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

U.S. Nuclear Regulatory Commission

Table of Contents

ACRONYMS/ABBREVIATIONS

AEA	Atomic Energy Act of 1954, as amended
AEC	U.S. Atomic Energy Commission
ALARA	as low as reasonably achievable
ARM	Accelerator-produced radioactive material
CFR	Code of Federal Regulations
CRCPD	Conference of Radiation Control Program Directors, Inc.
DOE	Department of Energy
DOT	Department of Transportation
EPA	Environmental Protection Agency
EPAct	Energy Policy Act of 2005
FONSI	Finding of No Significant Impact
FR	Federal Register
IAEA	International Atomic Energy Agency
LLRWPAA	Low-Level Radioactive Waste Policy Amendments Act
NARM	naturally occurring and accelerator-produced radioactive material (in this document, limited to that made byproduct material by the EPAct)
NMSS	Office of Nuclear Materials Safety and Safeguards
NORM	naturally occurring radioactive material
NRC	U.S. Nuclear Regulatory Commission
OAS	Organization of Agreement States, Inc.
OSHA	Occupational Safety and Health Administration
Pub. L.	Public Law
RCRA	Resource Conservation and Recovery Act
SS&D	Sealed Source and Device
SSRs	Suggested State Regulations for the Control of Radiation
U.S.C.	United States Code

1.0 INTRODUCTION

The U.S. Nuclear Regulatory Commission (NRC) is amending its regulations to include certain radium sources, certain naturally occurring radioactive material, and accelerator-produced radioactive materials as required by Section 651(e) of the Energy Policy Act of 2005 (EPAct), which was signed into law on August 8, 2005. The EPAct expanded the definition of byproduct material in Section 11e. of the Atomic Energy Act of 1954 (AEA) to include certain naturally occurring and accelerator-produced radioactive materials (NARM), placing these byproduct materials under NRC authority. The EPAct also required the NRC to provide a regulatory framework for licensing and regulating this NARM. The NRC prepared this environmental assessment to determine whether adopting these regulations, which provide the required regulatory framework, will have any significant environmental impact.

Background

Radioactive materials may be divided into two general groups: naturally occurring radioactive material (NORM), which would exist in nature even in the absence of human activity, and radioactive materials that are produced by the technological activities of humankind. The second group, which makes up the vast majority of radioactive material used in human activity, includes products of nuclear reactors and accelerator-produced radioactive material (ARM).

Collectively, “naturally occurring and accelerator-produced radioactive material,” other than source material, is referred to as NARM. The significance of the distinction between source material and the products of nuclear fission reactors and NARM is that prior to the passage of the EPAct in 2005, the NRC had no regulatory authority over NARM. Since the passage of the AEA, the NRC and its predecessor agency, the Atomic Energy Commission (AEC), have regulated the acquisition, possession, use, transfer, and disposal of byproduct material, as well as source material and special nuclear material. Byproduct material was originally defined to include only materials made radioactive in the production or utilization of special nuclear material; i.e., radioactive material produced in a fission reactor, and later to also include tailings and waste produced by the extraction or concentration of uranium or thorium from any ore processed primarily for its source material content. The regulation of NORM other than source material (and that in the tailings and waste produced by the extraction or concentration of uranium or thorium from any ore processed primarily for its source material content), and accelerator-produced radioactive material was left primarily to the individual States. Although efforts were made by several States to provide a uniform regulatory environment, there was no nationwide consistency to the regulation of NARM. Other Federal agencies exercised limited regulatory authority over activities involving NARM consistent with their primary missions, but again there was no overall, consistent regulation as in the case of byproduct, source, and special nuclear material.

The Energy Policy Act of 2005

On August 8, 2005, the President signed into law the Energy Policy Act of 2005. Among other provisions, Section 651(e) of the EPAct expanded the definition of byproduct material in Section 11 e. of the AEA and required the Commission to provide a regulatory framework for licensing and regulating this NARM in accordance with the expanded definition of byproduct material.

Specifically, as stated in Section 651(e) of the EPAct, the definition of byproduct material, as provided in Section 11 e.(1) and (2) of the AEA, is expanded to include:

> "(3)(A) any discrete source of radium-226 that is produced, extracted, or converted after extraction, before, on, or after the date of enactment of this paragraph for use for a commercial, medical, or research activity; or
>
> (B) any material that —
>
> (i) has been made radioactive by use of a particle accelerator; and
>
> (ii) is produced, extracted, or converted after extraction, before, on, or after the date of enactment of this paragraph for use for a commercial, medical, or research activity; and
>
> (4) any discrete source of naturally occurring radioactive material, other than source material, that —
>
> (A) the Commission, in consultation with the Administrator of the Environmental Protection Agency, the Secretary of Department of Energy, the Secretary of the Department of Homeland Security, and the head of any other appropriate Federal agency, determines would pose a threat similar to the threat posed by a discrete source of radium-226 to the public health and safety or the common defense and security; and
>
> (B) before, on, or after the date of enactment of this paragraph is extracted or converted after extraction for use in a commercial, medical, or research activity."

The EPAct's expanded byproduct material definition introduces the term, "discrete source," as applied to radium-226 and certain other sources of NORM. Section 651(e) also requires the NRC to define this term by rulemaking. Finally, the EPAct clarifies that NARM, as included in the expanded byproduct material definition, shall not be considered low-level radioactive waste for disposal for the purposes of meeting the provisions of the Low-Level Radioactive Waste Policy Amendments Act (LLRWPAA).

Prior to enactment of the EPAct, the NRC had neither authority over NARM nor regulations for such material. The current regulatory structure for the control of radioactive materials was established by the AEA, as amended. The AEA authorizes States to assume regulatory control over radioactive materials produced in or by a nuclear reactor, provided the State has an adequate, NRC-compatible program to protect the public health and safety and enters into an agreement with the NRC. The activities regulated by these "Agreement States" include the use of byproduct, source, and limited quantities of special nuclear material. Each Agreement State issues licenses to persons who use these materials in that State. The NRC issues licenses to persons using these materials in non-Agreement States, plus certain categories of entities and activities nationwide. Currently, there are 34 Agreement States and 16 non-Agreement States, plus U. S. territories, Government agencies, and Federally recognized Indian tribes. (Note: Minnesota's agreement, effective as of March 31, 2006, is included in this summation.)

Although the NRC has not regulated most NARM in the past, all Agreement States and certain non-Agreement States have established regulatory programs for NARM. Some States have different regulations for other, typically diffuse types of NORM. Some Government agencies have developed "self-regulating" programs internally applying NRC radiation safety requirements to NARM uses. For years, Agreement States have regulated NARM use in a fairly uniform and consistent manner. This was accomplished by using the same standards to regulate NARM as those used to regulate other byproduct, source, and special nuclear material. In many respects, regulations adopted by the Agreement States are compatible with

the NRC regulations in Title 10 of the Code of Federal Regulations (10 CFR) for the current materials program, or the Suggested State Regulations for the Control of Radiation (SSRs) developed by the Conference of Radiation Control Program Directors, Inc. (CRCPD). The regulatory structure for control of NARM in non-Agreement States varies greatly from State to State. While some non-Agreement States have established NARM regulatory structures similar to those established by the Agreement States, other non-Agreement States have elected to use facility and/or device registration as their regulatory structure for managing NARM users. It was, in part, due to this lack of national consistency, that the EPAct added these materials to the AEA definition of byproduct material.

