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

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