections aspects. (See Section IX.)

(12) Draft regulatory analysis. (See Section X.)

(13) Impacts on small businesses. (See Section XI.)

III. Section by Section Analysis of Substantive Changes

Part 20 - Standards for Protection Against Radiation.

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

Section 20.1003 Definitions.

The definition of *Byproduct material* would be 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* would be added.

A definition of *Waste* would be 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 20.2001 General requirements.

Paragraph (a)(4) would be revised to include the new 10 CFR 20.2008 which addresses disposal of waste.

Section 20.2006 Transfer for disposal and manifests.

Paragraph (e) would be added to require the use of uniform manifests for disposal of 11e.(3) and 11e.(4) byproduct material 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 would be added to Part 20 to address disposal requirements for byproduct material as defined in Sections 11e.(3) and 11e.(4) of the AEA.

Part 30 - Rules of General Applicability to Domestic Licensing of Byproduct Material.

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

Section 30.3 Activities requiring license.

This section would be 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 the NRC's waiver of 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 such 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 rule.

This section would also be 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 would revise 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* would be revised to be consistent with the new definition in the AEA, with the exception that it would not include byproduct material as defined in Section 11e.(2) of the AEA.

The following definitions would be added to this section: *Accelerator-produced*

radioactive material, *Cyclotron*, *Discrete source*, and *Particle accelerator*.

Section 30.15 Certain items containing byproduct material.

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

Section 30.18 Exempt quantities.

Paragraph (b) would be revised to include accelerator-produced radioactive material, now considered byproduct material, that might have been distributed under an authorization of a State, that was received or acquired before September 25, 1971, under the general license then provided in 10 CFR 31.4 or similar general license of a State.

Section 30.20 Gas and aerosol detectors containing byproduct material.

Paragraph (a) would be 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)(1) would be revised to accept information from sealed source or device registrations with regard to NARM issued by States under provisions comparable to 10 CFR 32.210 as a basis for licensing the use of sources and devices.

Section 30.34 Terms and conditions of licenses.

Paragraph (g) would be 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.

Section 30.71 – Schedule B.

Schedule B would be revised to include 13 radionuclides, that are now considered byproduct material, and their associated activities.

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 would be revised to specifically include radium-226 and its associated values.

Part 31 - General Domestic Licenses for Byproduct Material.

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

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

Paragraph (b)(1) would be 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) would be 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 heading and paragraph (a) would be revised to include radium-226 in this general license for calibration and reference sources.

Paragraph (b) would be revised to include radium-226 calibration or reference 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) would be revised to include an activity limit of 0.185 MBq (5 FCi) of radium-226.

Paragraph (c)(2) would be 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) would be 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) would be revised to include cobalt-57 to the list of authorized byproduct material for use in in vitro clinical or laboratory testing.

Paragraph (d) would be 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 would be 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.

A new section, 10 CFR 31.12, would be added to the regulations to add a general license for certain items and self-luminous products containing radium-226 that were manufactured prior to the effective date of the rule. The general license addresses radium-226 contained in products such as antiquities originally intended for use by the general public, luminous items installed in aircraft, luminous items no longer installed in aircraft, other luminous products including timepiece hands and dials no longer installed in timepieces, and small radium sources containing no more than 0.037 MBq (1 FCi) of radium-226.

The general license would exempt persons from the provisions of 10 CFR Parts 19, 20, and 21 to the extent that receipt, possession, use, or transfer are within the terms of the general license. However, the exemption shall not be deemed to apply to any person who is also specifically licensed by the Commission.

The general license would include requirements for notification, reporting, and disposal. The general license would prohibit abandoning the device, and it would not authorize the manufacture, assembly, disassembly, repair, or import of products containing radium-226. Export shall only be in accordance with 10 CFR Part 110.

Part 32 - Specific Domestic Licenses to Manufacture or Transfer Certain Items Containing Byproduct Material.

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

Section 32.1 Purpose and scope.

A new paragraph (c) would be 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 would allow 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 would be revised to add radium-226.

Section 32.58 Same: Labeling of devices.

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

Section 32.59 Same: Leak testing of each source.

This section would be 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) would be added to include cobalt-57, in units not exceeding 0.37 MBq (10 FCi), each, to the list of authorized byproduct material approved for distribution.

Paragraph (c)(1) would be 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 10 CFR part 35.

Paragraph (a) would be revised to ensure that the NRC regulation encompasses all byproduct, non-PET accelerator-produced radioactive material, and PET drug production facilities registered with the FDA or a State agency.

Paragraph (b) would be revised to authorize PET radionuclide production, if under the supervision of an authorized user; to recognize nuclear pharmacists who, before the effective date of the final rule, prepared only accelerator-produced radioactive drugs as authorized nuclear pharmacists under the NRC's waiver of August 31, 2005; and to allow the use of the notification process as specified in 10 CFR 35.14 for authorized nuclear pharmacists who, before the effective date of the final rule, prepared accelerator-produced radioactive drugs, and who were identified on permits issued by the master materials licensees, or on permits issued by master materials permittees of broad scope, to also work as authorized nuclear pharmacists

at a commercial nuclear pharmacy under the notification process.

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

The heading and section would be revised to include radium-226.

Part 33 – Specific Domestic Licenses of Broad Scope for Byproduct Material.

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

Section 33.100 Schedule A.

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

Part 35 - Medical Use of Byproduct Material.

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

Section 35.2 Definitions.

The definitions of *Authorized nuclear pharmacists* and *Authorized user* would be revised to encompass those individuals who, before the EPAct, only used accelerator-produced radioactive material and discrete sources of radium-226 in non-Agreement States, Agreement States, or Federal facilities that may have never been identified on a license or a permit.

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

Section 35.10 Implementation.

A new paragraph (a) would be 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 individuals using this material for medical use on when they must comply with the requirements of this part.

Section 35.11 License required.

A new paragraph (a), with the remaining paragraphs redesignated, would be 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 of August 31, 2005, to have time to apply for and receive a new medical use license. This section would provide the time period for applying for a new license.

Section 35.13 License amendments.

Paragraph (a) would be 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 of August 31, 2005, to continue to use this material provided that they submit application to amend their licenses. This section would provide the time period for amending licenses.

A new paragraph (b)(4)(v) would be added to grandfather physicians and pharmacists who only used accelerator-produced radioactive materials or discrete sources of radium-226 during the NRC's waiver of August 31, 2005.

Paragraph (e) would be 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 radionuclide delivery line from the PET radionuclide 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 would continue to be excluded from this requirement.

Section 35.14 Notifications.

Paragraph (a) would be revised to address 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 of August 31, 2005.

Paragraph (b) would be 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 radionuclide delivery line from the PET radionuclide production area.

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

Paragraph (f) would be revised to retain the existing notification exemption for addition 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 radionuclide delivery line from the PET radionuclide production area.

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) would be added to grandfather Radiation Safety Officers, medical physicists, or nuclear pharmacists who only used accelerator-produced radioactive materials or discrete sources of radium-226 during the NRC's waiver of August 31, 2005.

A new paragraph (b)(3) would be added to grandfather physicians, dentists, or podiatrists who only used accelerator-produced radioactive materials or discrete sources of radium-226 under the NRC's waiver of August 31, 2005.

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

This section would be revised to add a new provision in paragraphs (b)(2) and (c)(3) to include an NRC or Agreement State medical use licensee with a PET radionuclide production facility.

Section 35.69 Labeling of vials and syringes and transport radiation shields.

The heading would be revised to add transport radiation shields, and the section would be revised to reorganize existing text and add a new provision to address labeling requirements for medical use licensees that are authorized for noncommercial distribution of PET drugs.

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

Paragraph (a) of this section would be revised to permit medical use licensees to obtain PET radionuclides and drugs by noncommercial transfer from an NRC or Agreement State

medical use licensee with a PET radionuclide production facility.

Paragraph (b) of this section would be revised to continue to allow medical use licensees to obtain unsealed byproduct material for uptake, dilution, and excretion studies from individuals listed within this paragraph, with the exception of obtaining PET radionuclides produced by these individuals.

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

Paragraph (a) of this section would be revised to permit medical use licensees to obtain PET radionuclides and drugs by noncommercial transfer from an NRC or Agreement State medical use licensee with a PET radionuclide production facility.

Paragraph (b) of this section would be revised to continue to allow medical use licensees to obtain unsealed byproduct material for uptake, dilution, and excretion studies from individuals listed within this paragraph, with the exception of obtaining PET radionuclides produced by these individuals.

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

The heading of this section would be revised to add strontium-82 and strontium-85.

Paragraph (a) of this section would be revised to address acceptable strontium-82 and strontium-85 concentrations when eluting strontium-82/rubidium-82 generators.

Paragraph (c) of this section would be revised and redesignated, and a new paragraph (c) would be 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) of this section would be revised to permit medical use licensees to obtain PET radionuclides and drugs by noncommercial transfer from an NRC or Agreement State medical use licensee with a PET radionuclide production facility.

Paragraph (b) of this section would be revised to continue to allow medical use licensees to obtain unsealed byproduct material for uptake, dilution, and excretion studies from individuals listed within this paragraph, with the exception of obtaining PET radionuclides produced by these individuals.

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

The heading would be revised to add strontium-82 and strontium-85, and this section would be 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 would be revised to reflect the EPAct.

Section 50.2 Definitions.

The definition of *Byproduct material* would be 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 would be revised to reflect the EPAct.

Section 61.2 Definitions.

The definition of *Waste* would be 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 would be revised to reflect the EPAct.

Section 62.2 Definitions.

The definition of *Low-level radioactive waste* would be revised to correct a cross reference and 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.

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

Section 72.3 Definitions.

The definition of *Byproduct material* would be revised to be consistent with the definition in 10 CFR 30.4. This definition would be 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 would be revised to reflect the EPAct.

Section 110.2 Definitions.

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

Part 150 - Exemptions and Continued Regulatory Authority in Agreement States and in Offshore Waters Under Section 274

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

Section 150.3 Definitions.

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

A definition of *Discrete source* would be 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 would be revised to reflect the EPAct.

Section 170.3 Definitions.

The definition of *Byproduct material* would be revised to be consistent with the new definition in the AEA, with the exception that it would 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 would be revised to include licenses that would not be included in existing fee categories. Fee Category 3.B. would be revised to include licenses for repair, assembly, and disassembly of products containing radium-226. Two new fee categories, 3.R. and 3.S., would be 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 would be revised to reflect the EPAct.

Section 171.5 Definitions.

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

Section 171.16 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.

This section would be revised to include licenses that would not be included in existing fee categories. Fee Category 3.B. would be revised to include licenses for repair, assembly, and disassembly of products containing radium-226. Two new fee categories, 3.R. and 3.S., would be 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.

IV. Criminal Penalties

For the purpose of Section 223 of the Atomic Energy Act (AEA), the Commission is proposing to amend 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.

V. 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 proposed rule would be a matter of compatibility between the NRC and the Agreement States, thereby providing consistency among the Agreement States and the NRC requirements. The NRC staff analyzed the proposed 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/).

NRC program elements (including regulations) are placed into four compatibility categories (See the Draft 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 Atomic Energy Act, as amended, or provisions of Title 10 of the Code of Federal Regulations. These program elements are not adopted by 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 NRC invites comment on the compatibility category designations in the proposed rule and suggests that commenters refer to Handbook 5.9 of Management Directive 5.9 for more information. The NRC notes that, like the rule text, the compatibility category designations can change between the proposed rule and final rule, based on comments received and Commission decisions regarding the final rule. The NRC encourages anyone interested in commenting on the compatibility category designations in any manner to do so during the comment period.

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 would be amended to reflect the changes to the AEA. The definition of *Byproduct material* in Parts 50, 72, 170, and 171 is reserved to NRC. For the definition of *Byproduct material* in 10 CFR Parts 20, 30 and 150, the NRC proposes to identify it 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,” since 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 proposed rule as H&S since it is a part of the definition of *Byproduct material*. NRC specifically requests comments on the compatibility designations. In particular, NRC requests comments on whether the definitions of *Byproduct material* and *Discrete source* are correctly identified as H&S, considering the procedures in Management Directive 5.9 and considering that the EPAct redefined the term byproduct material and required the NRC to include a definition of *Discrete source* in its final regulations. If commenters believe that these definitions should not be identified as H&S, the NRC requests comment and justification for a different compatibility category under Management Directive 5.9.

Draft 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: *Waste*	-	B
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
30.3 (a)	Amend	Activities requiring license (add reference to paragraph (c))	C	C

Section	Change	Subject	Compatibility	
			Existing	New
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
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

Section	Change	Subject	Compatibility	
			Existing	New
30.4	Amend	Definition: *Byproduct material* (add 11e.(3) & 11e.(4) material)	[A]	[H&S]
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)	B (all § 30.15)	B
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)(1)	Amend	Application for specific licenses	C	C
30.34 (g)	Amend	Terms and conditions of licenses (add strontium-82/rubidium-82 generators)	D	H&S
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
31.5 (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

Section	Change	Subject	Compatibility	
			Existing	New
31.11	Amend	General license for use of byproduct material for certain in vitro clinical or laboratory testing (add cobalt-57)	D	D
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 cobalt-57, radium-226, & sodium-22)	D	D
35.2	Amend	Definition: *Authorized nuclear pharmacist* (recognize pharmacist, who used 11e.(3) material)	B	B
35.2	Amend	Definition: *Authorized user* (recognize authorized user, who used 11e.(3) material)	B	B
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

Section	Change	Subject	Compatibility	
			Existing	New
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
35.13 (a)(1)	Amend	License amendments (authorize medical use of 11e.(3) materials by Government agecies 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 materials while applying for amendment)	-	D
35.13 (b)(4)(v)	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

Section	Change	Subject	Compatibility	
			Existing	New
35.57 (a)(3) & (b)(3)	Amend	Training for experienced Radiation Safety Officer, teletherapy or medical physicist, authorized user, and nuclear pharmacist (grandfather RSO, who used 11e.(3) material)	B	B
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
35.63 (b)(2)(iii)	Add	Determination of dosages of unsealed byproduct material for medical use (recognize State licenses of PET facilities)	-	H&S
35.69 (b)	Add	Labeling of vials and syringes (to include PET drugs)	H&S	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

Section	Change	Subject	Compatibility	
			Existing	New
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
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 Part 170 address areas that generally are applicable only to NRC's regulatory program; therefore, no compatibility designation is assigned.				
170.3	Amend	Definition: *Byproduct material* (add 11e.(3) & 11e.(4) material)	-	-
170.31 Table: 3B	Amend	Other licenses for possession and use of byproduct material issued under Part 30 (revise to include radium-226)	-	-
170.31 Table: 3R.1.	Add	Possession of items or products containing radium-226 (add a new fee category)	-	-

Section	Change	Subject	Compatibility	
			Existing	New
170.31 Table: 3R.2.	Add	Possession of items or products containing radium-226 (add a new fee category)	-	-
170.31 Table: 3S	Add	License for production of accelerator-produced radionuclides (add a new fee category)	-	-
10 CFR Part 171 address areas that generally are applicable only to NRC's regulatory program; therefore, no compatibility designation is assigned.				
171.5	Amend	Definition: *Byproduct material* (add 11e.(3) & 11e.(4) material)	-	-
171.16 Table: 3B	Amend	Other licenses for possession and use of byproduct material issued under Part 30 (revise to include radium-226)	-	-
171.16 Table: 3R	Add	Possession of items or products containing radium-226 (add a new fee category)	-	-
171.16 Table: 3S	Add	License for production of accelerator-produced radionuclides (add a new fee category)	-	-

VI. Plain Language

The Presidential Memorandum dated June 1, 1998, entitled "Plain Language in Government Writing," directed that the Government's writing be in plain language. The NRC requests comments on this proposed rule specifically with respect to the clarity and effectiveness of the language used. Comments should be sent to the address listed under the heading "ADDRESSES" above.

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 proposed rule, the NRC would assume 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 required 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 proposed 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 the proposed rule.

VIII. Environmental Assessment and Finding of No Significant Environmental Impact: Availability

The Commission is preparing an environmental assessment to determine if an environmental impact statement would be required for this proposed rule. Under the National Environmental Policy Act of 1969, as amended, and the Commission's regulations in Subpart A of 10 CFR Part 51, an environmental impact statement is required if this proposed rule, if adopted, is likely to be a major Federal action significantly affecting the quality of the

human environment.

Amendments to the NRC's regulations would incorporate new materials into the NRC's byproduct material regulatory program or establish new program elements, if needed. Before the EPAct, the regulation of naturally occurring and accelerator-produced radioactive material (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 proposed amendments to the NRC regulations would provide a uniform regulatory environment for the acquisition, possession, use, transfer, and disposal of NARM. This uniform regulatory environment would be 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 would start with the existing generic requirements for accelerator-produced radioactive material that had already been developed by the States for the SSRs, little, if any, change is expected to the byproduct material regulatory programs already in place for Agreement States. Consequently, for Agreement States, the primary foreseeable impact of the regulatory changes applicable to accelerator-produced radioactive material is that the regulations would be uniformly applied by all Agreement States. Therefore, for the regulation of accelerator-produced radioactive material by the Agreement States, the proposed amendments to the NRC regulations, if adopted, are not expected to have any adverse environmental impacts.

In non-Agreement States, the proposed amendments to the NRC regulations would most likely 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, if any, the result would most 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 would most likely continue with its current practice, and no substantial impact on the environment would be anticipated. Therefore, it is expected that the overall environmental impacts of the proposed regulation of accelerator-produced radioactive material by non-Agreement States, if adopted, would be positive.

The effects of the proposed amendments to the NRC regulations applicable to discrete sources of radium-226 and discrete sources of other naturally occurring radioactive material would 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 would 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 proposed NRC regulations applicable to discrete sources of naturally occurring radioactive material, if adopted, is anticipated to be beneficial to the environment, and it is expected that the overall environmental impacts would be positive.

Therefore, the preliminary determination of this environmental assessment is that there will be no significant impact to the public from this action. However, the general public should note that the NRC welcomes public participation. Comments on any aspect of the environmental assessment may be submitted to the NRC as indicated under the ADDRESSES heading.