Need for the Preferred Action

The EPAct became effective on August 8, 2005. The EPAct requires the NRC to provide a regulatory framework for licensing and regulating the naturally occurring and accelerator-produced radioactive materials that are included in the expanded byproduct material definition in Section 651(e) of the Act. The EPAct directed the NRC to promulgate regulations to establish a national program for NARM.

The Preferred Action

The Commission's regulations in Part 30 (in Title 10 of the Code of Federal Regulations) set out the basic requirements for domestic licensing of byproduct material. The NRC is incorporating NARM into the byproduct material definition under §§ 20.1003, 30.4, 50.2, 72.3, 150.3, 170.3, and 171.5 to agree with the expanded byproduct material definition provided in Section 651(e) of the EPAct. In addition, the NRC is amending its regulations governing the receipt, possession, use, storage, transfer, and disposal of byproduct material to conform with this expanded byproduct material definition. The preferred action is to amend the Commission's regulations in 10 CFR Parts 20, 30, 31, 32, 33, 35, 50, 61, 62, 72, 110, 150, 170, and 171.

The major features of the final amendments address:

- revising the byproduct material definition to reflect the expanded definition provided in Section 651(e) of the EPAct;
- defining or redefining the terms: accelerator-produced radioactive material, consortium, cyclotron, discrete source, low-level radioactive waste, particle accelerator, positron emission tomography (PET) radionuclide production facility, and waste;
- delineating licensing provisions for manufacture, possession, use, transfer, ownership, and disposal of NARM and products containing NARM, including provisions for exemptions from licensing requirements;
- specifying exempt quantity limits applicable to ARM;
- specifying NARM packaging and labeling requirements;
- specifying requirements for manufacture, preparation, and transfer of radioactive drugs containing ARM;
- delineating licensing requirements for persons who manufacture, produce, acquire, receive, possess, prepare, use, or transfer NARM-containing medical products; including provisions for obtaining licenses and license amendments;
- specifying requirements for medical professionals who are experienced users of NARM; and
- specifying testing requirements for sources containing NARM.

2.0 PREFERRED ACTION AND ALTERNATIVES

To define the alternatives considered in the implementation of the EPAct, the NRC staff differentiated between the actions specifically required by the Act and areas where the Act allows flexibility in the degree of regulatory authority to be applied in the rule. Based on this review, the staff developed alternatives to the regulatory framework with regard to areas where the EPAct allows flexibility. The alternatives include a no-action alternative; a second alternative which would implement the requirements specifically mandated by the Act and the highest degree of regulatory authority and control included within the bounds allowed by the flexibility within the EPAct; and the preferred alternative, which reflects the staff's approach for accomplishing the EPAct's requirements, described as a graded approach.

Requirements of the EPAct

Section 651(e)(4)(B) of the EPAct requires the Commission to use model State standards, to the "maximum extent practicable," in developing the regulations. The NARM regulations for most Agreement States are based on model regulations, known as the Suggested State Regulations for the Control of Radiation (SSRs). The SSRs for radioactive materials are compatible in many respects with the NRC regulations.

Section 651(e) of the EPAct mandates that NARM not be considered low-level radioactive waste for the purposes of the Low-Level Radioactive Waste Policy Amendments Act (42 U.S.C. 2021b) (LLRWPAA). This provision is consistent with current NRC policy, under which NARM would be classified as "radioactive waste" for disposal purposes and may be disposed of according to Federal and State hazardous waste laws. This provision would be included in all of the alternatives.

Areas Where EPAct Allows Flexibility

During the process of developing a regulatory framework for licensing and regulating NARM, the staff identified several areas where the Act allows some degree of flexibility. As discussed below, the EPAct does not specifically address the type of license to be required for NARM licensed activities or whether incidentally irradiated material should be regulated. Furthermore, the EPAct delegated, to the NRC, the responsibility for defining the term "discrete source," as it applies to radium-226 and certain other NORM.

Section 651(e) of the EPAct requires the Commission to develop regulations to establish the regulatory requirements necessary to carry out this section of the Act. While the requirement to maintain consistency with current State regulations strongly suggests using a similar regulatory framework of specific and general licenses and exemptions, the EPAct does not mandate which license type (i.e., general or specific) would be required for NARM, nor does the Act specify whether allowances for exemptions from byproduct material regulations should be provided in the final regulations. Under the AEA, the Commission has authority to issue both general and specific licenses for the use of byproduct material and also to exempt byproduct material from regulatory control under the AEA. Because of the flexibility allowed by current regulations and Section 651(e) of the EPAct, it is reasonable to consider more than one alternative specifying different license types and exemption allowances, depending upon whether or not there exist model State regulations upon which the rule could be based.

Section 651(e) of the EPAct requires the Commission to include, as byproduct material, certain accelerator-produced radioactive material (ARM). This expanded byproduct material definition

only includes material that is produced, extracted, or converted specifically for use in a commercial, medical, or research activity. The radioactive material intentionally produced by activation of the target is commonly referred to as "product ARM." The EPAct does not specifically address whether material that is incidentally irradiated during operation of an accelerator (referred to as "incidental ARM") should be regulated. Because of the flexibility allowed by the EPAct in this respect, it is reasonable to consider more than one alternative with differing regulatory approaches for incidental ARM.

Section 651(e)(4)(A)(ii) of the EPAct requires the Commission to define the term "discrete source" as applied to radium-226 and certain other NORM in the expanded definition of byproduct material. A discrete source would be defined to include a concentrated radioactive material that is distinct from the radiation present in nature. The flexibility allowed by this requirement relates to whether or not the radionuclide or radioactive material specifically has been concentrated on purpose for use for commercial, medical, or research activity. A broad "discrete source" definition could include any concentrated radium-226 or other NORM, regardless of whether it was concentrated specifically for its radiological properties or incidentally from a process that extracts or produces products, such as fertilizer, fly ash, or residue from the purification of water. A more limited "discrete source" definition would only include radioactive material in which the radionuclide was concentrated with the intent of using its properties, thereby excluding NRC jurisdiction over inadvertent movement or concentration of NORM. Because of the flexibility in allowing the Commission to provide this definition, it is reasonable to consider more than one alternative, each with a different discrete source definition.

