NUCLEAR REGULATORY COMMISSION

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

RIN 3150–AH84

Requirements for Expanded Definition of Byproduct Material

AGENCY: Nuclear Regulatory Commission.

ACTION: Proposed rule.

SUMMARY: The Nuclear Regulatory Commission (NRC) is proposing to amend its regulations to include jurisdiction over certain radium sources, accelerator-produced radioactive materials, and certain naturally occurring radioactive material, as required by the Energy Policy Act of 2005 (EPAct), which was signed into law on August 8, 2005. The EPAct expanded the Atomic Energy Act of 1954 definition of byproduct material to include any discrete source of radium-226, any material made radioactive by use of a particle accelerator, and any discrete source of naturally occurring radioactive material, other than source material, that the Commission, in consultation with other Federal officials named in the EPAct, determines would pose a similar threat to the public health and safety or the common defense and security as a discrete source of radium-226, that are extracted or converted after extraction for use for a commercial, medical, or research activity. In so doing, these materials were placed under the NRC's regulatory authority. The EPAct also mandated that the Commission, after consultation with States and other stakeholders, issue final regulations establishing requirements that the Commission determines necessary under the EPAct. This rulemaking effort is being undertaken in response to that mandate and includes significant contributions from many States that have regulated the naturally occurring and accelerator-produced radioactive material, the Organization of Agreement States, Inc., and the Conference of Radiation Control Program Directors, Inc. (CRCPD). In addition, this proposed rule was informed and guided by the CRCPD's applicable Suggested State Regulations for the Control of Radiation. Licensees and individuals who are engaged in activities involving the newly defined byproduct material in both Agreement States and non-Agreement States and United States Territories may be affected by this rulemaking.

DATES: Submit comments on the rule by September 11, 2006. Submit comments specific to the information collections aspects of this rule by August 28, 2006. Comments received after the above dates will be considered if it is practical to do so, but assurance of consideration cannot be given to comments received after these dates. A copy of the draft proposed rule was made available on April 7, 2006 on the NRC's rulemaking Web site at *http://ruleforum.llnl.gov.*

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

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

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

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

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

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

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

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

FOR FURTHER INFORMATION CONTACT: Lydia Chang, Office of Nuclear Material Safety and Safeguards, U.S. Nuclear Regulatory Commission, Washington, DC 20555–0001, telephone (301) 415–6319, e-mail *lwc1@nrc.gov.*

SUPPLEMENTARY INFORMATION:

I. Background

The Energy Policy Act of 2005

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

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

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

Although Section 651(e) of the EPAct became effective on August 8, 2005, the NRC did not have regulations in place that would specifically apply to this newly covered byproduct material (hereafter referred to as NARM). However, the EPAct allowed the NRC 18 months from the date that the legislation was signed into law by the President to issue regulations to establish a national program for NARM. The EPAct also allowed the NRC to issue waivers to States and other entities while a regulatory framework for NARM was developed. A waiver was issued on August 31, 2005 (70 FR 51581).

Current Regulatory Structures for NARM

The AEA authorizes States to assume regulatory control of radioactive materials produced in or by a nuclear reactor, provided the State has an adequate program to protect the public health and safety and is compatible with the NRC's program for regulation of these materials and enters into an agreement with the NRC. As authorized by Section 274b of the AEA, 34 States have assumed responsibility for regulating certain activities related to radioactive material by entering into agreements with the NRC. The activities regulated by these ''Agreement States'' include the use of byproduct material, source, and special nuclear material. Each Agreement State issues licenses to persons who use these materials in that State except for DOE, other Government agencies, and Federally recognized Indian Tribes. The NRC issues licenses to persons using these materials in non-Agreement States.

Before enactment of the EPAct, the NRC did not have authority over NARM nor regulations for this type of material. Although the NRC has not regulated NARM in the past, all 33 Agreement States and certain non-Agreement States have regulatory programs for NARM. The NRC's current regulations do require licensees to account for dose contributed from NARM, as well as dose contributed from other byproduct, source, or special nuclear material, because the definition of occupational dose encompasses both licensed material and nonlicensed material such as NARM sources at a licensed facility. In addition, the NRC requires, in its radiological criteria for license termination, that licensees consider other nondiscrete sources including radium during decommissioning activities at sites contaminated with source material, such as rare-earth processing facilities.

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

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

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

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

Other Federal Agencies' Regulatory Authority Over NARM

Before the passage of the EPAct, NARM was regulated as a radioactive material and/or a hazardous substance but was not regulated by the NRC. Although States had the primary responsibility for regulating the use of these materials, certain Federal regulations did and will continue to apply under some circumstances, such as environmental protection, workplace safety, drug safety, transportation, and disposal. With the passage of the EPAct, the NRC will have primary responsibility for radiation safety and in regulating the use of these materials in cooperation with the States, with the exception of those activities that are self-regulated by the DOE.

Other Federal agencies have established programs in regulating certain aspects of activities involving NARM. The Department of Transportation (DOT) regulates interstate transport of NARM. In cooperation with DOT, the NRC approves Type B packages through regulations in 10 CFR Part 71. The EPA has established controls for certain

NARM through several authorities, including the Clean Air Act, the Safe Drinking Water Act, the Toxic Substances Control Act, the Resource Conservation and Recovery Act, and the Comprehensive Environmental Response, Compensation, and Liability Act. The Department of Labor (DOL) has established regulations addressing the exposure of minors to radioactive material in the workplace. The Occupational Safety and Health Administration (OSHA) has the oversight for occupational health and safety for non-AEA materials. The Department of Commerce (DOC) has controlled the export of radioactive material. Prior to the enactment of the EPAct, the DOC regulated the export of all radium-226. With the enactment of the EPAct, NRC will regulate the export of discrete sources of radium-226; DOC retains jurisdiction to regulate the export of nondiscrete sources of radium-226. The Consumer Product Safety Commission regulations have addressed hazardous substances other than byproduct, source, and special nuclear materials currently regulated by the NRC. The Food and Drug Administration (FDA) regulates all drugs (including drugs containing radioactive materials) by requiring good manufacturing practices to assure the purity, potency, and consistency of finished drugs with their labeling in establishing the safety and effectiveness of these drugs.

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

Development of the Suggested State Regulations

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

In 1968, CRCPD was chartered as a nonprofit organization to provide a forum for enhancing communication among States and Federal agencies regarding radiation regulations and to promote a uniform radiation protection environment for all radioactive material. Throughout the years, CRCPD developed policies and guidance for its member States. In addition, CRCPD is responsible for the development of model regulations, known as the SSRs. CRCPD has formed many working groups to develop a set of SSRs for radioactive material compatible in many respects to the NRC regulations. Under the SSRs' regulatory framework, NARM is a regulated radioactive material comparable to byproduct material. Nearly all of the Agreement States have based their regulations on this model for NARM.

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

Issuance of Waiver on August 31, 2005

Section 651(e) of the EPAct became effective immediately upon signature by the President on August 8, 2005. Before enactment of the EPAct, the NRC did not have authority over NARM and currently does not have regulations in place that would specifically apply to this material. Nonetheless, persons engaged in activities involving NARM could be, and States seeking to continue regulation of NARM would be, in technical violation of the AEA. Therefore, the NRC determined that it would be prudent to establish a mechanism to permit individuals currently engaged in activities involving NARM to continue with their activities. Although the Commission could have proceeded through issuing orders on a case-by-case basis to oversee activities involving NARM while establishing the regulatory framework for regulating this material, the Commission determined that this would be inefficient and resource intensive.

Section 651(e)(5) of the EPAct authorizes the Commission to issue a waiver of the requirements of Section 651(e) to any entity with respect to NARM for specified periods of time if the Commission determines that the waiver is in accordance with the protection of the public health and safety, and the promotion of the common defense and security. The Commission determined that this waiver could be granted to entities that engaged in activities involving NARM. The Commission determined that there was no basis to conclude that these materials would not continue to be used in a manner that is protective of public health and safety while the waiver is in effect. The Commission also determined that it would be in the best interests of the public to allow continued use of NARM, especially for medical purposes, and to allow the States to continue to regulate NARM until the Commission could codify new regulations for these materials.

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

Therefore, the Commission granted a waiver (70 FR 51581; August 31, 2005) from the requirements of Section 651(e) of the EPAct to: (1) All persons engaged in export from or import into the U.S. of byproduct material through August 7, 2006, unless terminated sooner if the Commission determined that an earlier termination was warranted; and except with regard to the requirements of the DOC relating to export of byproduct material; (2) all persons acquiring, delivering, receiving, possessing, owning, using, or transferring byproduct material through August 7, 2009, unless terminated sooner if the Commission determined that an earlier termination

was warranted; and (3) all States that had entered into an agreement with the Commission under Section 274b. of the AEA, and States that had not entered into such an Agreement, through August 7, 2009, unless terminated sooner if the Commission determined an earlier termination was warranted, or for an Agreement State if the Commission made certain determinations required by Section 651(e)(5)(B)(ii) of the EPAct.

II. Discussion

A. Initiating the Rulemaking Process

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

Forming Working Groups

In October 2005, the NRC formed a NARM Rulemaking Working Group for developing a regulatory framework for the expanded definition of byproduct material and for drafting this proposed rule. In addition to the NRC staff, the NARM Working Group also included participants from the State of Florida and the State of Oregon representing the CRCPD, the State of Texas representing the OAS, and the State of Michigan. Weekly meetings were held to take full use of the expert resources available within the NARM Working Group.

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

In addition, a Steering Committee was formed to provide oversight for both the NMSS EPAct Task Force and NARM Rulemaking Working Group. The Steering Committee is comprised of managers from the affected NRC program offices and principals from OAS and CRCPD. During the proposed rule development process, the Steering Committee met weekly to resolve issues and to provide management direction on the rulemaking. The Steering Committee plans to continue to meet on a regular basis until the rule is final.

Roundtable Public Meeting

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

During the public meeting, the NRC provided an overview of the EPAct and discussed the rulemaking process and the role of the NMSS EPAct Task Force that was established to help implement the requirements of the EPAct. Other topics that were discussed included the role of State regulations, potential implications regarding production of radiopharmaceuticals and availability of radiopharmaceuticals to patients, definition of discrete source, the NRC jurisdiction over accelerator-produced radioactive material, and waste and transportation issues.

Following the public meeting, the NRC received five written comments from interested parties related to the discussion at the meeting and the rulemaking activities. These comment letters are available via the NRC rulemaking Web site at *http://ruleforum.llnl.gov* and have been reviewed and considered by the NRC staff in the development of this proposed rule.

Interface With Other Federal Agencies and States

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

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

An ad hoc focus group was formed to specifically address issues related to the broad spectrum of old radium-226 sources and to formulate a regulatory strategy. The focus group included individuals from the NRC Headquarters and Regions and representatives from the States of Florida, North Carolina, Illinois, Michigan, Oregon, and Texas. Although many of the old discrete radium-226 sources have been used for decades, no specific quantitative nor

qualitative technical information was identified during the development of the proposed rule that would support a broad exemption for these old discrete radium-226 sources. Because of the lack of specific health and safety information associated with many of the old radium-226 sources, the NRC is proposing a graded approach by using a general license to regulate different groups of radium-226 sources. In addition, in this proposed rule, the NRC is asking the public for any technical information that may be available to support an exemption, now or in the future.

B. The New Expanded Definition of Byproduct Material

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

Radium-226

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

Although radium was discovered in the ore pitchblende by the chemists Marie and Pierre Curie in 1898, no one understood the dangers of radium until later in the twentieth century. Based on radium's properties, especially its ability to stimulate luminescence, industries started manufacturing hundreds of consumer products containing radium. With advertisements proclaiming its special powers, radium was added to products such as hair tonic, toothpaste, ointments, and elixirs. Radium paint was used in the mid-1900s to paint the hands and numbers of some clocks, watches, doorknobs, and other objects to make them glow in the dark. Glow-in-the-dark watch and clock faces were particularly popular. Radium was also used as a radiation source in needles or as plaques for cancer treatment. Most of these uses were eventually discontinued for health and safety reasons, but its wide use in luminescent paints continued through World War II because radium's luminescent glow made aircraft and vehicle dials, gauges, and other instruments visible at night. Many of these early products still remain in the possession of museums and individual collectors. Large inventories of radium luminescent military and aircraft devices remain and periodically turn up in repair shops and have resulted in contamination incidents. In more recent times, radium sources were used in industrial radiography and industrial smoke detectors. Currently, radium sources are still being used in some industrial products such as industrial gauges that measure certain physical properties such as moisture and density.

Accelerator-Produced Radioactive Material

Particle Accelerators

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

The two basic designs of particle accelerators are linear and circular. In either case, charged particles are injected into the accelerator to form a beam. The beam is accelerated and focused onto the target. In the circular designs, the beam must also be bent into the circular shaped path. The process of accelerating, focusing, and bending (if necessary) the beam is accomplished by a combination of electrically charged structures and magnetic fields in the accelerator. During operation, these internal structures will be struck by particles from the beam and activated incidentally. In some cases, targets consist of nuclides intended for activation and other nuclides that are also incidentally activated. Accelerators may also produce a neutron flux capable of activating materials. The production of incidental radioactive material is an inextricable part of any accelerator operation.

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

For the purposes of this rulemaking, the NRC divided particle accelerators into three groupings: (1) Those that are always operated to intentionally produce radioactive materials in quantities useful for their radioactive properties for a commercial, medical or research activity; (2) those that are operated to produce only particle beams and not radioactive materials; and (3) accelerators that are used to produce both radioactive materials and particle beams for other uses. Examples of accelerators that are operated to produce only particle beams and not radioactive

materials include linear accelerators used for medical treatment of cancer and other health-related conditions. Other examples include the experimental particle physics research colliders used to probe the fundamental properties of nature (as long as that is their only use) and electron microscopes, i.e., particle accelerators that probe the structure of materials at a very small dimension (high magnification). Ion implanters are particle accelerators used to modify the electrical properties of materials in semiconductor fabrication. In these activities, no radioactive material is intentionally created; all activation is incidental to the intended use of the accelerator.

The NRC proposes to regulate the radioactive material both intentionally and incidentally produced by all accelerators that are intentionally operated to produce a radioactive material for its radioactive properties. The NRC does not propose to regulate the incidental radioactive material produced by accelerators that are operated to produce only particle beams and not radioactive materials for use for a commercial, medical, or research activity. For those accelerators that are used to produce both radioactive material and particle beams, the NRC proposes to regulate the intentionally produced radioactive material and all of the incidentally produced radioactive material, including incidental radioactive material produced when the accelerator is operated to produce radioactive material, as well as incidental radioactive material produced when it is operated to produce only a particle beam. The incidental radioactive materials produced in these accelerators are indistinguishable, so both are covered by this proposed rule. The NRC believes very few, if any, accelerators are operated in this way. NRC is seeking comments on the extent, if any, that accelerators are used to intentionally produce radioactive material and to provide beams for basic science research.

The EPAct does not give the NRC authority to regulate the possession or use of particle accelerators. The NRC does not propose to adopt any rule regarding the operation of a particle accelerator or the qualification of any person maintaining or operating a particle accelerator. However, nothing in the EPAct directs the NRC to change the policy that radiation safety standards must consider unregulated as well as regulated sources of radiation. The NRC will continue to require any person subject to the dose limits in 10 CFR Part 20 to continue to include radiation dose from the operation of a particle accelerator in meeting the dose limitations. The NRC is aware that the operation of a particle accelerator may activate materials in the structure of the building and facilities housing the accelerator. The NRC is considering how to assure the safe decommissioning of particle accelerator buildings and facilities, including the removal and disposal of activated building materials, to assure that the dose limits to members of the public are not exceeded. Comments are requested on the decommissioning of accelerator facilities, specifically addressing the extent to which accelerator components and facility building materials may become activated, the need to remove and properly dispose of the activated material during decommissioning to meet the radiation dose limits in 10 CFR Part 20 Subpart E—Radiological Criteria for License Termination, the costs of the decommissioning and disposal, if required, and the need for financial assurance by accelerator facilities to guarantee sufficient funding for proper decommissioning.

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

Accelerator-Produced Radioactive Material Used in Medical Activities

Medical use of radioactive material began over 50 years ago. The medical use of sealed and unsealed radioactive materials is now an important component of medical specialties for both diagnosis and therapy purposes. Today, the use of unsealed radioactive materials in nuclear medicine offers procedures that are essential in many medical specialties, from pediatrics to cardiology to psychiatry. Approximately 4,000 hospital-based nuclear medicine departments and many freestanding imaging centers in the U.S. perform millions of nuclear medicine imaging studies every year. Nuclear medicine is now an integral part of patient care and is extremely valuable in the early diagnosis and treatment of medical conditions. Nuclear medicine uses very small amounts of radioactive materials (radiopharmaceuticals) to diagnose and treat disease. In diagnosis, the radiopharmaceuticals are used and then detected by special cameras with the aid of computers in providing very precise images for the area of interest. In therapeutic nuclear medicine applications, the radiopharmaceuticals can be directed to the specific organ being treated. Radiation oncology uses larger amounts of radioactivity in sealed sources to deliver therapeutic or palliative radiation doses.

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

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

There are a limited number of commercial manufacturers in the U.S. that produce radiopharmaceuticals using radionuclides, such as thallium-201, iodine-123, indium-111, and gallium-67, that are produced in particle accelerators. The use of fluorine-18, carbon-11, nitrogen-13, and oxygen-15 in radiopharmaceuticals, also known as the PET drugs, has increased in recent years. PET radionuclides and drugs are primarily produced in cyclotron facilities (often referred to as PET centers). PET drugs use radionuclides that decay by positron emission, which provides dual photons traveling in opposite directions that give a better spacial resolution of images for the area of diagnostic interest. Due to the relatively short half life (minutes to hours), PET radionuclides and drugs are produced at locations in close proximity to the patients (*e.g.*, in hospitals or academic institutions) or at nearby locations.

Palladium-103 is the most common accelerator-produced medical use radionuclide contained in a sealed source. Palladium-103 manual brachytherapy sources were originally produced at reactor facilities, but currently all palladium-103 used in the U.S. is commercially produced by accelerators with a significant amount produced by U.S. accelerators. Other medical use radionuclides, used in radiation therapy, can also be produced with either reactors or accelerators. With the new definition of byproduct material, sealed sources that can be produced from either pathway will be uniformly regulated. At this time, there are no remote afterloader or gamma stereotactic radiosurgery units with accelerator-produced sources.

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

Other Naturally Occurring Radioactive Material With Similar Risk as Radium-226

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

The inclusion of discrete sources of naturally occurring radioactive material into the definition of Byproduct material is contingent on the Commission's determination, in consultation with other Federal agencies, that such discrete sources would pose a threat similar to the threat posed by a discrete source of radium-226. At this time, the proposed rule does not suggest any discrete sources of naturally occurring radioactive material for inclusion, and the proposed rule does not contain criteria for making such a determination. For comparison, the International Atomic Energy Agency (IAEA) has identified a list of sources that are considered to pose a high risk to human health and safety if not managed safely and securely. The IAEA Code of Conduct on the Safety and Security of Radioactive Sources (Code of Conduct) identified certain quantities of 26 radionuclides that pose a significant risk to individuals, society, and the environment. The activity of these radionuclides at the IAEA Code of Conduct Category 1 or 2 levels could be fatal or cause permanent injury to a person, who handled them or was otherwise in contact with them, for a short time if not safely managed or securely protected. Of these 26 sources, only two naturally occurring radionuclides are listed: radium-226 and polonium-210. Since this proposed rule addresses discrete sources of radium-226, the only other naturally occurring radioactive material similar in hazard to radium-226 is polonium-210 when using the IAEA criteria. However, naturally occurring polonium is scarce. One ton of uranium ore contains only about 100 micrograms (0.0001 grams) of polonium. Due to its scarcity, polonium-210 used for commercial purposes is usually produced by bombarding bismuth-209 with neutrons in a nuclear reactor. Therefore, the polonium-210 used in commerce had been regulated by the NRC before the EPAct. Additionally, polonium-210 is very unlikely to be commercially used in individual radioactive sources with activity levels that would place them within IAEA Code of Conduct Category 1 or 2.