The NRC has sent a copy of the environmental assessment and this proposed rule to every State Liaison Officer and request their comments on the environmental assessment. The environmental assessment may be examined at the NRC Public Document Room, O-1F21, 11555 Rockville Pike, Rockville, MD. Single copies of the environmental assessment will be

available from Lydia Chang, Office of Nuclear Material Safety and Safeguards, U.S. Nuclear Regulatory Commission, Washington, DC 20555-0001, telephone (301) 415-6319, e-mail lwc1@nrc.gov.

IX. Paperwork Reduction Act Statement

This proposed 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 information collection requirements have been submitted to the Office of Management and Budget for review and approval. The proposed changes to 10 CFR Parts 33, 50, 61, 62, 72, 110, 150, 170 and 171 do not contain new or amended information collection requirements.

Type of submission, new or revision: Revision.

The title of the information collection: 10 CFR Parts 20, 30, 31, 32, 33, 35, 50, 61, 62, 72, 110, 150, 170, and 171, "Requirements for Expanded Definition of Byproduct Material."

The form number if applicable: Not applicable.

How often the collection is required: Initially, periodically based on regulated activity, quarterly, annually, and at license termination.

Who will be required or asked to report: New licensees that operate certain linear accelerators or cyclotrons for the purposes of producing radionuclides, new licensees that manufacture or transfer certain items containing discrete radium-226 sources, new licensees that possess products that contain radium-226 sources, and existing licensees who may have additional testing, labeling, or reporting requirements due to their possession of radioactive material that fits the definition of expanded definition of byproduct material.

An estimate of the number of annual responses: 1,431 (10 CFR 19 - 150 responses; 10 CFR 20 - 183 responses; 10 CFR 30 - 122 responses; 10 CFR 31 - 203 responses; 10 CFR 32 - 22 responses; 10 CFR 35 - 751 responses).

The estimated number of annual respondents: 744.

An estimate of the total number of hours needed annually to complete the requirement or request: The total burden increase for this rulemaking is 29,425 hours (10 CFR 19 - 3,911 hours; 10 CFR 20 - 6,539 hours; 10 CFR 30 - 4,928 hours; 10 CFR 31 - 127 hours; 10 CFR 32 - 8,643 hours; 10 CFR 35 - 5,277 hours.

Abstract: The NRC is proposing to amend its regulations to include jurisdiction over certain radium sources, accelerator-produced radioactive materials, and certain naturally occurring radioactive material, as required by the EPAct, which was signed into law on August 8, 2005. Section 651(e) of the EPAct expanded the AEA 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, 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 in a commercial, medical, or research activity. In so doing, these materials were placed under the NRC's regulatory authority. Section 651(e) of the EPAct also mandated that the Commission, after consultation with States and other stakeholders, issue final regulations establishing requirements that the Commission determines necessary to carry out this section and the amendments made by this section. This rulemaking effort is being 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 OAS, and the CRCPD. In addition, the NRC considers and uses to the maximum extent practicable the CRCPD's applicable SSRs in developing this proposed rule. Licensees and individuals who are engaged in activities involving the newly defined byproduct material in Agreement States and non-Agreement States and U.S. Territories may be affected by this rulemaking. Only 10 CFR Parts 19, 20, 30, 31, 32, and 35 would have an impact on the information collection requirements.

The U.S. Nuclear Regulatory Commission is seeking public comment on the potential impact of the information collections contained in the proposed rule and on the following issues:

1. Is the proposed information collection necessary for the proper performance of the functions of the NRC, including whether the information will have practical utility?
2. Is the estimate of burden accurate?
3. Is there a way to enhance the quality, utility, and clarity of the information to be collected?

4. How can the burden of the information collection be minimized, including the use of automated collection techniques?

A copy of the OMB clearance package may be viewed free of charge at the NRC Public Document Room, One White Flint North, 11555 Rockville Pike, Room O-1 F21, Rockville, MD 20852. The OMB clearance package and rule are available at the NRC worldwide Web site: http://www.nrc.gov/public-involve/doc-comment/omb/index.html for 60 days after the signature date of this notice and are also available at the rule forum site, http://ruleforum.llnl.gov.

Send comments on any aspect of these proposed information collections, including suggestions for reducing the burden and on the above issues, by **[insert date 30 days after publication in the Federal Register]** to the Records and FOIA/Privacy Services Branch (T-5F53), U.S. Nuclear Regulatory Commission, Washington, DC 20555-0001, or by Internet electronic mail to INFOCOLLECTS@NRC.GOV and to the Desk Officer, John A. Asalone, Office of Information and Regulatory Affairs, NEOB-10202 (3150-0014, 0017, 0016, 0001, 0015, 0010, 0011, 0135, 0143, 0132, 0032), Office of Management and Budget, Washington, DC 20503. Comments received after this date will be considered if it is practical to do so, but assurance of consideration cannot be given to comments received after this date. You may also e-mail comments to John_A._Asalone@omb.eop.gov or comment by telephone at (202) 395-4650.

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 draft regulatory analysis on this proposed regulation. The draft regulatory analysis examines the costs and benefits of the alternatives considered by the Commission.

The Commission requests public comment on the draft regulatory analysis. Comments on the draft regulatory analysis may be submitted to the NRC as indicated under the ADDRESSES heading. The draft 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 Nuclear Material Safety and Safeguards, 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 would not, if promulgated, 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 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. However, the proposed 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 draft regulatory analysis, the NRC believes that the selected alternative reflected in the proposed 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.

Because of the broad spectrum of products and uses for this newly defined byproduct material and the potential impact to a wide population of individuals, businesses, and licensees, the NRC is specifically requesting public comment concerning the impact of the proposed regulation. The NRC particularly desires comment from individuals, businesses, or licensees, who qualify as small businesses, as to how the proposed regulation will affect them and how the requirements imposed on small entities may be modified to be less stringent while still adequately protecting the public health and safety. Comments on how the regulation could be modified to take into account the differing needs of small entities should specifically discuss:

1. Are small businesses likely to be affected by the proposed regulations? If so, for

what types of material and/or equipment that are currently, or may potentially be, used (e.g., accelerators, cyclotrons, radium sources)? How many small businesses would be affected by the proposed regulations?

2. If small businesses are likely to be affected by the proposed regulations, is the significance of the potential economic burden related to the size of the business? If so, how? How does this burden compare to larger organizations in the same business community?
3. How could the proposed regulations be modified to take into account the differing needs or capabilities of small businesses while maximizing potential benefits and minimizing the potential economic burden? What would be the approximate level of benefits to your entity if this change was made in the proposed rule?
4. How would these modifications to the proposed regulations (from question 3) act to more closely equalize the impact of the regulations or create more equal access to the benefits as opposed to providing special advantages to any individuals or groups?
5. Would these modifications (from question 3) act to increase, maintain, or decrease the NRC's ability to adequately protect public health and safety? How?

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 proposed rule because this amendment would not involve any provisions that would impose backfits as defined in 10 CFR Chapter 1. Therefore, a backfit analysis is not

required.

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, Non-payment 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. 553; the NRC is proposing to adopt 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. 806-10 (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 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 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 material will be used for its radiological properties.

* * * * *

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 § 20.2001, 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.

* * * * *

4. In § 20.1009, paragraph (b) is revised to read as follows:

§ 20.1009 Information collection requirements: OMB approval.

(a) * * *

(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, 20.2102, 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, 20.2008, 20.2301, and appendix G to this part.

* * * * *

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 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.

PART 30 - RULES OF GENERAL APPLICABILITY TO DOMESTIC LICENSING OF BYPRODUCT MATERIAL

7. 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. 806-10 (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).

8. 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 **[DATE 60 DAYS AFTER DATE OF PUBLICATION OF 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 **[DATE 8 MONTHS AFTER DATE OF PUBLICATION OF 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 tribe submits an application for a license authorizing activities involving these materials on or before **[DATE 1 YEAR AND 2 MONTHS AFTER DATE OF PUBLICATION OF 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 individual submits an amendment application on or before August 7, 2009, or earlier as noticed by the NRC.

(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 individual submits a license application on or before August 7, 2009, or earlier as noticed by the NRC.

(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.

9. In § 30.4, the definition of *Byproduct material* is revised, and the definitions of *Accelerator-produced radioactive material*, *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.

* * * * *

Cyclotron means a circular particle accelerator in which charged particles are bent traveling through the accelerator. 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 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 material will be used for its radiological properties.

* * * * *

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.

* * * * *

10. 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 **[DATE 60 DAYS AFTER THE DATE OF PUBLICATION OF THE FINAL RULE]**.

* * * * *

11. 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 for accelerator-produced radioactive material, 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 of this chapter to the extent that this person possesses, uses, transfers, or owns byproduct material.

* * * * *

12. 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 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 manufactures, processes, produces, or initially transfers 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 **[DATE 60 DAYS AFTER THE DATE OF PUBLICATION OF THE 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.

* * * * *

13. In § 30.32, paragraph (g)(1) is revised 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 with a State regarding source or device containing radium-226 or accelerator-produced radioactive material under provisions comparable to § 32.210 of this chapter; or

* * * * *

14. In § 30.34, paragraph (g) is revised 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.

* * * * *

15. 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 and numerical order by isotope 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
* * * * *	

16. 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

17. 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. 806-10 (42 U.S.C. 2014, 2021, 2021b, 2111).

18. In § 31.4, paragraph (b) is revised to read as follows:

§ 31.4 Information collection requirements: OMB approval.

(a) * * *

(b) The approved information collection requirements contained in this part appear in §§ 31.5, 31.8, 31.11, and 31.12.

* * * * *

19. In § 31.5, paragraphs (b)(1)(i), (b)(1)(ii), and (c)(13)(i) are revised and (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.

* * * * *

(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.

* * * * *

(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.

* * * * *

20. 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 these 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 RADIUM-226, as appropriate]. DO NOT TOUCH RADIOACTIVE PORTION OF THIS SOURCE.

_____

(Name of manufacturer or initial transferor)

---

[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 **[DATE 60 DAYS AFTER THE DATE OF PUBLICATION OF THE FINAL RULE]** shall be labeled in accordance with the applicable State regulations at the time of manufacture or import.

(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.

21. 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 **[DATE 60 DAYS AFTER THE DATE OF PUBLICATION OF THE FINAL RULE]**, 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]

22. 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 **[DATE 60 DAYS AFTER DATE OF PUBLICATION OF 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) Luminous items installed in aircraft.

(3) Luminous items no longer installed in aircraft, provided that no more than 100 are used or stored at the same location at any one time.

(4) Other luminous products including timepiece hands and dials no longer installed in timepieces, provided that no more than 50 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 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, 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 parts 19, 20, and 21, 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 Nuclear Material Safety and Safeguards, 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 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 Nuclear Material Safety and Safeguards, 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.

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

23. 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. 806-10 (42 U.S.C. 2014, 2021, 2021b, 2111).

24. 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 **[DATE 60 DAYS AFTER DATE OF PUBLICATION OF 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 or part 35 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 **[DATE 1 YEAR AND 2 MONTHS AFTER DATE OF PUBLICATION OF FINAL RULE]** or an amendment application for these activities on or before **[DATE 8 MONTHS AFTER DATE OF PUBLICATION OF 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 (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 or part 35 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 individual submits a license application or amendment on or before August 7, 2009, or earlier as noticed by the NRC.

25. 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:

* * * * *

26. 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.

_____

(Name of manufacturer or initial transferor)

27. Section 32.59 is revised to read as follows:

[1]Sources licensed under § 32.57 before January 19, 1975, may bear labels authorized by the regulations in effect on January 1, 1975.

§ 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.

28. 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

* * * * *

29. In § 32.72, paragraphs (a)(2)(i), (a)(2)(iii), (a)(2)(iv), and (b) 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) A licensee described by paragraph (a)(2)(iii) or (iv) of this section:

(1) May produce Positron Emission Tomography (PET) radionuclides provided that the PET radionuclide production is under the supervision of an authorized user who meets the

requirements of § 30.33(a)(3) of this chapter.

(2) May prepare radioactive drugs for medical use, as defined in § 35.2 of this chapter, provided that the radioactive drugs are prepared by either an authorized nuclear pharmacist, as specified in paragraphs (b)(3) and (b)(5) of this section, or an individual under the supervision of an authorized nuclear pharmacist as specified in § 35.27 of this chapter.

(3) May allow a pharmacist to work as an authorized nuclear pharmacist if:

(i) This individual qualifies as an authorized nuclear pharmacist as defined in § 35.2 of this chapter;

(ii) This individual meets the requirements specified in §§ 35.55(b) and 35.59, and the licensee has received an approved license amendment identifying this individual as an authorized nuclear pharmacist; or

(iii) This individual is designated as an authorized nuclear pharmacist in accordance with paragraph (b)(5) of this section.

(4) The actions authorized in paragraphs (b)(1), (b)(2), and (b)(3) of this section are permitted in spite of more restrictive language in license conditions.

(5) 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 **[DATE 60 DAYS AFTER DATE OF PUBLICATION OF FINAL RULE]** or at all other pharmacies before August 8, 2009, or an earlier date as noticed by the NRC.

(6) Shall provide to the Commission a copy of each individual's certification by the Board of Pharmaceutical Specialties, the Commission or Agreement State license, Commission master materials licensee permit, 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, and a copy of the state pharmacy licensure or registration, no later than 30 days after the date that the licensee allows, pursuant to paragraphs (b)(3)(i) and (b)(3)(iii) of this section, the individual to work as an authorized nuclear pharmacist.

* * * * *

30. 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

31. 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. 806-10 (42 U.S.C. 2014, 2021, 2021b, 2111).

32. 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

33. 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. 806-10 (42 U.S.C. 2014, 2021, 2021b, 2111).

34. In § 35.2, the definitions for *Authorized nuclear pharmacist* and *Authorized user* are revised, and new definitions for *Cyclotron* and *Positron Emission Tomography (PET) radionuclide production facility* are added alphabetically to read as follows:

§ 35.2 Definitions.

* * * * *

Authorized nuclear pharmacist means a pharmacist who--

(1) Meets the requirements in §§ 35.55(a) and 35.59; or

(2) Is identified as an authorized nuclear pharmacist on--

(i) A specific license issued by the Commission or Agreement State that authorizes medical use or the practice of nuclear pharmacy;

(ii) A permit issued by a Commission master material licensee that authorizes medical use or the practice of nuclear pharmacy;

(iii) A permit issued by a Commission or Agreement State broad scope medical use licensee that authorizes medical use or the practice of nuclear pharmacy; or

(iv) A permit issued by a Commission master material license broad scope medical use permittee that authorizes medical use or the practice of nuclear pharmacy; or

(3) Is identified as an authorized nuclear pharmacist by a commercial nuclear pharmacy that has been authorized to identify authorized nuclear pharmacists; or

(4) Is designated as an authorized nuclear pharmacist in accordance with § 32.72(b)(5) of this chapter; or

(5) Prepared only radioactive drugs containing accelerator-produced radioactive materials at a pharmacy at a Government agency or Federally recognized Indian Tribe before **[DATE 60 DAYS AFTER DATE OF PUBLICATION OF FINAL RULE]** or at all other pharmacies before August 8, 2009, or an earlier date as noticed by the NRC.

Authorized user means a physician, dentist, or podiatrist who--

(1) Meets the requirements in §§ 35.59 and 35.190(a), 35.290(a), 35.390(a), 35.392(a), 35.394(a), 35.490(a), 35.590(a), or 35.690(a); or

(2) Is identified as an authorized user on–

(i) A Commission or Agreement State license that authorizes the medical use of byproduct material;

(ii) A permit issued by a Commission master material licensee that is authorized to permit the medical use of byproduct material;

(iii) A permit issued by a Commission or Agreement State specific licensee of broad scope that is authorized to permit the medical use of byproduct material; or

(iv) A permit issued by a Commission master material license broad scope permittee that is authorized to permit the medical use of byproduct material; or

(3) Used only accelerator-produced radioactive materials, discrete sources of radium-226, or both, for medical uses at a Government agency or Federally recognized Indian Tribe before **[DATE 60 DAYS AFTER DATE OF PUBLICATION OF 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.

* * * * *

Cyclotron means a circular particle accelerator in which charged particles are bent traveling through the accelerator. 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.

* * * * *

35. 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 **[DATE 60 DAYS AFTER DATE OF PUBLICATION OF 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.

* * * * *

36. 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 individual submits a medical use license application on or before **[DATE 1 YEAR AND 2 MONTHS AFTER DATE OF PUBLICATION OF 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 individual submits a medical use license application on or before August 7, 2009, or earlier as noticed by the NRC.

37. In § 35.13, paragraphs (a) and (e) are revised and paragraph (b)(4)(v) 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 **[DATE 8 MONTHS AFTER DATE OF PUBLICATION OF FINAL RULE]**.

(2) Except as provided in (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 individual submits a medical use license application on or before August 7, 2009, or earlier as noticed by the NRC.

(b) * * *

(4) * * *

(v) An individual who uses only accelerator-produced radioactive materials, discrete sources of radium-226, or both, for medical use or in the practice of nuclear pharmacy at a Government agency or Federally recognized Indian Tribe before **[DATE 60 DAYS AFTER DATE OF PUBLICATION OF 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 radionuclide delivery line from the PET radionuclide production area. Other areas of use where byproduct material is used only in accordance with either § 35.100 or § 35.200 are exempted;

* * * * *

38. 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 **[DATE 60 DAYS AFTER DATE OF PUBLICATION OF 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 radionuclide delivery line from the PET radionuclide production area.

* * * * *

39. 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) regarding additions to or changes in the areas of use identified in the application, or on the license where byproduct material is used in accordance with either § 35.100 or § 35.200, if the change does not include addition or relocation of either an area where PET radionuclides are produced or a radionuclide delivery line from the PET radionuclide production area.

* * * * *

40. 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 **[DATE 60 DAYS AFTER DATE OF PUBLICATION OF 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.

(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 **[DATE 60 DAYS AFTER DATE OF**

PUBLICATION OF 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.

41. 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) An NRC or Agreement State medical use licensee with a PET radionuclide production facility.

(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) An NRC or Agreement State medical use licensee with a PET radionuclide production facility.

* * * * *

42. Section 35.69 is revised to read as follows:

§ 35.69 Labeling of vials and syringes and transport radiation shields.

(a) Each syringe and vial used for medical use that contains unsealed byproduct material must be labeled to identify the radioactive drug. Each syringe shield and vial shield must also be labeled unless the label on the syringe or vial is visible when shielded.