Section 651(e)(4)(D) of the EPAct requires the Commission to consider the impact on the availability of pharmaceuticals to physicians and patients in promulgating these regulations. This requirement does not prescribe how to consider the potential impact of the regulations on the medical community or patients; nor the approach to be taken to address potential impacts. This requirement allows flexibility in the regulatory framework that is applied to ARM products generated for medical activities, as well as the implementation aspects for the regulations. Although the EPAct allows flexibility in considering the regulation's potential impacts on the medical community or patient, and it is reasonable to consider more than one alternative with differing medical ARM product licensing requirements and implementation plans, there are no discernable differences between the environmental impacts of the alternative approaches to addressing pharmaceutical availability. Therefore, both the preferred action and Alternative 2 would establish a similar set of regulations and an implementation process to minimize the regulatory impact on the availability of accelerator-produced radioactive drugs. The key points associated with this area of the final regulations are summarized later in this section, under the discussion of Alternative 3.

Based on the staff's review of the actions specifically mandated by the EPAct and areas where the EPAct allows flexibility in the degree of regulatory authority and control, the staff identified three alternatives: (1) to take no action; (2) to establish regulations that apply the greatest extent of regulatory authority and control allowed by the EPAct; and (3) to establish regulations that apply a graded, risk-informed approach to exercising the regulatory authority provided by the EPAct. The following provides a more detailed discussion of each alternative. The discussion under the Alternative 3 description and in Section 4.0 provides the basis for choosing Alternative 3 as the preferred alternative.

Alternative 1: The No-Action Alternative

The no-action alternative is to maintain the status quo. Under the no-action alternative, the Commission would neither adopt the expanded definition of byproduct material provided in Section 651(e) of the EPAct, nor provide a regulatory framework for licensing and regulating NARM. The staff understands that the no-action alternative is not acceptable, as this rulemaking activity is Congressionally mandated; however, this alternative provides the baseline against which the other alternatives are assessed.

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

This alternative would establish regulations to implement the requirements specifically required by the EPAct and the highest degree of regulatory authority and control included within the bounds allowed by the flexibility within the EPAct. In accordance with EPAct Section 651(e)(4)(B), the NARM regulatory framework would be based, to the maximum extent practicable, on the SSRs.

This alternative is to establish regulations and an implementation process that would minimize the regulatory impact on the availability of accelerator-produced radioactive drugs by taking the following actions: (1) applying NRC's established regulatory framework to the commercial distribution of these drugs; (2) expanding the regulations to permit noncommercial distribution of PET drugs within a consortium; (3) "grandfathering" current users of accelerator-produced drugs; and (4) permitting individuals and other entities to continue to prepare and use radioactive drugs while they are applying for new licenses or amendments.

Under this alternative, the revised regulations would require more specific licenses for the production, use, transfer, and distribution of NARM material and products containing NARM. In areas where the SSRs do not specifically address material within the scope of the new byproduct material definition or where there are few model State regulations at the national consensus level upon which the NRC can base its regulations, this alternative would require specific licenses. Part N of the SSRs address NORM; however, this is generally applicable to diffuse sources of NORM, which have not been produced for the purpose of using the radioactive material within for commercial, medical, or research activities.

SSR requirements for ARM and discrete sources of radium are the same as for reactor-produced radioactive material as they are all covered under provisions for "radioactive material." Only a few provisions in the model State regulations are specific to discrete sources of radium and accelerator-produced radioactive material. Specific provisions concerning ARM radionuclides include: (1) a general license and associated requirements for cobalt-57 *in vitro* clinical or laboratory tests, (2) contamination levels for strontium-82/rubidium-82 generators for medical use, (3) exempt quantity limits for certain accelerator-produced radionuclides. With respect to radium, the SSRs include: (1) an exemption for previously acquired timepieces containing up to 37 kilobecquerels (kBq) (1 microcurie (μCi)) of radium-226, (2) an exemption for other previously acquired self-luminous products containing up to 3.7 kBq (0.1 μCi) of radium-226, (3) a provision to allow a specifically licensed person to possess up to 185 kBq (5 μCi) of radium-226 in calibration and reference sources under a general license, and (4) an exemption for gas and aerosol detectors containing NARM, with a limit of 3.7 kBq (0.1 μCi) of radium-226 that may be incorporated into smoke detectors distributed for use under exemption from licensing. Under this alternative, these specific requirements would be included in the regulations.

However, the SSRs do not specifically address certain categories of products and discrete sources containing radium-226 which are in the public domain but may not be otherwise covered under a license. Therefore, under this alternative, the regulations would require specific licenses for discrete sources of radium-226 that may not be otherwise covered under a general license or an exemption in the SSRs. For NARM material and products containing NARM that are addressed in the SSRs, such as those discussed above, this alternative would include a regulatory framework similar to the SSRs.

Section 651(e)(4)(A)(ii) of the EPAct requires the Commission to define the term "discrete source" as applied to radium-226 and other NORM in the expanded definition of byproduct material. Under this alternative, discrete source would be defined broadly to include any concentrated radium-226 or other NORM, regardless of whether it was intentionally concentrated or incidentally concentrated from a process that extracts or produces products not intended to be radioactive. This definition would not limit the NRC's jurisdiction to only include radionuclides that are concentrated and used purposefully for their properties. This broader definition would divert the NRC's regulatory efforts away from those materials that pose the greatest health and security risk by including an array of NORM sources, including sources that were created through inadvertent movement or concentration of naturally occurring radioactive material, such as that found in scaling on pipes from the fossil fuel industry, in fly ash from coal burning, or in fertilizers.

Under this alternative, any material rendered radioactive by a particle accelerator, including incidental radioactive materials, would be covered by the Commission's regulations from the time at which it is initially irradiated. Byproduct material would include product ARM and all incidental ARM, including irradiated target material, accelerator internal structures, and facility building materials, regardless of the accelerator type or use.

In accordance with Section 651(e)(3), for disposal purposes, this newly defined byproduct material would be classified only as radioactive waste, and would not be considered to be low-level radioactive waste for the purposes of the LLRWPAA.

Alternative 3: Revise Regulations to Apply a Graded, Risk-Informed Approach for Regulatory Authority over NARM

The NRC proposed and is now finalizing an alternative that revises its regulations by applying a graded approach to exercising regulatory authority over NARM in order to focus the staff's regulatory efforts on those activities that pose the greatest risk to protection of the public health and safety and promotion of the common defense and security. Beyond implementing the requirements specifically mandated by the EPAct, this alternative addresses the flexibility within the EPAct by establishing regulations that are commensurate with the potential health and safety consequences applicable to each NARM-containing product type. As required by the EPAct, the NARM regulatory framework has been based, to the maximum extent practicable, on the SSRs.

This preferred alternative includes general licensing provisions for certain products and discrete sources containing radium-226 that are apparently in the public domain but may not be otherwise covered under a license and are not specifically addressed in the SSRs. This alternative also accommodates generally licensed devices meeting the restrictions of the general licenses that were previously approved by States under existing regulations. This alternative is to regulate NARM under most of the same requirements as reactor-produced radioactive material. Additionally, this alternative adds certain products and materials

containing NARM to some of the current exemptions, thereby allowing these NARM-containing products to be used without any regulatory requirements imposed on the user. This alternative does not require any changes be made to the exempt concentrations for radionuclides included in the SSRs, and adopts appropriate values for exempt quantities for the newly defined byproduct material consistent with the SSRs. The preferred alternative also adopts an exemption for timepieces containing 37 kBq (1 μCi) or less of radium-226 and adopts the requirement to allow a specifically licensed person to possess up to 185 kBq (5 μCi) of radium-226 in calibration and reference sources under a general license.