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

At this time, the NRC staff has determined that no other discrete sources of naturally occurring radioactive material pose a threat similar to radium-226-level or IAEA Code of Conduct Category 1 or 2 sources. In developing the proposed rule, and interacting with other Federal agencies and States, the NRC concluded that only polonium-210 has the potential to pose a threat similar to the threat posed by a discrete source of radium-226 to the public health and safety or the common defense and security. The NRC had already been regulating the use and possession of polonium-210 because it is produced in nuclear reactors and is rarely extracted as naturally occurring radioactive material. Therefore, this proposed rule does not propose to add any discrete sources of naturally occurring radioactive material to the definition of Byproduct material, other than radium-226 and polonium-210 covered elsewhere in the definition of Byproduct material. The EPAct has provided a mechanism for the Commission to include additional discrete sources of naturally occurring radioactive material in the future following consultation with other Federal agencies, if the need arises to consider other naturally occurring radioactive material for byproduct material.

C. The NRC's Regulatory Approach

Consideration of SSRs

All 34 Agreement States have regulations for NARM. Twelve non-Agreement States and certain U.S. Territories have some type of regulatory structure for NARM, while four non-Agreement States have no program for regulating NARM. The EPAct mandated that the NRC use model State regulations to the maximum extent practicable in issuing regulations for the expanded definition of byproduct material. CRCPD published SSRs which included the model regulations for radioactive materials. Because SSRs are the model regulations that most CRCPD member States have adopted, or States have issued requirements that are similar to the SSRs, then the SSRs provide the NRC a model for the basic regulatory framework for regulating the additional byproduct materials as defined by the EPAct. The SSRs are available on the CRCPD Web site at *http://www.crcpd.org/free_docs.asp.* The majority of stakeholders at the November 9, 2005, public meeting supported the recognition of SSRs as the model regulations referred to in the EPAct. Although varying slightly from State to State, the majority of States regulating NARM have adopted the guidelines in SSRs.

The NRC considered the SSRs in developing the proposed rule. The NRC considered the SSRs in evaluating NARM radionuclides for potential inclusion in radionuclide-specific values listed in 10 CFR Part 20, Appendices B and C. The NRC found that there are no other radionuclides identified in comparable provisions in

Part D of the SSRs that are not already included in 10 CFR Part 20. The NRC evaluated values in SSRs for exempt concentrations (Schedule A to 10 CFR Part 30) and exempt quantities (Schedule B to 10 CFR Part 30). These exemption values were carefully reviewed because of their potential impact on interstate commerce, reciprocity, and other commercial activities. The NRC determined that these values included in SSRs were consistent with the existing NRC approach and were derived using the same methodology. Hence, there is no change needed in the regulatory approach for exempt concentrations. With respect to the exempt quantities, the NRC is proposing to adopt the values included in SSRs into 10 CFR Part 30.

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

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

Paragraphs (j) and (k) of Section C.28 of the SSRs were reviewed for specific information on NARM radiopharmaceuticals or PET drugs, but no such information was found. Section G.48 of the SSRs includes contamination limits for strontium-82/rubidium-82 generators. The contamination limits from the SSRs are more than 0.02 kilobecquerel of strontium-82 per megabecquerel of rubidium-82 chloride injection (0.02 microcurie of strontium-82 per millicurie of rubidium-82 chloride), or more than 0.2 kilobecquerel of strontium-85 per megabecquerel of rubidium-82 chloride injection (0.2 microcurie of strontium-85 per millicurie of rubidium-82). In this proposed rule, the contamination limits and requirements to measure the contamination limits were added to 10 CFR 35.204 with corresponding recordkeeping requirements added to 10 CFR 35.2204. There were no additional regulatory requirements in the SSRs applicable to medical use licensees.

In developing this proposed rule, and as specifically discussed at the November 9, 2005, roundtable public meeting, the NRC learned that few SSRs specifically address accelerator-produced radioactive material. Because most Agreement States have regulated accelerator-produced radioactive material in a manner similar to and under the same requirements as reactor-produced radioactive material, few SSRs exist solely to address accelerator-produced radioactive material. While SSRs do exist that address naturally occurring radioactive material issues, there appear to be few model State regulations specific to accelerator-produced radioactive material upon which the NRC can base this proposed rule. However, there is general agreement among the States, and reflected in the SSRs, that accelerator-produced radioactive material should be regulated under the same requirements as reactor-produced radioactive material. This proposed rule takes the same regulatory approach.

Common Defense and Security Considerations

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

The NRC has published a final rule relating to the export and import of radioactive materials for certain radionuclides listed in the Code of Conduct (70 FR 37985; July 1, 2005) and a proposed rule for national source tracking of sealed sources (70 FR 43646; July 28, 2005). In a separate rulemaking, the NRC will amend its regulations in 10 CFR Part 110 on export and import of radioactive material to address discrete sources of radium-226 in a manner consistent with the Code of Conduct.

Definition of Discrete Sources

The EPAct extended the definition of Byproduct material to include any discrete source of radium-226 that is produced, extracted, or converted after extraction, before, on, or after the date of the enactment of the EPAct, for use for a commercial, medical, or research activity. The EPAct gives the NRC authority over discrete sources of radium-226 but not over diffuse sources of radium-226. The result did not extend the NRC's authority over radium-226 as it occurs in nature, nor over other processes where radium-226 may be unintentionally concentrated. Scale from pipes used in the fossil fuel industry, fly ash from coal power plants, phosphate fertilizers, or residuals from treatment of water to meet drinking water standards are not considered as discrete sources; however, uranium and thorium within these materials may become licensable source material

depending upon their concentration. To more clearly establish the limit of its authority regarding radium-226, the NRC was tasked with defining what constitutes a discrete source. The NRC is defining the term in this proposed rule.

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

The NRC believes that this new authority over radium-226 and other naturally occurring radioactive material was not intended to extend to all naturally occurring radioactive material. The focus was on those materials that presented a threat to public health and safety or to the common defense and security similar to the threat posed by discrete radium-226 sources. The authority does not extend to naturally occurring radioactive material that is found in nature in its original form and location, nor to naturally occurring radioactive material moved or concentrated inadvertently in some man-made process. The intent of the NRC in developing the definition of Discrete source for radium-226 and other naturally occurring radioactive material was to better define the materials covered by the new authority.

In defining radium-226 and other naturally occurring radioactive material as byproduct material, Discrete source means ''a radioactive source with physical boundaries, which is separate and distinct from the radioactivity present in nature, and in which the radionuclide concentration has been increased by human processes with the intent that the concentrated radioactive material will be used for its radiological properties.'' The discrete source will have the same radiological characteristics (type of radiation, half-life, etc.) as the radionuclide found in nature, but will have been concentrated and purposefully used for its radiological properties, after it has been removed from its original location in nature. This excludes the NRC jurisdiction over inadvertent movement or concentration of naturally occurring radioactive material. It does not change the NRC's authority, in any manner, over source material. This definition of Discrete source clarifies those radium-226 sources and other naturally occurring radioactive material, other than source material, that will be delineated as byproduct material and will fall under the expanded definition of Byproduct material as mandated in the EPAct. This definition of Discrete source does not include material encapsulated or sealed only for disposal. However, it should be noted that once a radioactive material, as defined under this definition of Discrete source, becomes a byproduct material, it will continue to be regulated as a byproduct material even if the discrete radioactive source is leaking or broken, or no longer has a physical boundary.

D. Changes to Existing NRC Regulations To Accommodate the New Byproduct Material

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

In considering the expansion of the definition of Byproduct material to include discrete sources of radium-226 and accelerator-produced radioactive material, the NRC has evaluated products and materials previously approved by States for use under an exemption from licensing and under a general license. Generally, the NRC's intent in this proposed rule is to accommodate existing products and materials that were previously regulated by the States under similar provisions if the potential doses are similar to those expected from other currently regulated products and materials. Many of these products have not been made for some time, so some of the provisions in this proposed rule are only intended to accommodate items manufactured in the past, which may still be in use or in storage. For example, radium-226 was used in timepieces and other self-luminous products, and in smoke detectors. Some time ago, promethium-147 and tritium replaced radium-226 in self-luminous products. For many years, americium-241 has been the primary radionuclide used in smoke detectors; consequently, the use of radium-226 in the manufacture of smoke detectors stopped several years ago.

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

Exemptions From Licensing

Part 30 of Title 10 of the Code of Federal Regulations includes a number of exemptions from licensing requirements. These exemptions allow for certain products and materials containing byproduct material to be used without any regulatory requirements imposed on the user. The two exemptions in 10 CFR 30.19 and 10 CFR 30.20, Self-luminous products and Gas and aerosol detectors, respectively, are class exemptions, which cover a broad class of products. Under these provisions, new products can be approved for use through the licensing process if the applicant demonstrates that the specific product is within the class and meets certain radiation dose criteria. This contrasts with other exemptions for which the level of safety is controlled through such limits as specification of radionuclides and quantities. Sections 30.14 and 30.18 of NRC's regulations, Exempt concentrations and Exempt quantities, respectively, are broad materials exemptions, which allow the use of a large number of radionuclides. The specific radionuclide limits on these concentrations and quantities are contained in tables in 10 CFR 30.70 and

10 CFR 30.71, respectively. The remaining exemptions from licensing are product specific, for which many assumptions can and have been made concerning how the product is distributed, used, and disposed of. The proposed rule would add some products and materials containing NARM to some of the current exemptions. The table of exempt concentrations in 10 CFR 30.70 already includes all of the radionuclides and associated limits contained in the equivalent section of the SSRs. Thus, the NRC is not proposing to revise the exempt concentration table in this proposed rule.

Exempt Quantities

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

The NRC considered whether there were additional radionuclides in use under comparable State exemptions that should be accommodated under 10 CFR 30.71. It was noted that a few of the States' regulations for exempt quantities include additional radionuclide-specific values, each appearing in only one or two State's regulations. These radionuclides are specifically exempted in only one or two States; thus, they do not represent nationally recognized exemptions. It was also not clear as to what approach was used to calculate their exemption values. Therefore, the NRC is proposing to add only the 13 radionuclides and values from the SSRs, and no further additions to 10 CFR 30.71 are included in the proposed rule. It is noted, however, that for other byproduct material, excluding alpha emitters, which is the last item on the list in 10 CFR 30.71, Schedule B, allows for 3.7 kBq (0.1 μCi) to be used as an exempt quantity. This would apply to accelerator-produced radionuclides as well.

Timepieces Containing Radium-226

The exemption in 10 CFR 30.15(a)(1) would be revised to include timepieces (including dials, watch faces, and hands) that were manufactured prior to the effective date of the rule and containing no more than 37 kBq (1 μCi) of radium-226. This limit is consistent with the SSRs. However, as the hazard of handling non-intact timepieces and hands and dials, particularly the repair, may be more significant because of the effects of aging on the radium-containing paint, the exemption in the proposed rule would be limited to ''intact'' timepieces, with an exception to allow for repairing a limited number of timepieces, per year, proposed as ten. This latter exception is intended to recognize historical practices and minimize impacts on small businesses and antique collectors, while NRC gathers data to determine if more specific requirements should be placed on the possession and repair of antiques containing radium-226. It is believed that the incidence of handling of watch and other timepiece parts and the repair of timepieces containing radium-226 is generally limited; however, the Commission requests input regarding the appropriateness of this number and other comments concerning how active the repair of radium timepieces may be, the safety significance of this exemption, alternatives to potential regulations, or justification for continuing the exemption in this area. As discussed later, the possession, but not the repair, of a larger number of timepiece parts would be covered by a proposed new general license. However, if a significant number of such items are being handled in a facility, the controls associated with a specific license would be appropriate. As noted elsewhere in this **Federal Register** notice, the Commission will be gathering additional information about the quantities of radium-226 in products in order to better evaluate the health and safety implications associated with the various products and activities involving radium-226.

Self-Luminous Products

Although the SSR section similar to 10 CFR 30.19 includes an exemption for previously acquired self-luminous articles containing less than 3.7 kBq (0.1 μCi) of radium-226, 10 CFR 30.19 would not be amended to include this exemption. The basis for not including this exemption is that, as currently written, 10 CFR 30.19 only applies to products manufactured and distributed under a specific license issued under 10 CFR 32.22. The SSR exemption does not require that these products be previously manufactured and distributed under a specific license, nor do the SSRs provide for such a license with regard to radium. Instead, the possession, use, and transfer of these items would be subject to the general license for certain previously manufactured items and self-luminous products containing radium-226 established in 10 CFR Part 31. The NRC plans to further evaluate the health and safety implications of self-luminous products to determine if exemptions may be appropriate.

Smoke Detectors

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

Distribution to Exempt Persons

The NRC continues to retain the authority for authorizing distribution of products and materials where the end user is exempt from licensing and regulatory requirements by regulation in 10 CFR 150.15(a)(6). The current 10 CFR 150.15(a)(6) states, in part, that persons in Agreement States are not exempt from the Commission's licensing and regulatory requirements with respect to the transfer of possession or control of any equipment, device, commodity, or other products containing byproduct material to persons who are exempt from licensing and regulatory requirements of the Commission. The NRC does not transfer this authority when a State enters into an Agreement with the NRC. Therefore, persons who initially transfer products containing byproduct material to persons who are exempt from licensing and regulatory requirements must have a license from the NRC authorizing these activities.

These distributors also need a specific license from either an Agreement State or from the NRC authorizing the possession and use of the byproduct material. As a result of the expansion of the definition of Byproduct material, the distribution of NARM to exempt persons, including distribution by licensees in Agreement States, will also be authorized only by the NRC. Currently, States have only authorized a few distribution licensees for distribution to persons exempt from licensing requirements of exempt quantities of accelerator-produced radioactive material. These distribution licensees already have an NRC license under 10 CFR 32.18 authorizing the distribution of exempt quantities of pre-EPAct byproduct material. Thus, only a simple amendment of those NRC licenses will be required as a result of this aspect of this proposed rule.

Existing General Licenses

General License for Devices in 10 CFR 31.5

Section 31.5 is the primary general license provision in 10 CFR Part 31. It covers a broad range of devices: those ''designed and manufactured for the purpose of detecting, measuring, gauging, or controlling thickness, density, level, interface location, radiation, leakage, or qualitative or quantitative chemical composition, or for producing light or an ionized atmosphere.'' These devices must be distributed under specific licenses issued under 10 CFR 32.51 or equivalent regulations of an Agreement State. There are numerous SS&D certificates for devices containing NARM that have been approved by States for use under a general license. These are almost all for devices containing cobalt-57, sodium-22, or radium-226. In many cases, models have been approved which are authorized to contain one of these radionuclides or one or more other radionuclides that were byproduct material before the EPAct. They have been evaluated under equivalent, in most cases, or at least comparable, standards by the States. The proposed rule would accommodate generally licensed devices meeting the restrictions of the general license that were previously approved by States under comparable provisions to 10 CFR 32.51. Active certificates would stand with amendments, if needed, being made to the distributors' licenses to cover changes in response to this proposed rule. Any new certificates would be issued by the NRC or the Agreement States under the AEA encompassing the new definition of Byproduct material.

The criteria for registration of generally licensed devices under 10 CFR 31.5(c)(13)(i) would be revised to include a criterion for registration by general licensees of devices containing 3.7 megabecquerels (MBq) (0.1 millicurie (mCi)) or more of radium-226. This registration is separate and quite different from the SS&D registration by the distributors. It requires physical inventories and certification of device information by general licensees, allows the NRC and Agreement States with equivalent regulations to more fully track generally licensed devices meeting these criteria, and serves to remind general licensees of their responsibilities under the general license. SS&D certificates for generally licensed devices that would come under 10 CFR 31.5 include devices with 37 MBq (1 mCi) or more of radium-226. These devices would be subject to the registration requirement. Other certificates, which include devices with radium-226, allow only much smaller quantities. These devices would not be required to be registered. This criterion for registration of radium-226 was chosen because of the low concentration levels which typically are required for decontamination and decommissioning involving radium-226, as well as the relative dispersibility of radium-226. A principal purpose of the registration process concerns reducing losses of devices that could significantly contaminate a smelter, if inadvertently melted. At this time, the NRC does not believe there are accelerator-produced materials used in significant quantities in these types of generally licensed devices to warrant registration.

Distributors of NARM have typically also been distributors of pre-EPAct byproduct material. Many of them have not excluded information about transfers of devices containing NARM from reports of transfers made to the NRC on generally licensed devices transferred into the NRC jurisdiction. Therefore, the NRC already has information on some of these devices in its general license tracking system. Information available from States will also be added. It is expected that the registration process will identify additional devices containing registrable quantities of radium-226, as users in many cases will already be registering other devices with the NRC containing other radionuclides and would need to add devices containing radium-226 during the registration process.

Calibration and Reference Sources in 10 CFR 31.8

Section 31.8 of 10 CFR Part 31 currently provides a general license for the use of up to 185 kBq (5 μCi) of americium-241 in calibration and reference sources. The SSRs and many State regulations also include radium-226 in their comparable provisions to the general license. This proposed rule would add radium-226 to 10 CFR 31.8, consistent with the SSRs. This general license is only applicable to specific licensees that have calibration, and reference sources as defined in 10 CFR 31.8, and simply eliminates certain administrative requirements to address these sources under the specific license. The sources are covered by requirements applicable under the specific license, as well as additional requirements in 10 CFR 31.8.

General License for in vitro Test Kits in 10 CFR 31.11

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

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

A new section would be added to 10 CFR Part 31 to provide a general license to any person for other products and discrete sources containing radium-226 which are apparently in the public domain but may not be otherwise covered under a license and are not specifically addressed in the SSRs. The general license would include: (1) Antiquities originally intended for use by the general public and distributed in the late 19th and early 20th centuries, such as radium emanator jars, revigators, radium water jars, radon generators, refrigerator cards, radium bath salts, healing pads, etc.; (2) luminous hands and dials not contained in timepieces and other luminous items, provided that no more than 50 are used or stored at the same location at any one time; (3) luminous gauges and other aircraft safety items containing radium-226 installed in aircraft; (4) luminous aircraft gauges and other aircraft safety items containing radium-226 no longer installed in aircraft, provided that no more than 100 are used or stored at the same location at any one time; and (5) small radium sources containing no more than 37 kBq (1 μCi) of radium-226 as discrete survey instrument calibration sources, sources contained in radiation measuring instruments, sources used in educational demonstrations (such as cloud chambers, spinthariscopes, etc.), electron tubes, lightning rods, ionization sources, and static eliminators.

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

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

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

The Commission specifically requests comments to provide information that may assist the NRC to more fully evaluate potential impact to public health and safety and the environment due to activities involving radium-226 sources. In particular, the Commission requests input on any quantitative or qualitative health and safety information regarding radium-226 sources that may be used to support a regulatory framework other than general licensing, such as an exemption. The Commission also requests comments regarding the specific constraints in the proposed exemption in 10 CFR 30.15(a)(1)(viii) and in its general license approach for certain items and self-luminous products containing radium-226 that were manufactured prior to the effective date of the rule, regarding under what circumstances an exemption is a more effective and viable approach, and requests additional information for the technical basis supporting an exemption in lieu of a general license. In particular, the Commission would appreciate input on whether this general license approach, and its allowances and restrictions, is reasonable while the Commission evaluates the products; whether the general license should allow possession of radium-226 luminous items, such as individual watch hands, dials, gauge indicators and faces, which are not contained in an intact finished product regardless of number; whether commercial transfers should be restricted and require a specific license; or whether data are available to justify an exemption for certain types of radium-226 sources, now or in the future.

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

Section 651(e) of the EPAct requires the NRC to consider the impact of its regulations on the availability of radioactive drugs to physicians and patients. The NRC has a well established regulatory framework for the commercial production, distribution, and use of in vitro test kits, radioactive drugs, biologics, and SS&Ds for medical activities involving byproduct material yielded in, or made radioactive by, exposure to the radiation incident to the process of producing or using special nuclear material. The NRC believes this existing regulatory framework is also applicable to the commercial producers, distributors, and medical users of in vitro test kits, radionuclides, radioactive drugs, biologics, and SS&Ds containing NARM that are now included in the EPAct's expanded definition of byproduct material. The NRC also believes this framework will minimize the impact of its regulations on the availability of radioactive drugs containing accelerator-produced radionuclides.