(b) Each label affixed to a transport radiation shield or syringe, vial, or other container used to hold a PET drug to be transferred for noncommercial distribution by the medical use licensee shall meet the requirements in 10 CFR 32.72(a)(4).

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;

(2) The licensee's noncommercial PET radionuclide production facility; or

(3) The noncommercial transfer of a PET radionuclide or drug from an NRC or Agreement State medical use licensee with a PET radionuclide production facility; 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;

(2) The licensee's noncommercial PET radionuclide production facility; or

(3) The noncommercial transfer of a PET radionuclide or drug from an NRC or Agreement State medical use licensee with a PET radionuclide production facility; 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;

(2) The licensee's noncommercial PET radionuclide production facility; or

(3) The noncommercial transfer of a PET radionuclide or drug from an NRC or Agreement State medical use licensee with a PET radionuclide production facility; 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. 806-10 (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. 806-10 (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. 806-10 (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 is revised 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. 806-10 (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 to read as follows:

§ 110.2 Definitions.

* * * * *

Accelerator-produced radioactive material means any material made radioactive by a particle accelerator.

* * * * *

Discrete source means 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 material will be used for its radiological properties.

* * * * *

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. 806-10 (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 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 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 material will be used for its radiological properties.

* * * * *

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. 806-10 (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 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	$3,500.
* * * * *	
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.[5]	
1. Possession of quantities exceeding the number of items or limits in 10 CFR 31.12(a)(3), (4), or (5) but less than or equal to 10 times the number of items or limits specified.	
Application	$450.
2. Possession of quantities exceeding 10 times the number of items or limits specified in 10 CFR 31.12(a)(3), (4), or (5).	
Application	$1,110.
S. Licenses for production of accelerator-produced radionuclides.	
Application	$4,700.
* * * * *	

* * * * *

[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 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.

* * * * *

[5] 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).

62. 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.

* * * * *

63. In § 171.16, paragraph (d), in the table, Schedule of Materials Annual Fees and Fees for Government Agencies Licensed by NRC, paragraph 3.B. is revised, and new

categories 3.R. and S. and corresponding fees are added to read as follows:

§ 171.16 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.

* * * * *

Schedule of Materials Annual Fees and Fees for Government Agencies Licensed by 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.		
		Application	8,200
* * * * *			
	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)(3), (4), or (5) but less than or equal to 10 times the number of items or limits specified.	1,600
		2. Possession of quantities exceeding 10 times the number of items or limits specified in 10 CFR 31.12(a)(3), (4), or (5).	2,500

	S. Licenses for production of accelerator-produced radionuclides.	10,200
	* * * * *	
	* * * * *	

[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 licenses 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 _____, 2006.

For the Nuclear Regulatory Commission.

_____
Annette L. Vietti-Cook,
Secretary for the Commission.

Environmental Assessment for Proposed Rulemaking - Expanded Definition of Byproduct Material Established by Section 651(e) of the Energy Policy Act of 2005

Draft Report

U.S. Nuclear Regulatory Commission

Table of Contents

ACRONYMS/ABBREVIATIONS

AEA	Atomic Energy Act of 1954
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
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

Environmental Assessment for
Proposed Rulemaking - Expanded Definition of Byproduct Material
Established by Section 651(e) of the Energy Policy Act of 2005

1.0 INTRODUCTION

The U.S. Nuclear Regulatory Commission (NRC) is proposing to amend 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" (hereafter referred to as NARM), placing these byproduct materials under NRC authority. The EPAct also required the NRC to provide a regulatory framework for licensing and regulating NARM. The NRC has prepared this environmental assessment to determine whether the promulgation of the proposed rule, which provides 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 radioactivity used in human activity, includes the 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, which was 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 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 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 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 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 for use for a commercial, medical, or research activity; and
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> (4) any discrete source of naturally occurring radioactive material, other than source material, that —
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> (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
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> (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 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).

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 radiological materials was established by the AEA, as amended. The AEA authorizes States to assume regulatory control of radiological 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 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. Currently, there are 34 Agreement States and 16 non-Agreement States, plus U. S. territories. (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. 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 existing AEA definition of byproduct material.

Need for the Proposed 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 allows the NRC 18 months from the effective date of the Act to promulgate regulations to establish a national program for NARM.

The Proposed 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 proposing to incorporate NARM in 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 proposing to amend its regulations governing the receipt, possession, use, storage, transfer, and disposal of NARM to conform with this expanded byproduct material definition. The proposed action would 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 proposed amendments address:

- revising the byproduct material definition to reflect the expanded definition provided in Section 651(e) of the EPAct;
- defining new terms for accelerator-produced radioactive material, authorized nuclear pharmacist, authorized user, cyclotron, discrete source, 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 NARM;
- specifying NARM packaging and labeling requirements;
- specifying requirements for manufacture, preparation, and transfer of radioactive drugs containing NARM;
- delineating licensing requirements for persons who manufacture, produce, acquire, receive, possess, prepare, use, or transfer NARM-containing medical products; including provisions for obtaining license amendments;
- specifying training requirements for medical professionals using NARM; and
- specifying testing requirements for sources containing NARM.

2.0 PROPOSED ACTION AND ALTERNATIVES

To define the alternatives to be 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 proposed 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 preferred alternative, which reflects the staff's proposed approach for accomplishing the EPAct's requirements; and a third alternative that would implement the requirements specifically mandated by the Act and any additional regulatory authority included within the bounds allowed by the flexibility within the EPAct.

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 promulgating the regulations. The NARM regulations for most Agreement States are based on model regulations, known as the 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 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 licenses 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 other NORM.

Section 651(e) of the EPAct requires the Commission to promulgate 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 NRC can base the proposed rule.

Section 651(e) of the EPAct requires the Commission to include, as byproduct material, certain accelerator-produced radioactive material, hereafter referred to as "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 the production of radioactive material (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 other NORM in the expanded definition of byproduct material. A discrete source would be defined to include a concentrated radioactive material source with physical boundaries, which is separate and distinct from the radiation present in nature. The flexibility allowed by this requirement relates to the purpose for which the material is concentrated. A general discrete source definition would 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 non-radiological products, such as fertilizer, fly ash, or purified water. A more limited discrete source definition would only include radioactive material that was concentrated with the intent of using its radiological 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 the regulations. This requirement does not prescribe how to consider the potential impact of the proposed 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 requirements for the proposed regulations. Although the EPAct allows flexibility in considering the proposed 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, the proposed action and alternatives 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 proposed 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 promulgate regulations that apply the highest degree of regulatory authority allowed by the EPAct; and (3) to promulgate regulations that apply a graded approach to the regulatory authority allowed by the EPAct. The following provides a more detailed discussion of each alternative, and Section 4.0 provides the basis for choosing Alternative 3 as the proposed 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 achievable, as this rulemaking activity is Congressionally mandated; however, this alternative provides the baseline against which the other alternatives will be assessed.

Alternative 2: Revise Regulations to Maximize NRC's Regulatory Authority

This alternative would promulgate regulations to implement the requirements specifically required by the EPAct and any additional regulatory authority 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 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 action: (1) applying its established regulatory framework to the commercial distribution of these drugs; (2) expanding the regulations to permit noncommercial distribution of these drugs by medical use licensees; (3) expanding the authorization for commercial nuclear pharmacies to produce PET radionuclides; (4) "grandfathering" current users of accelerator-produced drugs; and (5) permitting individuals 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. Based on information obtained by the staff during the development of this rule, it is understood that SSRs do exist that address naturally occurring radioactive material, but that there appear to be few model State regulations at the national consensus level specific to accelerator-produced radioactive material. In general, with the exception of general licensing requirements for cobalt-57 sources and contamination levels for strontium-82/rubidium-82 generators for medical use, SSR requirements for accelerator-produced radioactive material are the same as for reactor-produced radioactive material. The SSRs include an exemption for timepieces and other articles containing 37 kilobecquerels (kBq) (1 microcurie (μCi)) of radium-226, a requirement to allow a specifically licensed individual to possess up to 185 kBq (5 μCi) of radium-226 calibration sources under a general license, and a limit of 3.7 kBq (0.1 μCi) of radium-226 that may be incorporated into smoke detectors distributed under an exempt license. 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 license. 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 sources would be defined broadly to include any concentrated radium-226 or other NORM, regardless of whether it was concentrated intentionally for its radiological properties or incidentally from a process that extracts or produces non-radiological products. This definition would not limit the NRC's jurisdiction to only

include radionuclides that are concentrated and used purposefully for their radiological properties. This more general definition would divert the staff's regulatory efforts away from those materials that pose the greatest health and security risk by including a vast 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.

Alternative 3: Revise Regulations to Apply a Graded Regulatory Authority over NARM

The NRC proposes an alternative that would promulgate regulations to apply a graded regulatory authority over NARM by focusing the staff's regulatory responsibilities 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 would address 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 would be based, to the maximum extent practicable, on the SSRs.

This proposed alternative would include 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 proposed alternative would also accommodate generally licensed devices meeting the restrictions of the general licenses that were previously approved by States under existing regulations. This proposed alternative would regulate accelerator-produced radioactive material under the same requirements as reactor-produced radioactive material. Additionally, this proposed alternative would add 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 proposed alternative would make no changes to the exempt concentrations for radionuclides included in the SSRs, and would adopt appropriate values for exempt quantities for the newly defined byproduct material. This proposed alternative would also adopt an exemption for timepieces or other articles containing 37 kBq (1 μCi) or less of radium-226 and would adopt the requirement to allow a specifically licensed individual to possess up to 185 kBq (5 μCi) of radium-226 calibration sources under a general license.

Under this proposed alternative, discrete sources would be defined to include only radioactive material that was concentrated with the intent of using its radiological properties. This proposed definition of 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

concentrated, and purposefully used for their radiological properties. This proposed definition would limit 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. Once a radioactive material, defined as a discrete source, becomes byproduct material, it will continue to be regulated as byproduct material, even if the discrete source is leaking or broken, or no longer has a physical boundary. Contamination resulting from a breach of the physical boundaries containing a discrete source would continue to be regulated as byproduct material.

Under this proposed alternative, the NRC would 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 proposed 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 neutron radiography used for medical imaging). 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 proposed 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 proposed rule.

The regulatory framework and implementation process associated with radiopharmaceuticals under this proposed alternative would be the same as that described previously for Alternative 2. This proposed 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 action: (1) applying its established regulatory framework to the commercial distribution of these drugs; (2) expanding the regulations to permit noncommercial distribution of these drugs by medical use licensees; (3) expanding the authorization for commercial nuclear pharmacies to produce PET radionuclides; (4) "grandfathering" current users of accelerator-produced drugs; and (5) permitting individuals to continue to prepare and use radioactive drugs while they are applying for new licenses or amendments.

Under the proposed 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.

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 current regulatory framework, NRC does not regulate NORM radionuclides (except source material), 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 through 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 radioactive properties, radium-226 poses a potential threat to public health and safety if not managed safely and securely.

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. 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 radioactive 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 produce only 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 very precise 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, reactor-produced byproduct material radionuclides are imported into the U.S., where they are used to produce specific radioactive drugs and 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 produces 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.

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 the 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 materials 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 requires licensees to consider other non-discrete sources, including radium, during decommissioning activities at NRC-licensed sites contaminated with source material, such as rare-earth processing 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 an unnamed 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. 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 will allow accommodation of generally licensed devices meeting the restrictions of the general licenses that were previously approved by States under comparable provisions of 10 CFR 32.51.

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 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 current regulatory structure provides the NRC control over byproduct material only if it is produced in a nuclear reactor or included in ore 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 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. (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. 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.

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 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 Department of Labor has the oversight for occupational health and safety for non-AEA materials, including regulations addressing exposure of minors to radioactive material in the workplace. 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 (including drugs containing radioactive materials) by requiring accepted manufacturing practices to assure the purity, potency, and consistency of finished drugs in establishing the safety and effectiveness of these drugs.

4.0 ENVIRONMENTAL IMPACTS

The proposed amendments would 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 proposed alternative would apply a graded licensing approach to the NARM regulatory framework by including provisions for general licenses and regulatory exemptions for NARM materials and products that represent a low level of risk to public health and safety and common defense and security, and specific licenses for NARM materials and products 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 proposed alternative, the NRC's intent would be 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 proposed amendments would provide a national regulatory structure for NARM under which persons in non-Agreement States would be governed by regulations that are generally consistent with those applicable in Agreement States. The proposed regulatory structure would be 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 would 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 proposed 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 timepieces and § 30.20 for gas and aerosol detectors. However, both of these exemptions are limited to previously manufactured products. Thus, they would allow for the continued use, without regulatory controls, of a dwindling supply of products produced some time ago. They would not allow for future manufacture and distribution, greatly minimizing any environmental impacts from uncontrolled disposal.

The one other exemption from licensing included in the proposed 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 proposed for addition 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 proposed 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 would be added, is only applicable to specific licensees that have calibration and reference sources, and simply eliminates certain administrative requirements to address these sources under the specific license.

The general license in § 31.11 would be revised to add 10 FCi 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 would be revised to accommodate devices approved by States under provisions comparable to § 32.51. Thus, these devices would have been reviewed by States as meeting the same safety criteria as other products 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 0.1 FCi would 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 proposed. It is for certain items and self-luminous products containing radium-226. It does not authorize manufacture, assembly, disassembly, repair, or import of these products, which were generally manufactured some time ago. Although not specifically exempted under State regulations, they have usually not come under regulatory controls. The proposed requirements in this provision would be limited, but intended to improve the likelihood of proper disposal and identification of significant instances of contamination. General licensees would 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 proposed 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 materials 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 compacting process implemented in accordance with the LLRWPAA is not to be affected by the addition of NARM into the definition of byproduct material. The proposed action would implement this requirement by redefining the 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 would 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 proposed 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 proposed regulations would regulate incidental ARM resulting from the operation of particle accelerators that intentionally produce radioactive material, such as the structures of buildings and structures housing the accelerators. Consequently, the NRC is considering additional regulatory actions 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 are 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.

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 proposed 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 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. 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 proposed 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 proposed rule. The State members of the NMSS EPAct Task Force have assisted in the proposed rule development, and have provided input to the rulemaking process.

In addition, a Steering Committee was formed to provide oversight for both the NMSS 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 proposed rule development process, the Steering Committee met weekly to resolve issues and to provide management direction on the rulemaking. The Steering Committee plans to continue to meet on a regular basis until the final rule is promulgated.

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 have been reviewed and considered by the NRC staff in the development of this proposed 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 this proposed rule, the NRC proposes to 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.

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 proposed 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 proposed alternative, which provides a graded approach by using a general license to regulate different groups of radium-226 sources. In addition, in this proposed rule, the NRC is asking the public for any technical information that may be available to support an exemption, now or in the future.

The NRC staff has determined that the proposed action is not a type of activity that has potential to cause effects on historic properties because it is an administrative action that revises the Commission's regulations, but does not directly involve changes to any specific site, area, or region. Therefore, no further consultation is required under Section 106 of the National Historic Preservation Act. Additionally, the NRC staff has determined that Section 7 consultation with the U.S. Fish and Wildlife Service is not required because the proposed action is administrative in nature and will not affect listed species or critical habitat.

6.0 CONCLUSION

The NRC is proposing to amend 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 the amendments, if adopted, would be a major Federal action but would not significantly affect the quality of the human environment, and therefore that an environmental impact statement is not required.

7.0 LIST OF PREPARERS

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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 Proposed Rulemaking - Expanded Definition of Byproduct Material Established by Section 651(e) of the Energy Policy Act of 2005

Draft Report for Comment

U.S. Nuclear Regulatory Commission
Office of Nuclear Materials Safety and Safeguards

March 2006

Enclosure

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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 proposing to amend 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). The EPAct expanded the definition of byproduct material in Section 11e. of the Atomic Energy Act of 1954 (AEA) to include certain discrete sources of naturally occurring radioactive material and accelerator-produced radioactive material. The EPAct also required the NRC to provide a regulatory framework for licensing and regulating this additional radioactive material. The regulatory framework would be implemented through rulemaking, following a public comment period.

The purpose of this regulatory analysis is to evaluate the costs and benefits associated with the proposed rule under consideration by the Commission. The proposed rule (Reference 1) would amend 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 are 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," or 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 radioactivity used in human activity, includes the products of nuclear reactor technology and products activated in a particle accelerator.

Collectively, the "naturally occurring and accelerator-produced radioactive materials" are referred to as NARM. The significance of the distinction between 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 except for uranium and thorium that is source material. 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. This byproduct material was defined to include only radioactive material produced in a fission reactor, and tailings and wastes produced from uranium and thorium mining operations.

The regulation of NORM, other than source material, was left primarily to the individual States. Although efforts were made by States to provide a uniform regulatory environment, there was a lack of national consistency in the regulation of NARM. Other Federal agencies exercised limited regulatory authority over activities involving NARM consistent with their primary missions, but there was no overall, consistent federal regulation as in the case of byproduct material produced in a fission reactor.

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 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 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 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 materials, as included in the expanded byproduct material definition, shall not be considered to be low-level radioactive waste.

1.1.2 Current Status of NRC Requirements

The AEA authorizes States to assume regulatory control of radioactive materials produced in or by a nuclear reactor, provided the State has an adequate program to protect the public health and safety, the program is compatible with NRC's program, and the State has entered 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. Minnesota's agreement is the most recent, it being effective March 31, 2006. 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 and Federal facilities. The NRC issues licenses to persons using these materials in Federal facilities, 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 33 Agreement States and certain non-Agreement States have regulated 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, since 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 nondiscrete 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 materials. 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 material 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 the passage of the EPAct, the NRC will have primary responsibility for radiation safety and in regulating the use of these radioactive and hazardous 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.
Department of Labor	Has established regulations addressing the exposure of minors to radioactive material in the workplace.
Occupational Safety and Health Administration	Oversight for occupational health and safety for non-AEA materials; 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 paragraphs 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 turn of the century, naturally occurring radioactive material, including radium-226, was routinely used in consumer products and in cancer treatment (Reference 2). Since there was no Federal mandate to regulate these materials, most States have 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 currently does 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 will be amending 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 proposed rule related to implementing a National Source Tracking System for certain sealed sources (70 FR 43646; July 28, 2005). The proposed amendments would require licensees to report certain transactions involving these sealed sources to the National Source Tracking System. These transactions would include manufacture, transfer, receipt, or disposal of the nationally tracked source. The proposed amendment would also require each licensee to provide its initial inventory of nationally tracked sources to the National Source Tracking System and annually verify and reconcile the information in the system with the licensee's actual inventory. In addition, the proposed amendment would 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. It 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 Proposed 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 allows the NRC 18 months, from the effective date of the EPAct, to promulgate regulations that establish a national program for NARM. These regulations are the subject of the proposed rule. The NRC is proposing to amend 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 promulgating 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 promulgated 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.