Under this preferred alternative, *discrete source* is defined to include only radionuclides that were concentrated with the intent of using the radionuclides for commercial, medical, or research activities. *Discrete source* is defined in the final rule as "a radionuclide that is distinct from the sources of radiation present in nature, and that has been processed so that its concentration within a material has been purposely increased for use in commercial, medical, or research activities." Under this definition, discrete sources of radium-226 or discrete sources of naturally occurring radioactive material may have the same radiological characteristics (i.e., type of radiation, half-life, etc.) as the radionuclides found in nature, but the radionuclides will have been purposely concentrated for use of the radionuclides specifically. This definition limits NRC's jurisdiction, by excluding inadvertent movement or concentration of naturally occurring radioactive material, such as that found in scaling on pipes from the fossil industry, in fly ash from coal burning, or in fertilizers. NRC's authority over source material will not be changed by this definition. This definition is revised from that proposed for clarification purposes. Under the revised definition, once a radioactive material, defined as a discrete source, becomes byproduct material, it continues to be byproduct material, even if no longer "discrete" in the usual sense. Contamination resulting from the use of discrete sources of radium-226, or other radionuclide identified under Section 11e.(4) of the AEA, is still byproduct material.

Under this preferred alternative, the NRC will regulate the radioactive material (product and incidental ARM) produced by all accelerators that intentionally produce a radioactive material for its radioactive properties (e.g., PET production facilities). The rationale for this approach is that this incidentally produced radioactive material is a direct result of producing the radioactive material for use for a commercial, medical, or research activity. In addition, it is necessary for the NRC to consider all radioactive material in its regulatory evaluation to ensure health and safety of the radioactive material production. This preferred alternative will not regulate incidental ARM that results from the operation of accelerators that only produce particle beams and do not intentionally produce radioactive materials for use for a commercial, medical, or research activity (e.g., electron microscopes and medical therapy linear accelerators). The reasons for not regulating this incidentally produced radioactive material are: (1) no radioactive material is produced for use for a commercial, medical, or research activity from such operation, and (2) the incidentally produced radioactive material resides within the accelerator or facility. For those accelerators that are used to produce both radioactive material and particle beams, the preferred alternative will apply NRC regulations to the incidental ARM, as well as the product ARM, produced by the accelerator. The incidental ARM produced in such accelerators during the production of radioactive material for use for a commercial, medical, or research activity is indistinguishable from that produced when the same accelerator is operated to produce only particle beams, so both are covered by this final rule.

The regulatory framework and implementation process associated with radiopharmaceuticals under this preferred alternative will be the same as that described previously for Alternative 2. This preferred alternative will establish regulations and an implementation process that will minimize the regulatory impact on the availability of accelerator-produced radioactive drugs by

taking the following actions: (1) applying its established regulatory framework to the commercial distribution of these drugs; (2) expanding the regulations to permit noncommercial distribution of PET drugs within a consortium; (3) "grandfathering" current users of accelerator-produced drugs; and (4) permitting individuals and other entities to continue to prepare and use radioactive drugs while they are applying for new licenses or amendments.

Under the preferred alternative, as required by Section 651(e)(3), NARM-containing byproduct material will be classified only as radioactive waste, and will not be considered to be low-level radioactive waste for the purposes of the LLRWPAA.

3.0 AFFECTED ENVIRONMENT AND CURRENT REGULATORY STRUCTURE

The alternatives evaluated in this environmental assessment involve establishing and promulgating changes to the Commission's regulations in order to implement the Commission's regulatory authority over certain radium sources, certain naturally occurring radioactive material, and accelerator-produced radioactive materials as provided by Section 651(e) of the EPAct. The human environment affected by this activity includes the physical environment in which the NARM is produced, received, possessed, used, transferred, distributed, and disposed and the regulatory environment that defines the rules and regulations governing activities associated with NARM. Ultimately, the impact on the human environment will be dependent on changes to the current regulatory environment and the resultant impacts on the physical environment.

3.1 Affected Physical Environment

Radium-226 and Other NORM with Similar Risk as Radium-226

Under the previous regulatory framework, NRC did not directly regulate NORM radionuclides (except source material and those in mill tailings and waste), including radium-226 and other NORM that would pose a similar threat to that posed by a discrete source of radium-226. Radium-226 is a NORM radionuclide that can be found in all uranium ores. Since its discovery in 1898 until the early 1900's, the dangers of radium were not fully understood. Because of its ability to stimulate luminescence, industries manufactured many consumer products containing radium. Manufacture of most of these products was discontinued for health and safety reasons, but the wide use of radium in luminescent paints for items such as watch hands and faces and aircraft instruments, dials, and gauges continued until after World War II. Many of these early products, such as radium emanator jars, radium bath salts, and healing pads, still remain in the possession of museums and individual collectors. More recently, radium sources were used in industrial radiography, industrial smoke detectors, and some industrial products, such as gauges. Because of its radiological properties, radium-226 poses a potential threat to public health and safety if not managed safely and securely.

The International Atomic Energy Agency (IAEA) identified a list of sources that are considered to pose a high risk to human health and safety if not managed safely and securely. Of the 33 radionuclides identified by the IAEA Code of Conduct to cause deterministic detrimental effects at reference doses, only two that are not source material are naturally occurring radionuclides: radium-226 and polonium-210. Therefore, using the IAEA criteria, the only other NORM similar in hazard to radium-226 is polonium-210. However, naturally occurring polonium that has been extracted or concentrated for use is scarce. Commercially used polonium-210 is produced in a nuclear reactor. Consequently, polonium-210 is already regulated by the NRC as

byproduct material. At this time, no other discrete sources of NORM were identified that would pose a hazard similar to radium-226.

Accelerator-Produced Radioactive Material

Particle accelerators produce radioactive material by directing a beam of high-speed particles at a target composed of a specifically selected element, which is usually not radioactive. When the nuclei in the target are struck by the high-speed particles, they undergo a nuclear transformation and a new nuclide is formed. The nuclide produced during this activation process is usually radioactive and is useful because of its radiological properties. Most of the accelerator-produced radioactive material today is created for use in medicine.

Particle Accelerators

A particle accelerator is a device that imparts kinetic energy to subatomic particles by increasing their speed through electromagnetic interactions. Particle accelerators are used to produce radioactive material by directing a beam of high-speed particles at a target composed of a specifically selected element, which is usually not radioactive. The target element is activated when its nuclei are struck by high-speed particles and undergo a nuclear transformation. Usually, the nuclide produced is radioactive and is useful because of its radiological properties.

Particle accelerators may be separated into three functional groupings:
(1) those that are operated exclusively to intentionally produce radioactive materials in quantities useful for their radiological properties for a commercial, medical, or research activity (e.g., PET production facilities and other accelerators that produce radioactive material for use in medical activities);
(2) those that are intended to only produce particle beams and not radioactive materials (e.g., electron microscopes, linear accelerators used for the medical treatment of cancer); or
(3) those that intentionally produce both radioactive materials and particle beams (few, if any, accelerators are in this grouping).