This regulatory framework for the commercial radioactive drug manufacturer and the commercial nuclear pharmacy consists of licenses (or authorizations) issued under 10 CFR Part 30 to possess and use the radioactive materials, a distribution license issued under 10 CFR 32.71 to distribute certain in vitro test kits to generally licensed medical and veterinary clinical laboratories, and a medical distribution license issued under 10 CFR 32.72 to distribute radioactive drugs to medical use licensees. While the medical SS&D manufacturers also have licenses (or authorizations) issued under 10 CFR Part 30, their medical distribution licenses are issued under 10 CFR 32.74. The medical distribution licenses (or authorizations) issued under 10 CFR 32.72 and 10 CFR 32.74 authorize distribution to medical use licensees, but do not authorize the possession and use of byproduct material.

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

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

The extremely short half-life radionuclides used for medical use have to be administered immediately after production and would essentially necessitate that the cyclotron be located in the medical facility. Some hospitals form ''consortiums'' with adjacent or nearby hospitals to make PET radionuclides and drugs available to these associated facilities through noncommercial distributions. While the NRC's existing regulatory framework works for the commercial production and distribution of PET radionuclides and drugs, it was not developed to handle the noncommercial distribution between medical use licensees. Failure to address noncommercial distribution would impact the availability of these radioactive drugs to physicians and patients.

Therefore, the NRC developed a new regulatory process based upon existing practices to minimize impact on the noncommercial distribution of PET radionuclides, drugs, and biologics among medical use licensees. In accordance with this process, a medical use facility, which uses its own cyclotron to produce PET radionuclides for use under its own medical use license, would not need a medical distribution license, but it would need to have either a separate 10 CFR Part 30 license for the PET radionuclide production facility or a 10 CFR Part 30 authorization for this production facility on its medical use license. As with other radionuclide production facilities, the radiation safety program will be reviewed in accordance with the criteria in 10 CFR 30.33. If the licensee has a broad scope authorization for 10 CFR Part 30 uses, then the program also will be reviewed in accordance with 10 CFR Part 33.

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

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

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

Authorized nuclear pharmacists will continue to be authorized to use already produced reactor-produced radionuclides, PET radionuclides, and other accelerator-produced radionuclides to prepare PET drugs and other radioactive drugs, *i.e.,* compound PET drugs and other radioactive drugs, under the practice of pharmacy. Medical use licensees that receive PET radionuclides that are added to ''cold kits'' may prepare them under the same authorization in 10 CFR 35.100(b), 35.200(b), and 35.300(b) as other unsealed byproduct materials for medical use.

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

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

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

In summary, to minimize the regulatory impact on the availability of accelerator-produced radioactive drugs, the NRC is taking the following actions: (1) Applying its established regulatory framework to the commercial distribution of these drugs; (2) expanding the regulations to permit noncommercial distribution of these drugs by medical use licensees; (3) expanding the authorization for commercial nuclear pharmacies to

produce PET radionuclides; (4) ''grandfathering'' current users of accelerator-produced radioactive drugs; (5) retaining the existing training and experience criteria in 10 CFR Part 35 for authorized individuals; and (6) permitting individuals to continue to prepare and use radioactive drugs while they are applying for new licenses or amendments.

The medical use of extremely short half-life radionuclides, *e.g.*, oxygen-15, requires the radionuclide to be administered in the imaging and localization medical use area (10 CFR 35.200) immediately after the radionuclide is produced by the cyclotron. This necessitates the medical use area to be co-located with the cyclotron or to have a radionuclide delivery line from the PET radionuclide production area. This introduces the potential for a high radiation area in a medical use area that is normally considered a low radiation area. This is a unique situation and was not envisioned when NRC developed the requirements that permitted licensees to make changes in the areas where byproduct material is used only in accordance with 10 CFR 35.100 or 10 CFR 35.200 without submitting a license amendment. These requirements are found in 10 CFR 35.13, ''License amendments,'' 10 CFR 35.14, ''Notifications,'' and 10 CFR 35.15, ''Exemptions regarding Type A specific licenses of broad scope.'' The proposed rule clarifies that an amendment would be required in the unique situation described previously if the changes involved movement of the cyclotron or a radionuclide delivery line from the PET radionuclide production area. Changes to the typical 10 CFR 35.100 and 10 CFR 35.200 medical use areas are not affected.

Consideration of NARM in 10 CFR Part 20, Appendix B

The comparable provisions in Part D of the SSRs do not include any new accelerator-produced radionuclides other than the ones already in 10 CFR Part 20, Appendix B. The NRC considered whether some other radionuclide-specific values should be added to 10 CFR Part 20, Appendix B. Since nitrogen-13 and oxygen-15 are two of the accelerator-produced radionuclides that are produced for medical uses, the NRC performed a preliminary calculation of values based on dose factors published in National Council on Radiation Protection and Measurements (NCRP) Report No. 123I on Screening Models for Releases of Radionuclides to Atmosphere, Surface Water, and Ground. Certain dose conversion factors were not readily available. Results from these preliminary calculations yielded a derived air concentration (DAC) based on the submersion scenario for both nitrogen-13 and oxygen-15 of about 4×10^{-6} microcurie per milliliter (1.48×10^{-2} becquerels per milliliter) for occupational exposure and a corresponding effluent concentration of 2×10^{-8} microcurie per milliliter (7.4×10^{-4} becquerels per milliliter) for exposure of members of the public. The above calculated values are larger than the default values for DAC and effluent concentration by a factor of 40 and 20, respectively, in 10 CFR Part 20, Appendix B. Because the approach used in calculating values for nitrogen-13 and oxygen-15 is different from that used for other radionuclides included in 10 CFR Part 20, Appendix B, the NRC is not proposing to add specific values for these radionuclides in this rulemaking at this time. Since certain medical communities have expressed the desire of having specific DACs for these two radionuclides, the Commission specifically requests public comment on the default values, and whether it should include larger specific values for oxygen-15 and nitrogen-13 in the final rule.

Emergency Planning

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

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

Low-Level Radioactive Waste and Decommissioning

Low-Level Radioactive Waste

Section 651(e)(3) of the EPAct mandates that the newly added byproduct material is not considered to be low-level radioactive waste for the purposes of the Low-Level Radioactive Waste Policy Amendments Act (42 U.S.C. 2021b) (LLRWPAA). The intent of this provision is that the newly added byproduct material is not to be impacted by the compact process of the LLRWPAA. This provision does not have an impact on the NRC policy and requires only a minor change to the regulations to ensure that the term ''low-level radioactive waste,'' when used in the NRC requirements, does not include the newly added byproduct material.

Although the newly added byproduct material is not considered low-level radioactive waste, it does pose a similar hazard, and it does need to be disposed of appropriately. Section 651(e)(3) of the EPAct requires that the newly added

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

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

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

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

Decommissioning Issues

The inclusion of accelerator-produced radioactive material that is used for a commercial, medical, or research activity, in the definition of Byproduct material, requires the NRC to ensure that decommissioning funding is adequate at accelerator facilities to adequately decontaminate and decommission their facilities for license termination. Radioactive materials produced in accelerator facilities, that are extracted or converted after extraction for use for commercial, medical, or research purposes and that are no longer residing in the accelerator, are not a concern for decommissioning. However, materials intentionally or incidentally made radioactive as a result of the production of the radioactive materials for use for commercial, medical, or research purposes must be managed safely. Any radioactive material residing in the accelerator or within the facility that houses the accelerator must be adequately considered for safe operation, and managed appropriately at the time of decommissioning of the accelerator-produced radionuclide production facility, including the accelerator, and the NRC must ensure that adequate financial assurances are put in place to address the costs of decommissioning when the radionuclide production operation ceases, and the accelerator is shutdown, and the license is terminated. As with all decontamination and decommissioning situations, short-lived radionuclides are expected to decay to safe levels before license termination. Therefore, only radionuclides with a half-life of more than 120 days, that are present in sufficient quantities to cause a public health and safety concern, need to be addressed for the purposes of establishing adequate financial assurances for decommissioning leading to license termination.

Similarly, the addition of discrete sources of radium-226 in the definition of byproduct material requires the NRC to ensure that decommissioning funding is adequate for holders of specific licenses for possession of discrete sources of radium-226. Radium-226 is already included in Appendix B of 10 CFR Part 30 to determine the required level of financial assurance for holders of specific licenses in accordance with the requirements of 10 CFR 30.35. Therefore, applicants for specific licenses to possess discrete sources of radium-226 will need to assure that adequate financial assurances are provided for the types of sources and the total amount of radium-226 contained in the sources they will possess. Holders of general licenses for possession of discrete sources of radium-226 do not need financial assurance for decommissioning. However, in accordance with the approach for general and specific licensing of discrete sources of radium-226 being proposed by the NRC, a general licensee may become subject to specific licensing if a large number of discrete sources of radium-226 are accumulated (e.g., more than 50 luminous products in one location). If a general licensee becomes subject to specific-licensing, the licensee would be required to acquire the financial assurances required under 10 CFR 30.35.

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

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

addresses the current contamination and any previous onsite disposals.

There are no similar assurances for any facility that is currently contaminated from discrete sources of radium-226. With the inclusion of discrete sources of radium-226 in the definition of byproduct material, the NRC acquires the regulatory authority to address these situations where a specific license has not been issued (or where a potential licensee cannot be identified). There is not enough known about the breadth or depth of these potential radium-226 contamination situations, and how many of them exist at facilities that will apply for specific licenses, to propose any additional requirements to address them at this time. Therefore, the NRC proposes to address these situations on a case-by-case basis as they are identified following issuance of the new requirements for the newly added byproduct material.

E. License Application and Annual Fees

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

Persons applying for a license with the NRC, or requesting an amendment to their current licenses that may result in addition of a new fee category, are required to pay a license application fee under 10 CFR Part 170, unless exempt under the fee exemption provisions of 10 CFR 170.11. The application fees for materials users are 'flat' fees that are calculated by multiplying the average professional staff hours needed to process the application by the Materials Program hourly rate in 10 CFR 170.20 (currently $197). An application fee must generally be paid for each applicable fee category.

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

The annual fees for the materials users fee class are calculated based on the NRC's budgeted resources allocated to regulating these types of licensees, less any receipts received from this fee class for Part 170 activities. The net dollar value of budgeted resources for this fee class is allocated to all materials users fee categories (subclasses) based on the average application and inspection costs associated with each category. This approach provides a proxy for allocating the generic and other regulatory resources to the diverse categories of licensees based on how much it costs the NRC to regulate each fee category. The fee calculation also considers the inspection frequency (priority), which is indicative of the safety risk and resulting regulatory costs associated with these categories of licenses. The annual fees for a materials users license (other than a master materials license) currently range from $750 for fee category 2.B (shielding) to $27,300 for fee category 7.B (broad-scope medical).

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

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

The NRC is proposing three new fee categories for activities that are currently not covered by its regulations, but are covered under this proposed rule. The new fee categories would apply to certain previously manufactured items and self-luminous products containing radium-226 and to the production of accelerator-produced radioactive material. In determining the fees for these new categories, the NRC evaluated existing fee categories that NRC believes require a similar level of regulatory effort as these newly regulated activities for actions such as licensing, inspection, and event response.

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

The first proposed new fee category, 3.R.1., is for individuals possessing quantities greater than the number of items or limits in 10 CFR 31.12(a)(3), (4), or (5), but less than or equal to 10 times these quantities. Since the estimated level of regulatory effort is comparable to the level of effort for category 8, civil defense, the license application and annual fees for 3.R.1. would be $450 and $1,600, respectively. The second proposed new fee category, 3.R.2., is for individuals possessing quantities greater than 10 times the number of items or limits in 10 CFR 31.12(a)(3), (4), or (5). The license application and annual fees for this new category, 3.R.2., would be $1,100 and $2,500, respectively, comparable to the fees for category 3.P., ''All other specific byproduct material licenses, except those in Categories 4A through 9D.''

Persons who wish to disassemble, repair, or assemble products containing radium-226 would be required to obtain a specific license and would be subject to the applicable license application and annual fees. The NRC is proposing to include this use in fee category 3.B., Other licenses for possession and use of byproduct material issued under 10 CFR Part 30 of this chapter for processing or

manufacturing of items containing byproduct material for commercial distribution. The license fee for this category is currently $3,500, and the annual fee is currently $8,200.

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

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

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

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

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

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

F. Implementation Strategy

Several actions are planned or must occur coincident with, or following, the NRC issuance of final rules covering the newly added byproduct material, including:

(1) Issuance and publication of a transition plan for the orderly transition of regulatory authority for the newly added byproduct material for Agreement and non-Agreement States;

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

(3) An implementation period for users of the newly added byproduct material to come into compliance with the newly issued regulations.

Transition Plan

Section 651(e) of the EPAct requires the NRC, in issuing new regulations for the newly added byproduct material, to prepare and publish a transition plan for the orderly transition of regulatory authority over the newly added byproduct material for Agreement and non-Agreement States. The EPAct requires that the transition plan describe the conditions under which a State (including U.S. Territories and the District of Columbia) may exercise authority over the newly added byproduct material, and include a statement of the Commission that any agreement between the Commission and a State, under Section 274b. of the AEA covering byproduct material and entered into before the date of publication of the transition plan, be considered to include the newly added byproduct material. The statement of the Commission is subject to a certification provided by the Governor of the State to the Commission on the date of publication of the transition plan that: (1) The State has a program for licensing the newly covered byproduct material that is adequate to protect the public health and safety, as determined by the Commission; and (2) the State intends to continue to implement the regulatory responsibility of the State with respect to the byproduct material. The NRC also intends to include in the transition plan the process it will use to terminate the waiver issued by the NRC on August 31, 2005, and for the transition of regulatory authority following expiration or earlier termination of the waiver.

Termination of Waiver

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

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

With regard to States that do not have an existing agreement with the Commission under section 274b. of the AEA (non-Agreement States), the waiver period provides additional time for

those States that desire to establish such an agreement for the newly added byproduct materials to develop a program. To establish such an agreement with the Commission, the Governor of the current non-Agreement State will need to request an agreement with the Commission. The process of establishing these agreements can take three or more years to complete. If a State requests an agreement with the Commission, but the agreement cannot be established while the waiver is in effect, *i.e.*, through August 7, 2009, a special arrangement would need to be made with the Commission for the State to continue its regulatory program over the newly added byproduct material. Without an agreement or special arrangement, regulatory authority over the newly added byproduct material will automatically remain with the Commission on the date the waiver expires, or is terminated earlier by the Commission.

If an Agreement or non-Agreement State notifies the Commission, during the waiver period, that it does not intend to continue with its regulatory program with respect to the newly added byproduct material, the NRC, in coordination with the State, will determine an appropriate date to terminate the waiver for the State. Users of the material in the State will be subject to NRC regulatory authority on the termination date of the waiver. Specific actions for users in the State to comply with the new requirements of the rule will be noticed in the **Federal Register** (Notification of Waiver Termination and Implementation Dates of Rule). Additional details on the process that the NRC will use to terminate the waiver for Agreement and non-Agreement States and users in these States will be provided in the Commission's transition plan, as required by Section 651(e) of the EPAct.

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

The purpose of the waiver is to allow time for the States and individuals to have an orderly transition of the regulatory authority for NARM. Terminating the waiver for the Government agencies and Federally recognized Indian Tribes on the effective date of the final rule provides for regulatory oversight of the newly added byproduct material. A ''Notification of Waiver Termination and Implementation Dates of Rule'' applicable to Government agencies and Federally recognized Indian Tribes will be included with the publication of the final rule.

Implementation Period

Although Government agencies and Federally recognized Indian Tribes are already being regulated by NRC for the AEA 11e.(1) and 11e.(2) byproduct material, the NRC is proposing a transitional period for them to submit a license amendment or a new license application for the newly added byproduct material. The proposed rule would allow an additional 6-month period from the effective date of the final rule to apply for a license amendment; and an additional 12-month period from the effective date of the final rule to apply for a new license. In addition, the proposed rule contains specific provisions that would give Governmental agencies and Federally recognized Indian Tribes authority to continue to use the newly added byproduct material during the period when the waiver is terminated until the date of NRC's final licensing determination provided that either a license amendment or a license application is submitted within the specified time frame and while complying with all other aspects of the regulations (*e.g.*, event reporting, personnel dosimetry) upon the effective date of the final rule.

For individuals owning, using, and otherwise engaging in activities involving the newly added byproduct material, the date on which compliance with the rule will be required will depend on the date of waiver termination. For certain States and individuals, the NRC plans to terminate the waiver earlier than the final date of the waiver, *i.e.*, August 7, 2009. A decision for early termination will depend on a number of factors, including the status of an Agreement State Governor's certification of adequate program for the newly added byproduct material, status of a non-Agreement State's application to become an Agreement state, and activities or areas under exclusive NRC jurisdiction. The NRC plans to terminate the waiver for Government agencies and Federally recognized Indian Tribes on the effective date of the final rule, and these users will be subject to the new requirements on that date. The effective date of the rule will be 60 days after the date of publication of the final rule to give the Government agencies and Federally recognized Indian Tribes time to comply with the requirements. The NRC is proposing to provide Government agencies and Federally recognized Indian Tribes 6 months from the effective date (or 8 months from the date of publication of the final rule) to apply for a license amendment for the newly added byproduct material if they hold an NRC specific byproduct materials license, and 12 months from the effective date of the final rule to submit a new license application for the newly added byproduct material if a new NRC specific byproduct materials license is needed. It is noted that authorization statements for certain licenses are inclusive of byproduct materials and their uses so that an amendment may not be needed to specifically add NARM to the license.

The NRC plans to separately solicit information from the States on their intentions concerning continuing with, or establishing new, regulatory programs for the newly added byproduct material. Users will be subject to NRC regulatory authority upon expiration or termination of the waiver if they are located either in an Agreement State that does not intend to continue its regulatory program with respect to the newly added byproduct material or in a non-Agreement State that does not enter into an agreement with the Commission under section 274b. of the AEA that covers the newly added byproduct material. For these users, the waiver termination process, specific authority, and condition to continue activities involving the newly added byproduct material will be described in the Commission's transition plan, required by Section 651(e) of the EPAct. Specific actions for these users to comply with the new requirements of the rule will be noticed in the **Federal Register** (Notification of Waiver Termination and Implementation Dates of Rule). For users of the material who transition from a State regulatory program to NRC's regulatory program, the NRC expects to provide, in the notification, a similar provision allowing a 6-month period for submitting an amendment and a 12-month period for submitting a new license application provided that a license amendment or license application is submitted on or before August 7, 2009. At this time, the NRC is not aware of any Agreement State that does not intend to continue its regulatory program with respect to the newly added byproduct material. The NRC requests comments on the

proposed effective date for the final rule and other implementation periods, to ensure that the affected individuals have sufficient time to come into compliance with the new requirements.

G. Summary of Issues for Public Comment

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

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

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

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

(4) The adequacy of the applicable default ALIs and DACs in Appendix B to 10 CFR 20 for oxygen-15 and nitrogen-13, and whether staff should develop larger specific values for these radionuclides.

(5) The appropriateness of the number of timepieces containing radium-226 (proposed as ten per year) for an exemption to allow repairing and other comments concerning how active the repair of timepieces containing radium-226 may be, the safety significance of this proposed exemption, alternatives to potential regulations or justification for continuing the exemption in this areas. (See Section II, Item D, Subsection, ''Timepieces containing radium-226.'')

(6) The health and safety impact from activities involving radium-226 sources, in particular, an alternative to the general licensing approach, such as an exemption. A technical basis supporting an exemption. (See Section II, Item D, ''New General License for Certain Items and Self-Luminous Products Containing Radium-226.'')

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

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

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

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

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

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

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

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

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

III. Section by Section Analysis of Substantive Changes

Part 20—Standards for Protection Against Radiation

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

Section 20.1003 Definitions

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

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

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

Section 20.2001 General requirements

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

Section 20.2006 Transfer for disposal and manifests

Paragraph (e) would be added to require the use of uniform manifests for disposal of 11e.(3) and 11e.(4) byproduct material if intended for ultimate disposal at a land disposal facility licensed under 10 CFR part 61.

Section 20.2008 Disposal of certain byproduct material

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

Part 30—Rules of General Applicability to Domestic Licensing of Byproduct Material

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

Section 30.3 Activities requiring license

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

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

Section 30.4 Definitions

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

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

Section 30.15 Certain items containing byproduct material

This section would be revised to add paragraph (a)(1)(viii) to authorize 0.037 MBq (1 μCi) of radium-226 per

timepiece in intact timepieces manufactured before the effective date of the rule, and limited repair activities involving non-intact timepieces.