The Commission’s proposed 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 entitled “U.S. Nuclear Regulatory Commission Strategic Plan, Fiscal Year 2000-2005,” 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. The Commission’s proposed 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 has 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 proposed 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 proposed 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. In addition, 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.

2.1 Comparison of Alternatives

NRC proposes the following three alternatives for regulatory analysis:

1. take no action, which provides a baseline to assess the other two alternatives;

2. revise regulations to maximize NRC regulatory authority allowed by the EPAct; and

3. revise regulations to apply a graded 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 that may be applied in the proposed rule. Alternative 3 represents this degree of flexibility by 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 promulgating 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 would be 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 licenses 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 other NORM.

Section 651(e) of the EPAct requires the Commission to promulgate 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 NRC can base the proposed rule.

Section 651(e) of the EPAct requires the Commission to include, as byproduct material, certain accelerator-produced radioactive material, hereafter referred to as "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 the production of radioactive material (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 other NORM in the expanded definition of byproduct material. A discrete source would be defined to include a concentrated radioactive material source with physical boundaries, which is separate and distinct from the radiation present in nature. The flexibility allowed by this requirement relates to the purpose for which the material is concentrated. A general discrete source definition would 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 non-radiological products, such as fertilizer, fly ash, or purified water. A more limited discrete source definition would only include radioactive material that was concentrated with the intent of using its radiological 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 the regulations. This requirement does not prescribe how to consider the potential impact of the proposed

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 requirements for the proposed regulations. Although the EPAct allows flexibility in considering the proposed 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, the proposed action and alternatives 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 proposed 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 promulgate regulations that apply the highest degree of regulatory authority allowed by the EPAct; and (3) to promulgate regulations that apply a graded approach to the regulatory authority allowed 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 proposed alternative.

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 practical, 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 promulgate regulations to implement the requirements specifically required by the EPAct and any additional regulatory authority 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 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 action: (1) applying its established regulatory framework to the commercial distribution of these drugs; (2) expanding the regulations to permit noncommercial distribution of these drugs by medical use licensees; (3) expanding the authorization for commercial nuclear pharmacies to produce PET radionuclides; (4) "grandfathering" current users of accelerator-produced drugs; and (5) permitting individuals 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. Based on information obtained by the staff during the development of this rule, it is understood that SSRs do exist that address naturally occurring radioactive material, but that there appear to be few model State regulations at the national consensus level specific to accelerator-produced radioactive material. In general, with the exception of general licensing requirements for cobalt-57 sources and contamination levels for strontium-82/rubidium-82 generators for medical use, SSR requirements for accelerator-produced radioactive material are the same as for reactor-produced radioactive material. The SSRs include an exemption for timepieces and other articles containing 37 kilobecquerels (kBq) (1 microcurie (μCi)) of radium-226, a requirement to allow a specifically licensed individual to possess up to 185 kBq (5 μCi) of radium-226 calibration sources under a general license, and a limit of 3.7 kBq (0.1 μCi) of radium-226 that may be incorporated into smoke detectors distributed under an exempt license. 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 license. 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 sources would be defined broadly to include any concentrated radium-226 or other NORM, regardless of whether it was concentrated intentionally for its radiological properties or incidentally from a process that extracts or produces non-radiological products. This definition would not limit the NRC’s jurisdiction to only include radionuclides that are concentrated and used purposefully for their radiological properties. However, no additional NORM has been identified at this time that has useful chemical properties and with attendant radiological risk subject to NRC regulation. There are no economic effects from this other NORM, such as 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 proposes an alternative that would promulgate regulations to apply a graded regulatory authority over NARM by focusing the staff’s regulatory responsibilities 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 would address 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 would be based, to the maximum extent practicable, on the SSRs.

This proposed alternative would include 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 proposed alternative would also accommodate generally licensed devices meeting the restrictions of the general licenses that were previously approved by States under existing regulations. This proposed alternative would regulate accelerator-produced radioactive material under the same requirements as reactor-produced radioactive material. Additionally, this proposed alternative would add 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 proposed alternative would make no changes to the exempt concentrations for radionuclides included in the SSRs, and would adopt appropriate values for exempt quantities for the newly defined byproduct material. This proposed alternative would also adopt an exemption for timepieces or other articles containing 37 kBq (1 µCi) or less of radium-226 and would adopt the requirement to allow a specifically licensed individual to possess up to 185 kBq (5 µCi) of radium-226 calibration sources under a general license.

Under this proposed alternative, discrete sources would be defined to include only radioactive material that was concentrated with the intent of using its radiological properties. This proposed definition of 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 concentrated, and purposefully used for their radiological properties. This proposed definition would limit 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. Once a radioactive material, defined as a discrete source, becomes byproduct material, it will continue to be regulated as byproduct material, even if the discrete source is leaking or broken, or no longer has a physical boundary. Contamination resulting from a breach of the physical boundaries containing a discrete source would continue to be regulated as byproduct material.

Under this proposed alternative, the NRC would 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 proposed 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 neutron radiography used for medical imaging). 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 proposed 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 proposed rule.

The regulatory framework and implementation process associated with radiopharmaceuticals under this proposed alternative would be the same as that described previously for Alternative 2. This proposed 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 action: (1) applying its established regulatory framework to the commercial distribution of these drugs; (2) expanding the regulations to permit noncommercial distribution of these drugs by medical use licensees; (3) expanding the authorization for commercial nuclear pharmacies to produce PET radionuclides; (4) "grandfathering" current users of accelerator-produced drugs; and (5) permitting individuals to continue to prepare and use radioactive drugs while they are applying for new licenses or amendments.

Under the proposed 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 proposed 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 proposed rule. The benefits and costs are analyzed for implementation of the proposed 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 shows 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 proposed 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 $23 million and $27 million, discounted at 7 percent and 3 percent, respectively. Under the Maximum Regulation alternative, the estimated costs are about $64 million and $72 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 proposed 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 proposed 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 record-keeping 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 support development of the rule following publication in the *Federal Register* through publication of the final rule. NRC will also need 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 proposed 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 proposed 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 portable 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) portable 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 portable 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. Portable gauges with gamma sources were analyzed in the evaluation, and were ranked as a "moderately high" risk. Based on the number of gauges using different sources, only gauges with Am-241, Cs-137, Co-60, I-125, and Gd-153 were included in the risk analysis.

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 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 proposed alternatives 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 proposed regulatory framework to ensure proper management and safe use of the newly defined byproduct material (discrete sources of radium-226, product ARM, and discrete sources of naturally occurring radioactive material) 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 as 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 proposed 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 3550 licensees. This is due to the large number of accelerator and cyclotron facilities with incidental radioactive material that could be regulated under a strict interpretation of the Energy Policy Act. 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 160 licensees. About 50 of these licensees are expected to be from the industrial sector and 110 are expected to be from the medical sector. None from the industrial sector are expected to be in well-logging or radiography applications.

- 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 and NARM materials. 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 particle accelerators that fall under the proposed regulatory framework. Alternative 2 assumes 3500 particle accelerators while Alternative 3 assumes 150.

We also have made assumptions for the number of specific licenses for persons with products and materials containing radium-226. For these licensees, we estimated 200 additional licenses for Alternative 2 compared to 100 for Alternative 3. Appendix A shows the line item assumptions for the implementation and annual operating expense for Alternative 2.

<u>10 CFR Part 19, Notices, Instructions and Reports to Workers: Inspection and Investigations</u>

- We assumed 3500 new particle accelerator licensees of which 600 would have one-time set-up costs to comply with 10 CFR 19.12 regarding radiation exposure reports and instructions to workers. This is 450 more licensees than Alternative 3, the Graded Approach. It is about 15 percent of the additional particle accelerator population above the population used for the Graded Approach, Alternative 3.

- About 550 of the total 3500 particle accelerators would be affected by annual reporting requirements under 10 CFR 19.13 regarding notifications and reports to workers.

10 CFR Part 20, Standards for Protection Against Radiation

- The 600 licensees with implementation costs for 10 CFR Part 19 also 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 part. These licensees also would have one-time labor expense to comply with 10 CFR 20.2102 regarding ALARA records retention.
- We assume 550 of these licensees would have an annual labor expense to identify, under 10 CFR 20.1406, their ability to minimize, to the extent practical, contamination of the facility and the environment using their facility design and operating procedures. Other reporting requirements under 10 CFR 20.1601, 20.2103, and 20.2108 will affect all new licensees.
- All 3500 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 3500 new licensees with particle accelerators would have one-time labor costs for license application under 10 CFR 30.9 and 30.32. We assume 200 new licenses under 10 CFR 30.32, mostly for moisture density gauges containing radium-226/beryllium.
- Only 42 of the new licensees, the same as under Alternative 3, have one-time labor expense to comply with financial assurance requirements for decommissioning under 10 CFR 30.35.
- Of the total 3500 new licensees, about 2 percent (70) are assumed to have quantities of material that would require annual compliance with the emergency planning regulations in 10 CFR 30.32. The annual costs for emergency planning and decommissioning financial assurance requirements are about 80 percent of the estimated annual labor expense for licensees under 10 CFR Part 30 in Alternative 2.

10 CFR Part 31, General Domestic Licenses for Byproduct Material

- We assume that an additional 50 persons compared to Alternative 3, for a total of 150 persons, 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. Most significantly, we assume all of a group of 1900 licensees would have a 2.5 hour labor burden each to prepare procedures consistent with the requirements in 10 CFR 35.24 (management approval of certain actions). Another one-time labor expense is expected to be incurred by 15 licensees under 10 CFR 35.69, for labeling of vials and syringes. These numbers of affected licenses are about 5 percent higher than those assumed under Alternative 3.
- 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 double the assumptions used to represent Alternative 2; for example, an increase of 10 percent above the number of respondents shown in the most current OMB submission statement is assumed for Alternative 2, while an increase of 5 percent above the number of respondents was assumed for Alternative 3.
- 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. Another significant annual labor expense is due to an estimated 1935 licensees complying with the requirements in 10 CFR 35.2024 regarding records retention.

Additional Cost to NRC

- We assume 3700 new license applications with a one-time implementation effort of 40 hours staff time to process each new license. 3500 are for particle accelerators and 200 are for portable gauges containing radium-226.
- We assume 2000 labor hours by NRC staff, and $50,000 contractor expense, to work on the proposed rule up to the time a Final Rule is published.
- 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 material amounts of radioactive waste for modeling waste costs. The other 3350 accelerators are non-producing ARM with minimal radioactive waste. We assume the 150 with product ARM generate, on average, about one-half the waste stream assumed for the 45 particle accelerators producing waste under Alternative 3.

- No costs were assumed for waste disposal and decommissioning the 200 licensees with portable gauges containing radium-226, and the small number of sites where there are collections of products 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 150 licensees would have one-time set-up costs to comply with 10 CFR 19.12 regarding worker radiation exposure reporting.
- About 75 percent of these licensees (110) also would be affected by annual reporting requirements under 10 CFR 19.13 regarding notifications and reports to workers. We used in this analysis an estimate that is 20 percent of the OMB labor burden estimate to properly account for the fewer employees and more simplified organizational structure that exist at byproduct facilities, compared to the larger facilities such as nuclear power plants that were used in the collection of licensees' burden hours to comply with 10 CFR 19.13.

10 CFR Part 20, Standards for Protection Against Radiation

- We assume 5 percent of the 150 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.
- All 150 licensees rule would have one-time labor expense to comply with 10 CFR 2102. The assumption is 20 hours per licensee.
- All 150 licensee would have an annual labor expense to identify, under 10 CFR 20.1406, their ability to minimize, to the extent practical, contamination of the facility and the environment using their facility design and operating procedures. Other significant annual expense would be incurred under 10 CFR 20.2103, and 20.2108 for the 160 licensees.
- A subset of these licensees would have additional annual reporting requirements. For example, an estimated 25 accelerator facilities with a potential for high radiation areas would be required to report under 10 CFR 20.1601 and 20.2107.

10 CFR Part 30, Rules of General Applicability to Domestic Licensing of Byproduct Material

- We assume that all 150 licensees with particle accelerators would have one-time labor costs for license application under 10 CFR 30.9 and 30.32. We assume 100 new licenses under 10 CFR 30.32 for moisture density gauges containing radium-226.
- A subset of the particle accelerator licensees, estimated at 42, 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 10,000 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). Of the

42 licensees in this analysis, the assumption is that 20 are medical cyclotrons, 20 are industrial cyclotrons, and 2 are sites with portable gauges, or disassembly and repair operations, of products containing radium-226. As was done under the 10 CFR Part 19 assumptions, the analysis assumes an estimate that is 20 percent of the OMB burden estimate for 10 CFR 30.35 labor hours. This acknowledges less complicated decommissioning plans for production accelerators compared to the population used to derive the OMB burden estimate, which includes irradiators and waste brokers.

- Most of the annual burden hours is in the licensee's revision of their financial assurance requirements. This is assumed to be done every three years by the licensee consistent with the regulation under 10 CFR 30.35.

10 CFR Part 31, General Domestic Licenses for Byproduct Material

- We assume that 100 persons would have additional annual operating expense for recordkeeping and reporting to comply with 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

- 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 the three sealed source facilities under 10 CFR 32.74 have an new annual labor burden of about 3 hours each for labeling.

10 CFR Part 35, Medical Use of Byproduct Material

- There would be one-time labor expense under 10 CFR Part 35; most significantly, we assume all of a group of 1800 licensees would have a 2.5 hour labor burden each to prepare procedures consistent with the requirements in 10 CFR 35.24 (management approval of certain actions). A smaller one-time expense is incurred by 550 licensees to establish training and experience documentation procedures consistent with the requirements in 10 CFR 35.14. Another one-time labor expense is expected to be incurred by 15 licensees under 10 CFR 35.69, for labeling of vials and syringes. The number of affected licensees noted above is about 5 percent above the number of respondents shown in the most recent OMB submission statement for this activity.
- The 10 CFR Part 35 annual labor burden has many specific line items, shown in Appendix B. A large portion of the total expense is due to an estimated 80 licensees annually with an approximate 42 hour labor burden to record dosages of unsealed byproduct material for medical use consistent with the requirements in 10 CFR 35.2063. The 80 licensees represent 5 percent of the total increased population affected by the requirements in 10 CFR 35.2063. Another significant annual labor expense is due to an estimated 1800 licensees complying with the requirements in 10 CFR 35.2024 regarding records retention. The 1800 licensees represents the entire population of affected

licensees, which is about a 5 percent increase above the population in the most recent OMB submission statement.

Additional Cost to NRC

- We assume 250 new license applications with a one-time effort of 40 hours staff time to process each new license. 150 are particle accelerators and 100 are specific licenses for portable gauges containing radium-226.
- We assume 2000 labor hours by NRC staff, and $50,000 contractor expense, to work on the proposed rule up to the time a Final Rule is published.
- 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 150 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 100 licensees with portable gauges containing radium-226, and the small number of sites where there are people who have large collections of products containing radium-226. The portable gauges are believed to be owned by companies with larger numbers of portable gauges containing other radioactive material, and the waste and decommissioning related to radium-226 gauges is low compared to other obligations. We note that the U.S. Department of Energy sponsors a program to recover excess and unwanted radioactive sealed sources that present disposal difficulties. Traditionally, the program has dealt mainly with americium-241 sources, but the program is also accepting other radioactive sealed sources of concern, including those with radium-226. The link for more information on this program and for registering sources is http://osrp.lanl.gov.

4.0 Results

This section presents results of values and impacts that are expected to be derived from the proposed 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	(63,577,819)	(71,789,278)
3. Graded Regulatory Authority	(22,568,369)	(26,840,846)

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 costs are all one-time capital and labor expense, in 2005 dollars, and are thus not discounted. The other four attribute 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	(12,597,758)	(12,597,758)	(1,604,745)	(1,604,745)
Industry Operation	(35,287,544)	(42,948,484)	(18,560,316)	(22,557,534)
NRC Implementation	(13,126,100)	(13,126,100)	(1,120,100)	(1,120,100)
NRC Operation	(2,566,417)	(3,116,936)	(1,283,208)	(1,558,468)
Total	(63,577,819)	(71,789,278)	(22,568,369)	(26,840,846)

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 30 regulations, with the requirements in 10 CFR Part 35 not far behind. The largest *annual cost* to industry for Alternative 3 is to comply with 10 CFR Part 35 regulations, followed by the requirements in 10 CFR Part 32 and 10 CFR Part 20.

An “impact per entity” for one-time costs to comply with the rule is about $7,500 for each of the estimated 150 licensees who are affected by the new regulations under 10 CFR Part 19, 20 and 30, for the preferred Alternative 3. In general, this cost would be applied to renovate an existing facility in order to comply with radiation protection safety functions that the licensee may not have fully implemented before the effective date of the rule. This type of implementation cost may be required at facilities that operate production accelerators.

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	(939,600)	(621,963)	(234,900)	(124,915)
20	(7,044,000)	(2,022,315)	(341,000)	(568,893)
30	(4,108,575)	(235,970)	(550,275)	(162,446)
31	0	(29,885)	0	(20,967)
32	(3,828)	(748,148)	(3,828)	(748,148)
35	(501,755)	(1,414,463)	(474,742)	(1,008,962)
NRC Operation	0	(365,400)	0	(182,700)
NRC Implementation	(13,126,100)	0	(1,120,100)	0
Waste and Decommissioning	0	(28,200)	0	(19,900)
Total	(25,723,858)	(5,466,343)	(2,724,845)	(2,836,931)

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 proposed 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 web-site, 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 proposed 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 proposed 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

Several actions are planned or must occur coincident with, or following, the NRC issuance of final rules 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 for Agreement and non-Agreement States;

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

3. an implementation period for users of the newly added byproduct material to come 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 proposed rule would have no significant adverse effects on other Federal regulatory agencies.