In addition to the radioactive material intentionally produced by particle accelerators, the production of incidental ARM is an inextricable part of any accelerator operation. Incidental ARM may include accelerator internals and materials in the structure of the building and facilities housing the accelerator. For those accelerators that are used to intentionally produce radioactive material (i.e., functional groups (1) and (3), above), the incidental ARM that results during the production of product ARM is indistinguishable from that which would be produced from the particle beam alone. For accelerators that are used to produce particle beams only (i.e., functional group (2), above), no radioactive material is produced for use for a commercial, medical, or research activity from such operation, and the incidental ARM that results from operation resides within the accelerator or facility.

Accelerator-Produced Radioactive Material Used in Medical Activities

The majority of accelerator-produced radioactive material is created for use in medicine. Approximately 4,000 hospital-based nuclear medicine departments and many freestanding imaging centers in the U.S. perform a large number of nuclear medicine imaging studies every year. Nuclear medicine is an integral part of patient care and is valuable in the early diagnosis and treatment of many medical conditions. Nuclear medicine uses radioactive materials (radiopharmaceuticals) to diagnose and treat disease. In diagnosis, the radiopharmaceuticals

are introduced into the body through injection or ingestion, then detected by special "cameras" with the aid of computers to provide images of the area of interest. In treatment, the radiopharmaceuticals can be directed to a specific organ being treated.

Radiopharmaceuticals can be made from radionuclides produced in nuclear reactors or in particle accelerators. Currently, most reactor-produced byproduct material radionuclides are imported into the U.S., where they are used to produce specific radioactive drugs (including biologics). There are a limited number of commercial manufacturers in the U.S. that produce radiopharmaceuticals using radionuclides such as thallium-201, iodine-123, indium-111, and gallium-67 that are produced in particle accelerators. In recent years, radiopharmaceuticals known as PET drugs have been produced in cyclotron facilities (known as PET centers). PET imaging devices produce diagnostic images with better spacial resolution than other traditional diagnostic imaging techniques. Due to their short half-lives, PET radionuclides and drugs are produced at locations in close proximity to the patients, such as hospitals. Manual brachytherapy sources containing accelerator-produced palladium-103 also represent a significant medical use of ARM material in therapy treatments.

Radiation Dose from NARM

The principal public health and safety consideration associated with the expanded byproduct material definition pertains to the occupational dose resulting from the regulation of this material. The source of the radiation exposure may be the radioactive material itself (i.e., NARM and NARM-containing products), or structures or equipment that have become irradiated by a particle beam. The NRC's standards for the protection of radiation workers and members of the public from the hazardous effects of radiation are provided in 10 CFR Part 20. These regulations specify provisions for radiation protection programs (including requirements to use procedures and controls to achieve doses that are as low as is reasonably achievable (ALARA)), occupational and public dose limits, engineering and administrative controls to reduce exposure, respiratory protection requirements, and material storage and control requirements. Occupational dose is defined to include dose received in the course of employment as a result of exposure to licensed (regulated) and unlicensed (unregulated) sources. Licensees are not required to differentiate between dose contributed from NARM and dose contributed from other byproduct, source, or special nuclear material. Although 10 CFR Part 20 does not differentiate between dose obtained from regulated or unregulated sources of radiation, Part 20 is only applicable to activities conducted under NRC-issued licenses. As a result, industrial and private activities that only involve products containing NARM, and not any other previously licensed radioactive material, would not have been provided the protection afforded by Part 20 prior to implementation of the EPAct requirements.

Disposal of NARM-Containing Radioactive Waste

Under the current practices, radioactive wastes containing NARM and NARM-containing products, including decommissioning waste containing incidental ARM, are disposed of at State-permitted hazardous and solid waste disposal facilities and at the regional radioactive waste disposal facilities located in Barnwell, South Carolina, and Richland, Washington. The authority to permit disposal of NARM is provided by Federal or State hazardous waste laws and State radioactive waste laws, including the Solid Waste Disposal Act, which are not affected by the provisions of the EPAct.

Decommissioning Issues

In addition to the radioactive material intentionally produced by particle accelerators, the production of incidental ARM is an inextricable part of any accelerator operation. Incidental ARM may include accelerator internals and materials in the structure of the building and facilities housing the accelerator. In its radiological criteria for license termination, the NRC already requires licensees to consider sources other than AEA material, including radium, during decommissioning activities at NRC-licensed sites contaminated with source material, such as rare-earth processing facilities. The primary effect of the EPAct with respect to decommissioning is that regulations governing decommissioning will be applied to additional facilities.

3.2 Current Regulatory Environment

Because a well-established regulatory framework for control of NARM already exists in many Agreement States, the EPAct requirements to expand the byproduct material definition to include NARM and establish the necessary regulatory framework will have little, if any, direct impact on the physical environment. This section discusses the NRC's current regulatory structure and the regulatory structures established by Agreement States for control over NARM, including both NORM (i.e., radium-226 and other NORM) and the material produced by particle accelerators.

Current NRC Regulatory Framework for Byproduct Material

Under the AEA, the Commission has authority to issue both general and specific licenses for the use of byproduct material and also to exempt byproduct material from regulatory control. A specific license is issued by the Commission to grant authority to a person who has filed a license application with the Commission. These are issued under Part 30, with additional specific licensing requirements for certain activities contained in Parts 32, 33, 34, 35, 36, and 39.

A general license grants authority to unnamed persons for certain activities involving byproduct material, and is effective without the filing of an application with the Commission or the issuance of a licensing document to a particular person, although certain general licenses require registration with the Commission. 10 CFR Part 31 establishes general licenses for the possession and use of byproduct material and a general license for ownership of byproduct material. Many provisions in Part 30 are also applicable to general licenses established by Part 31. The EPAct provisions allow accommodation of generally licensed sources and devices meeting the restrictions of the general licenses that were previously approved by States under comparable provisions to 10 CFR Part 32.

10 CFR Part 30 includes a number of exemptions from licensing requirements. These exemptions allow for certain products and materials containing byproduct material to be used without any regulatory requirements imposed on the user. Class exemptions are provided that cover a broad class of products, such as gas and aerosol detectors and self-luminous products. Under class exemption provisions, new products can be approved for use through the licensing process if an applicant demonstrates that the specific product is within the class and meets certain radiation dose criteria. This contrasts with materials exemptions, for which the level of safety is controlled for a large number of radionuclides through such means as specification of radionuclide types and quantities. The remaining exemptions from licensing are product-specific, for which many assumptions can be and have been made concerning how the product

is distributed, used, and disposed. The NRC retains the authority for authorizing distribution of products and materials where the end user is exempt from licensing and regulatory requirements.