Section 30.18 Exempt quantities

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

Section 30.20 Gas and aerosol detectors containing byproduct material

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

Section 30.32 Application for specific licenses

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

Section 30.34 Terms and conditions of licenses

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

Section 30.71 Schedule B

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

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

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

Part 31—General Domestic Licenses for Byproduct Material

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

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

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

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

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

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

Paragraph (b) would be revised to include radium-226 calibration or reference sources manufactured or initially transferred in accordance with the specifications contained in a specific license issued by a State with comparable provisions to 10 CFR 32.57.

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

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

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

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

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

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

Sections 31.12, 31.13, and 31.14 would be redesignated as §§ 31.21, 31.22, and 31.23, respectively

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

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

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

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

Part 32—Specific Domestic Licenses To Manufacture or Transfer Certain Items Containing Byproduct Material

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

Section 32.1 Purpose and scope

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

agencies and Federally recognized Indian Tribes on the effective date of the final rule.

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

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

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

Section 32.58 Same: Labeling of devices

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

Section 32.59 Same: Leak testing of each source

This section would be revised to include radium-226.

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

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

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

Section 32.72 Manufacture, preparation, or transfer for commercial distribution of radioactive drugs containing byproduct material for medical use under 10 CFR part 35

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

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

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

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

Part 33—Specific Domestic Licenses of Broad Scope for Byproduct Material

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

Section 33.100 Schedule A

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

Part 35—Medical Use of Byproduct Material

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

Section 35.2 Definitions

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

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

Section 35.10 Implementation

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

Section 35.11 License required

A new paragraph (a), with the remaining paragraphs redesignated, would be added to allow Government agencies, Federally recognized Indian Tribes, and other persons who possessed and used accelerator-produced radioactive materials or discrete sources of radium-226, under the provisions of the NRC's waiver of August 31, 2005, to have time to apply for and receive a new medical use license. This section would provide the time period for applying for a new license.

Section 35.13 License amendments

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

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

Paragraph (e) would be modified to require an amendment before a licensee adds to, or changes, areas of use identified in the application or on the license, including areas used in accordance with either 10 CFR 35.100 or 35.200 if the change includes the addition or relocation of either an area where PET radionuclides are produced or a radionuclide delivery line from the PET radionuclide production area. Other areas of use where byproduct material is used only in accordance with either 10 CFR 35.100 or 10 CFR 35.200 would continue to be excluded from this requirement.

Section 35.14 Notifications

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

Paragraph (b) would be revised to retain, in the notification requirements, any additions or changes in 10 CFR 35.100 or 10 CFR 35.200 areas of use, if the changes do not involve additions or

relocations of either an area where PET radionuclides are produced or a radionuclide delivery line from the PET radionuclide production area.

Section 35.15 Exemptions regarding Type A specific licenses of broad scope

Paragraph (f) would be revised to retain the existing notification exemption for addition or changes in 10 CFR 35.100 or 10 CFR 35.200 areas of use, if the changes do not involve additions or relocations of either an area where PET radionuclides are produced or a radionuclide delivery line from the PET radionuclide production area.

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

A new paragraph (a)(3) would be added to grandfather Radiation Safety Officers, medical physicists, or nuclear pharmacists who only used accelerator-produced radioactive materials or discrete sources of radium-226 during the NRC's waiver of August 31, 2005.

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

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

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

Section 35.69 Labeling of vials and syringes and transport radiation shields

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

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

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

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

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

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

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

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

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

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

Paragraph (c) of this section would be revised and redesignated, and a new paragraph (c) would be added to address measuring requirements for strontium-82 and strontium-85.

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

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

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

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

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

Part 50—Domestic Licensing of Production and Utilization Facilities

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

Section 50.2 Definitions

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

Part 61—Licensing Requirements for Land Disposal of Radioactive Waste

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

Section 61.2 Definitions

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

Part 62—Criteria and Procedures for Emergency Access to Non-Federal and Regional Low-Level Waste Disposal Facilities

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

Section 62.2 Definitions

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

Part 72—Licensing Requirements for the Independent Storage of Spent Nuclear Fuel, High-Level Radioactive Waste, and Reactor-Related Greater Than Class C Waste

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

Section 72.3 Definitions

The definition of Byproduct material would be revised to be consistent with the definition in 10 CFR 30.4. This definition would be consistent with the definition of Byproduct material in the EPAct, with the exception that it will

not include byproduct material as defined in Section 11e.(2) of the AEA.

Part 110—Export and Import of Nuclear Equipment and Material

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

Section 110.2 Definitions

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

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

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

Section 150.3 Definitions

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

A definition of Discrete source would be added.

Part 170—Fees for Facilities, Materials, Import and Export Licenses, and Other Regulatory Services Under the Atomic Energy Act of 1954, as Amended

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

Section 170.3 Definitions

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

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

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

Part 171—Annual Fees for Reactor Licenses and Fuel Cycle Licenses and Materials Licenses, Including Holders of Certificates of Compliance, Registrations, and Quality Assurance Program Approvals and Government Agencies Licensed by the NRC

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

Section 171.5 Definitions

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

Section 171.16 Annual Fees for Reactor Licenses and Fuel Cycle Licenses and Materials Licenses, Including Holders of Certificates of Compliance, Registrations, and Quality Assurance Program Approvals and Government Agencies Licensed by the NRC

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

IV. Criminal Penalties

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

V. Agreement State Compatibility

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

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

Health and Safety (H&S) are program elements that are not required for compatibility but are identified as having a particular health and safety role (*i.e.*, adequacy) in the regulation of agreement material within the State. Although not required for compatibility, the State should adopt program elements in this H&S category based on those of the NRC that embody the essential objectives of the NRC program elements, because of particular health and safety considerations. Compatibility Category NRC are those program elements that address areas of regulation that cannot be relinquished to Agreement States under the Atomic Energy Act, as amended, or provisions of Title 10 of the Code of Federal Regulations. These program elements are not adopted by Agreement States.

The following table lists the Parts and Sections that would be revised and their corresponding categorization under the ''Policy Statement on Adequacy and Compatibility of Agreement State Programs.'' A bracket around a category means that the section may have been adopted elsewhere, and it is not necessary to adopt it again.

The NRC invites comment on the compatibility category designations in the proposed rule and suggests that commenters refer to Handbook 5.9 of Management Directive 5.9 for more information. The NRC notes that, like the rule text, the compatibility category designations can change between the proposed rule and final rule, based on comments received and Commission decisions regarding the final rule. The NRC encourages anyone interested in commenting on the compatibility category designations in any manner to do so during the comment period.

The definition of Byproduct material in the AEA was expanded by Section 651(e) of the EPAct to incorporate certain discrete sources of radium-226 and certain accelerator produced radioactive materials. The definition of Byproduct material in 10 CFR Parts 20, 30, 50, 72,150, 170, and 171 would be amended to reflect the changes to the AEA. The definition of Byproduct material in Parts 50, 72, 170, and 171 is reserved to NRC. For the definition of Byproduct material in 10 CFR Parts 20, 30 and 150, the NRC proposes to identify it as H&S. This designation is for regulatory program elements that have particular health and safety significance. The H&S designation indicates that the definition is needed for purposes of ''adequacy,'' since if NARM is included in the Agreement between the NRC and the Agreement State, then NARM would be a necessary program element of the Agreement State program to adequately ensure public health and safety. The definition of Discrete source has also been identified in this proposed rule as H&S since it is a part of the definition of Byproduct material. NRC specifically requests comments on the compatibility designations. In particular, NRC requests comments on whether the definitions of Byproduct material and Discrete source are correctly identified as H&S, considering the procedures in Management Directive 5.9 and considering that the EPAct redefined the term byproduct material and required the NRC to include a definition of Discrete source in its final regulations. If commenters believe that these definitions should not be identified as H&S, the NRC requests comment and justification for a different compatibility category under Management Directive 5.9.

DRAFT COMPATIBILITY TABLE

Section	Change	Subject	Compatibility	
			Existing	New
20.1003	Amend	Definition: Byproduct Material (add 11e.(3) & 11e.(4) material).	[A]	[H&S]
20.1003	Add	Definition: Discrete Source		H&S
20.1003	Add	Definition: Waste		B
20.2001(a)(4)	Amend	General requirements (add reference to new § 20.2008)	C	C
20.2006(e)	Add	Transfer for disposal and manifests (add 11e.(3) and 11e.(4) byproduct material).		B
20.2008	Add	Disposal of 11e.(3) and 11e.(4) byproduct material (new section).		B
30.3(a)	Amend	Activities requiring license (add reference to paragraph (c)).	C	C
30.3(b)(1)	Add	Activities requiring license (requirements that apply to Government agencies and Federally recognized Indian Tribes at waiver termination).		NRC
30.3(b)(2)	Add	Activities requiring license (authorization for Government agencies and Federally recognized Indian Tribes to possess and use 11e.(3) materials while applying for a license amendment).		NRC
30.3(b)(3)	Add	Activities requiring license (authorization for Government agencies and Federally recognized Indian Tribes to possess and use 11e.(3) materials while applying for a new license).		NRC
30.3(c)(1)	Add	Activities requiring license (requirements that apply to all other persons at waiver termination).		D
30.3(c)(2)	Add	Activities requiring license (authorization for all other persons to possess and use 11e.(3) materials while applying for a license amendment).		D
30.3(c)(3)	Add	Activities requiring license (authorization for all other persons to possess and use 11e.(3) materials while applying for a new license).		D
30.3(d)	Add	Activities requiring license (continuation of authority for failure to submit amendment or license).		D
30.4	Add	Definition: Accelerator-produced radioactive material		H&S
30.4	Amend	Definition: Byproduct material (add 11e.(3) & 11e.(4) material).	[A]	[H&S]
30.4	Add	Definition: Cyclotron		D
30.4	Add	Definition: Discrete source		H&S
30.4	Add	Definition: Particle Accelerator		H&S
30.15(a)(1)(viii)	Add	Certain items containing byproduct material (add radium-226 intact timepieces and limited repairs).	B (all § 30.15)	B
30.18(b)	Amend	Exempt quantities (add 11e.(3) material)	B (all § 30.18)	B
30.20(a)	Amend	Gas and aerosol detectors containing byproduct material (grandfather 11e.(3) detectors).	B (all § 30.20)	B

DRAFT COMPATIBILITY TABLE—Continued

Section	Change	Subject	Compatibility	
			Existing	New
30.32(g)(1)	Amend	Application for specific licenses	C	C
30.34(g)	Amend	Terms and conditions of licenses (add strontium-82/rubidium-82 generators).	D	H&S
30.71	Amend	Schedule B (add 11e.(3) material)	B	B
30.72	Amend	Schedule C—Quantities of radioactive materials requiring consideration of the need for an emergency plan for responding to a release (add radium-226).	H&S	H&S
31.5(b)(1) & (c)(13)	Amend	Certain detecting, measuring, gauging, or controlling devices and/or an ionizing atmosphere (add devices with NARM approved by States).	B (all § 31.5)	B
31.8	Amend	Americium-241 in the form of calibration or reference sources (add radium-226).	D	D
31.11	Amend	General license for use of byproduct material for certain in vitro clinical or laboratory testing (add cobalt-57).	D	D
31.12	Add	General license for certain items and self-luminous products containing radium-226 (new section).		C
32.1(c)(1)	Add	Purpose and scope (requirements that apply to Government agencies and Federally recognized Indian Tribes at waiver termination and authorization to manufacture and distribute items with 11e.(3) material while applying for amendment or license).		NRC
32.1(c)(2)	Add	Purpose and scope (requirements that apply to all other persons at waiver termination and authorization to manufacture and distribute items with 11e.(3) material while applying for amendment or license).		D
32.57	Amend	Calibration or reference sources containing americium-241: Requirements for license to manufacture or initially transfer (add radium-226).	B	B
32.58	Amend	Same: Labeling of devices (add radium-226)	B	B
32.59	Amend	Same: Leak testing of each source (add radium-226)	B	B
32.71(b)(8) & (c)(1)	Add	Manufacture and distribution of byproduct material for certain in vitro clinical or laboratory testing under general license (add cobalt-57).	B	B
32.72(a)(2)(i), (iii), (iv), (v), & (b).	Amend	Manufacture, preparation, or transfer for commercial distribution of radioactive drugs containing byproduct material for medical use under Part 35 (recognize FDA and State registrations of PET facilities and pharmacist using 11e.(3) material).	B	B
32.102	Amend	Schedule C—prototype tests for calibration or reference sources containing americium-241 (add radium-226).	B	B
33.100	Amend	Schedule A (add beryllium-7, cobalt-57, radium-226, & sodium-22).	D	D
35.2	Amend	Definition: Authorized nuclear pharmacist (recognize pharmacist, who used 11e.(3) material).	B	B
35.2	Amend	Definition: Authorized user (recognize authorized user, who used 11e.(3) material).	B	B
35.2	Add	Definition: Cyclotron		D
35.2	Add	Definition: Positron Emission Tomography (PET) radionuclide production facility.		H&S
35.10(a)	Add	Implementation (requirements that apply at waiver termination).		D
35.10(g)	Redesignated	Implementation		D
35.11(a)	Amend	License required (reference to 35.11(c)	C	C
35.11(c)(1)	Add	License required (authorize medical use of 11e.(3) materials by Government agencies and Federally recognized Indian Tribes while applying for license).		NRC
35.11(c)(2)	Add	License required (authorize medical use of 11e.(3) materials by all other persons while applying for license).		D
35.13(a)(1)	Amend	License amendments (authorize medical use of 11e.(3) materials by Government agencies and Federally recognized Indian Tribes while applying for amendment).		NRC
35.13(a)(2)	Amend	License amendments (authorize medical use of 11e.(3) materials by all other materials while applying for amendment).		D
35.13(b)(4)(v)	Add	License amendments (grandfather physicians and pharmacists that used 11e.(3) material).	D	D
35.13(e)	Amend	License amendments (clarify amendment need)	D	D
35.14(a) and (b)(4)	Amend	Notifications (using notification to allow continued operation for certain 11e.(3) material).	D	D

DRAFT COMPATIBILITY TABLE—Continued

Section	Change	Subject	Compatibility	
			Existing	New
35.15(f)	Amend	Exemptions regarding Type A specific licenses of broad scope (clarify the exemption).	D	D
35.57(a)(3) & (b)(3)	Amend	Training for experienced Radiation Safety Officer, teletherapy or medical physicist, authorized user, and nuclear pharmacist (grandfather RSO, who used 11e.(3) material).	B	B
35.63(b)(2)(ii) & (c)(3)	Amend	Determination of dosages of unsealed byproduct material for medical use (recognize State licenses and State requirements).	H&S	H&S
35.63(b)(2)(iii)	Add	Determination of dosages of unsealed byproduct material for medical use (recognize State licenses of PET facilities).		H&S
35.69(b)	Add	Labeling of vials and syringes (to include PET drugs)	H&S	H&S
35.100(a) & (b)	Amend	Use of unsealed byproduct material for uptake, dilution, and excretion studies for which a written directive is not required (allow use of PET radionuclides).	H&S	H&S
35.200(a) & (b)	Amend	Use of unsealed byproduct material for imaging and localization studies for which a written directive is not required (allow use of PET radionuclides).	H&S	H&S
35.204(a)	Amend	Permissible molybdenum-99 concentrations (add strontium-82 & strontium-85).	H&S	H&S
35.204(c)	Add	Permissible molybdenum-99 concentrations (add strontium-82 & strontium-85.		D
35.204(d)	Redesignated	Permissible molybdenum-99 concentrations	D	D
35.300(a) and (b)	Amend	Use of unsealed byproduct material for which a written directive is required (allow use of PET radionuclides).	H&S	H&S
35.2204	Amend	Records of molybdenum-99 concentrations (add strontium-82 & strontium-85).	D	D
50.2	Amend	Definition: Byproduct material (add 11e.(3) & 11e.(4) material).	NRC	NRC
61.2	Amend	Definition: Waste (clarify 11e.(3) & 11e.(4) material)	B	B
62.2	Amend	Definition: Low-level radioactive waste (clarify 11e.(3) & 11e.(4) material).	NRC	NRC
72.3	Amend	Definition: Byproduct material (add 11e.(3) & 11e.(4) material).	NRC	NRC
110.2	Add	Definition: Accelerator-produced radioactive material		NRC
110.2	Add	Definition: Discrete source		NRC
110.2	Add	Definition: Particle accelerator		NRC
150.3	Amend	Definition: Byproduct material (add 11e.(3) & 11e.(4) material).	A	H&S
150.3	Add	Definition: Discrete source		H&S
10 CFR Part 170 address areas that generally are applicable only to NRC's regulatory program; therefore, no compatibility designation is assigned.				
170.3	Amend	Definition: Byproduct material (add 11e.(3) & 11e.(4) material).		
170.31 Table: 3B	Amend	Other licenses for possession and use of byproduct material issued under Part 30 (revise to include radium-226).		
170.31 Table: 3R.1.	Add	Possession of items or products containing radium-226 (add a new fee category).		
170.31 Table: 3R.2.	Add	Possession of items or products containing radium-226 (add a new fee category).		
170.31 Table: 3S	Add	License for production of accelerator-produced radionuclides (add a new fee category).		
10 CFR Part 171 address areas that generally are applicable only to NRC's regulatory program; therefore, no compatibility designation is assigned.				
171.5	Amend	Definition: Byproduct material (add 11e.(3) & 11e.(4) material).		
171.16 Table: 3B	Amend	Other licenses for possession and use of byproduct material issued under part 30 (revise to include radium-226).		
171.16 Table: 3R	Add	Possession of items or products containing radium-226 (add a new fee category).		
171.16 Table: 3S	Add	License for production of accelerator-produced radionuclides (add a new fee category).		

VI. Plain Language

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

VII. Voluntary Consensus Standards

The National Technology Transfer and Advancement Act of 1995 (Pub. L. 104–113) requires that Federal agencies use technical standards that are developed or adopted by voluntary consensus standards bodies unless the use of such a standard is inconsistent with applicable law or otherwise impractical. In this proposed rule, the NRC would assume regulation of certain discrete sources of naturally occurring radioactive material and accelerator-produced radioactive material in addition to those byproduct materials already under the NRC's jurisdiction. This action does not constitute the establishment of a standard that establishes generally applicable requirements.

The EPAct required that the NRC use model State standards to the maximum extent practicable in developing and issuing regulations for the newly expanded definition of byproduct material. In developing this proposed rule, the NRC has consulted with Agreement and non-Agreement States about their regulations. To the maximum extent practicable, the NRC has incorporated the CRCPD's SSRs into the proposed rule.

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

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

Amendments to the NRC's regulations would incorporate new materials into the NRC's byproduct material regulatory program or establish new program elements, if needed. Before the EPAct, the regulation of naturally occurring and accelerator-produced radioactive material (NARM), other than source material, was left primarily to the individual States. Although efforts were made by several States to provide a uniform regulatory environment, particularly for accelerator-produced radioactive material, there is currently no nationwide consistency to the regulation of NARM. The proposed amendments to the NRC regulations would provide a uniform regulatory environment for the acquisition, possession, use, transfer, and disposal of NARM. This uniform regulatory environment would be developed in cooperation with the States, using model State standards in existence to the maximum extent practicable. Because the approach for developing the generic NRC requirements would start with the existing generic requirements for accelerator-produced radioactive material that had already been developed by the States for the SSRs, little, if any, change is expected to the byproduct material regulatory programs already in place for Agreement States. Consequently, for Agreement States, the primary foreseeable impact of the regulatory changes applicable to accelerator-produced radioactive material is that the regulations would be uniformly applied by all Agreement States. Therefore, for the regulation of accelerator-produced radioactive material by the Agreement States, the proposed amendments to the NRC regulations, if adopted, are not expected to have any adverse environmental impacts.

In non-Agreement States, the proposed amendments to the NRC regulations would most likely impose more restrictive requirements on the acquisition, possession, use, transfer, and disposal of accelerator-produced radioactive materials. In situations where the new NRC requirements are more restrictive than those already imposed by individual States' existing regulations, if any, the result would most likely be a positive impact on the environment. In situations where the NRC's requirements are less restrictive than the individual State's regulations, it is likely that the licensee would most likely continue with its current practice, and no substantial impact on the environment would be anticipated. Therefore, it is expected that the overall environmental impacts of the proposed regulation of accelerator-produced radioactive material by non-Agreement States, if adopted, would be positive.