8.0 Effect on Small Entities

This rule may, if promulgated, have a minor economic impact on a large number of small entities in non-Agreement States. A number of businesses that would 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

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	3500	17%	600	18	17%	600	0.2	$ (939,600)	$ (10,440)
19.13(a)	3500	0%	0	0	16%	550	0.2	$ -	$ (9,570)
19.13(b)	3500	0%	0	0	16%	550	8.4	$ -	$ (402,036)
19.13(c)	3500	0%	0	0	16%	550	3.3	$ -	$ (157,139)
19.13(e)	3500	0%	0	0	16%	550	0.9	$ -	$ (42,778)
							Total	**$ (939,600)**	**$ (621,963)**

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 *	3500	17%	600	$ (10,000)	0	0%	0	0	$ (6,000,000)	$ -
20.1406	3500	0%	0	$ -	0	16%	550	20	$ -	$ (957,000)
20.1601(c)	25	0%	0	$ -	0	100%	25	8	$ -	$ (17,400)
20.1906(e)	3500	0%	0	$ -	0	16%	550	1	$ -	$ (47,850)
20.2102(a)&(b)	3500	17%	600	$ -	20	16%	550	4	$ (1,044,000)	$ (191,400)
20.2103(a)&(b)	3500	0%	0	$ -	0	16%	550	8	$ -	$ (382,800)
20.2107(a)	25	0%	0	$ -	0	100%	25	5	$ -	$ (10,875)
20.2108(a)	3500	0%	0	$ -	0	16%	550	8	$ -	$ (382,800)
20.2201(a)	36	0%	0	$ -	0	100%	36	3	$ -	$ (9,396)
20.2201(b)	36	0%	0	$ -	0	100%	36	3	$ -	$ (9,396)
20.2201(d)	36	0%	0	$ -	0	100%	36	3	$ -	$ (9,396)
20.2202(b)	1	0%	0	$ -	0	100%	1	40	$ -	$ (3,480)
20.2203(a)	1	0%	0	$ -	0	100%	1	6	$ -	$ (522)
								Total	**$ (7,044,000)**	**$ (2,022,315)**

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)	3500	100%	3500	1	5%	175	1.0	$ (304,500)	$ (15,225)
30.32	200	100%	200	7	5%	10	1.0	$ (121,800)	$ (870)
30.32 (i)	3500	100%	3500	10	2%	70	10.0	$ (3,045,000)	$ (60,900)
30.32 (i)	3500	100%	3500	1	2%	70	1.0	$ (304,500)	$ (6,090)
30.34(e)(4) - Orders	5	0%	0	0	100%	5	3.0	$ -	$ (1,305)
30.34(e)(4) - Sfguards	5	0%	0	0	100%	5	0.5	$ -	$ (218)
30.34(h)	160	0%	0	0	100%	1	0.5	$ -	$ (44)
30.35(a)&(b) - Certific	42	100%	42	20	33%	14	20.0	$ (73,080)	$ (24,116)
30.35(a)&(b) - F Plan	42	100%	42	60	33%	14	60.0	$ (219,240)	$ (72,349)
30.35(g)	42	100%	42	10	100%	42	10.0	$ (36,540)	$ (36,540)
30.41(c)&(d)	45	0%	0	0	100%	45	4.0	$ -	$ (15,660)
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	**$ (4,108,575)**	**$ (235,970)**

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 moisture density gauges containing radium-226/berylliem.
30.32 (i)	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.
30.34(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.
30.35(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 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)	150	0%	0	0.0	100%	150	0.3	$ -	$ (3,263)
31.5(c)(8)	150	0%	0	0.0	100%	150	0.6	$ -	$ (7,830)
31.5(c)(9)	150	0%	0	0.0	100%	150	1.0	$ -	$ (13,050)
31.5(c)(11)	150	0%	0	0.0	100%	150	0.3	$ -	$ (4,437)
31.5(c)(14)	150	0%	0	0.0	100%	150	0.1	$ -	$ (1,305)
31.12	0	0%	0	4.0	0%	0	4.0	$ -	$ -
							Total	**$ -**	**$ (29,885)**

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.

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	0%	0	0	$ (3,828)	$ -
32.74(a)(2)(viii)	3	0%	0	0	100%	3	2.8	$ -	$ (731)
							Total	**$ (3,828)**	**$ (748,148)**

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 certification information 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 32

Alternative 2

10 CFR Part 35

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	21	0%	0	0	100%	21	4.0	$ -	$ (7,308)
35.14	583	100%	583	0.5	5%	29	0.5	$ (25,361)	$ (1,262)
35.19	2	0%	0	0.0	100%	2	1.0	$ -	$ (174)
35.24 (a)	1900	100%	1900	2.5	10%	190	2.5	$ (413,250)	$ (41,325)
35.24 (b)	385	0%	0	0.0	100%	385	0.5	$ -	$ (16,748)
35.24 (f)	440	0%	0	0.0	100%	440	0.5	$ -	$ (19,140)
35.26	176	100%	176	0.5	100%	176	0.5	$ (7,656)	$ (7,656)
35.27	225	0%	0	0.0	100%	225	1.0	$ -	$ (19,575)
35.40 (a)(1)	1178	0%	0	0.0	30%	353	1.8	$ -	$ (53,744)
35.40 (c)(1)	1178	0%	0	0.0	30%	353	2.5	$ -	$ (76,778)
35.41	107	0%	0	0.0	100%	107	0.5	$ -	$ (4,655)
35.2060	49	0%	0	0.0	100%	49	5.1	$ -	$ (21,741)
35.61	49	0%	0	0.0	100%	49	0.0	$ -	$ (128)
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)
35.69(b)	15	100%	15	42.5	100%	15	15.6	$ (55,489)	$ (20,358)
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	176	0%	0	0.0	100%	176	1.0	$ -	$ (15,924)
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	109	0%	0	0.0	100%	109	0.1	$ -	$ (948)
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	59	0%	0	0.0	100%	59	1.2	$ -	$ (6,262)
35.2406	39	0%	0	0.0	100%	39	3.0	$ -	$ (10,179)
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	429	0%	0	0.0	30%	129	3.0	$ -	$ (33,669)
35.2630	109	0%	0	0.0	100%	109	0.5	$ -	$ (4,742)
35.2024 (a)	1900	0%	0	0.0	100%	1900	1.3	$ -	$ (206,625)
35.2024 (b)	1900	0%	0	0.0	100%	1900	0.1	$ -	$ (16,530)
35.2026	1900	0%	0	0.0	100%	1900	0.3	$ -	$ (41,325)
35.2040	1178	0%	0	0.0	30%	353	2.6	$ -	$ (79,849)
35.2041	107	0%	0	0.0	100%	107	0.1	$ -	$ (465)
35.2061	176	0%	0	0.0	100%	176	0.4	$ -	$ (5,742)
35.2075 (a)	605	0%	0	0.0	30%	182	1.5	$ -	$ (23,751)
35.2075 (b)	605	0%	0	0.0	30%	182	0.4	$ -	$ (6,334)
35.3045(c)	40	0%	0	0.0	30%	12	0.5	$ -	$ (522)
35.3045(d)	40	0%	0	0.0	30%	12	8.0	$ -	$ (8,352)
35.3045(e)	40	0%	0	0.0	30%	12	2.0	$ -	$ (2,088)
35.3045(g)	40	0%	0	0.0	30%	12	0.5	$ -	$ (522)
35.3047(c)	3	0%	0	0.0	30%	1	0.5	$ -	$ (44)
35.3047(d)	3	0%	0	0.0	30%	1	8.0	$ -	$ (696)
35.3047(e)	3	0%	0	0.0	30%	1	2.0	$ -	$ (174)
35.3047(f)	3	0%	0	0.0	30%	1	0.5	$ -	$ (44)
35.3067	2	0%	0	0.0	30%	1	2.0	$ -	$ (174)
							Total	**$ (501,755)**	**$ (1,414,463)**

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.

Alternative 2

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	3700	40 hours	$ (12,876,000)	
New license amendments annually	150	20 hours		$ (261,000)
Inspections of licensee facilities	50 / year	24 hours		$ (104,400)
			$ -	$ (365,400)

NRC		2005	2006
After proposed rule FRN to final rule FRN			
Labor hours April 2006-Mar 2007			2,000
Assumed wage rate			87
Labor expense			$ (174,000)
Other direct costs			$ (50,000)
	Total		$ (224,000)
Guidance	300 hours		$ (26,100)
New licenses applications			$ (12,876,000)
Total one-time implementation			$ (13,126,100)

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)

Waste and Decommissioning
Alternative 2

APPENDIX B

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	150	100%	150	18	100%	150	0.2	$ (234,900)	$ (2,610)
19.13(a)	150	0%	0	0	73%	110	0.2	$ -	$ (1,914)
19.13(b)	150	0%	0	0	73%	110	8.4	$ -	$ (80,407)
19.13(c)	150	0%	0	0	73%	110	3.3	$ -	$ (31,428)
19.13(e)	150	0%	0	0	73%	110	0.9	$ -	$ (8,556)
							Total	**$ (234,900)**	**$ (124,915)**

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 *	150	5%	8	$ (10,000)	0	0%	0	0	$ (80,000)	$ -
20.1406	150	0%	0	$ -	0	100%	150	20	$ -	$ (261,000)
20.1601(c)	25	0%	0	$ -	0	100%	25	8	$ -	$ (17,400)
20.1906(e)	150	0%	0	$ -	0	100%	150	1	$ -	$ (13,050)
20.2102(a)&(b)	150	100%	150	$ -	20	100%	150	4	$ (261,000)	$ (52,200)
20.2103(a)&(b)	150	0%	0	$ -	0	100%	150	8	$ -	$ (104,400)
20.2107(a)	25	0%	0	$ -	0	100%	25	5	$ -	$ (10,875)
20.2108(a)	150	0%	0	$ -	0	100%	150	8	$ -	$ (104,400)
20.2201(a)	2	0%	0	$ -	0	100%	2	3	$ -	$ (522)
20.2201(b)	2	0%	0	$ -	0	100%	2	3	$ -	$ (522)
20.2201(d)	2	0%	0	$ -	0	100%	2	3	$ -	$ (522)
20.2202(b)	1	0%	0	$ -	0	100%	1	40	$ -	$ (3,480)
20.2203(a)	1	0%	0	$ -	0	100%	1	6	$ -	$ (522)
								Total	**$ (341,000)**	**$ (568,893)**

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)	150	100%	150	1	5%	8	1.0	$ (13,050)	$ (696)
30.32	100	100%	100	7	5%	5	1.0	$ (60,900)	$ (435)
30.32 (i)	150	100%	150	10	5%	8	10.0	$ (130,500)	$ (6,960)
30.32 (i)	150	100%	150	1	5%	8	1.0	$ (13,050)	$ (696)
30.34(e)(4) - Orders	5	0%	0	0	100%	5	3.0	$ -	$ (1,305)
30.34(e)(4) - Sfguards	5	0%	0	0	100%	5	0.5	$ -	$ (218)
30.34(h)	160	0%	0	0	100%	1	0.5	$ -	$ (44)
30.35(a)&(b) - Certific	42	100%	42	20	33%	14	20.0	$ (73,080)	$ (24,116)
30.35(a)&(b) - F Plan	42	100%	42	60	33%	14	60.0	$ (219,240)	$ (73,080)
30.35(g)	42	100%	42	10	100%	42	10.0	$ (36,540)	$ (36,540)
30.41(c)&(d)	45	0%	0	0	100%	45	4.0	$ -	$ (15,660)
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	**$ (550,275)**	**$ (162,446)**

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 moisture density gauges containing radium-226/berylliem.
30.32 (i)	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.
30.34(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.
30.35(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)	100	0%	0	0.0	100%	100	0.6	$ -	$ (5,220)
31.5(c)(9)	100	0%	0	0.0	100%	100	1.0	$ -	$ (8,700)
31.5(c)(11)	100	0%	0	0.0	100%	100	0.3	$ -	$ (2,958)
31.5(c)(14)	100	0%	0	0.0	100%	100	0.1	$ -	$ (870)
31.12	300	0%	0	0.0	1%	3	4.0	$ -	$ (1,044)
							Total	**$ -**	**$ (20,967)**

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

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	0%	0	0	$ (3,828)	$ -
32.74(a)(2)(viii)	3	0%	0	0	100%	3	2.8	$ -	$ (731)
							Total	**$ (3,828)**	**$ (748,148)**

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 certification information 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.

Alternative 3

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	10	0%	0	0	100%	10	4.0	$ -	$ (3,480)
35.14	550	100%	550	0.5	5%	28	0.5	$ (23,925)	$ (1,218)
35.19	1	0%	0	0.0	100%	1	1.0	$ -	$ (87)
35.24 (a)	1800	100%	1800	2.5	10%	180	2.5	$ (391,500)	$ (39,150)
35.24 (b)	368	0%	0	0.0	100%	368	0.5	$ -	$ (16,008)
35.24 (f)	420	0%	0	0.0	100%	420	0.5	$ -	$ (18,270)
35.26	88	100%	88	0.5	100%	88	0.5	$ (3,828)	$ (3,828)
35.27	112	0%	0	0.0	100%	112	1.0	$ -	$ (9,744)
35.40 (a)(1)	1125	0%	0	0.0	30%	338	1.8	$ -	$ (51,461)
35.40 (c)(1)	1125	0%	0	0.0	30%	338	2.5	$ -	$ (73,515)
35.41	54	0%	0	0.0	100%	54	0.5	$ -	$ (2,349)
35.2060	25	0%	0	0.0	100%	25	5.1	$ -	$ (11,093)
35.61	25	0%	0	0.0	100%	25	0.0	$ -	$ (65)
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)
35.69(b)	15	100%	15	42.5	100%	15	15.6	$ (55,489)	$ (20,358)
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	88	0%	0	0.0	100%	88	1.0	$ -	$ (7,962)
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	55	0%	0	0.0	100%	55	0.1	$ -	$ (479)
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	30	0%	0	0.0	100%	30	1.2	$ -	$ (3,184)
35.2406	20	0%	0	0.0	100%	20	3.0	$ -	$ (5,220)
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	410	0%	0	0.0	30%	123	3.0	$ -	$ (32,103)
35.2630	55	0%	0	0.0	100%	55	0.5	$ -	$ (2,393)
35.2024 (a)	1800	0%	0	0.0	100%	1800	1.3	$ -	$ (195,750)
35.2024 (b)	1800	0%	0	0.0	100%	1800	0.1	$ -	$ (15,660)
35.2026	1800	0%	0	0.0	100%	1800	0.3	$ -	$ (39,150)
35.2040	1125	0%	0	0.0	30%	338	2.6	$ -	$ (76,456)
35.2041	54	0%	0	0.0	100%	54	0.1	$ -	$ (235)
35.2061	88	0%	0	0.0	100%	88	0.4	$ -	$ (2,871)
35.2075 (a)	578	0%	0	0.0	30%	173	1.5	$ -	$ (22,577)
35.2075 (b)	578	0%	0	0.0	30%	173	0.4	$ -	$ (6,020)
35.3045(c)	38	0%	0	0.0	30%	11	0.5	$ -	$ (479)
35.3045(d)	38	0%	0	0.0	30%	11	8.0	$ -	$ (7,656)
35.3045(e)	38	0%	0	0.0	30%	11	2.0	$ -	$ (1,914)
35.3045(g)	38	0%	0	0.0	30%	11	0.5	$ -	$ (479)
35.3047(c)	3	0%	0	0.0	30%	1	0.5	$ -	$ (44)
35.3047(d)	3	0%	0	0.0	30%	1	8.0	$ -	$ (696)
35.3047(e)	3	0%	0	0.0	30%	1	2.0	$ -	$ (174)
35.3047(f)	3	0%	0	0.0	30%	1	0.5	$ -	$ (44)
35.3067	2	0%	0	0.0	30%	1	2.0	$ -	$ (174)
							Total	**$ (474,742)**	**$ (1,008,962)**

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.

NRC Costs
Alternative 3

NRC	Units	Staff time per	One Time	Annual
New licenses applications	250	40 hours	$ (870,000)	
New license amendments annually	75	20 hours		$ (130,500)
Inspections of licensee facilities	25 / year	24 hours		$ (52,200)
			$ -	$ (182,700)

NRC		2005	2006
After proposed rule FRN to final rule FRN			
Labor hours April 2006-Mar 2007			2,000
Assumed wage rate			87
Labor expense			$ (174,000)
Other direct costs			$ (50,000)
	Total		$ (224,000)
Guidance	300 hours		$ (26,100)
New licenses applications			$ (870,000)
Total one-time implementation			$ (1,120,100)

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

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2. "The First Nuclear Industry," *Scientific American*, v247, November 1982, pages 180-193.
3. Environmental Assessment for Proposed 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.

Organization of Agreement States

February 2, 2006

Ms. Lydia Chang
U.S. Nuclear Regulatory Commission
Washington, D.C. 20555-0001

Subject: Request For Comments – Draft Proposed Rule: 10 CFR Parts 20, 30, 31, 32, 35, 40, "Expanded Definition of Byproduct Material" (STP-06-001)

Dear Ms. Chang:

The Board of the Organization of Agreement States (OAS) provides the enclosed comments requested in the subject letter of transmittal dated January 3, 2006. The draft proposed rule would amend the NRC regulations to include certain Naturally Occurring and Accelerator Produced Radioactive Materials (NARM). The rule is necessary to conform to the requirements of Section 651(e) of the Energy Policy Act of 2005.

The most significant concern expressed throughout the OAS Board's comments is the U.S. Nuclear Regulatory Commission's (NRC's) method of implementing requirements equivalent to States' regulations that most of the States have been using for decades. These States' regulations are based on the Conference of Radiation Control Program Directors, Inc. (CRCPD) model State Radiation Control Regulations—the *Suggested State Regulations* (SSR).

Specifically, the *Requirements for Expanded Definition of Byproduct Material* has several definitions tailored to the NRC regulatory scheme (e.g., the definition of "byproduct material") that are in the draft proposed rule with a Category B compatibility level assigned. Assigning Category B compatibility level to these definitions and then implementing the NRC's policies regarding compatibility may have a serious and significant impact upon the Agreement States and all but four other States. The States' use of the terms "radioactive material" and "particle accelerator" as defined in the SSRs already cover all the material that the NRC has to add to its rules by use of these definitions. In most cases, the States do not need the newly developed definitions and adding them will only confuse readers of the States' statutes and regulations as the States have always used the term "radioactive material" rather than "byproduct material," except for mill tailings, throughout the text of the rest of their regulations.