Regulation of NARM in Agreement States and Non-Agreement States

As established by the AEA, the previous regulatory structure provides the NRC control of materials as byproduct material only if it is produced in a nuclear reactor or included in mill tailings or waste. The AEA authorizes States to assume regulatory control of radioactive materials produced in or by a nuclear reactor, provided the State has an adequate NRC-compatible program to protect the public health and safety and enters into an agreement with the NRC. The activities regulated by these "Agreement States" include the use of byproduct, source, and limited quantities of special nuclear material. Except for activities that are regulated solely by the NRC, each Agreement State issues licenses to persons who use these materials in that State. The NRC issues licenses to persons using these materials in non-Agreement States. Currently, there are 34 Agreement States and 16 non-Agreement States plus U.S. territories.

Although the NRC has not regulated most NARM in the past, all Agreement States and certain non-Agreement States have established regulatory programs for NARM. For years, Agreement States have regulated NARM use in a fairly uniform and consistent manner. The regulatory structure used by Agreement States generally does not distinguish between NARM and other radioactive material. NARM users in Agreement States are expected to implement all aspects of standards for their radiation protection programs with respect to NARM, including those aspects relating to receipt, possession, use, storage, transfer, transportation, and disposal of NARM. This regulatory structure also subjects NARM users in the Agreement States to the same licensing, inspection, and enforcement policies as those using other byproduct material, or source or special nuclear material. In addition, this regulatory structure allows for both specific and general licensing of various products and the distribution of certain NARM items to end users that are exempt from regulation, and, in many cases, includes provisions to review and approve proposals for sealed sources and devices containing NARM.

Nearly all of the Agreement States have based their NARM regulation in large part on model regulations, known as the SSRs. The SSRs are compatible in many respects to the NRC regulations. Under the SSRs' regulatory framework, NARM is a regulated radioactive material comparable to other byproduct material. Adoption of the SSR regulations for NARM by most of the Agreement States accounts for the relatively high degree of uniformity and consistency in the Agreement States' regulations. Note, there is also a separate part of the SSR's for Technologically Enhanced Naturally Occurring Radioactive Material (TENORM). This covers NORM that was not redefined as byproduct material by the EPAct.

The regulatory structure for control of NARM in non-Agreement States varies greatly from State to State. While some non-Agreement States have established a NARM regulatory structure similar to those established by the Agreement States, other non-Agreement States have elected to use facility and/or device registration as their regulatory structure for managing NARM users, and a few non-Agreement States have neither structure in place.

Other Federal Agencies' Regulatory Authority over NARM

Prior to the passage of the EPAct, many States regulated NARM as a radioactive material and/or a hazardous substance, but the NRC generally had no corresponding regulations.

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

Other Federal agencies have established programs in regulating certain aspects of activities involving NARM. The Department of Transportation (DOT) regulates interstate transport of NARM. In cooperation with DOT, the NRC approves Type B packages through regulations in 10 CFR Part 71. The Environmental Protection Agency (EPA) has established controls for certain NARM through several authorities, including the Clean Air Act, the Safe Drinking Water Act, the Toxic Substances Control Act, the Comprehensive Environmental Response, Compensation, and Liability Act, and the Solid Waste Disposal Act, also known as the Resource Conservation and Recovery Act (RCRA). The Occupational Safety and Health Administration (OSHA) of the Department of Labor has the oversight for occupational health and safety including for radiation protection. It has regulations governing radiation protection in the workplace, including provisions addressing exposure of minors to radioactive material in the workplace, but defers to NRC on AEA materials. The Department of Commerce has controlled the export of radioactive material. The Consumer Product Safety Commission regulations have addressed hazardous substances other than byproduct, source, and special nuclear materials currently regulated by the NRC. The Food and Drug Administration (FDA) regulates all drugs and medical devices (including drugs and medical devices containing radioactive materials) by requiring accepted manufacturing practices to assure the purity and potency of drugs, and consistency of finished drugs and medical devices in establishing the safety and effectiveness of these drugs and medical devices.

4.0 ENVIRONMENTAL IMPACTS

The final amendments will have no significant impacts on the public or the environment.

In general, the Commission's regulatory philosophy is to develop regulations that focus the staff's regulatory responsibilities on those activities that pose the greatest risk to protection of public health and safety and promotion of common defense and security. The Commission believes that, through the development of risk-informed and performance-based regulations, greater flexibility can be provided, while continuing to provide adequate protection of public health and safety. Consistent with this philosophy, the preferred alternative will apply a graded licensing approach to the NARM regulatory framework by including provisions for general licenses and regulatory exemptions for NARM and products containing NARM that represent a low level of risk to public health and safety and common defense and security, and specific licenses for NARM and products containing NARM that pose a higher level of risk. In considering the expansion of the definition of byproduct material to include discrete sources of radium-226 and accelerator-produced radioactive material, the NRC evaluated products and materials previously approved by States for use under an exemption from licensing and under a general license. Under the preferred alternative, the NRC's intent is to accommodate existing products and materials that were previously regulated by the States under similar provisions if the potential doses are similar to those expected from other currently regulated products and materials.

The final amendments will provide a national regulatory structure for NARM under which persons in non-Agreement States will be governed by regulations that are generally consistent with those applicable in Agreement States. The regulatory structure is based in large part on the regulations currently used by most Agreement States. These regulations have been found to be adequate to protect the public health and safety. The regulatory structure used by Agreement States generally does not distinguish between NARM and other radioactive material. NARM users in Agreement States are expected to implement all aspects of standards for their radiation protection programs with respect to NARM, including those aspects relating to receipt, possession, use, storage, transfer, transportation, and disposal of NARM. This regulatory structure also subjects NARM users in Agreement States to the same licensing, inspection, and enforcement policies as those using other byproduct, source, or special nuclear material. In addition, this regulatory structure allows for both specific and general licensing of various NARM products and the distribution of certain NARM items to end users that are exempt from regulation, and, in many cases, includes provisions to review and approve proposals for sealed sources and devices containing NARM. The promulgation of regulations that are consistent with the Agreement States' current regulatory structure will benefit the environment by allowing the continuation of regulatory and compliance practices that have already proven to be protective of the environment and the public health and safety.

Exemptions

The exemptions included in this final rule cover products and materials previously allowed to be used under exemption from licensing by States. Exemptions from licensing requirements allow for uncontrolled disposal, such that products and materials covered by such exemptions are normally disposed of in landfills and municipal incinerators. Thus, such provisions have potential for resulting in environmental impacts.

Two are for products containing radium-226, a very long-lived alpha-emitter. These are § 30.15(a)(1)(viii) for intact timepieces with no more than 37 kBq (1 μCi) of radium-226 and § 30.20 for gas and aerosol detectors, if approved by a State under provisions comparable to § 32.26. However, both of these exemptions are limited to previously manufactured products. Thus, they will allow for the continued use, without regulatory controls, of a dwindling supply of products produced some time ago. They do not allow for future manufacture and distribution, greatly minimizing any environmental impacts from uncontrolled disposal. The NRC also conducted a screening level dose assessment of timepieces containing radium-226 to further support the exemption.