The effects of the proposed amendments to the NRC regulations applicable to discrete sources of radium-226 and discrete sources of other naturally occurring radioactive material would be greater for the non-Agreement States than for the Agreement States because certain non-Agreement States do not have a regulatory program addressing this material. The imposition of regulations on the acquisition, possession, use, transfer, and disposal of these discrete sources of naturally occurring radioactive material would provide greater assurance that these activities are performed in a manner that is expected to be less harmful to the environment than would be assured without these regulations. Therefore, the effect of the proposed NRC regulations applicable to discrete sources of naturally occurring radioactive material, if adopted, is anticipated to be beneficial to the environment, and it is expected that the overall environmental impacts would be positive.

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

The NRC has sent a copy of the environmental assessment and this proposed rule to every State Liaison Officer and request their comments on the environmental assessment. The environmental assessment may be examined at the NRC Public Document Room, O–1F21, 11555 Rockville Pike, Rockville, MD. Single copies of the environmental assessment will be available from Lydia Chang, Office of Nuclear Material Safety and Safeguards, U.S. Nuclear Regulatory Commission, Washington, DC 20555–0001, telephone (301) 415–6319, e-mail *lwc1@nrc.gov.*

IX. Paperwork Reduction Act Statement

This proposed rule amends information collection requirements contained in 10 CFR parts 19, 20, 30, 31, 32, and 35 that are subject to the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 *et seq.*). These information collection requirements have been submitted to the Office of Management and Budget for review and approval. The proposed changes to 10 CFR parts 33, 50, 61, 62, 72, 110, 150, 170 and 171 do not contain new or amended information collection requirements.

Type of submission, new or revision: Revision.

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

The form number if applicable: NRC Forms 4, 5, 313, 313A, 314, and 664.

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

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

An estimate of the number of annual responses: 5,258 (10 CFR part 19—350 responses; 10 CFR 20—511 responses; 10 CFR 30—250 responses; 10 CFR part 31—540 responses; 10 CFR 32—220 responses; 10 CFR 35—759 responses; NRC Form 4—30 responses; NRC Form 5—1,030 responses; NRC Form 313—1,250 responses; NRC Form 313A—300 responses; NRC Form 314—1 response; NRC Form 664—15 responses).

The estimated number of annual respondents: 2,358 (10 CFR 19—200 respondents; 10 CFR 20—250 respondents; 10 CFR 30—10 respondents; 10 CFR 31—40 respondents; 10 CFR 32—110 respondents; 10 CFR 35—122 respondents; NRC Form 4—30 recordkeepers; NRC Form 5—30 respondents; NRC Form 313—1,250 respondents; NRC Form 313A—300 respondents; NRC Form 314—1 respondent; NRC Form 664—15 respondents).

An estimate of the total number of hours needed annually to complete the requirement or request: The total burden increase for this rulemaking is 110,600 hours (10 CFR part 19 —4,811 hours; 10 CFR 20—8,843 hours; 10 CFR 30—5,393 hours; 10 CFR part 31—200 hours; 10 CFR 32—43,019 hours; 10 CFR 35—29,526 hours; NRC Form 4—21 hours; NRC Form 5—2,231 hours; NRC Form 313—15,550 hours; NRC Form 313A—1,000 hours; NRC Form 314—1 hour; NRC Form 664—5 hours).

Abstract: The NRC is proposing to amend its regulations to include jurisdiction over certain radium sources, accelerator-produced radioactive materials, and certain naturally occurring radioactive material, as required by the EPAct, which was signed into law on August 8, 2005. Section 651(e) of the EPAct expanded the AEA's definition of byproduct material to include any discrete source of radium-226, any material made radioactive by use of a particle accelerator, and any discrete source of naturally occurring radioactive material, other than source material, that the Commission, in consultation with other Federal officials, determines would pose a similar threat to the public health and safety or the common defense and security as a discrete source of radium-226, that are extracted or converted after extraction for use in a commercial, medical, or research activity. In so doing, these materials were placed under the NRC's regulatory authority. Section 651(e) of the EPAct also mandated that the Commission, after consultation with States and other stakeholders, issue final regulations establishing requirements that the Commission determines necessary to carry out this section and the amendments made by this section. This proposed rule would establish licensing requirements with associated recordkeeping and reporting requirements that would be applied to licensees that possess, transfer, manufacture or distribute these radioactive materials newly placed under NRC jurisdiction. The NRC has used to the maximum extent practicable the CRCPD's applicable SSRs in developing this proposed rule. The U.S. Nuclear Regulatory Commission is seeking public comment on the potential impact of the information collections contained in the proposed rule and on the following issues:

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

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

Send comments on any aspect of these proposed information collections, including suggestions for reducing the burden and on the above issues, by August 28, 2006 to the Records and FOIA/Privacy Services Branch (T–5 F53), U.S. Nuclear Regulatory Commission, Washington, DC 20555–0001, or by Internet electronic mail to *INFOCOLLECTS@NRC.GOV* and to the Desk Officer, John A. Asalone, Office of Information and Regulatory Affairs, NEOB–10202 (3150–0044, –0014, –0017, –0016, –0001, –0010, –0005, –0006, –0120, –0028, and –0198), Office of Management and Budget, Washington, DC 20503. Comments received after this date will be considered if it is practical to do so, but assurance of consideration cannot be given to comments received after this date. You may also e-mail comments to *John_A._Asalone@omb.eop.gov* or comment by telephone at (202) 395–4650.

Public Protection Notification

The NRC may not conduct or sponsor, and a person is not required to respond to, a request for information or an information collection requirement unless the requesting document displays a currently valid OMB control number.

X. Regulatory Analysis

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

The Commission requests public comment on the draft regulatory analysis. Comments on the draft regulatory analysis may be submitted to the NRC as indicated under the **ADDRESSES** heading. The draft regulatory analysis is available for inspection in the NRC Public Document Room, 11555 Rockville Pike, Rockville, MD, and may be downloaded from the rule forum website at *http://ruleforum.llnl.gov.* Single copies of the regulatory analysis are available from Lydia Chang, Office of Nuclear Material Safety and Safeguards, U.S. Nuclear Regulatory Commission, Washington, DC 20555–0001, telephone (301) 415–6319, e-mail *lwc1@nrc.gov.*

XI. Regulatory Flexibility Certification

In accordance with the Regulatory Flexibility Act of 1980 (5 U.S.C. 605(b)), the Commission certifies that this rule would not, if promulgated, have a significant economic impact on a substantial number of small entities. The majority of companies that own these businesses do not fall within the scope of the definition of ''small entities'' set forth in the Regulatory Flexibility Act or the Small Business

Size Standards set out in regulations issued by the Small Business Administration at 13 CFR part 121.

Section 651(e) of the EPAct expanded the definition of Byproduct material in Section 11e. of the AEA to include any discrete source of radium-226, any material made radioactive by use of a particle accelerator, and any discrete source of naturally occurring radioactive material that would pose a similar threat to the public health and safety or the common defense and security as a discrete source of radium-226 that is extracted or converted after extraction for use in a commercial, medical, or research activity. This rulemaking would amend the NRC regulations to include this newly defined byproduct material. This amendment would potentially affect large numbers of individuals, businesses, or licensees engaged in activities involving discrete radium-226 sources or accelerator-produced radioactive material used for commercial, medical, or research activities. Many individuals, businesses, or licensees would qualify as small business entities as defined by 10 CFR 2.810. However, the proposed rule is not expected to have a significant economic impact on these individuals, businesses, or licensees because the NRC is using the existing regulatory framework to regulate these materials and is allowing sufficient time for individuals, businesses, and licensees to implement the requirements for this radioactive material. Based on the draft regulatory analysis, the NRC believes that the selected alternative reflected in the proposed amendment is protective of public health and safety and is not overly burdensome to accomplish the NRC's regulatory objective. The NRC also notes that several Agreement States have imposed similar requirements on their licensees either by rule, order, or license condition.

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

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

2. If small businesses are likely to be affected by the proposed regulations, is the significance of the potential economic burden related to the size of the business? If so, how? How does this burden compare to larger organizations in the same business community?

3. How could the proposed regulations be modified to take into account the differing needs or capabilities of small businesses while maximizing potential benefits and minimizing the potential economic burden? What would be the approximate level of benefits to your entity if this change was made in the proposed rule?

4. How would these modifications to the proposed regulations (from question 3) act to more closely equalize the impact of the regulations or create more equal access to the benefits as opposed to providing special advantages to any individuals or groups?

5. Would these modifications (from question 3) act to increase, maintain, or decrease the NRC's ability to adequately protect public health and safety? How?

XII. Backfit Analysis

The NRC has determined that the backfit rule (10 CFR 50.109, 70.76, 72.62, or 76.76) does not apply to this proposed rule because this amendment would not involve any provisions that would impose backfits as defined in 10 CFR Chapter 1. Therefore, a backfit analysis is not required.

List of Subject

10 CFR Part 20

Byproduct material, Criminal penalties, Licensed material, Nuclear materials, Nuclear power plants and reactors, Occupational safety and health, Packaging and containers, Radiation protection, Reporting and recordkeeping requirements, Source material, Special nuclear material, Waste treatment and disposal.

10 CFR Part 30

Byproduct material, Criminal penalties, Government contracts, Intergovernmental relations, Isotopes, Nuclear materials, Radiation protection, Reporting and recordkeeping requirements.

10 CFR Part 31

Byproduct material, Criminal penalties, Labeling, Nuclear materials, Packaging and containers, Radiation protection, Reporting and recordkeeping requirements, Scientific equipment.

10 CFR Part 32

Byproduct material, Criminal penalties, Labeling, Nuclear materials, Radiation protection, Reporting and recordkeeping requirements.

10 CFR Part 33

Byproduct material, Criminal penalties, Nuclear materials, Radiation protection, Reporting and recordkeeping requirements.

10 CFR Part 35

Byproduct material, Criminal penalties, Drugs, Health facilities, Health professions, Medical devices, Nuclear materials, Occupational safety and health, Radiation protection, Reporting and recordkeeping requirements.

10 CFR Part 50

Antitrust, Classified information, Criminal penalties, Fire protection, Intergovernmental relations, Nuclear power plants and reactors, Radiation protection, Reactor siting criteria, Reporting and recordkeeping requirements.

10 CFR Part 61

Criminal penalties, Low-level waste, Nuclear materials, Reporting and recordkeeping requirements, Waste treatment and disposal.

10 CFR Part 62

Administrative practice and procedure, Denial of access, Emergency access to low-level waste disposal, Low-level radioactive waste, Low-level radioactive waste treatment and disposal, Low-level waste policy amendments act of 1985, Nuclear materials, Reporting and recordkeeping requirements.

10 CFR Part 72

Administrative practice and procedure, Criminal penalties, Manpower training programs, Nuclear materials, Occupational safety and health, Penalties, Radiation protection, Reporting and recordkeeping requirements, Security measures, Spent fuel, Whistleblowing.

10 CFR Part 110

Administrative practice and procedure, Classified information, Criminal penalties, Export, Import, Intergovernmental relations, Nuclear

materials, Nuclear power plants and reactors, Reporting and recordkeeping requirements, Scientific equipment.

10 CFR Part 150

Criminal penalties, Hazardous materials transportation, Intergovernmental relations, Nuclear materials, Reporting and recordkeeping requirements, Security measures, Source material, Special nuclear material.

10 CFR Part 170

Byproduct material, Import and export licenses, Intergovernmental relations, Nonpayment penalties, Nuclear materials, Nuclear power plants and reactors, Source material, Special nuclear material.

10 CFR Part 171

Annual charges, Byproduct material, Holders of certificates, registrations, approvals, Intergovernmental relations, Nonpayment penalties, Nuclear materials, Nuclear power plants and reactors, Source material, Special nuclear material.

For the reasons set out in the preamble and under the authority of the Atomic Energy Act of 1954, as amended; the Energy Reorganization Act of 1974, as amended; and 5 U.S.C. 553; the NRC is proposing to adopt the following amendments to 10 CFR parts 20, 30, 31, 32, 33, 35, 50, 61, 62, 72, 110, 150, 170, and 171.

PART 20—STANDARDS FOR PROTECTION AGAINST RADIATION

1. The authority citation for part 20 is revised to read as follows:

Authority: Secs. 53, 63, 65, 81, 103, 104, 161, 182, 186, 68 Stat. 930, 933, 935, 936, 937, 948, 953, 955, as amended, sec. 1701, 106 Stat. 2951, 2952, 2953 (42 U.S.C. 2073, 2093, 2095, 2111, 2133, 2134, 2201, 2232, 2236, 2297f), secs. 201, as amended, 202, 206, 88 Stat. 1242, as amended, 1244, 1246 (42 U.S.C. 5841, 5842, 5846); sec. 1704, 112 Stat. 2750 (44 U.S.C. 3504 note); sec. 651(e), Pub. L. 109–58, 119 Stat. 806–810 (42 U.S.C. 2014, 2021, 2021b, 2111).

2. In § 20.1003, the definition of Byproduct material is revised, and definitions of Accelerator-produced radioactive material, Discrete source, Particle accelerator, and Waste are added to read as follows:

§ 20.1003 Definitions.

* * * * *

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

* * * * *

Byproduct material means—

(1) Any radioactive material (except special nuclear material) yielded in, or made radioactive by, exposure to the radiation incident to the process of producing or using special nuclear material;

(2) The tailings or wastes produced by the extraction or concentration of uranium or thorium from ore processed primarily for its source material content, including discrete surface wastes resulting from uranium solution extraction processes. Underground ore bodies depleted by these solution extraction operations do not constitute ''byproduct material'' within this definition;

(3)(i) Any discrete source of radium-226 that is produced, extracted, or converted after extraction, before, on, or after August 8, 2005, for use for a commercial, medical, or research activity; or

(ii) Any material that—

(A) Has been made radioactive by use of a particle accelerator; and

(B) Is produced, extracted, or converted after extraction, before, on, or after August 8, 2005, for use for a commercial, medical, or research activity; and

(4) Any discrete source of naturally occurring radioactive material, other than source material, that—

(i) The Commission, in consultation with the Administrator of the Environmental Protection Agency, the Secretary of Energy, the Secretary of Homeland Security, and the head of any other appropriate Federal agency, determines would pose a threat similar to the threat posed by a discrete source of radium-226 to the public health and safety or the common defense and security; and

(ii) Before, on, or after August 8, 2005, is extracted or converted after extraction for use in a commercial, medical, or research activity.

* * * * *

Discrete source means a radioactive source with physical boundaries, which is separate and distinct from the radioactivity present in nature, and in which the radionuclide concentration has been increased by human processes with the intent that the concentrated radioactive material will be used for its radiological properties.

* * * * *

Particle accelerator means any machine capable of accelerating electrons, protons, deuterons, or other charged particles in a vacuum and of discharging the resultant particulate or other radiation into a medium at energies usually in excess of 1 megaelectron volt. For purposes of this definition, ''accelerator'' is an equivalent term.

* * * * *

Waste means those low-level radioactive wastes containing source, special nuclear, or byproduct material that are acceptable for disposal in a land disposal facility. For the purposes of this definition, low-level radioactive waste means radioactive waste not classified as high-level radioactive waste, transuranic waste, spent nuclear fuel, or byproduct material as defined in paragraphs (2), (3), and (4) of the definition of Byproduct material set forth in this section.

* * * * *

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

§ 20.1009 Information collection requirements: OMB approval.

* * * * *

(b) The approved information collection requirements contained in this part appear in §§ 20.1003, 20.1101, 20.1202, 20.1203, 20.1204, 20.1206, 20.1208, 20.1301, 20.1302, 20.1403, 20.1404, 20.1406, 20.1501, 20.1601, 20.1703, 20.1901, 20.1904, 20.1905, 20.1906, 20.2002, 20.2004, 20.2005, 20.2006, 20.2102, 20.2103, 20.2104, 20.2105, 20.2106, 20.2107, 20.2108, 20.2110, 20.2201, 20.2202, 20.2203, 20.2204, 20.2205, 20.2206, 20.2008, 20.2301, and appendix G to this part.

* * * * *

4. In § 20.2001, paragraph (a)(4) is revised to read as follows:

§ 20.2001 General requirements.

(a) * * *

(4) As authorized under §§ 20.2002, 20.2003, 20.2004, 20.2005, or 20.2008.

* * * * *

5. In § 20.2006, paragraph (e) is added to read as follows:

§ 20.2006 Transfer for disposal and manifests.

* * * * *

(e) Any licensee shipping byproduct material as defined in paragraphs (3) and (4) of the definition of Byproduct material set forth in § 20.1003 intended for ultimate disposal at a land disposal facility licensed under part 61 of this chapter must document the information required on NRC's Uniform Low-Level Radioactive Waste Manifest and transfer this recorded manifest information to the intended consignee in accordance with appendix G to this part.

6. Section 20.2008 is added to Subpart K—Waste Disposal—to read as follows:

§ 20.2008 Disposal of certain byproduct material.

(a) Licensed material as defined in paragraphs (3) and (4) of the definition of Byproduct material set forth in § 20.1003 may be disposed of in accordance with part 61 of this chapter, even though it is not defined as low-level radioactive waste. Therefore, any licensed byproduct material being disposed of at a facility, or transferred for ultimate disposal at a facility licensed under part 61 of this chapter, must meet the requirements of § 20.2006.

(b) A licensee may dispose of byproduct material, as defined in paragraphs (3) and (4) of the definition of Byproduct material set forth in § 20.1003, at a disposal facility authorized to dispose of such material in accordance with any Federal or State solid or hazardous waste law, including the Solid Waste Disposal Act, as authorized under the Energy Policy Act of 2005.

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

7. The authority citation for part 30 is revised to read as follows:

Authority: Secs. 81, 82, 161, 182, 183, 186, 68 Stat. 935, 948, 953, 954, 955, as amended, sec. 234, 83 Stat. 444, as amended (42 U.S.C. 2111, 2112, 2201, 2232, 2233, 2236, 2282); secs. 201, as amended, 202, 206, 88 Stat. 1242, as amended, 1244, 1246 (42 U.S.C. 5841, 5842, 5846); sec. 1704, 112 Stat. 2750 (44 U.S.C. 3504 note); sec. 651(e), Pub. L. 109–58, 119 Stat. 806–810 (42 U.S.C. 2014, 2021, 2021b, 2111).

Section 30.7 also issued under Pub. L. 95–601, sec. 10, 92 Stat. 2951 as amended by Pub. L. 102–486, sec. 2902, 106 Stat. 3123 (42 U.S.C. 5851). Section 30.34(b) also issued under sec. 184, 68 Stat. 954, as amended (42 U.S.C. 2234). Section 30.61 also issued under sec. 187, 68 Stat. 955 (42 U.S.C. 2237).

8. Section 30.3 is revised to read as follows:

§ 30.3 Activities requiring license.

(a) Except as provided in paragraphs (b)(2), (b)(3), (c)(2), and (c)(3) of this section and for persons exempt as provided in this part and part 150 of this chapter, no person shall manufacture, produce, transfer, receive, acquire, own, possess, or use byproduct material except as authorized in a specific or general license issued in accordance with the regulations in this chapter.

(b)(1) The requirements, including provisions that are specific to licensees, in this part and parts 19, 20, 21, and 71, of this chapter, as well as the additional requirements for specific broad scope, industrial radiography, irradiator, or well logging uses in 10 CFR parts 33, 34, 36, or 39, respectively, shall apply to Government agencies or Federally recognized Indian tribes on [date 60 days after date of publication of final rule], when conducting activities under the authority provided by paragraphs (b)(2) and (b)(3) of this section.

(2) A specifically licensed Government agency or Federally recognized Indian tribe that possesses and uses accelerator-produced radioactive material or discrete sources of radium-226 for which a license amendment is required to authorize the activities in paragraph (a) of this section, may continue to use these materials for uses permitted under this part until the date of the NRC's final licensing determination, provided that the licensee submits an amendment application on or before [date 8 months after date of publication of final rule].