The efficient cost effective solution to this dilemma would be for the NRC to continue to recognize the long-standing practice of accepting the alternative language used by the States, as described in Management Directive 5.9, section VI. The OAS Board suggests this recognition be included in the proposed rule, clearly stating that the States can continue to use "radioactive material" rather than mandating revision of all the States' statutes and regulations to use definitions that the NRC must use to begin to regulate what the States have regulated for decades. The States do not need this new definition of "byproduct material" in the States' regulations, and the States should not have to add definitions of terms that the States do not use in the States regulations. Without this continued recognition, expanded to include the definition of "particle accelerators, and other terms that have been in use for decades due to the States' broader authority, the assigned compatibility Category B level as proposed and as the NRC typically administers compatibility will not allow the rational solution that the OAS Board is suggesting.

Thank you for the opportunity to comment on these important documents and please contact me at Bhamrick@dhs.ca.gov or telephone 714-257-2031 or fax at 916-341-7222 if you have any questions.

Sincerely,

Barbara L. Hamrick

Barbara L. Hamrick, Esq., CHP, JD, Chair
Organization of Agreement States

Enclosure

Cc: Janet Schlueter, Director
Office of State and Tribal Programs
U.S. Nuclear Regulatory Commission

OAS Board

Debra McBaugh, Chair
Conference of Radiation Control Program Directors

OAS Board Comments on the US NRC's

draft proposal for

Requirements for Expanded Definition of Byproduct Material

Generally the NRC's draft proposed rule *Requirements for Expanded Definition of Byproduct Material* is well conceived and the Organization of Agreement States (OAS) Board is in agreement with the stated objectives and methods proposed to implement the provisions by the NRC for the NRC. There are a number of specific concerns described in the following paragraphs, which the NRC could address before the rule is proposed by following the EPAct--using "model State standards in existence on the date of enactment of this Act." (A quote from the EPAct.)

Comment 1: The *Requirements for Expanded Definition of Byproduct Material* has several definitions specific to the NRC regulatory scheme (e.g., types of new byproduct material) that are in the draft proposed rule with a Category B compatibility level assigned. The OAS Board is confident that the NRC's State and Tribal Programs (STP) staff who have worked many years with the Conference of Radiation Control Program Directors' (CRCPD) Suggested State Regulations (SSR) system would agree that the States' use of the terms "radioactive material" and "particle accelerator" as defined in the SSRs already cover all the material that NRC has to add to its rules by use of these definitions. In most cases, the States do not need these definitions and adding them will only confuse readers of the States' statutes and regulations as the States have always used the term "radioactive material" rather than "byproduct material." It would be preferable if NRC clearly stated in writing that the States can continue to use "radioactive material" rather than revising the States' statutes and regulations to use "byproduct material" throughout the States regulations, and that the States do not have to add definitions of terms that the States do not use in the States regulations. The assigned compatibility Category B level as the NRC typically administers compatibility will not allow the rational solution that the OAS is suggesting. For this rulemaking, the NRC should designate the definitions it is changing to bring its regulations in line with the EPAct and the CRCPD's SSRs as compatibility Category C. The NRC is adding the terms not only because the EPAct has the terms, but because its regulations use the term "byproduct material" generally and defining two more categories of radioactive material to be "byproduct material" efficiently resolves the NRC's regulatory issues. The States have used the term "byproduct material" typically only with reference to mill tailings and the term "radioactive material" for all that the NRC is proposing to define to be "byproduct material" except for mill tailings. As noted in the FRN on pages 31, 32 and 61 and in comment number 23, the States use of "radioactive material" has always included NARM and discrete radium as the NRC proposal defines these terms.

Comment 2: On page 15 in the first sentence of the second paragraph, there needs to be clarification of working group and task force representation and resource persons. Illinois has provided assistance only through a resource person.

Comment 3: On page 21 in the last line of the center paragraph, The OAS Board recommends that "any" be "an" in ..."an inextricable part of any accelerator operation."

Comment 4: On page 23 the sentence at the end of the first paragraph indicates that the NRC is seeking comments on the extent, if any, that accelerators are used to intentionally produce radioactive material and to provide beams for basic science research. The OAS is not providing comments on this but encourages specific States comments because there are so few States to which this applies and those States and the licensees themselves should comment on it.

Comment 5: At the end of page 23 and continuing on page 24, the NRC requests comments "on the decommissioning of accelerator facilities, specifically addressing the extent to which accelerator components and facility building materials may become activated, 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, the cost of the decommissioning and disposal, if required, and the need for financial assurance by accelerator facilities to guarantee sufficient funding for proper decommissioning."

In the experience of the OAS Board, medical treatment accelerators (generally, linear accelerators referred to as linacs) and non-medical linacs (generally, industrial radiography use) have no real decommissioning issues regardless of the energy level because the induced radioactive is usually short lived and the machines are so valuable that older machines are traded in on newer machines or are refurbished by knowledgeable persons who know what components may be activated, how to measure the radiation level, and how to safely work with the "hot" components during the refurbishment process. The half-life of the "hot" components is so short that there is no "disposal" issue with regard to "low level radioactive waste" and there should be no export issues due to radioactivity. The NRC should clearly focus the application of its efforts on "production accelerators"—those used to produce radioactive materials for medical or other use. The States have licensed these types of accelerators, have required decommissioning cost estimates and, in some cases, have completed the decommissioning process for licensed accelerator facilities. Current information from one State that requires "Persons who use particle accelerators to manufacture radionuclides for distribution to other licensees or customers" to submit a reclamation plan and cost estimate for approval by the Agency; and, secure a financial arrangement in the amount specified on the Agency-approved cost estimate." The Reclamation Plans outline the types of machines and activated hardware that must be dispositioned and estimates the amount of concrete from the target vaults that require removal for disposal. These types of facilities

reconfigure their operations from time to time based on product needs and changes. Sometimes the shielding material is reused. The number of vaults, targets, etc. drive the costs of decommissioning. For financial assurance cost estimating, most licensees plan on removing all of the concrete shielding.

CONFIDENTIAL—NOT for Public Disclosure follows in brackets [ ]

CONFIDENTIAL—NOT for Public Disclosure above in brackets [ ]

Comment 6: On pages 30 and 31 the NRC indicates that it proposes to revise its rules to match the SSRs. We agree that this is the right way to go. For cases in which NRC is proposing a revision and a State has already adopted a comparable requirement that has stood the test of time; the States want a written statement by the NRC that the States do not have to revise the rule language to be like NRC even if it the NRC assigns a compatibility Category B or Category A.

For the column breakthrough limit (see page 31) the OAS Board recommends that the NRC state that the proposed criterion is from the US Pharmacopoeia, which is the criterion the States have used.

Comment 7: On page 33 and 34 there is a discussion under the title Definition of Discrete Sources that could be expanded to clearly state that residuals from treatment of water to meet drinking water criteria and residuals from treatment of waste water from public sewer treatment facilities are not discrete sources of radium regardless of the concentration of radium; however, some of these residuals may become licensable quantities of "source material" due to the concentration of uranium (and thorium).

Comment 8: On page 36 there is a discussion of the NRC's intent to accommodate existing products and materials that were previously regulated by the States under similar provisions. The OAS Board would like the NRC to clearly state that the wording in the States rules that covered this prior to the NRC receiving its new authority will not have to be revised because the NRCs phrases used to accomplish the same purpose may be different and the rule has a compatibility Category B or Category A assigned by the NRC.

Comment 9: On page 37 in the center of the page is a sentence that states "Some time ago, tritium and then promethium-147 replaced radium in self-luminous products." The memory of some States' older regulatory personnel is that promethium-147 and then tritium replaced radium in self-luminous products.

Please confirm the historical accuracy of the statement. These States' older personnel do not claim to possess perfect recall of such information.

Comment 10: On the bottom of page 41, the NRC proposes to "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." The OAS Board supports this approach. The OAS Board requests the NRC to clearly state that the States with provisions comparable to the NRC proposal, as evidenced by the fact that the rule was on the States' books and other States had not objected to it prior to this rulemaking by the NRC, will not have to revise the comparable provisions in order to be compatible with the NRCs new rule language even if the NRC rule is a compatibility Category B or Category A.

Comment 11: On page 42 the NRC discusses the registration requirement for radium-226 sources under a general license that are 0.1 mCi or more. Illinois searched its database and found that there were two known to be in Illinois. North Carolina has no such sources under a general license. It would be good if other States with a database that tracks these were checked to see if any exist and if so what are they and how much activity is there per device.

Comment 12: On page 44 is the term "revigarators" but a check of a device clearly showed the spelling to be "revigators" instead. Check the historical records and use correct term or, if both terms were used, then use both terms here and elsewhere in this FRN where the term is used. Also, the examples used were made of uranium ore rather than radium. This sentence could be deleted or new examples are needed.

Much more importantly is the proposed new general license for certain items and self-luminous products containing radium, which makes sense with one possible exception: antiquities. The experience of the OAS Board is that many of the antiques mentions in the proposed Section 31.12(a) are held by members of the public or by organizations in private collections. These items are collected and thus no longer being used for their original purpose. Most, if not all, of these items have been considered as practically exempt from regulation by the States for decades. The transition from exempt to a general license may be problematic since a) many of the owners of these items are likely unaware of the radioactive content and thus unaware of regulatory requirements - current or future and b) we do not know the details of who has them - just the big picture. We are also unaware of any data that suggests these items pose significant enough risk to warrant regulation. The NRC should consider including these antique items under an exemption, as has been the State practice for decades.

Comment 13: On page 45 is a discussion of a proposed general license that would prohibit ...assembly, disassembly, repair... of products containing radium-226. There is not a consensus of the States on this issue. These folks have not been regulated in the past for radiation safety purposes. There have been a few

problems because of this. Contact California, Illinois or Wisconsin for examples. Given the uncertainty of who may be performing service of radium-226 items, it seems appropriate to the OAS Board to recommend that the NRC require a specific license at this point. In order to be sensitive to the cost issue, the NRC could establish a separate, lower cost license category or fee reduction while still requiring a license. Finally, we also believe the NRC proposed regulations may (likely will) impact some facilities that have not previously been regulated by NRC or the states, such as facilities that restore antique aircraft containing radium dial gauges. We believe that an outreach effort will be needed to educate previously unregulated entities prior to implementation of the new NARM regulations. The NRC should collaborate with the States on this outreach.

Comment 14: On page 45 at the center of the page, end of first full paragraph is a statement that persons possessing these devices under a general license are to respond to written requests for information from the NRC. It appears that this sentence should end with "from the NRC or the appropriate Agreement State."

Comment 15: On page 46, the NRC makes the following requests to which index numbers have been inserted by the commenter in italics: "The Commission specifically requests comments to provide information that may assist the NRC to more fully evaluate potential impact to public health and safety and the environment due to activities involving radium-226 sources. *(1)* In particular, the Commission requests input on any quantitative or qualitative health and safety information regarding radium-226 sources that may be used to support a regulatory framework other than general licensing, such as an exemption. *(2)* The Commission also requests comments regarding its general license approach for certain items and other self-luminous products containing radium-226, *(3)* asks for comments on whether an exemption is a more effective and viable approach, and *(4)* requests additional information for the technical basis supporting an exemption in lieu of a general license. *(5)* In particular, the Commission would appreciate input on whether this general license approach, and its allowances and restrictions, is reasonable while the Commission evaluates the products; *(6)* whether the general license should allow possession of radium-226 luminous items, such as individual watch hands, dials, gauge indicators and faces, etc., which are not contained in an intact product regardless of number; *(7)* whether commercial transfers should be restricted and require a specific license; or *(8)* whether data are available to justify an exemption for certain types of radium-226 sources, now or in the future."

(1) Other than anecdotal information from State Radiation Control Programs seasoned staff members, that there have been only a small percentage of leaking or failed sources, there is no information known to exist.

(2) The OAS Board is in general agreement with the approach; however, see Comment 12.

(3) An exemption, when justifiable, is a better approach than a general license. We therefore recommend using exemptions rather than general licenses.

(4) Other than the qualitative statement that the States are not aware of significant problems with the sources, the States do not have technical data supporting an exemption in lieu of a general license or vice versa.

(5) The approach is reasonable while the NRC evaluates the products; however, see Comment 12.

(6) There is a possession level beyond which a specific license is preferable (possibly, a number of items that is at least the exempt quantity value times ten). The NRC should propose a value in the FRN and ask for comment.

(7) Commercial transfers are nearly the same considerations as for quantities needing a specific license for dials. It is case specific and would require knowledge and experience. In some cases the answer is yes, but could be costly and also urgent, as professionals with direct knowledge of radium are becoming aged.

(8) The OAS Board is not aware of the existence of such data.

Comment 16: On pages 47 and 48 the NRC describes its regulatory structure that is set up for separate licenses for production, and distribution, and possession and use. Some of the Agreement States have for many years combined the license authorizations as much as feasible for these because there is only one radiation safety program to be evaluated at a facility and the authorization takes only the addition of a few lines of text to a license document so the licensee should not have to pay two or three separate licensing fees for the authorization of work at one facility under one regulatory agency, for one radiation safety program under one management. Some Agreement States have the same licensing structure as the NRC. The OAS recommends that the NRC continue to allow this flexibility.

Comment 17: On page 53, the second sentence of the last paragraph on the page states in part "The intent of this provision is that the compacting process implemented in accordance with the LLWPA is not to be affected by"... It appears that the word "compacting" should be "Compact."

Comment 18: On page 58 at the end of the first paragraph, the document states ..."a facility-specific decommissioning plan that addresses the current contamination and any previous disposals." It appears that this should state ..."any previous on-site disposals."

Comment 19: On page 58, at the center of the page, is a discussion regarding the potential for the existence of facilities currently contaminated from discrete sources of radium-226 and the NRC's proposal to address these situations on a case-by-case basis as they are identified following promulgation of new requirements. The OAS Board reminds NRC that radium-226 was once relatively common and unregulated. Therefore, NRC can reasonably expect radium-226 to turn up on a regular basis. NRC should be prepared to address voluminous situations requiring the NRC's technical, public relations, and political resources.

Comment 20: On page 59 in the discussion of the transition plan, is specified "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"... The States would like a clear statement that the date of publication of the transition plan will be provided well in advance so the States can get the certifications provided on the exact date of publication of the plan.

Comment 21: On page 61 in the fourth line from the top is stated ..."and a 12-month period from the effective date for the affected individuals to apply for a new license application." This should indicate "apply for a new license with an application" or something similar rather than "apply for a new license application."

Comment 22: On page 61 in the middle of the page and last sentence of the paragraph, the FRN states "The Commission specifically requests comments on the proposed effective date for the final rule and other implementation period to ensure the affected individuals have sufficient time to come into compliance with the new requirements and to apply for an appropriate license or license amendment for the material, if applicable." The OAS Board agrees with the proposed timeframe found at the top of this page 61; however, it is concerned about the ability of currently non-licensed persons and those who will have a new general license to be aware of the existence of the requirements.

Comment 23: On the bottom of page 61 in the last paragraph is the statement that inspires many of the OAS Boards concerns regarding compatibility and the NRC's implementation of its new authority, which took away what the Agreement States had been doing in a fairly uniform comparable manner for decades and now gives it back with requirements that include the NRC's concept of "make the States regulations read exactly like our new ones." The OAS Board suggests that the FRN include a statement that the NRC will accept as compatible each Agreement States regulations that were essentially the same as the CRCPD's SSR on the date of the NRC's final rule. It may help the NRC to understand the States' concern if the NRC views this process as the NRC becoming compatible with the Agreement States and living up to the requirement in the Atomic Energy Act that NRC also must use its best efforts to maintain compatible programs when it signed each of the agreements.

Comment 24: On page 65 Section 30.34, perhaps there should be a reference to the US Pharmacopoeia as the source of this requirement for element breakthrough in the eluant on the first elution of a generator.

Comment 25: On page 66 Section 31.8 reference to Paragraph (b), the OAS Board hopes that the States do not have to demonstrate that its provisions were comparable to 10 CFR 32.57 because some of these may have been done many years before 10 CFR 32.57 was adopted in its current form. 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 NRC should clearly communicate in the FRN what it plans to require for this, if anything. The OAS Board thinks that, unless the NRC has knowledge of problems of leaking sources of this type that it should be clearer in a written statement that these sources are acceptable as manufactured.

Comment 26: On page 67 Section 31.12, were luminous devices for ships considered for inclusion in this GL, and if so, were they excluded because of higher activities involved? Marine compasses are mentioned in another current rulemaking. It might be helpful to address marine compasses in this section perhaps by reference to the section where they are addressed.

Comment 27: On page 68 Section 31.12 in the last paragraph before Part 32, the OAS Board wishes to know if the NRC plans to monitor this for compliance by a strictly reactive process.

Comment 28: On page 70 Section 35.2 Definitions, the proposed changes are because of the NRC's use of the term "byproduct material" and the NRC should clearly state that States who use the term "radioactive material" as defined by CRCPD's SSRs do not need to amend their definitions to be compatible even if the compatibility Category B or Category A is assigned because the States definitions already include what NRC is including with the proposed revision. Perhaps the NRC could designate the 11e(3) and 11e(4) additions to the definition as compatibility Category C to resolve the issue.

Comment 29: On page 81 at the top of the page is the statement "NRC specifically requests comments on the Compatibility designation. In particular, NRC request comments on whether the definition of *Discrete source* is correctly designated as Compatibility Category B, considering the procedures in Management Directive 5.9 and that Congress assigned NRC the task of defining *Discrete source* in the EPAct." The OAS Board suggests that the FRN include a statement acknowledging that the CRCPD SSR and Agreement States term *Sealed source* is comparable and the Agreement States do not have to change their definitions to incorporate the definition of *Discrete source* or that the term is Category C.

Comment 30: On page 81 at the top of the Table for 20.1003 for the Definition of *Byproduct Material* and Sections 20.2006 (e) and 20.2008 the OAS Board wants NRC to acknowledge the Agreement States use of the term "Radioactive material" instead of "Byproduct material" and that the term "Radioactive material" includes what the NRC is including with its change in its definition of "Byproduct product" and that regardless of whether the compatibility is designated Category A, Category [A], Category B, or Category C the Agreement States do not have to revise their regulations to be compatible with the changes NRC has to make to include what the Agreement States already include in "Radioactive material." This comment also applies to the other Sections where the same terms are defined.