The one other exemption from licensing included in the final rule is the expansion of the list of exempt quantities in § 30.71 used under the exemption from licensing in § 30.18. None of the 13 radionuclides being added are alpha-emitters. (As alpha-emitters present a relatively high internal hazard, they generally have more potential for presenting environmental impacts.) All of these radionuclides are relatively short-lived. Only one, sodium-22, has a half-life greater than a year: 2.6 years. Also, none of these materials are expected to be distributed in large quantities. Primarily as a result of the short half-lives, this provision has little potential for resulting in any adverse environmental impacts.

General Licenses

There are four general licenses in the final rule. Three of these are existing general licenses being revised to accommodate products previously approved for distribution for use by general licensees under provisions of State regulations similar to NRC's existing regulations. All four of

these general licenses require controlled disposal of the covered products. However, general licensees are typically less reliable than specific licensees in meeting all regulatory requirements. Thus, there may exist a higher probability of products becoming "orphaned" or being incorrectly disposed.

The general license in § 31.8, to which radium-226 will be added, is only applicable to specific licensees that have calibration and reference sources, and simply eliminates certain administrative requirements that would exist if these sources were under the specific license.

The general license in § 31.11 will be revised to add 370 kBq (10 μCi) of cobalt-57 used in in vitro kits. Persons using this general license must be specifically licensed or preregistered with the NRC. These materials have a low probability of being disposed of improperly in significant quantities and very limited potential for causing environmental impacts.

The general license in § 31.5 will be revised to accommodate devices approved by States under provisions comparable to § 32.51. Thus, these devices will have been reviewed by States as meeting the same safety criteria as other devices used under § 31.5. The registration requirement in the general license in § 31.5 is intended to reduce the probability of loss of control of devices by the general licensee. It is being revised to include a criterion for registration for radium-226. Devices containing radium-226 were mostly distributed some time ago and few remain in use. Those with more than 3.7 MBq (0.1 mCi) will come under the registration requirement. The only accelerator-produced radionuclides approved by States for use under comparable provisions of State regulations are cobalt-57 and sodium-22; these are generally used in relatively small quantities. This limited expansion of this general license is not projected to have a significant potential for adverse environmental impacts.

One new general license provision is being added. It is for certain previously manufactured items and self-luminous products containing radium-226. Except for the disassembly and repair of timepieces, it does not authorize manufacture, assembly, disassembly, repair, or import of these products, which were generally manufactured some time ago. As noted, intact timepieces with no more than 37 kBq (1 μCi) of radium-226 are being exempted from licensing requirements under this final rule. Timepieces with larger quantities of radium and repairs of any timepieces are covered by this general license. Although not specifically exempted under State regulations, these products have usually not come under regulatory controls. The requirements in this provision are limited, but intended to improve the likelihood of proper disposal and identification of significant instances of contamination. General licensees will be required to notify NRC concerning damage to products and potential contamination incidents, so that appropriate regulatory actions can be taken to ensure proper cleanup. These provisions, though limited, should be beneficial to the environment.

Impacts on Other Federal Agencies

Other Federal agencies have established programs in regulating certain aspects of activities involving NARM. The regulatory structure was developed with the support and coordination of other Federal agencies to ensure that the NRC's regulations complement the other Federal agencies' regulatory missions without duplicating their regulations. Certain Federal regulations, such as those applicable to environmental protection, workplace safety, drug safety, transportation, and disposal, will continue to apply under some circumstances, but the NRC will have primary responsibility for radiation safety and in regulating the use of NARM in cooperation with the States. Implementation of regulations that are consistent with the NRC's regulatory mission and complement the other Federal agencies' regulatory missions, maximizes

each agency's regulatory effectiveness by allowing the agencies to continue to perform the functions for which they are most qualified, thereby maintaining the appropriate focus on protection of the public health and safety.

Waste Impacts

Section 651(e)(3) of the EPAct mandates that the newly added byproduct materials (i.e., NARM): (1) are not considered to be a low-level radioactive waste for the purposes of the Low-Level Radioactive Waste Policy Amendments Act (LLRWPAA); and (2) may only be disposed of in a facility that is adequate to protect public health and safety and is either licensed by the Commission or by an Agreement State or is permitted under a Federal or State hazardous or solid waste disposal law. The intent of this provision is that the process of developing compacts as implemented in accordance with the LLRWPAA is not to be affected by the addition of NARM into the definition of byproduct material. The preferred action will implement this requirement by adding a definition of waste in 10 CFR 20.1003 to ensure that the term "low-level radioactive waste," when used in the NRC requirements, does not include NARM. This change will ensure that the health and safety of the public is protected by requiring disposal of this material in NRC-regulated disposal facilities or disposal facilities permitted under Federal or State solid or hazardous waste laws, including the Solid Waste Disposal Act.

Decommissioning

The preferred action does not change the NRC's criteria for decommissioning licensed facilities, although it may result in additional facilities being subject to the decommissioning criteria. The regulations will be applied to incidental ARM, such as that in the structures of buildings and structures housing the accelerators, resulting from the operation of particle accelerators that intentionally produce radioactive material. Consequently, the NRC considered whether additional regulatory actions might be needed to provide for the safe decommissioning of particle accelerator buildings and facilities, including the removal and disposal of activated building materials, in order to assure that the dose limits to workers and members of the public are not exceeded. Comments were requested on the decommissioning of accelerator facilities, specifically addressing: (1) the extent to which accelerator components and facility building materials may become activated; (2) the need to remove and properly dispose of such activated material during decommissioning in order to meet the radiation dose limits in 10 CFR Part 20 Subpart E--Radiological Criteria for License Termination; (3) the costs of the decommissioning and disposal, if required; and (4) the need for financial assurance by accelerator facilities to guarantee sufficient funding for proper decommissioning. Only limited technical information was submitted. At this time, the Commission believes that the existing requirements in this area are appropriate and adequate for their application to accelerator facilities. No unique problems are expected that would result in significant impacts to the environment from the application of existing regulations governing decommissioning to these newly regulated sites.

5.0 AGENCIES AND PERSONS CONSULTED

The program for revising the Commission's regulations and the associated guidance documents has involved extensive interactions and consultations with potentially affected parties (primarily representatives from the other Federal agencies, States, the medical community, and the public).

Initiating the Rulemaking Process

The NRC took several initiatives in an effort to enhance stakeholder involvement and to improve efficiency during this rulemaking process. With assistance from the Organization of Agreement States (OAS) and CRCPD, the NRC was able to obtain participation of several State representatives in various working groups in the development of the rule. Principals from OAS and CRCPD, representing interests for both Agreement States and non-Agreement States, also participated in the steering committee by forming a partnership with the NRC in making rulemaking decisions. In an effort to keep stakeholders informed, the NRC held a public roundtable meeting in early November 2005 and established the "Expanded Definition of Byproduct Material (NARM Rulemaking)" web page via the rulemaking website http://ruleforum.llnl.gov for posting rulemaking-related documents. In addition, the NRC met with other Federal agencies to ensure coordination regarding this rulemaking. For example, on August 30, 2005, NRC staff met with OSHA staff to discuss the NRC's role under the EPAct.