(3) A Government agency or Federally recognized Indian tribe that possesses and uses accelerator-produced radioactive material or discrete sources of radium-226 for which a specific license is required in paragraph (a) of this section, may continue to use such material for uses permitted under this part until the date of the NRC's final licensing determination provided that the agency or tribe submits an application for a license authorizing activities involving these materials on or before [date 1 year and 2 months after date of publication of final rule].

(c)(1) The requirements, including provisions that are specific to licensees in this part and parts 19, 20, 21 and 71, of this chapter, as well as the additional requirements for specific broad scope, industrial radiography, irradiator, or well logging uses in 10 CFR parts 33, 34, 36, or 39, respectively, shall apply to all persons, other than those included in paragraph (b)(1) of this section, on August 8, 2009, or earlier as noticed by the NRC, when conducting activities under the authority provided by paragraphs (c)(2) and (c)(3) of this section.

(2) Except as provided in paragraph (b)(2) of this section, all other licensees who possess and use accelerator-produced radioactive material or discrete sources of radium-226 for which a license amendment is required to authorize the activities in paragraph (a) of this section, may continue to use these materials for uses permitted under this part until the date of the NRC's final licensing determination provided that the individual submits an amendment application on or before August 7, 2009, or earlier as noticed by the NRC.

(3) Except as provided in paragraph (b)(3) of this section, all other persons who possess and use accelerator-produced radioactive material or discrete sources of radium-226 for which a specific license is required in paragraph (a) of this section, may continue to use such material for uses permitted under this part until the date of the NRC's final licensing determination provided that the individual submits a license application on or before August 7, 2009, or earlier as noticed by the NRC.

(d) If a person or licensee is required to file an application for a license or amendment in accordance with paragraphs (b)(2), (b)(3), (c)(2), and (c)(3) of this section, but does not file for the license or amendment within the required time, the authority provided by paragraphs (b)(2), (b)(3), (c)(2), and (c)(3) of this section to receive or use the accelerator-produced radioactive material or discrete sources of radium-226 shall expire with respect to the person's or licensee's authority to receive and use such byproduct material. This authority shall not expire with respect to the responsibility of the person or licensee regarding the possession of such byproduct material, the decommissioning (including financial assurance) of facilities, or the disposal of such byproduct material.

9. In § 30.4, the definition of Byproduct material is revised, and the definitions of Accelerator-produced radioactive material, Cyclotron, Discrete source, and Particle accelerator are added alphabetically to read as follows:

§ 30.4 Definitions.

* * * * *

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

* * * * *

Byproduct material means—

(1) Any radioactive material (except special nuclear material) yielded in, or made radioactive by, exposure to the radiation incident to the process of producing or using special nuclear material;

(2)(i) Any discrete source of radium-226 that is produced, extracted, or converted after extraction, before, on, or after August 8, 2005, for use for a commercial, medical, or research activity; or

(ii) Any material that—

(A) Has been made radioactive by use of a particle accelerator; and

(B) Is produced, extracted, or converted after extraction, before, on, or after August 8, 2005, for use for a commercial, medical, or research activity; and

(3) Any discrete source of naturally occurring radioactive material, other than source material, that—

(i) The Commission, in consultation with the Administrator of the Environmental Protection Agency, the Secretary of Energy, the Secretary of Homeland Security, and the head of any other appropriate Federal agency, determines would pose a threat similar to the threat posed by a discrete source of radium-226 to the public health and safety or the common defense and security; and

(ii) Before, on, or after August 8, 2005, is extracted or converted after extraction for use in a commercial, medical, or research activity.

* * * * *

Cyclotron means a circular particle accelerator in which charged particles are bent traveling through the accelerator. A cyclotron accelerates charged particles at energies usually in excess of 10 megaelectron volts and is commonly used for production of short half-life radionuclides for medical use.

* * * * *

Discrete source means a radioactive source with physical boundaries, which is separate and distinct from the radioactivity present in nature, and in which the radionuclide concentration has been increased by human processes with the intent that the concentrated radioactive material will be used for its radiological properties.

* * * * *

Particle accelerator means any machine capable of accelerating electrons, protons, deuterons, or other charged particles in a vacuum and of discharging the resultant particulate or other radiation into a medium at energies usually in excess of 1 megaelectron volt. For purposes of this definition, accelerator is an equivalent term.

* * * * *

10. In § 30.15, paragraph (a)(1)(viii) is added to read as follows:

§ 30.15 Certain items containing byproduct material.

(a) * * *

(1) * * *

(viii) 0.037 megabecquerel (1 microcurie) of radium-226 per timepiece in intact timepieces manufactured prior to [date 60 days after the date of publication of the final rule]. However, notwithstanding the requirement that timepieces be intact, antique collectors and watch repair facilities may repair no more than 10 timepieces in any one year.

* * * * *

11. In § 30.18, paragraph (b) is revised to read as follows:

§ 30.18 Exempt quantities.

* * * * *

(b) Any person who possesses byproduct material received or acquired before September 25, 1971, under the general license then provided in § 31.4 of this chapter or similar general license of a State for accelerator-produced radioactive material, is exempt from the requirements for a license set forth in section 81 of the Act and from the regulations in parts 30 through 34 of this chapter to the extent that this person possesses, uses, transfers, or owns byproduct material.

* * * * *

12. In § 30.20, paragraph (a) is revised to read as follows:

§ 30.20 Gas and aerosol detectors containing byproduct material.

(a) Except for persons who manufacture, process, produce, or initially transfer for sale or distribution gas and aerosol detectors containing byproduct material, any person is exempt from the requirements for a license set forth in section 81 of the Act and from the regulations in parts 20, and 30 through 36, and 39 of this chapter to the extent that the person receives, possesses, uses, transfers, owns, or acquires byproduct material, in gas and aerosol detectors designed to protect life or property from fires and airborne hazards, and manufactures, processes, produces, or initially transfers in accordance with a specific license issued under § 32.26 of this chapter, which license authorizes the initial transfer of the product for use under this section. This exemption also covers gas and aerosol detectors manufactured or distributed before [date 60 days after the date of publication of the final rule] in accordance with a specific license issued by a State under comparable provisions to § 32.26 of this chapter authorizing distribution to persons exempt from regulatory requirements.

* * * * *

13. In § 30.32, paragraph (g)(1) is revised to read as follows:

§ 30.32 Application for specific licenses.

* * * * *

(g) * * *

(1) Identify the source or device by manufacturer and model number as registered with the Commission under § 32.210 of this chapter, with an Agreement State, or with a State regarding source or device containing radium-226 or accelerator-produced radioactive material under provisions comparable to § 32.210 of this chapter; or

* * * * *

14. In § 30.34, paragraph (g) is revised to read as follows:

§ 30.34 Terms and conditions of licenses.

* * * * *

(g) Each licensee preparing technetium-99m radiopharmaceuticals from molybdenum-99/technetium-99m generators or rubidium-82 from strontium-82/rubidium-82 generators shall test the generator eluates for molybdenum-99 breakthrough or strontium-82 and strontium-85 contamination, respectively, in accordance with § 35.204 of this chapter. The licensee shall record the results of each test and retain each record for 3 years after the record is made.

* * * * *

15. Section 30.71 is revised by adding Cesium 129 (Cs 129), Cobalt 57 (Co 57), Gallium 67 (Ga 67), Germanium 68 (Ge 68), Gold 195 (Au 195), Indium 111 (In 111), Iodine 123 (I 123), Iron 52 (Fe 52), Potassium 43 (K 43), Rubidium 81 (Rb 81), Sodium 22 (Na 22), Yttrium 87 (Y 87), and Yttrium 88 (Y 88) in alphabetical order by element as follows:

§ 30.71 Schedule B.

Byproduct material	Microcuries
* * * * *	
Cesium 129 (Cs 129)	100
* * * * *	
Cobalt 57 (Co 57)	100
* * * * *	
Gallium 67 (Ga 67)	100
* * * * *	
Germanium 68 (Ge 68)	10
* * * * *	
Gold 195 (Au 195)	10
* * * * *	
Indium 111 (In 111)	100
* * * * *	
Iodine 123 (I 123)	100
* * * * *	
Iron 52 (Fe 52)	10
* * * * *	
Potassium 43 (K 43)	10
* * * * *	
Rubidium 81 (Rb 81)	10
* * * * *	
Sodium 22 (Na 22)	10

Byproduct material	Microcuries
* * * * *	
Yttrium 87 (Y 87)	10
Yttrium 88 (Y 88)	10
* * * * *	

16. Section 30.72 is revised by adding radium-226 in alphabetical order to read as follows:

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

Radioactive material [1]	Release fraction	Quantity (curies)
* * * * *		
Radium-226	0.001	100
* * * * *		

[1] For combinations of radioactive materials, consideration of the need for an emergency plan is required if the sum of the ratios of the quantity of each radioactive material authorized to the quantity listed for that material in Schedule C exceeds one.

PART 31—GENERAL DOMESTIC LICENSES FOR BYPRODUCT MATERIAL

17. The authority citation for part 31 is revised to read as follows:

Authority: Secs. 81, 161, 183, 68 Stat. 935, 948, 954, as amended (42 U.S.C. 2111, 2201, 2233); secs. 201, as amended, 202, 88 Stat. 1242, as amended, 1244 (42 U.S.C. 5841, 5842); sec. 1704, 112 Stat. 2750 (44 U.S.C. 3504 note); sec. 651(e), Pub. L. 109–58, 119 Stat. 806–810 (42 U.S.C. 2014, 2021, 2021b, 2111).

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

§ 31.4 Information collection requirements: OMB approval.

* * * * *

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

* * * * *

19. In § 31.5, paragraphs (b)(1)(i), (b)(1)(ii), and (c)(13)(i) are revised and paragraph (b)(1)(iii) is added to read as follows:

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

* * * * *

(b)(1) * * *

(i) A specific license issued under § 32.51 of this chapter;

(ii) An equivalent specific license issued by an Agreement State; or

(iii) An equivalent specific license issued by a State with provisions comparable to § 32.51 of this chapter.

* * * * *

(c) * * *

(13)(i) Shall register, in accordance with paragraphs (c)(13)(ii) and (iii) of this section, devices containing at least 370 megabecquerels (10 millicuries) of cesium-137, 3.7 megabecquerels (0.1 millicurie) of strontium-90, 37 megabecquerels (1 millicurie) of cobalt-60, 3.7 megabecquerels (0.1 millicurie) of radium-226, or 37 megabecquerels (1 millicurie) of americium-241 or any other transuranic (i.e., element with atomic number greater than uranium (92)), based on the activity indicated on the label. Each address for a location of use, as described under paragraph (c)(13)(iii)(D) of this section, represents a separate general licensee and requires a separate registration and fee.

* * * * *

20. Section 31.8 is revised to read as follows:

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

(a) A general license is issued to those persons listed in this section to own, receive, acquire, possess, use, and transfer, in accordance with the provisions of paragraphs (b) and (c) of this section, americium-241 or radium-226 in the form of calibration or reference sources:

(1) Any person in a non-Agreement State who holds a specific license issued under this chapter which authorizes receipt, possession, use, and transfer of byproduct material, source material, or special nuclear material; and

(2) Any Government agency, as defined in § 30.4 of this chapter, which holds a specific license issued under this chapter which authorizes it to receive, possess, use, and transfer byproduct material, source material, or special nuclear material.

(b) The general license in paragraph (a) of this section applies only to calibration or reference sources which have been manufactured or initially transferred in accordance with the specifications contained in a specific license issued under § 32.57 of this chapter or in accordance with the specifications contained in a specific license issued to the manufacturer by an Agreement State which authorizes manufacture of the sources for distribution to persons generally licensed by the Agreement State, or in accordance with a specific license issued by a State with comparable provisions to § 32.57.

(c) The general license in paragraph (a) of this section is subject to the provisions of §§ 30.14(d), 30.34 (a) to (e), and 30.50 to 30.63 of this chapter, and to the provisions of parts 19, 20, and 21, of this chapter. In addition, persons who own, receive, acquire, possess, use, and transfer one or more calibration or reference sources under this general license:

(1) Shall not possess at any one time, at any one location of storage or use, more than 0.185 megabecquerel (5 microcuries) of americium-241 or 0.185 megabecquerel (5 microcuries) of radium-226 in these sources;

(2) Shall not receive, possess, use, or transfer a source unless the source, or the storage container, bears a label which includes the following statement or a substantially similar statement which contains the information called for in the following statement: [1]

The receipt, possession, use, and transfer of this source, Model XX, Serial No. XX, are subject to a general license and the regulations of the United States Nuclear Regulatory Commission or of a State with which the Commission has entered into an agreement for the exercise of regulatory authority. Do not remove this label.

CAUTION—RADIOACTIVE MATERIAL—THIS SOURCE CONTAINS AMERICIUM-241 [or RADIUM-226, as appropriate]. DO NOT TOUCH RADIOACTIVE PORTION OF THIS SOURCE.

(Name of manufacturer or initial transferor)

(3) Shall not transfer, abandon, or dispose of a source except by transfer to a person authorized by a license issued under this chapter or by an Agreement State to receive the source.

(4) Shall store a source, except when the source is being used, in a closed container adequately designed and constructed to contain americium-241 or radium-226 which might otherwise escape during storage.

(5) Shall not use a source for any purpose other than the calibration of radiation detectors or the standardization of other sources.

(d) This general license does not authorize the manufacture or import of calibration or reference sources containing americium-241 or radium-226.

(e) This general license does not authorize the export of calibration or

[1] Sources generally licensed under this section before January 19, 1975, may bear labels authorized by the regulations in effect on January 1, 1975. Sources containing radium-226 generally licensed under this section and manufactured before [DATE 60 DAYS AFTER THE DATE OF PUBLICATION OF THE FINAL RULE] shall be labeled in accordance with the applicable State regulations at the time of manufacture or import.

reference sources containing americium-241 or radium-226.

21. In § 31.11, paragraph (a)(8) is added, and paragraphs (c)(1) and (d)(1) are revised to read as follows:

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

(a) * * *

(8) Cobalt-57, in units not exceeding 0.37 megabecquerel (10 microcuries) each for use in in vitro clinical or laboratory tests not involving internal or external administration of byproduct material, or the radiation therefrom, to human beings or animals.

* * * * *

(c) * * *

(1) The general licensee shall not possess at any one time, under the general license in paragraph (a) of this section, at any one location of storage or use, a total amount of iodine-125, iodine-131, selenium-75, cobalt-57 and/or iron-59 in excess of 7.4 megabecquerels (200 microcuries).

* * * * *

(d) * * *

(1) Except as prepackaged units which are labeled in accordance with the provisions of a specific license issued under the provisions of § 32.71 of this chapter or in accordance with the provisions of a specific license issued by an Agreement State, or before [date 60 days after the date of publication of the final rule], the provisions of a specific license issued by a State with comparable provisions to § 32.71 that authorize manufacture and distribution of iodine-125, iodine-131, carbon-14, hydrogen-3 (tritium), selenium-75, iron-59, cobalt-57, or Mock Iodine-125 for distribution to persons generally licensed by the Agreement State or the State with comparable provisions to § 32.71.

* * * * *

§§ 31.12, 31.13, and 31.14 [Redesignated]

22. Sections 31.12, 31.13, and 31.14 are redesignated as § 31.21, § 31.22, and § 31.23, respectively, and new §§ 31.13 through 31.20 are added and reserved, and a new § 31.12 is added to read as follows:

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

(a) A general license is hereby issued to any person to acquire, receive, possess, use, or transfer, in accordance with the provisions of paragraphs (b), (c), and (d) of this section, radium-226 contained in the following products manufactured prior to [date 60 days after date of publication of final rule]:

(1) Antiquities originally intended for use by the general public. For the purposes of this paragraph, antiquities mean products originally intended for use by the general public and distributed in the late 19th and early 20th centuries, such as radium emanator jars, revigators, radium water jars, radon generators, refrigerator cards, radium bath salts, and healing pads.

(2) Luminous items installed in aircraft.

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

(4) Other luminous products including timepiece hands and dials no longer installed in timepieces, provided that no more than 50 items are used or stored at the same location at any one time.

(5) Small radium sources containing no more than 0.037 megabecquerel (1 microcurie) of radium-226. For the purposes of this paragraph, ''small radium sources'' means discrete survey instrument calibration sources, sources contained in radiation measuring instruments, sources used in educational demonstrations (such as cloud chambers, and spinthariscopes), electron tubes, lightning rods, ionization sources, static eliminators, or as designated by the NRC.

(b) Persons who acquire, receive, possess, use, or transfer byproduct material under the general license issued in paragraph (a) of this section are exempt from the provisions of parts 19, 20, and 21, of this chapter, to the extent that the receipt, possession, use, or transfer of byproduct material is within the terms of the general license; provided, however, that this exemption shall not be deemed to apply to any such person specifically licensed under this chapter.

(c) Any person who acquires, receives, possesses, uses, or transfers byproduct material in accordance with the general license in paragraph (a) of this section:

(1) Shall notify the NRC should there be any indication of possible damage to the product so that it appears it could result in a loss of the radioactive material. A report containing a brief description of the event, and the remedial action taken, must be furnished to the Director of the Office of Nuclear Material Safety and Safeguards, U.S. Nuclear Regulatory Commission, Washington, DC 20555–0001 within 30 days.

(2) Shall not abandon the device containing radium-226. The product, and any radioactive material from the product, may only be disposed of according to § 20.2008 or by transfer to a person authorized by a specific license to receive the radium-226 in the product or as otherwise approved by the NRC.

(3) Shall not export the device containing radium-226 except in accordance with part 110 of this chapter.

(4) Shall dispose of the product containing radium-226 by export only as provided by paragraph (c)(3) of this section, at a disposal facility authorized to dispose of radioactive material in accordance with any Federal or State solid or hazardous waste law, including the Solid Waste Disposal Act, as authorized under the Energy Policy Act of 2005, by transfer to a person authorized to receive radium-226 by a specific license issued under part 30 of this chapter, or equivalent regulations of an Agreement State, or as otherwise approved by the NRC.

(5) Shall respond to written requests from the NRC to provide information relating to the general license within 30 calendar days of the date of the request, or other time specified in the request. If the general licensee cannot provide the requested information within the allotted time, it shall, within that same time period, request a longer period to supply the information by providing the Director of the Office of Nuclear Material Safety and Safeguards, by an appropriate method listed in § 30.6(a) of this chapter, a written justification for the request.

(d) The general license in paragraph (a) of this section does not authorize the manufacture, assembly, disassembly, repair, or import of products containing radium-226.

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

23. The authority citation for part 32 is revised to read as follows:

Authority: Secs. 81, 161, 182, 183, 68 Stat. 935, 948, 953, 954, as amended (42 U.S.C. 2111, 2201, 2232, 2233); sec. 201, 88 Stat. 1242, as amended (42 U.S.C. 5841); sec. 1704, 112 Stat. 2750 (44 U.S.C. 3504 note); sec. 651(e), Pub. L. 109–58, 119 Stat. 806–810 (42 U.S.C. 2014, 2021, 2021b, 2111).

24. In § 32.1, paragraph (c) is added to read as follows:

§ 32.1 Purpose and scope.

* * * * *

(c)(1) The requirements in this part, including provisions that are specific to licensees, shall apply to Government agencies and Federally recognized Indian tribes with respect to accelerator-produced radioactive material or

discrete sources of radium-226 on [date 60 days after date of publication of final rule] except that the agency or tribe may continue to manufacture or initially transfer items containing accelerator-produced radioactive material or discrete sources of radium-226 for sale or distribution to persons exempted from the licensing requirements of part 30 of this chapter, and to persons generally licensed under part 31 or part 35 of this chapter, and radioactive drugs and sources and devices to medical use licensees, until the date of the NRC's final licensing determination, provided that the agency or tribe submits a new license application for these activities on or before [date 1 year and 2 months after date of publication of final rule] or an amendment application for these activities on or before [date 8 months after date of publication of final rule].

(2) The requirements in this part, including provisions that are specific to licensees, shall apply to all persons other than those included in (c)(1) of this section with respect to accelerator-produced radioactive material or discrete sources of radium-226 on August 8, 2009, or earlier as noticed by the NRC, except that these persons may continue to manufacture or initially transfer items containing accelerator-produced radioactive material or discrete sources of radium-226 for sale or distribution to persons exempted from the licensing requirements of part 30 of this chapter, and to persons generally licensed under part 31 or part 35 of this chapter, and to sell or manufacture radioactive drugs and sources and devices to medical use licensees until the date of the NRC's final licensing determination provided that the individual submits a license application or amendment on or before August 7, 2009, or earlier as noticed by the NRC.