Comment 31: On page 82 Section 30.4 Definitions of *Accelerator-produced radioactive material, Byproduct material, Positron Emission Tomography (PET)* and *Particle Accelerator*, the OAS Board suggests that the FRN state that the NRC will accept as compatible regardless of the Compatibility Category the current Agreement States definitions of the terms as long as they are consistent with the current CRCPD's SSR. This statement applies to the other Sections where the same terms are defined.

Comment 32: On pages 82 through 87 for all Sections not regarding the Definitions discussed in Comments 30 and 31, the OAS Board suggests that the FRN include an acknowledgement that the NRC is becoming compatible with the Agreement States by using language similar to that of the CRCPD's SSR and that any Agreement State that has rule language essentially the same as the current SSR provisions has compatible rules and does not have to revise those rules as a result of this NRC rulemaking regardless of the compatibility Category assigned by the NRC.

Comment 33: On page 88 at the top of the page the NRC states "The NRC requests comments on this proposed rule specifically with respect to the clarity and effectiveness of the language used. With the exception of the actions required of the Agreement States to be compatible with these rules, the OAS Board finds the FRN for the proposed rule is extremely well written, clear and easy to understand and effective in communicating requirements. The OAS Board has suggested substantive improvements to the FRN throughout this comment paper.

Comment 34: On page 88 in VII. Voluntary Consensus Standards at the bottom of the page the NRC states "To the maximum extent practicable, the NRC has incorporated the CRCPD's SSRs into the proposed rule." Based on the language and the NRC's stated intent this appears to be accurate; however, the proof will be in the NRC's implementation. The Agreement States were active in the development of the EPAct language requiring the NRC to use the CRCPD's Suggested State Regulations (SSR). The OAS Board is confident that the intent of the Agreement States and of the drafters of the EPAct language was to minimize the burden on the public and the States in the NRC's process of

developing and implementing compatible provisions and the desire was that the NRC become compatible with the CRCPD's SSR language, which essentially should guarantee that the Agreement States would not need to make many rule changes. Needlessly forcing the States to change statute and/or rules that currently mirror the SSRs does not meet the letter or spirit of the EPAct.

Comment 35: On page 90 in the second line the word "Agreement" needs to be deleted because some of the States who developed the ARM rules were not Agreement States but were States who regulated only NARM.

Comment 36: On page 95 under X. Regulatory Analysis in the beginning of the second paragraph is stated "The Commission requests public comment on the draft regulatory analysis." The OAS Board currently does not have time to look at this.

Comment 37: On pages 102 through 104 for the Definitions the OAS Board Comments 30, 31 and 32 apply.

Comment 38: On page 104 in Section 20.1003 Definitions and the definition of *Waste* the OAS Board that the last sentence that starts with the word "However" should not be in the definition. The sentence should be in rule text with requirements or a note or deleted but not in the definition. Including it in the definition may cause unnecessary rulemaking to add explanatory material that could be in a note or guidance or in the rule where requirements are specified. Either delete it or put it in somewhere as a compatibility Category C.

Comment 39: On page 105 in Section 20.2008 (a) the OAS Board recommends adding a phrase similar to the phrase "if acceptable to the Compact for that State" to the end of the first sentence.

Comment 40: On page 116 in Section 32.51 (c)(13)(i) for the last sentence the OAS Board recommends that the last sentence be deleted and leave this as an option for each State to do as it determines is in the best interest of the State. Some States find it more advantageous to allow multiple addresses for location of use for one general licensee, such as gauges at coal fired power plants. This is an item that may be addressed in the GL petition.

Comment 41: On page 121 in footnote 2 the items named "revigarators" should be referred to as "revigators." This term was used in one or two other places of the FRN.

Comment 42: On page 122 in the first sentence of Section 31.12 (c)(1) the OAS Board thinks that "Shall notify the NRC" should state "Shall notify the NRC or Agreement State where the damaged product is currently located.

Comment 43: On page 122 in the second sentence of Section 31.12 (c)(1) the OAS Board thinks that "disposed of" could be "dispositioned" or "disposed of or transferred" because transfer to a specific licensee is acceptable.

Comment 44: On page 127 for 32.72 the Agreement States do not need to amend their regulations or licenses because the terms used by the Agreement States already authorize all the things that NRC is including its regulations with these changes. The NRC is becoming compatible with the Agreement States and as long as the Agreement States has rule language comparable to the current CRCPD's SSR the Agreement State should not have to revise its regulations regardless of the NRC compatibility Category assigned.

Comment 45: On pages 131 through 133 for Section 35.2 Definitions of *Authorized nuclear pharmacist, Authorized user* and *Positron Emission Tomography (PET),* Any Agreement State that has rule language essentially the same as the current SSR provisions has should be considered to have compatible rules and should not have to revise those rules as a result of this NRC rulemaking regardless of the compatibility Category assigned by the NRC.

Staff Position on the Compatibility Category for the Definition of *Byproduct Material*

The staff has applied Management Directive 5.9, *"Adequacy and Compatibility of Agreement State Programs*," (see Handbook 5.9, Part III) with the following results:

> Question (1)—Do the essential objectives of the program element address a regulatory area reserved solely to the authority of the NRC? If the response to the question is "yes," the compatibility category is "NRC." If the response to the question is "no," then proceed to Question (2).

Since the AEA explicitly authorizes States to regulate byproduct material under section 274b Agreements, the answer to this question is "no."

> Question (2)—Do the essential objectives of the program element address or define a basic radiation protection standard as defined by the Policy Statement or is it a definition, term, sign, or symbol needed for a common understanding of radiation protection principles? If the response to this question is "yes," the compatibility category is "A." If the response to the question is "no," then proceed to Question (3).

The definition itself does not address or define a basic radiation protection standard. Further, it is not needed for a common understanding of radiation protection principles, since the radiation protection principles are independent of the source of radiation. There is one common set of radiation protection principles for both byproduct material and non-byproduct radioactive material. Therefore, the answer to this question is also "no."

> Question (3)—Do the essential objectives of the program element address or define an issue that has a significant, direct transboundary implication? If the response to this question is "yes," the compatibility category is "B." If the response to the question is "no," then proceed to Question (4).

Even if an Agreement State chose not to define 11e.(3) byproduct material in its regulations, a direct and significant transboundary implication would not exist since such material does not require unique radiation safety handling or management practices (e.g., different training requirements, or different labeling requirements) and is currently addressed in existing NARM regulations. Said another way, in order for a significant direct transboundary implication to occur, an Agreement State definition of byproduct material that did not include 11e.(3) would have to require a licensee using 11e.(3) byproduct material to operate its radiation safety program using different radiation safety requirements than the NRC definition of byproduct material would require. However, the Agreement States already regulate 11e.(3) material under State regulations that cover both byproduct material as we know it today and NARM using the same radiation safety requirements. The amended definition of byproduct material does not change that approach. Therefore, the answer to the question is "no."

> Question (4)—Would the absence of the essential objectives of the program element from an Agreement State program create a conflict or gap? If the response to this question is "yes," the compatibility category is "C." If the response to the question is "no," then the compatibility category is "D" and proceed to Question (5) to determine

whether the program element should be identified as having particular health and safety significance.

Gap is defined as - The essential objectives of NRC regulations or program elements are absent from the Agreement State program and an undesirable consequence is likely to result in another jurisdiction or in the regulation of agreement materials on a nationwide basis.

Conflict is defined as - The essential objectives of regulations or program elements are different and an undesirable consequence is likely to result in another jurisdiction or in the regulation of agreement material on a nationwide basis.

Note that the definitions of "gap" and "conflict" depend on an undesirable consequence in another jurisdiction or in the regulation of agreement materials on a nationwide basis. In other words, a conflict or gap may be thought of as an indirect, less significant form of a transboundary implication. A definition, however, specifies the meaning of a term only as that term is used in the regulations in which it appears. It does not impose any regulatory requirement on a licensee. If an Agreement State chose not to define 11e.(3) byproduct material, its absence would not create a gap, conflict or duplication on a nationwide basis because this material is currently regulated by the States under existing State regulations. Therefore, no gap or conflict would be created if the State did not adopt the amended definition of *byproduct material* in its regulations. Therefore, the answer to the question is "no."

Question (5)—Would the absence of the essential objectives of the program element from an agreement state program create a situation that could directly result in exposure to an individual in excess of the basic radiation protection standards found in compatibility category A? If the response to this question is "yes," the program element is not required for purposes of compatibility, but is identified as having particular health and safety significance.

If the answer to question 5 is no, then the proper categorization of the program element is "D." Note here the question addresses the absence of the essential objectives from the entire state program as opposed to the State regulations. If the definition of *byproduct material* or another term (such as *radioactive material*) which encompasses all of the byproduct materials 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 Part 20 limits. The answer to this question is "yes," and the proper categorization of the definition is "H&S." The State regulatory program must include 11e.(3) and (4) byproduct material in its regulatory program if the Agreement includes such material.

Organization of Agreement States

February 27, 2006

Charles Miller, PhD, Director
Division of Industrial and Medical Nuclear Safety
Mailstop 8 F5
U.S. Nuclear Regulatory Commission
Washington, D.C. 20555-0001

Subject: Draft Proposed Rule: 10 CFR Parts 20, 30, 31, 32, 35, 40, "Expanded Definition of Byproduct Material" (STP-06-001)

Dear Dr. Miller:

As Chair of the Organization of Agreement States (OAS), I am writing on behalf of the OAS membership to supplement and revise the comments provided by the OAS Executive Board on February 2, 2006. As you know, the OAS has facilitated participation of State representatives on the Naturally-Occurring & Accelerator-Produced Radioactive Material (NARM) Task Force and NARM Rulemaking Working Group (WG), as well as the joint Steering Committee overseeing both the NARM Task Force and NARM Rulemaking WG. Since the OAS Executive Board comment letter of February 2, 2006, the State representatives on the NARM Task Force, NARM Rulemaking WG and Steering Committee have all expressed very serious concerns to the OAS Executive Board regarding the proposed compatibility/adequacy designation for the definition of "Byproduct Material" (and other definitions included in the subject draft proposed rule). These concerns were passed on to the OAS State Program Directors, and the OAS Executive Board requested comments from the State Program Directors on these matters. This letter is provided to 1) revise the position of the OAS Executive Board, 2) provide justification for the revised position, and 3) transmit specific comments received from the State Program Directors in this regard.

In particular, the concerns of the State representatives on the NARM Task Force, Rulemaking WG and Steering Committee were related to:

1) A U.S. Nuclear Regulatory Commission (NRC) staff interpretation of compatibility designation "C" that: a) is not consistent with the definition in the NRC's Management Directive 5.9 Handbook, Part 1 or the NRC's Office of State and Tribal Programs' (STP's) Procedure SA-200, and b) is essentially equivalent to a Compatibility designation of "A" or "B."

2) The fact that both the "C" Compatibility designation and the "Health and Safety (H&S) Adequacy designation require the adoption of the "essential objectives" of a given

program element means these designations are essentially indistinguishable from the perspective of program implementation (i.e., the difference is only a matter of whether the "essential objectives" must be met for purposes of compatibility or adequacy, and not a matter of how they will be met), so a misinterpretation of the "C" designation implicates a future misinterpretation of an "H&S" designation, which still places the Agreement States in the position of potentially having to amend definitions in both state statute and rule;

3) The fact that proposals for these compatibility/adequacy designations were being developed solely by NRC staff, and outside of the NARM Task Force and NARM Rulemaking WG confines, which precluded any opportunity for the State representatives to these groups to object, or to provide formal dissenting opinions before the group recommendations moved forward to the Steering Committee.

In light of these concerns, and the overwhelming support of the Agreement State Program Directors for a "D" Compatibility designation (32 of 33 Agreement States), the OAS Executive Board reconsidered the original opinion expressed in the February 2, 2006 comments on the subject draft proposed rule. That opinion was based on an understanding that a "C" compatibility designation would not result in any requirement for substantive changes to State statutes or rules, since the Agreement States have been meeting the "essential objectives" of the new rules for the past 40 years or more.

In addition, in making the comments transmitted February 2, 2006, the OAS Executive Board had considered the express language of the Energy Policy Act of 2005 (EPAct) in making its comments. The EPAct requires that:

> "The Commission...to the maximum extent practicable--
> (i) cooperate with States; and
> (ii) use model State standards in existence on the date of enactment of this Act."

The OAS Executive Board took the plain language of the statute as a rather clear indication that the substantive burden would be upon the NRC to bring its regulations into conformance with the Agreement State regulations, since these regulations have, for 40 years or more, already provided for the safe control of the sources that will only now, after the enactment of the EPAct, come under the jurisdiction of the NRC.

In summary, the OAS Executive Board, and the overwhelming majority of the membership (32 of 33 Agreement States, agree that the appropriate Compatibility/Adequacy designation at this time is a "D" for the definition of "Byproduct Material" (one State recommends a "C" designation, and one pending Agreement State responded supporting the majority). Please also be aware that OAS communications with the States focused specifically on the definition of "Byproduct Material," but that other definitions that arise from the EPAct (e.g., "Particle Accelerator" and "Discrete") raise similar concerns.

Enclosed please find a document detailing the justification for the States' position that the definition of "Byproduct Material" (and other definitions arising from the EPAct) should carry a "D" compatibility designation. Additionally, we are providing a compilation of the comments from each of the States responding to the OAS Executive Board's request for comments on this matter.

Thank you for the opportunity to provide this additional input to you on this matter. Please contact me at 714-257-2031, or via the additional contact information below if you have any questions regarding this matter.

Sincerely,

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Enclosures: Justification of a "D" Designation for New Definitions Resulting from the Energy Policy Act 2005

State Comments on the Compatibility/Adequacy Designation for New Definitions Resulting from the Energy Policy Act 2005

Cc: Janet Schlueter, Director
Office of State and Tribal Programs
U.S. Nuclear Regulatory Commission

OAS Board (by email)

OAS State Program Directors (by email)

Debra McBaugh, Chair (by email)
Conference of Radiation Control Program Directors

Justification of a "D" Designation for New Definitions Resulting from the Energy Policy Act 2005

The Organization of Agreement States (OAS) Executive Board and 32 Agreement State Programs recommend that the Compatibility/Adequacy designation for definitions arising from the Energy Policy Act of 2005, with respect to the regulation of Naturally-Occurring and Accelerator-Produced Radioactive Material (NARM) in existing Agreement States be a "D;" i.e., not required for purposes of compatibility.

As stated in the Supplementary Information section of the draft Federal Register Notice for the Proposed Rule:

> "The regulatory structure used by Agreement States 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, source, or special nuclear material."

Simply stated, the existing Agreement States already have programs in place to regulate NARM, compatible with the programs implemented pursuant to their agreements with the NRC to regulate other byproduct, source and special nuclear material.

As stated in the September 3, 1997 "Policy Statement on Adequacy and Compatibility of Agreement State Programs":

> "An Agreement State radiation control program is compatible with the Commission's regulatory program when its program does not create conflicts, duplications, gaps, or other conditions that would jeopardize an orderly pattern in the regulation of agreement material on a nationwide basis."

The Agreement State programs do not anticipate any "conflicts, duplication, [or] gaps," with respect to the regulation of NARM in the Agreement States, even with no changes to their definitions. The Agreement States will simply continue to regulate these materials as they have for the past 40 years. A requirement to revise the definitions currently in use (which in many cases are in both state statute and regulation) would create an enormous and unnecessary burden upon the Agreement States, potentially cause confusion for Agreement State licensees, and would not provide any measurable improvement to the system of regulation, since these NARM materials are already regulated under a system that, as stated above, is completely compatible with the programs implemented to regulate other byproduct, source and special nuclear material. If an Agreement State is currently compatible with respect to their regulation of other byproduct, source or special nuclear material, they will continue to be compatible with respect to the NRC's addition of NARM, since these sources are all regulated in the same manner. The only gap at issue should be the very sizable gap in the NRC regulations created by the former exclusion of NARM from NRC jurisdiction, which the Agreement States have filled for many years. The NRC needs to work to fill that gap now that they have jurisdiction over these materials, and the Agreement States are willing and able to assist the NRC in this matter, but it is the NRC, in this case, that will need to move toward compatibility with the Agreement States on this issue and not vice versa.

The Energy Policy Act of 2005 includes the following language:

> "'The Commission shall, to the maximum extent practicable--
> (i) cooperate with States; and
> (ii) use model State standards in existence on the date of enactment of this Act.'

Justification of a "D" Designation for New Definitions Resulting from the Energy Policy Act 2005

It is clear from this language that Congress did not intend that this new authority granted to the NRC would or should disrupt the existing State programs already regulating the use of NARM, but that the NRC would "*to the maximum extent practicable,*" conform their program to the State programs.

With respect to Compatibility, the appropriate designation for definitions arising from the Energy Policy Act of 2005 relating to the regulation of NARM, is "D," except that the NRC should to the "maximum extent practicable" provide definitions in their own regulations that are consistent and compatible with the existing State regulations, though they needn't be "essentially identical," since the NRC still does not have jurisdiction over the complete suite of radioactive materials and sources regulated by the States – i.e., the NRC should strive to meet the essential objectives of the existing State regulations.

With respect to the proposed "health and safety" designation, the Office of State and Tribal Programs, SA-200, "Compatibility Categories and Health and Safety Identification for NRC Regulations and Other Program Elements," states in footnote 5:

> "If the essential objectives of the program element were not adopted, it could result directly...in an exposure to an individual in excess of the basic radiation protection standards."

It is inconceivable that the failure of the Agreement States to add or amend the definitions of "byproduct material," "particle accelerator," "discrete," or other terms arising from the NARM provisions in the Energy Policy Act of 2005 could ever result in an "exposure to an individual in excess of the basic radiation protection standards," given that the Agreement States' regulation of NARM, and generic definition of "radioactive material" already extends far beyond the NRC's new jurisdiction with respect to these materials. Simply put, the Agreement States are already far more protective than the NRC in this regard, regulating non-discrete sources of NARM, and all machine-produced radiation, whether or not it is for the purpose of creating radioactive material for extraction. Based on the NRC's written procedures regarding the application of the H&S designation, it appears to be completely inappropriate to designate the new definitions as such.