Forming Working Groups

In October 2005, the NRC formed a NARM Rulemaking Working Group to develop a regulatory framework for the expanded definition of byproduct material and to draft this rule. In addition to the NRC staff, the NARM Rulemaking Working Group included participants from the State of Florida and the State of Oregon, representing the CRCPD, and from the State of Texas, representing the OAS. Weekly meetings were held to fully utilize the expert resources available within the NARM Rulemaking Working Group.

The NRC also established an Office of Nuclear Materials Safety and Safeguards (NMSS) EPAct Task Force to help implement the various requirements of the EPAct, including the requirements in Section 651(e). The EPAct Task Force included members from the State of Illinois and the State of Oregon representing CRCPD and from the State of North Carolina representing OAS. The State representatives assisted the NARM Rulemaking Working Group by gathering State specific data, developing certain technical bases, and formulating certain regulatory approaches for the rule. The State members of the EPAct Task Force assisted in the rule development, and provided input to the rulemaking process.

In addition, a Steering Committee was formed to provide oversight for both the EPAct Task Force and NARM Rulemaking Working Group. The Steering Committee is comprised of managers from the affected NRC program offices and principals from OAS and CRCPD. During the early rule development process, the Steering Committee met weekly, and later less frequently, to resolve issues and to provide management direction on the rulemaking.

Roundtable Public Meeting

The NRC held a public meeting on November 9, 2005, to discuss rulemaking activities to accommodate NARM into its regulatory framework as mandated by the EPAct. The public meeting was in a "roundtable" format to allow stakeholders an opportunity to discuss concerns and to enhance interaction among all interested parties on the subject of the NRC regulating NARM. Representatives from other Federal agencies, States, and a broad spectrum of interest groups were invited to participate in the "roundtable" discussion. A transcript of this meeting is available on the NRC's rulemaking website.

During the public meeting, the NRC provided an overview of the EPAct and discussed the rulemaking process and the role of the NMSS EPAct Task Force. Other topics that were

discussed included the role of State regulations, potential implications regarding production of radiopharmaceuticals and availability of radiopharmaceuticals to patients, the definition of discrete source, NRC jurisdiction over accelerator-produced radioactive material, and waste and transportation issues.

Following the public meeting, the NRC received five written comments from interested parties related to the discussion at the meeting and the rulemaking activities. These comment letters are available on the NRC's rulemaking website and were reviewed and considered by the NRC staff in the development of this rule.

Interface With Other Federal Agencies and States

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

The NRC hosted a meeting of Federal agency representatives on November 22, 2005, to discuss the development of a definition of *Discrete source* to be added to the NRC regulations. The meeting consisted of members of the NRC's Interagency Coordinating Committee that had already been established for development of the National Source Tracking System. Agencies represented at this meeting were from DOT, DOE, including the National Nuclear Security Administration, DOD, DOC, EPA, and the U.S. Customs and Border Protection. The participants briefly discussed their agency's jurisdiction over, and involvement with, radium-226 and other NORM. At the conclusion of the meeting, a draft definition was formulated. This definition formed the basis for the definition in the proposed rule, with only minor changes and text rearrangement for clarity. As a result of public comment, the definition has been further clarified in the final rule.

An ad hoc focus group was formed to specifically address issues related to the broad spectrum of old radium-226 sources and to formulate a regulatory strategy. The focus group included individuals from both the NRC Headquarters and Regions and representatives from the States of Florida, North Carolina, Illinois, Michigan, Oregon, and Texas. Although many of the old discrete radium-226 sources have been used for decades, no specific quantitative or qualitative technical information was identified during the development of the rule that would support a broad exemption for these old discrete radium-226 sources. Due to lack of specific health and safety information associated with many of the old radium-226 sources, the NRC developed the preferred alternative, which provides a graded approach by using a general license to regulate different groups of radium-226 sources. In addition, in the proposed rule, the NRC asked for the public to provide any technical information that may be available to support exemptions, now or in the future. Limited information was provided as a result of public comment.

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

6.0 CONCLUSION

The NRC is amending its regulations to address certain radium sources, certain naturally occurring radioactive material, and accelerator-produced radioactive materials as required by Section 651(e) of the Energy Policy Act of 2005. This document was prepared so that the environmental impacts would be considered as part of the decision-making process. Based on currently available information, as described in this document, the Commission has determined under the National Environmental Policy Act of 1969, as amended, and the Commission's regulations in Subpart A of 10 CFR Part 51, that these amendments are a major Federal action but will not significantly affect the quality of the human environment, and therefore that an environmental impact statement is not required.

7.0 LIST OF PREPARERS

Neil Haggerty, Project Manager, All Sections
Derek Widmayer, Project Manager, Waste Management

8.0 LIST OF REFERENCES

Atomic Energy Act of 1954, as Amended, Pub. L. 83-703 (1954).

Energy Policy Act of 2005, Pub. L.109-58 (2005).
Code of Federal Regulations, Title 10, Energy, Part 20, "Standards for protection against radiation."

Code of Federal Regulations, Title 10, Energy, Part 30, "Rules of general applicability to domestic licensing of byproduct material."

Code of Federal Regulations, Title 10, Energy, Part 31, "General domestic licenses for byproduct material."

Code of Federal Regulations, Title 10, Energy, Part 32, "Specific domestic licenses to manufacture or transfer certain items containing byproduct material."

Code of Federal Regulations, Title 10, Energy, Part 33, "Specific domestic licenses of broad scope for byproduct material."

Code of Federal Regulations, Title 10, Energy, Part 35, "Medical use of byproduct material."

Code of Federal Regulations, Title 10, Energy, Part 50, “Domestic licensing of production and utilization facilities.”

Code of Federal Regulations, Title 10, Energy, Part 51, “Environmental protection regulations for domestic licensing and related regulatory functions.”

Code of Federal Regulations, Title 10, Energy, Part 61, “Licensing requirements for land disposal of radioactive waste.”

Code of Federal Regulations, Title 10, Energy, Part 62, “Criteria and procedures for emergency access to non-Federal and regional low-level waste disposal facilities.”

Code of Federal Regulations, Title 10, Energy, Part 72, “Licensing requirements for the independent storage of spent nuclear fuel, high-level radioactive waste, and reactor-related greater than Class C waste.”

Code of Federal Regulations, Title 10, Energy, Part 150, “Exemptions and continued regulatory authority in Agreement States and in offshore waters under Section 274.”

Code of Federal Regulations, Title 10, Energy, Part 170, “Fees for facilities, materials, import and export licenses, and other regulatory services under the Atomic Energy Act of 1954, as amended.”

Code of Federal Regulations, Title 10, Energy, Part 171, “Annual fees for reactor licenses and fuel cycle licenses and materials licenses, including holders of certificates of compliance, registrations, and quality assurance program approvals and government agencies licensed by the NRC.”

Low-Level Radioactive Waste Policy Amendments Act of 1985, Pub. L. 99-240 (1986).

National Environmental Policy Act of 1969, as amended, 42 U.S.C. §4231 et seq. (1970).