25. In § 32.57, the heading and the introductory text are revised to read as follows:

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

An application for a specific license to manufacture or initially transfer calibration or reference sources containing americium-241 or radium-226, for distribution to persons generally licensed under § 31.8 of this chapter, will be approved if:

* * * * *

26. Section 32.58 is revised to read as follows:

§ 32.58 Same: Labeling of devices.

Each person licensed under § 32.57 shall affix to each source, or storage container for the source, a label which shall contain sufficient information relative to safe use and storage of the source and shall include the following statement or a substantially similar statement which contains the information called for in the following statement.[1]

The receipt, possession, use, and transfer of this source, Model __–, Serial No. __–, are subject to a general license and the regulations of the United States Nuclear Regulatory Commission or of a State with which the Commission has entered into an agreement for the exercise of regulatory authority. Do not remove this label.

CAUTION—RADIOACTIVE MATERIAL—THIS SOURCE CONTAINS AMERICIUM-241 (or RADIUM-226). DO NOT TOUCH RADIOACTIVE PORTION OF THIS SOURCE.

_____

(Name of manufacturer or initial transferor)

27. Section 32.59 is revised to read as follows:

§ 32.59 Same: Leak testing of each source.

Each person licensed under § 32.57 shall perform a dry wipe test upon each source containing more than 3.7 kilobecquerels (0.1 microcurie) of americium-241 or radium-226 before transferring the source to a general licensee under § 31.8 of this chapter. This test shall be performed by wiping the entire radioactive surface of the source with a filter paper with the application of moderate finger pressure. The radioactivity on the paper shall be measured by using radiation detection instrumentation capable of detecting 0.185 kilobecquerel (0.005 microcurie) of americium-241 or radium-226. If this test discloses more than 0.185 kilobecquerel (0.005 microcurie) of radioactive material, the source shall be deemed to be leaking or losing americium-241 or radium-226 and shall not be transferred to a general licensee under § 31.8 of this chapter or equivalent regulations of an Agreement State.

28. In § 32.71, paragraph (b)(8) is added, and paragraph (c)(1) is revised to read as follows:

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

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

* * * * *

(b) * * *

(8) Cobalt-57 in units not exceeding 0.37 megabecquerel (10 microcuries) each.

(c) * * *

(1) Identifying the radioactive contents as to chemical form and radionuclide, and indicating that the amount of radioactivity does not exceed 0.37 megabecquerel (10 microcuries) of iodine-131, iodine-125, selenium-75, or carbon-14; 1.85 megabecquerels (50 microcuries) of hydrogen-3 (tritium); or 0.74 megabecquerel (20 microcuries) of iron-59; or Mock Iodine-125 in units not exceeding 1.85 kilobecquerels (0.05 microcurie) of iodine-129 and 0.185 kilobecquerel (0.005 microcurie) of americium-241 each; or cobalt-57 in units not exceeding 0.37 megabecquerel (10 microcuries); and

* * * * *

29. In § 32.72, paragraphs (a)(2)(i), (a)(2)(iii), (a)(2)(iv), and (b) are revised, and a new paragraph (a)(2)(v) is added to read as follows:

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

(a) * * *

(2) * * *

(i) Registered with the U.S. Food and Drug Administration (FDA) as the owner or operator of a drug establishment that engages in the manufacture, preparation, propagation, compounding, or processing of a drug under 21 CFR 207.20(a);

* * * * *

(iii) Licensed as a pharmacy by a State Board of Pharmacy;

(iv) Operating as a nuclear pharmacy within a Federal medical institution; or

(v) A Positron Emission Tomography (PET) drug production facility registered with a State agency.

* * * * *

(b) A licensee described by paragraph (a)(2)(iii) or (iv) of this section:

(1) May produce Positron Emission Tomography (PET) radionuclides provided that the PET radionuclide production is under the supervision of an authorized user who meets the requirements of § 30.33(a)(3) of this chapter.

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

of this section, or an individual under the supervision of an authorized nuclear pharmacist as specified in § 35.27 of this chapter.

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

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

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

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

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

(5) May designate a pharmacist (as defined in § 35.2 of this chapter) as an authorized nuclear pharmacist if:

(i) The individual was a nuclear pharmacist preparing only radioactive drugs containing accelerator-produced radioactive material, and

(ii) The individual practiced at a pharmacy at a Government agency or Federally recognized Indian tribe before [date 60 days after date of publication of final rule] or at all other pharmacies before August 8, 2009, or an earlier date as noticed by the NRC.

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

* * * * *

30. In § 32.102, the heading and the introductory paragraph are revised to read as follows:

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

An applicant for a license under § 32.57 shall, for any type of source which is designed to contain more than 0.185 kilobecquerel (0.005 microcurie) of americium-241 or radium-226, conduct prototype tests, in the order listed, on each of five prototypes of the source, which contains more than 0.185 kilobecquerel (0.005 microcurie) of americium-241 or radium-226, as follows:

* * * * *

PART 33—SPECIFIC DOMESTIC LICENSES OF BROAD SCOPE FOR BYPRODUCT MATERIAL

31. The authority citation for part 33 is revised to read as follows:

Authority: Secs. 81, 161, 182, 183, 68 Stat. 935, 948, 953, 954, as amended (42 U.S.C. 2111, 2201, 2232, 2233); sec. 201, 88 Stat. 1242, as amended (42 U.S.C. 5841); sec. 1704, 112 Stat. 2750 (44 U.S.C. 3504 note); sec. 651(e), Pub. L. 109–58, 119 Stat. 806–810 (42 U.S.C. 2014, 2021, 2021b, 2111).

32. Section 33.100 is revised by adding Beryllium-7, Cobalt-57, Radium-226, and Sodium-22 in alphabetical order to read as follows:

§ 33.100 Schedule A.

Byproduct material	Col. I curies	Col. II curies
* * *	*	*
Beryllium-7	10	0.1
* * *	*	*
Cobalt-57	10	0.1
* * *	*	*
Radium-226	0.01	0.0001
* * *	*	*
Sodium-22	0.1	0.001

* * * * *

PART 35—MEDICAL USE OF BYPRODUCT MATERIAL

33. The authority citation for part 35 is revised to read as follows:

Authority: Secs. 81, 161, 182, 183, 68 Stat. 935, 948, 953, 954, as amended (42 U.S.C. 2111, 2201, 2232, 2233); sec. 201, 88 Stat. 1242, as amended (42 U.S.C. 5841); sec. 1704, 112 Stat. 2750 (44 U.S.C. 3504 note); sec. 651(e), Pub. L. 109–58, 119 Stat. 806–810 (42 U.S.C. 2014, 2021, 2021b, 2111).

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

§ 35.2 Definitions.

* * * * *

Authorized nuclear pharmacist means a pharmacist who—

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

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

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

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

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

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

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

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

(5) Prepared only radioactive drugs containing accelerator-produced radioactive materials at a pharmacy at a Government agency or Federally recognized Indian tribe before [date 60 days after date of publication of final rule] or at all other pharmacies before August 8, 2009, or an earlier date as noticed by the NRC.

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

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

(2) Is identified as an authorized user on—

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

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

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

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

(3) Used only accelerator-produced radioactive materials, discrete sources of radium-226, or both, for medical uses at a Government agency or Federally recognized Indian tribe before [date 60 days after date of publication of final rule] or at all other locations of use before August 8, 2009, or an earlier date

as noticed by the NRC, and for only those materials and uses performed before these dates.

* * * * *

Cyclotron means a circular particle accelerator in which charged particles are bent traveling through the accelerator. A cyclotron accelerates charged particles at energies usually in excess of 10 megaelectron volts and is commonly used for production of short half-life radionuclides for medical use.

* * * * *

Positron Emission Tomography (PET) radionuclide production facility is defined as a facility operating a cyclotron or accelerator for the purpose of producing PET radionuclides.

* * * * *

35. In § 35.10, paragraph (a) is added to read as follows:

§ 35.10 Implementation.

(a) A Government agency or a Federally recognized Indian tribe that possesses and uses accelerator-produced radioactive material or discrete sources of radium-226 for which a specific medical use license is required by the Atomic Energy Act of 1954, as amended, must comply with the requirements of this part, including provisions that are specific to licensees, on [date 60 days after date of publication of final rule]. All other persons who possess and use accelerator-produced radioactive material or discrete sources of radium-226 for which a specific medical use license is required, must comply with the requirements of this part, including provisions that are specific to licensees, on August 8, 2009, or earlier as noticed by the NRC.

* * * * *

36. In § 35.11, paragraph (a) is revised, and paragraph (c) is added to read as follows:

§ 35.11 License required.

(a) A person may manufacture, produce, acquire, receive, possess, prepare, use, or transfer byproduct material for medical use only in accordance with a specific license issued by the Commission or an Agreement State, or as allowed in paragraph (b) or (c) of this section.

* * * * *

(c)(1) A Government agency or a Federally recognized Indian tribe that possesses and uses accelerator-produced radioactive material or discrete sources of radium-226 for which a specific medical use license is required in paragraph (a) of this section may continue to use such materials for medical uses until the date of the NRC's final licensing determination, provided that the individual submits a medical use license application on or before [date 1 year and 2 months after date of publication of final rule].

(2) Except as provided in paragraph (c)(1) of this section, all other persons who possess and use accelerator-produced radioactive material or discrete sources of radium-226 for which a specific medical use license is required in paragraph (a) of this section, may continue to use this type of material for medical uses permitted under this part until the date of the NRC's final licensing determination provided that the individual submits a medical use license application on or before August 7, 2009, or earlier as noticed by the NRC.

37. In § 35.13, paragraphs (a) and (e) are revised and paragraph (b)(4)(v) is added to read as follows:

§ 35.13 License amendments.

* * * * *

(a) Before it receives, prepares, or uses byproduct material for a type of use that is permitted under this part, but is not authorized on the licensee's current license issued under this part; except that—

(1) A Government agency or a Federally recognized Indian tribe licensee who possesses and uses accelerator-produced radioactive material or discrete sources of radium-226 may continue to use such material for medical uses permitted under this part until the date of the NRC's final licensing determination, provided that the licensee submits an amendment application on or before [date 8 months after date of publication of final rule].

(2) Except as provided in (a)(1) of this section, all other licensees who possess and use accelerator-produced radioactive material or discrete sources of radium-226 may continue to use those materials for medical uses permitted under this part until the date of the NRC's final licensing determination provided that the individual submits a medical use license application on or before August 7, 2009, or earlier as noticed by the NRC.

(b) * * *

(4) * * *

(v) An individual who uses only accelerator-produced radioactive materials, discrete sources of radium-226, or both, for medical use or in the practice of nuclear pharmacy at a Government agency or Federally recognized Indian tribe before [date 60 days after date of publication of final rule] or at all other locations of use before August 8, 2009, or an earlier date as noticed by the NRC, and for only those materials and uses performed before these dates.

* * * * *

(e) Before it adds to or changes the areas of use identified in the application or on the license, including areas used in accordance with either § 35.100 or § 35.200 if the change includes addition or relocation of either an area where PET radionuclides are produced or a radionuclide delivery line from the PET radionuclide production area. Other areas of use where byproduct material is used only in accordance with either § 35.100 or § 35.200 are exempted;

* * * * *

38. In § 35.14, the introductory text of paragraph (a) and paragraph (b)(4) are revised to read as follows:

§ 35.14 Notifications.

(a) A licensee shall provide the Commission a copy of the board certification and the written attestation(s), signed by a preceptor, the Commission or Agreement State license, the permit issued by a Commission master material licensee, the permit issued by a Commission or Agreement State licensee of broad scope, the permit issued by a Commission master material license broad scope permittee, or documentation that only accelerator-produced radioactive materials, discrete sources of radium-226, or both, were used for medical use or in the practice of nuclear pharmacy at a Government agency or Federally recognized Indian tribe before [date 60 days after date of publication of final rule] or at all other locations of use before August 8, 2009, or an earlier date as noticed by the NRC, and for each individual no later than 30 days after the date that the licensee permits the individual to work as an authorized user, an authorized nuclear pharmacist, or an authorized medical physicist, under § 35.13(b). For individuals permitted to work under § 35.13(b)(4), within the same 30-day time frame, the licensee shall also provide, as appropriate, verification of completion of;

* * * * *

(b) * * *

(4) The licensee has added to or changed the areas of use identified in the application or on the license where byproduct material is used in accordance with either § 35.100 or § 35.200 if the change does not include addition or relocation of either an area where PET radionuclides are produced or a radionuclide delivery line from the PET radionuclide production area.

* * * * *

39. In § 35.15, paragraph (f) is revised to read as follows:

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

* * * * *

(f) The provisions of § 35.14(b)(4) regarding additions to or changes in the areas of use identified in the application, or on the license where byproduct material is used in accordance with either § 35.100 or § 35.200, if the change does not include addition or relocation of either an area where PET radionuclides are produced or a radionuclide delivery line from the PET radionuclide production area.

* * * * *

40. In § 35.57, paragraphs (a)(3) and (b)(3) are added to read as follows:

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

(a) * * *

(3) A Radiation Safety Officer, a medical physicist, or a nuclear pharmacist who used only accelerator-produced radioactive materials, discrete sources of radium-226, or both, for medical uses or in the practice of nuclear pharmacy at a Government agency or Federally recognized Indian tribe before [date 60 days after date of publication of final rule] or at all other locations of use before August 8, 2009, or an earlier date as noticed by the NRC, need not comply with the training requirements of §§ 35.50, 35.51, or 35.55, respectively, when performing the same uses.

(b) * * *

(3) Physicians, dentists, or podiatrists who used only accelerator-produced radioactive materials, discrete sources of radium-226, or both, for medical uses performed at a Government agency or Federally recognized Indian tribe before [date 60 days after date of publication of final rule] or at all other locations of use before August 8, 2009, or an earlier date as noticed by the NRC, need not comply with the training requirements of subparts D through H of this part when performing the same medical uses.

41. In § 35.63, paragraphs (b)(2)(ii) and (c)(3) are revised, and paragraph (b)(2)(iii) is added to read as follows:

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

* * * * *

(b) * * *

(2) * * *

(ii) An NRC or Agreement State licensee for use in research in accordance with a Radioactive Drug Research Committee-approved protocol or an Investigational New Drug (IND) protocol accepted by FDA; or

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

(c) * * *

(3) Combination of volumetric measurements and mathematical calculations, based on the measurement made by:

(i) A manufacturer or preparer licensed under § 32.72 of this chapter or equivalent Agreement State requirements; or

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

* * * * *

42. Section 35.69 is revised to read as follows:

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

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

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

43. In § 35.100, paragraph (a) and the introductory text of paragraph (b) are revised to read as follows:

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

* * * * *

(a) Obtained from:

(1) A manufacturer or preparer licensed under § 32.72 of this chapter or equivalent Agreement State requirements;

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

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

(b) Excluding production of PET radionuclides, prepared by:

* * * * *

44. In § 35.200, paragraph (a) and the introductory text of paragraph (b) are revised to read as follows:

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

* * * * *

(a) Obtained from:

(1) A manufacturer or preparer licensed under § 32.72 of this chapter or equivalent Agreement State requirements;

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

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

(b) Excluding production of PET radionuclides, prepared by:

* * * * *

45. In § 35.204, the heading and paragraph (a) are revised, paragraph (c) is redesignated as (d) and revised, and a new paragraph (c) is added to read as follows:

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

(a) A licensee may not administer to humans a radiopharmaceutical that contains:

(1) More than 0.15 kilobecquerel of molybdenum-99 per megabecquerel of technetium-99m (0.15 microcurie of molybdenum-99 per millicurie of technetium-99m); or

(2) More than 0.02 kilobecquerel of strontium-82 per megabecquerel of rubidium-82 chloride injection (0.02 microcurie of strontium-82 per millicurie of rubidium-82 chloride); or more than 0.2 kilobecquerel of strontium-85 per megabecquerel of rubidium-82 chloride injection (0.2 microcurie of strontium-85 per millicurie of rubidium-82).

* * * * *

(c) A licensee that uses a strontium-82/rubidium-82 generator for preparing a rubidium-82 radiopharmaceutical shall, before the first patient use of the day, measure the concentration of radionuclides strontium-82 and strontium-85 to demonstrate compliance with paragraph (a) of this section.

(d) If a licensee is required to measure the molybdenum-99 concentration or strontium-82 and strontium-85 concentrations, the licensee shall retain a record of each measurement in accordance with § 35.2204.

46. In § 35.300, paragraph (a) and the introductory text of paragraph (b) are revised to read as follows:

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

* * * * *

(a) Obtained from:

(1) A manufacturer or preparer licensed under § 32.72 of this chapter or equivalent Agreement State requirements;

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

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

(b) Excluding production of PET radionuclides, prepared by:

* * * * *

47. Section 35.2204 is revised to read as follows:

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

A licensee shall maintain a record of the molybdenum-99 concentration or strontium-82 and strontium-85 concentration tests required by § 35.204(b) and (c) for 3 years. The record must include:

(a) For each measured elution of technetium-99m, the ratio of the measures expressed as kilobecquerel of molybdenum-99 per megabecquerel of technetium-99m (or microcuries of molybdenum per millicurie of technetium), the time and date of the measurement, and the name of the individual who made the measurement; or

(b) For each measured elution of rubidium-82, the ratio of the measures expressed as kilobecquerel of strontium-82 per megabecquerel of rubidium-82 (or microcuries of strontium-82 per millicurie of rubidium), kilobecquerel of strontium-85 per megabecquerel of rubidium-82 (or microcuries of strontium-85 per millicurie of rubidium), the time and date of the measurement, and the name of the individual who made the measurement.

PART 50—DOMESTIC LICENSING OF PRODUCTION AND UTILIZATION FACILITIES

48. The authority citation for part 50 is revised to read as follows:

Authority: Secs. 102, 103, 104, 161, 182, 183, 186, 189, 68 Stat. 936, 937, 938, 948, 953, 954, 955, 956, as amended, sec. 234, 83 Stat. 444, as amended (42 U.S.C. 2132, 2133, 2134, 2135, 2201, 2232, 2233, 2236, 2239, 2282); secs. 201, as amended, 202, 206, 88 Stat. 1242, as amended, 1244, 1246 (42 U.S.C. 5841, 5842, 5846); sec. 1704, 112 Stat. 2750 (44 U.S.C. 3504 note); sec. 651(e), Pub. L. 109–58, 119 Stat. 806–810 (42 U.S.C. 2014, 2021, 2021b, 2111). Section 50.7 also issued under Pub. L. 95–601, sec. 10, 92 Stat. 2951 (42 U.S.C. 5841). Section 50.10 also issued under secs. 101, 185, 68 Stat. 955, as amended (42 U.S.C. 2131, 2235); sec. 102, Pub. L. 91–190, 83 Stat. 853 (42 U.S.C. 4332). Sections 50.13, 50.54(dd), and 50.103 also issued under sec. 108, 68 Stat. 939, as amended (42 U.S.C. 2138).

Sections 50.23, 50.35, 50.55, and 50.56 also issued under sec. 185, 68 Stat. 955 (42 U.S.C. 2235). Sections 50.33a, 50.55a and Appendix Q also issued under sec. 102, Pub. L. 91–190, 83 Stat. 853 (42 U.S.C. 4332). Sections 50.34 and 50.54 also issued under sec. 204, 88 Stat. 1245 (42 U.S.C. 5844). Sections 50.58, 50.91, and 50.92 also issued under Pub. L. 97–415, 96 Stat. 2073 (42 U.S.C. 2239). Section 50.78 also issued under sec. 122, 68 Stat. 939 (42 U.S.C. 2152). Sections 50.80–50.81 also issued under sec. 184, 68 Stat. 954, as amended (42 U.S.C. 2234). Appendix F also issued under sec. 187, 68 Stat. 955 (42 U.S.C. 2237).

49. In § 50.2, the definition of *Byproduct material* is revised to read as follows:

§ 50.2 Definitions.