In conclusion, the Agreement States have long had programs to regulate NARM, which programs are completely integrated into, compatible and consistent with the programs to regulate other byproduct, source, and special nuclear material. At this time, it is the NRC that needs to move to become compatible with the Agreement States with respect to the regulation of NARM; thus, the Agreement States do not need to make any changes with respect to the new definitions arising from the Energy Policy Act of 2005 relating to NARM regulation, for purposes of compatibility; these new definitions should therefore receive a compatibility designation of "D" as applicable to the States. In addition, these new definitions do not, in anyway, meet the express written intent of the H&S designation respecting adequacy, because the Agreement States' regulations and definitions are already far more comprehensive and protective than the NRC's, since the Agreement States have much broader authority to regulate in this area. The OAS Executive Board, and a majority of the Agreement States (32 of 33) recommend that the definitions arising from the Energy Policy Act of 2005 NARM provisions, receive a compatibility designation of "D," and that it be acknowledged, given the Agreement States broad jurisdiction over NARM and machine-produced radiation, they are not required for the purposes of Health and Safety.

The OAS Executive Board polled the Agreement States' Radiation Control Program Directors regarding the proposed compatibility/adequacy designation. Excerpts from their responses are given in the attached document.

State Comments on the Compatibility/Adequacy Designation for New Definitions Resulting from the Energy Policy Act 2005

(1) Alabama:
"[It] is my recommendation that the compatibility designation be no greater than "D."

I had many concerns, and still do, about the NRC take-over of NARM...The states have a wealth of knowledge and experience, especially in NARM that NRC should tap into to make NRC a better agency. States should not be made to reinvent the wheel simply because the wheel now has another spoke - NRC! That "new spoke" should act like the others."

(2) Arizona:
"AZ suggests th[at] "D" is the proper compatibility class."

"I believe that [other States] have a point in that the changing of the definition [of] "byproduct material" may be a problem if the states are required in any way to adopt exacting wording. The new definition of "C" by staff is a violation of the intent of the "C" category...The need to redefine "byproduct material" is unique to NRC but not the states...when correctly understood, the states have already addressed the issue and no further action is necessary."

(3) Arkansas:
"Arkansas continues to support the "D" compatibility [designation] for this definition."

(4) California:
"California still strongly supports a "D" [designation]."

(5) Colorado:
"As indicated previously to OAS, Colorado prefers compatibility "D" designation for the expanded definition of 'byproduct material'."

(6) Florida:
"It needs to be a 'D.' There is no need for Florida to make changes to our regulations or our statutes to continue to do what we have always done...[the NRC] should be making the changes to be compatible with us."

(7) Georgia:
"Georgia recommends the Compatibility D designation."

(8) Illinois:
"Illinois firmly believes the definition of "Byproduct Material" be designated Compatibility Category D. As previously determined, it does not fit Category C, and it is further not appropriate to classify this definition as having a "health and safety significance" as described in Management Directive 5.9. It is important that the NRC begin to give professional recognition to the excellent regulatory programs that have been developed and administered by state radiation control programs prior to and in the absence of the NRC addressing such important issues as industrial radiography certification, effective general licensing, and NARM regulation."

State Comments on the Compatibility/Adequacy Designation for New Definitions Resulting from the Energy Policy Act 2005

(9) Iowa:

"As far as Iowa is concerned "D" is what is necessary at this point in time.

"[Iowa has a] definition of "byproduct material" in [rule] as a matter of compatibility (Category A). However, this definition does not include all that Iowa law allows us to regulate. Therefore, we define "radioactive material." This definition is all-inclusive, and, when we adopt or amend our rules, as a result of compatibility or otherwise, we substitute this term. Until NRC publishes a new definition, our agreement covers byproduct material and our state law covers NARM and NORM.

"If NRC adopts the definition of byproduct material exactly as it exists in the new Energy Policy Act, the same, but slightly modified situation still exists. The new definition does not include all that our state law allows us to regulate...We will still employ the use of "radioactive material" regardless of what the compatibility category is. However, we do recommend D."

"There is another...possibly larger issue...There is a contradiction in what...the NARM Steering Committee's interpretation of Category C when it comes to the definition of byproduct material. Let me quote removing any extraneous words and adding some emphasis and clarifications:

"...the NARM Steering Committee interpreted that any Compatibility C rating would require States that currently have the definition of 'byproduct material' in statutes or regulations [which is everyone since it's an A], to be essentially the same as the new definition..."

"[Isn't this] just the definition of Category B...? This is a dangerous precedent. Will all C's then be interpreted as B's? Agreement States can not function on interpretations, but must have definite, written criteria, especially when it comes to IMPEP."

(10) Kansas:

"[For the short term] I suggest the following:

"Start with a compatibility of "D" with the intent that the NRC will have a three year period to bring their regulations and programs up to a level that are adequate and compatible with the States' regulations and programs, then change it to a "C," provided "C" really means "C" and not "B," since there are still many radionuclides and forms that do not fall under the new definition of byproduct material. This will give time to "work out the bugs" without putting in jeopardy any of the States' licensees' ability to provide needed radioisotopes and services to the medical community and their patients. I believe it should also alleviate many of the State's concerns about making this transition.

"The idea of this being an H&S category is completely unacceptable. It is the NRC's program that has, with respect to NARM, been inadequate (due to its non-existence) to protect the health and safety of the public not the States. This fact was recognized by Congress in the...EPAct.

State Comments on the Compatibility/Adequacy Designation for New Definitions Resulting from the Energy Policy Act 2005

"Bottom line: "D" is the only acceptable compatibility category at this time."

In a separate communication, Kansas also provided the following:

"The compatibility should be "D" in order to avoid conflicts with existing state regulations that would disrupt the various affected industries (i.e. the medical industry and patient care). Perhaps when the NRC reaches the same level the states have in regulating NARM the compatibility could be changed to "C" but it is premature at this time.

The Act required NRC to consider the impact on production and availability of medical isotopes in implementing their regulation of accelerator-produced material. Putting too restrictive a compatibility requirement here would interfere with the ability of states to carry out their existing programs and cause disruption of the ability of medical isotope suppliers to legally produce and distribute their product!

I am very concerned about the "interpretation" of the Steering Committee with regard to the definition of byproduct material. As [Iowa] pointed out this is simply a redefinition of Category C to Category B which is unacceptable and sets a precedent the States cannot live with."

(11) Kentucky:
"Kentucky must vote for D also for the same reasons as Maine."

(12) Louisiana:
"Louisiana, as many other states, defines both byproduct material and radioactive material in legislation (R.S. 30:2103) and regulation. The definition of radioactive material captures NARM and our program appears to accomplish the essential objective of the corresponding (proposed) Commission program elements. Therefore it seems to be an unnecessary burden to change the definition in the Louisiana Revised Statutes and all of our regulations.

"Category C seems to be appropriate (the essential objective of regulating NARM should be met), but if category C compatibility is to be interpreted differently than the plain language, we recommend compatibility category D to ensure that states will not have to change definitions."

(13) Maine:
"Maine has to vote for D due primarily to the fact that I personally can't make sense out of this. The facts as I see them:

1. States (with programs) have regulated all materials for a large number of years.
2. These States have had years of input in the development and review of regulations, their own and the SSR's.
3. The NRC has determined that something they have never regulated (and didn't want to), but we have, is of Health and Safety significance.
4. They will be the ones to tell us if we are doing it right.

State Comments on the Compatibility/Adequacy Designation for New Definitions Resulting from the Energy Policy Act 2005

"This is just an idea:
1. Find out what the States all have for definitions, my guess is they are all similar or exactly the same.
2. Make NRC come into compliance with us."

(14) Maryland:
"The Agreement States have in the term, radioactive material, a definition that encompasses byproduct and NARM. If Section 274b were really being practiced as written, I believe the NRC would be working to gain compatibility with the Agreement States by adopting the definition that the States have used so successfully for so many years.

I believe category D is as close to the original intent of Section 274b of any provision developed and I still support it here. The addition of the health and safety consideration does not strengthen the definition of byproduct material, nor should it be used as an "end around" to coerce Agreement States to accept cumbersome, nondescript and impractical term. What's really obsolete here is the term, "byproduct material".

(15) Massachusetts:
"Massachusetts joins with its state partners in voting 'D'. As [NY-DOL] says, anything else would be a violation of both the text and spirit of the EPAct."

(16) Minnesota:
"I believe that there should be a nationally consistent program at some point but I feel the NRC is going about it backwards. Without federal direction and a framework, D is the most they can ask for at this time."

(17) Mississippi:
"Mississippi votes 'D'."

(18) Nebraska:
"Nebraska still votes for D."

(19) Nevada:
"For many of the reasons [Oklahoma] discusses...Nevada votes for the 'D' designation."

(20) New Hampshire:
"As we stated in our earlier email regarding this subject, NH supports a "D" designation for the revised definitions. In light of this new information, we do not support an H&S designation for the definition of "byproduct" material. NH has been regulating all radioactive material uniformly certainly since entering into the Agreement (April 1966), and was regulating non-AEA material well before that as well. We see no need to now to have to amend our statute, regulations or programs in this regard, which is still what an "H&S" designation would do. We must insist on the "D" designation."

(21) New Mexico:
New Mexico recommends the "D" designation for the same reasons [Oklahoma] so thoroughly discussed.

State Comments on the Compatibility/Adequacy Designation for New Definitions Resulting from the Energy Policy Act 2005

(22a) New York – DOL:
"According to the EPAct:

> "'The Commission shall, to the maximum extent practicable--
> (i) cooperate with States; and
> (ii) use model State standards in existence on the date of enactment of this Act.'

"This means that the Commission needs to define "Radioactive material" and "Radiation source" and reword the "scope" sections of its regulations to bring them into compliance with the existing State regulations and the SSRs. The States don't need definitions of byproduct, source and special nuclear material (except for clarification purposes), since their regulations cover all radioactive materials anyway.

"In order to comply with the statute, the maximum burden should be borne by the Commission in bringing their regulations into line with the States, not the other way round. While they are at it, the Commission needs to add another compatibility category:

> E - Program element, the essential objectives of which should be adopted by the Commission to avoid conflicts, duplications or gaps."

(22b) New York – DEC:
"I agree with the points presented [by other States]. NYSDEC votes for "D."

(22c) New York – DOH:
"New York State Department of Health recommends 'D'."

(22d) New York City:
"New York City votes for D."

23) North Carolina:
"We agree that the definition of "Byproduct Material" should not be required for compatibility; however, NC does not agree with the NRC that H&S is the right fit. This logic of not being required for compatibility seems to be consistent with what the EPAct has mandated of the NRC in bringing this material under their jurisdiction (after decades of this material and other material being under AS jurisdiction). It seems to me that a Compatibility D designation is the only logical fit. NC is voting for a D designation. This vote is also a product of the recent NRC's misinterpretation of Compatibility C."

(24) North Dakota:
"I agree with [Maryland's statements]. Compatibility D is best. Another issue to consider here is the magnitude of changes that can ripple through an entire rule when a definition is changed. NRC should focus more on performance not prescriptive rulemaking."

State Comments on the Compatibility/Adequacy Designation for New Definitions Resulting from the Energy Policy Act 2005

(25) Ohio:

"I believe this should be Compatibility "D." States are already adequately regulating this material, and have been doing so for quite some time. The NRC needs to recognize this and factor this into the appropriate designation."

(26) Oklahoma:

"As I understand it, NRC has directions in the EPAct to ensure that they work cooperatively with states, use existing state standards, and ensure that the production and use of medical isotopes is not disrupted. NRC's creative interpretation of what a "C" compatibility would mean on this issue, followed by a proposed "H&S" compatibility that would mean "states could be the same or more restrictive" causes me concern.

"The new rules on incorporating NARM into Byproduct Material regulation being promulgated under EPAct are to add accelerator-produced material, and a limited number of radium sources. An opening is left to allow regulation of certain other naturally-occurring radioactive materials, but I am unaware of any such sources being seriously considered to be added.

"The definition of accelerator-produced material is not in dispute or doubt, and to my knowledge, states are already largely or perhaps unanimously using the same standards to define what accelerator-produced materials are regulated.

Defining which radium (or other naturally occurring) sources is much less clear, and it appears there is some variance among states. Most of the variance occurs among things like aircraft instruments with radium paint, or old Revigators that pose extremely limited radiation threat, and are definitely of no use to an adversary for malevolent purposes.

Oklahoma does not believe that variations in how Revigators and old artificial horizons are regulated is a matter of health and safety significance. The H&S designation is not justified for this rule. More powerful sealed radium sources are definitely of H&S significance, but there is no controversy over regulating them. Conceivably there are a handful of radioactive sources in existence in the country that are in a gray area, but capturing them does not justify the disruption it would cause.

NRC seems intent on ensuring through one means or another, that all states adopt the exact or nearly exact wording of the proposed NRC definition of byproduct material, one that to my knowledge had no existence until developed under the EPAct. Their proposed compatibility definitions have repeatedly come back to this, even warping the established meaning of a "C" compatibility to accomplish it. This intent is inconsistent with the clear direction given under the EPAct that NRC respect state standards to the greatest extent possible, and that they avoid disruption of the provision of medical isotopes.

Oklahoma is concerned that if this approach is pursued to a conclusion, states will have to expend significant amounts of resources in rulemaking and legislative changes to change a definition that has very little real-world radiation safety importance. This would be unfortunate, given the large burden the states are under in carrying out the Increased Controls

as we are now. It would detract from the successful implementation of the Increased Controls inspections by drawing away staff time and management attention.

Similarly, implementation of this standard will create confusion over who has regulatory authority over many areas of accelerator-produced materials, some of which are critical for medical use. This confusion would persist until all states adopted the NRC wording. This is contrary to the intent of the EPAct, which specified that disruptions in production of these isotopes should be avoided.

Before the current discussions started, a "C" compatibility designation, using the traditional definition of "C" might have been acceptable. After seeing how this is going, I am concerned that NRC staff would misapply "C" compatibility, even if NRC now abandoned their flawed attempt to redefine "C". In short, Oklahoma believes that a "D" compatibility is the appropriate designation for the new definition."

(27) Oregon:
"Oregon agrees with a compatibility D designation for the byproduct material definition."

(28) Rhode Island:
"Rhode Island response- as before I feel that "D" is the proper response. I agree with [Texas] re: [a] need for better qualifiers on part of NRC if another compatibility is chosen, to avoid [problems] that could present...due to interpretation[s] on part of NRC staff."

(29) South Carolina:
"Call it anything you want to but the bottom line is the states must ensure and demand that NRC accept current state designations without undue and unnecessary burden to the States. We must insist on D. That's my vote."

(30) Tennessee:
"It is unfortunate that...NRC seem[s] unable to accept that the Agreement States got it right the first time, and that no further modification of either our enabling legislation or rules are necessary to accommodate whatever definition of byproduct material they may come up with. What we regulate is any "radiation source", which we define, and which includes "radioactive material", which we also define, and which includes as a subset whatever NRC might define as byproduct material. We really don't have a need for a definition of "byproduct material". Tennessee continues to advocate for Category 'D'."

(31) Texas
"The states developed the first well logging rules and when NRC adopted theirs years later, they required the states to fit into their "new mold" even though many states had adopted the well logging rules much earlier. The same thing happened with the Industrial Radiographer two-person rule. NRC's entry into NARM regulation should not supplant the state's efforts that have been in effect in many states prior to the Atomic Energy Act and Commission. The designation must be D or a very qualified C that future NRC staff will not try to interpret as B."

State Comments on the Compatibility/Adequacy Designation for New Definitions Resulting from the Energy Policy Act 2005

(32) Utah

"[Utah] believe[s] that category "C" is most applicable recognizing the definition changes to rules and statute that may be necessary."

(33) Washington:

"As we previously indicated, the only satisfactory category is D.

"There seems to be valid concern about additional work the states might be required to do if the compatibility rating for the expanded definition of "Byproduct Material" becomes a category C; therefore, we recommend compatibility category D."

(34) Wisconsin:

"[Wisconsin] also believe[s] that a 'D' compatibility rating may be the best option. Although a 'C' compatibility could work, an initial 'D' rating provides the best assurance that states (during this transition) won't be ratcheted into something that causes us problems."

Conference of Radiation Control Program Directors, Inc.

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March 1, 2006

Charles Miller, Ph.D, Director
Division of Industrial and Medical Nuclear Safety
Mailstop 8 F5
U.S. Nuclear Regulatory Commission
Washington, D.C. 20555-0001

Subject: Draft Proposed Rule: 10 CFR Parts 20, 30, 31, 32, 35, 40, "Expanded Definition of Byproduct Material" (STP-06-001)

As Chair of the Conference of Radiation Control Program Directors (CRCPD), I am writing on behalf of the CRCPD membership and Board of Directors to provide comments on the subject document. As you know, the CRCPD has facilitated participation of State representatives on the Naturally-Occurring & Accelerator-Produced Radioactive Material (NARM) Task Force and NARM Rulemaking Working Group (WG), as well as the joint Steering Committee overseeing both the NARM Task Force and NARM Rulemaking WG. Since approximately February 2, 2006, the State representatives on the NARM Task Force, NARM Rulemaking WG and Steering Committee have all expressed very serious concerns to the CRCPD Board of Directors regarding the proposed compatibility/adequacy designation for the definition of "Byproduct Material" (and other definitions included in the subject draft proposed rule).

After discussion, the CRCPD Board of Directors strongly supports the comments of the Organization of Agreement States (OAS) Board submitted to you February 27, 2006, by Barbara Hamrick, Chair of OAS. We believe Compatibility Level D is the only choice for this rule. Any other choice would be a contradiction of the spirit of EPAct and seriously impact States. We are very disappointed that it appears the statements made in the EPAct requiring "The Commission…to the maximum extent practicable--(i) cooperate with States; and (ii) use model State standards in existence on the date of enactment of this Act" are not being met. We hoped NRC would work to bring its regulations into conformance with the CRCPD model Suggested State Regulations (SSRs), since State regulations based on these have, for over 40 years, provided for the safe control of sources that will only now, after the enactment of the EPAct, come under the jurisdiction of the NRC.

Thank you for the opportunity to provide this additional input to you on this matter. We hope the comments from OAS and CRCPD will be considered and a decision made that truly meets the spirit of EPAct and acknowledges the expertise and experience of States in regulating NARM. Please do not hesitate to contact me at 360-236-3251 or debra.mcbaugh@doh.wa.gov

Sincerely,

Debra McBaugh, Chair
Conference of Radiation Control Program Directors, Inc.