* * * * *

Byproduct material means—

(1) Any radioactive material (except special nuclear material) yielded in, or made radioactive by, exposure to the radiation incident to the process of producing or using special nuclear material;

(2)(i) Any discrete source of radium-226 that is produced, extracted, or converted after extraction, before, on, or after August 8, 2005, for use for a commercial, medical, or research activity; or

(ii) Any material that—

(A) Has been made radioactive by use of a particle accelerator; and

(B) Is produced, extracted, or converted after extraction, before, on, or after August 8, 2005, for use for a commercial, medical, or research activity; and

(3) Any discrete source of naturally occurring radioactive material, other than source material, that—

(i) The Commission, in consultation with the Administrator of the Environmental Protection Agency, the Secretary of Energy, the Secretary of Homeland Security, and the head of any other appropriate Federal agency, determines would pose a threat similar to the threat posed by a discrete source of radium-226 to the public health and safety or the common defense and security; and

(ii) Before, on, or after August 8, 2005, is extracted or converted after extraction for use in a commercial, medical, or research activity.

* * * * *

PART 61—LICENSING REQUIREMENTS FOR LAND DISPOSAL OF RADIOACTIVE WASTE

50. The authority citation for part 61 is revised to read as follows:

Authority: Secs. 53, 57, 62, 63, 65, 81, 161, 182, 183, 68 Stat. 930, 932, 933, 935, 948, 953, 954, as amended (42 U.S.C. 2073, 2077, 2092, 2093, 2095, 2111, 2201, 2232, 2233); secs. 202, 206, 88 Stat. 1244, 1246 (42 U.S.C. 5842, 5846); secs. 10 and 14, Pub. L. 95–601, 92 Stat. 2951 (42 U.S.C. 2021a and 5851) and Pub. L. 102–486, sec 2902, 106 Stat. 3123, (42 U.S.C. 5851); sec. 1704, 112 Stat. 2750 (44 U.S.C. 3504 note); sec. 651(e), Pub. L. 109–58, 119 Stat. 806–810 (42 U.S.C. 2014, 2021, 2021b, 2111).

51. In § 61.2, the definition for *Waste* is revised to read as follows:

§ 61.2 Definitions.

* * * * *

Waste means those low-level radioactive wastes containing source, special nuclear, or byproduct material that are acceptable for disposal in a land disposal facility. For the purposes of this definition, low-level radioactive waste means radioactive waste not classified as high-level radioactive waste, transuranic waste, spent nuclear fuel, or byproduct material as defined in paragraphs (2), (3), and (4) of the definition of Byproduct material set forth in § 20.1003 of this chapter.

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

52. The authority citation for part 62 is revised to read as follows:

Authority: Secs. 81, 161, as amended, 68 Stat. 935, 948, 950, 951, as amended (42 U.S.C. 211, 2201); secs. 201, 209, as amended, 88 Stat. 1242, 1248, as amended (42 U.S.C. 5841, 5849); secs. 3, 4, 5, 6, 99 Stat. 1843, 1844, 1845, 1846, 1847, 1848, 1849, 1850, 1851, 1852, 1853, 1854, 1855, 1856, 1857 (42 U.S.C. 2021c, 2021d, 2021e, 2021); sec. 1704, 112 Stat. 2750 (44 U.S.C. 3504 note); sec. 651(e), Pub. L. 109–58, 119 Stat. 806–810 (42 U.S.C. 2014, 2021, 2021b, 2111).

53. In § 62.2, the definition for *Low-level radioactive waste* (LLW) is revised to read as follows:

§ 62.2 Definitions.

* * * * *

Low-level radioactive waste (LLW) means radioactive material that—

(1) Is not high-level radioactive waste, spent nuclear fuel, or byproduct material (as defined in paragraphs (2), (3), and (4) of the definition of Byproduct Material set forth in § 20.1003 of this chapter; and

(2) The NRC, consistent with existing law and in accordance with paragraph (1) of this definition, classifies as low-level radioactive waste.

* * * * *

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

54. The authority citation for part 72 continues to read as follows:

Authority: Secs. 51, 53, 57, 62, 63, 65, 69, 81, 161, 182, 183, 184, 186, 187, 189, 68 Stat. 929, 930, 932, 933, 934, 935, 948, 953, 954, 955, as amended, sec. 234, 83 Stat. 444, as amended (42 U.S.C. 2071, 2073, 2077, 2092, 2093, 2095, 2099, 2111, 2201, 2232, 2233, 2234, 2236, 2237, 2238, 2282); sec. 274, Pub. L. 86–373, 73 Stat. 688, as amended (42 U.S.C. 2021); sec. 201, as amended, 202, 206, 88 Stat. 1242, as amended, 1244, 1246 (42 U.S.C. 5841, 5842, 5846); Pub. L. 95–601, sec. 10, 92 Stat. 2951 as amended by Pub. L. 102–486, sec. 7902, 106 Stat. 3123 (42 U.S.C. 5851); sec. 102, Pub. L. 91–190, 83 Stat. 853 (42 U.S.C. 4332); secs. 131, 132, 133, 135, 137, 141, Pub. L. 97–425, 96 Stat. 2229, 2230, 2232, 2241, sec. 148, Pub. L. 100–203, 101 Stat. 1330–235 (42 U.S.C. 10151, 10152, 10153, 10155, 10157, 10161, 10168); sec. 1704, 112 Stat. 2750 (44 U.S.C. 3504 note); sec. 651(e), Pub. L. 109–58, 119 Stat. 806–810 (42 U.S.C. 2014, 2021, 2021b, 2111).

Section 72.44(g) also issued under secs. 142(b) and 148(c), (d), Pub. L. 100–203, 101 Stat. 1330–232, 1330–236 (42 U.S.C. 10162(b), 10168(c), (d)). Section 72.46 also issued under sec. 189, 68 Stat. 955 (42 U.S.C. 2239); sec. 134, Pub. L. 97–425, 96 Stat. 2230 (42 U.S.C. 10154). Section 72.96(d) also issued under sec. 145(g), Pub. L. 100–203, 101 Stat. 1330–235 (42 U.S.C. 10165(g)). Subpart J also issued under secs. 2(2), 2(15), 2(19), 117(a), 141(h), Pub. L. 97–425, 96 Stat. 2202, 2203, 2204, 2222, 2224 (42 U.S.C. 10101, 10137(a), 10161(h)). Subparts K and L are also issued under sec. 133, 98 Stat. 2230 (42 U.S.C. 10153) and sec. 218(a), 96 Stat. 2252 (42 U.S.C. 10198).

55. In § 72.3, the definition for *Byproduct material* is revised to read as follows:

§ 72.3 Definitions.

* * * * *

Byproduct material means—

(1) Any radioactive material (except special nuclear material) yielded in, or made radioactive by, exposure to the radiation incident to the process of producing or using special nuclear material;

(2)(i) Any discrete source of radium-226 that is produced, extracted, or converted after extraction, before, on, or after August 8, 2005, for use for a commercial, medical, or research activity; or

(ii) Any material that—

(A) Has been made radioactive by use of a particle accelerator; and

(B) Is produced, extracted, or converted after extraction, before, on, or after August 8, 2005, for use for a commercial, medical, or research activity; and

(3) Any discrete source of naturally occurring radioactive material, other than source material, that—

(i) The Commission, in consultation with the Administrator of the Environmental Protection Agency, the Secretary of Energy, the Secretary of Homeland Security, and the head of any other appropriate Federal agency, determines would pose a threat similar to the threat posed by a discrete source of radium-226 to the public health and safety or the common defense and security; and

(ii) Before, on, or after August 8, 2005, is extracted or converted after extraction for use in a commercial, medical, or research activity.

* * * * *

PART 110—EXPORT AND IMPORT OF NUCLEAR EQUIPMENT AND MATERIAL

56. The authority citation for part 110 is revised to read as follows:

Authority: Secs. 51, 53, 54, 57, 63, 64, 65, 81, 82, 103, 104, 109, 111, 126, 127, 128, 129, 161, 181, 182, 183, 187, 189, 68 Stat. 929, 930, 931, 932, 933, 936, 937, 948, 953, 954, 955, 956, as amended (42 U.S.C. 2071, 2073, 2074, 2077, 2092–2095, 2111, 2112, 2133, 2134, 2139, 2139a, 2141, 2154–2158, 2201, 2231–2233, 2237, 2239); sec. 201, 88 Stat. 1242, as amended (42 U.S.C. 5841); sec 5, Pub. L. 101–575, 104 Stat. 2835 (42 U.S.C. 2243); sec. 1704, 112 Stat. 2750 (44 U.S.C. 3504 note); Energy Policy Act of 2005; Pub. L. 109–58, 119 Stat. 594 (2005).

Sections 110.1(b)(2) and 110.1(b)(3) also issued under Pub. L. 96–92, 93 Stat. 710 (22 U.S.C. 2403). Section 110.11 also issued under sec. 122, 68 Stat. 939 (42 U.S.C. 2152) and secs. 54c and 57d., 88 Stat. 473, 475 (42 U.S.C. 2074). Section 110.27 also issued under sec. 309(a), Pub. L. 99–440. Section 110.50(b)(3) also issued under sec. 123, 92 Stat. 142 (42 U.S.C. 2153). Section 110.51 also issued under sec. 184, 68 Stat. 954, as amended (42 U.S.C. 2234). Section 110.52 also issued under sec. 186, 68 Stat. 955 (42 U.S.C. 2236). Sections 110.80–110.113 also issued under 5 U.S.C. 552, 554. Sections 110.130–110.135 also issued under 5 U.S.C. 553. Sections 110.2 and 110.42(a)(9) also issued under sec. 903, Pub. L. 102–496 (42 U.S.C. 2151 *et seq.*).

57. In § 110.2, definitions of *Accelerator-produced radioactive material, Discrete source,* and *Particle accelerator* are added to read as follows:

§ 110.2 Definitions.

* * * * *

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

* * * * *

Discrete source means a radioactive source with physical boundaries, which is separate and distinct from the radioactivity present in nature, and in which the radionuclide concentration has been increased by human processes with the intent that the concentrated radioactive material will be used for its radiological properties.

* * * * *

Particle accelerator means any machine capable of accelerating electrons, protons, deuterons, or other charged particles in a vacuum and of discharging the resultant particulate or other radiation into a medium at energies usually in excess of 1 megaelectron volt. For purposes of this definition, ''accelerator'' is an equivalent term.

* * * * *

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

58. The authority citation for part 150 is revised to read as follows:

Authority: Sec. 161, 68 Stat. 948, as amended, sec. 274, 73 Stat. 688 (42 U.S.C. 2201, 2021); sec. 201, 88 Stat. 1242, as amended (42 U.S.C. 5841); sec. 1704, 112 Stat. 2750 (44 U.S.C. 3504 note); sec. 651(e), Pub. L. 109–58, 119 Stat. 806–810 (42 U.S.C. 2014, 2021, 2021b, 2111).

Sections 150.3, 150.15, 150.15a, 150.31, 150.32 also issued under secs. 11e(2), 81, 68 Stat. 923, 935, as amended, secs. 83, 84, 92 Stat. 3033, 3039 (42 U.S.C. 2014e(2), 2111, 2113, 2114). Section 150.14 also issued under sec. 53, 68 Stat. 930, as amended (42 U.S.C. 2073). Section 150.15 also issued under secs. 135, 141, Pub. L. 97–425, 96 Stat. 2232, 2241 (42 U.S.C. 10155, 10161). Section 150.17a also issued under sec. 122, 68 Stat. 939 (42 U.S.C. 2152). Section 150.30 also issued under sec. 234, 83 Stat. 444 (42 U.S.C. 2282).

59. In § 150.3, the definition of *Byproduct material* is revised, and a definition of *Discrete source* is added to read as follows:

§ 150.3 Definitions.

* * * * *

Byproduct material means—

(1) Any radioactive material (except special nuclear material) yielded in, or made radioactive by, exposure to the radiation incident to the process of producing or using special nuclear material;

(2) The tailings or wastes produced by the extraction or concentration of uranium or thorium from ore processed primarily for its source material content, including discrete surface wastes resulting from uranium solution extraction processes. Underground ore

bodies depleted by these solution extraction operations do not constitute ''byproduct material'' within this definition;

(3)(i) Any discrete source of radium-226 that is produced, extracted, or converted after extraction, before, on, or after August 8, 2005, for use for a commercial, medical, or research activity; or

(ii) Any material that—

(A) Has been made radioactive by use of a particle accelerator; and

(B) Is produced, extracted, or converted after extraction, before, on, or after August 8, 2005, for use for a commercial, medical, or research activity; and

(4) Any discrete source of naturally occurring radioactive material, other than source material, that—

(i) The Commission, in consultation with the Administrator of the Environmental Protection Agency, the Secretary of Energy, the Secretary of Homeland Security, and the head of any other appropriate Federal agency, determines would pose a threat similar to the threat posed by a discrete source of radium-226 to the public health and safety or the common defense and security; and

(ii) Before, on, or after August 8, 2005, is extracted or converted after extraction for use in a commercial, medical, or research activity.

* * * * *

Discrete source means a radioactive source with physical boundaries, which is separate and distinct from the radioactivity present in nature, and in which the radionuclide concentration has been increased by human processes with the intent that the concentrated radioactive material will be used for its radiological properties.

* * * * *

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

60. The authority citation for part 170 is revised to read as follows:

Authority: Sec. 9701, Pub. L. 97–258, 96 Stat. 1051 (31 U.S.C. 9701); sec. 301, Pub. L. 92–314, 86 Stat. 227 (42 U.S.C. 2201w); sec. 201, Pub. L. 93–438, 88 Stat. 1242, as amended (42 U.S.C. 5841); sec. 205a, Pub. L. 101–576, 104 Stat. 2842, as amended (31 U.S. C. 901, 902); sec. 1704, 112 Stat. 2750 (44 U.S.C. 3504 note); sec. 623, Pub. L. 109–58, 119 Stat. 783 (42 U.S.C. 2201(w)); sec 651(e), Pub. L. 109–58, 119 Stat. 806–810 (42 U.S.C. 2014, 2021, 2021(b), 2111).

61. In § 170.3, the definition of *Byproduct material* is revised to read as follows:

§ 170.3 Definitions.

* * * * *

Byproduct material means—

(1) Any radioactive material (except special nuclear material) yielded in, or made radioactive by, exposure to the radiation incident to the process of producing or using special nuclear material;

(2)(i) Any discrete source of radium-226 that is produced, extracted, or converted after extraction, before, on, or after August 8, 2005, for use for a commercial, medical, or research activity; or

(ii) Any material that—

(A) Has been made radioactive by use of a particle accelerator; and

(B) Is produced, extracted, or converted after extraction, before, on, or after August 8, 2005, for use for a commercial, medical, or research activity; and

(3) Any discrete source of naturally occurring radioactive material, other than source material, that—

(i) The Commission, in consultation with the Administrator of the Environmental Protection Agency, the Secretary of Energy, the Secretary of Homeland Security, and the head of any other appropriate Federal agency, determines would pose a threat similar to the threat posed by a discrete source of radium-226 to the public health and safety or the common defense and security; and

(ii) Before, on, or after August 8, 2005, is extracted or converted after extraction for use in a commercial, medical, or research activity.

* * * * *

62. In § 170.31, in the table, ''Schedule of Materials Fees,'' paragraph 3.B. is revised, and new categories 3.R. and 3.S. and corresponding fees are added to read as follows:

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

* * * * *

SCHEDULE OF MATERIALS FEES

Category of materials licenses and type of fees [1]	Fee [2] [3]
* * * * * * *	
3. Byproduct material:	
* * * * * * *	
B. Other licenses for possession and use of byproduct material issued under part 30 of this chapter for processing or manufacturing of items containing byproduct material for commercial distribution. This category also includes licenses for repair, assembly, and disassembly of products containing radium-226.	
Application	$3,500.
* * * * * * *	
R. Possession of items or products containing radium-226 identified in 10 CFR 31.12 which exceed the number of items or limits specified in that section.[5]	
1. Possession of quantities exceeding the number of items or limits in 10 CFR 31.12(a)(3), (4), or (5) but less than or equal to 10 times the number of items or limits specified.	
Application	$450.
2. Possession of quantities exceeding 10 times the number of items or limits specified in 10 CFR 31.12(a)(3), (4), or (5).	
Application	$1,110.
S. Licenses for production of accelerator-produced radionuclides.	
Application	$4,700.
* * * * * * *	
* * * * * * *	

[1] Types of fees—Separate charges, as shown in the schedule, will be assessed for pre-application consultations and reviews; applications for new licenses, approvals, or license terminations; possession only licenses; issuance of new licenses and approvals; certain amendments and renewals to existing licenses and approvals; safety evaluations of sealed sources and devices; generally licensed device registrations; and certain inspections. The following guidelines apply to these charges:

(a) Application and registration fees. Applications for new materials licenses and export and import licenses; applications to reinstate expired, terminated, or inactive licenses except those subject to fees assessed at full costs; applications filed by Agreement State licensees to register under the general license provisions of 10 CFR 150.20; and applications for amendments to materials licenses that would place the license in a higher fee category or add a new fee category must be accompanied by the prescribed application fee for each category.

(1) Applications for licenses covering more than one fee category of special nuclear material or source material must be accompanied by the prescribed application fee for the highest fee category.

(2) Applications for new licenses that cover both byproduct material and special nuclear material in sealed sources for use in gauging devices will pay the appropriate application fee for fee Category 1C only.

(b) Licensing fees. Fees for reviews of applications for new licenses and for renewals and amendments to existing licenses, for preapplication consultations and for reviews of other documents submitted to NRC for review, and for project manager time for fee categories subject to full cost fees (fee Categories 1A, 1B, 1E, 2A, 4A, 5B, 10A, 11, 12, 13A, and 14) are due upon notification by the Commission in accordance with § 170.12(b).

(c) Amendment fees. Applications for amendments to export and import licenses must be accompanied by the prescribed amendment fee for each license affected. An application for an amendment to a license or approval classified in more than one fee category must be accompanied by the prescribed amendment fee for the category affected by the amendment unless the amendment is applicable to two or more fee categories, in which case the amendment fee for the highest fee category will apply.

(d) Inspection fees. Inspections resulting from investigations conducted by the Office of Investigations and nonroutine inspections that result from third-party allegations are not subject to fees. Inspection fees are due upon notification by the Commission in accordance with § 170.12(c).

(e) Generally licensed device registrations under 10 CFR 31.5. Submittals of registration information must be accompanied by the prescribed fee.

[2] Fees will not be charged for orders related to civil penalties or other civil sanctions issued by the Commission under 10 CFR 2.202 or for amendments resulting specifically from the requirements of these orders. For orders unrelated to civil penalties or other civil sanctions, fees will be charged for any resulting licensee-specific activities not otherwise exempted from fees under this chapter. Fees will be charged for approvals issued under a specific exemption provision of the Commission's regulations under Title 10 of the Code of Federal Regulations (e.g., 10 CFR 30.11, 40.14, 70.14, 73.5, and any other sections in effect now or in the future), regardless of whether the approval is in the form of a license amendment, letter of approval, safety evaluation report, or other form. In addition to the fee shown, an applicant may be assessed an additional fee for sealed source and device evaluations as shown in Categories 9A through 9D.

[3] Full cost fees will be determined based on the professional staff time multiplied by the appropriate professional hourly rate established in § 170.20 in effect at the time the service is provided, and the appropriate contractual support services expended. For applications currently on file for which review costs have reached an applicable fee ceiling established by the June 20, 1984, and July 2, 1990, rules, but are still pending completion of the review, the cost incurred after any applicable ceiling was reached through January 29, 1989, will not be billed to the applicant. Any professional staff-hours expended above those ceilings on or after January 30, 1989, will be assessed at the applicable rates established by § 170.20, as appropriate, except for topical reports whose costs exceed $50,000. Costs which exceed $50,000 for each topical report, amendment, revision, or supplement to a topical report completed or under review from January 30, 1989, through August 8, 1991, will not be billed to the applicant. Any professional hours expended on or after August 9, 1991, will be assessed at the applicable rate established in § 70.20.

* * * * * * * *

[5] Persons who possess radium sources that are used for operational purposes in another fee category are not also subject to the fees in this category. (This exception does not apply if the radium sources are possessed for storage only.)

* * * * * * * *

PART 171—ANNUAL FEES FOR REACTOR LICENSES AND FUEL CYCLE LICENSES AND MATERIALS LICENSES, INCLUDING HOLDERS OF CERTIFICATES OF COMPLIANCE, REGISTRATIONS, AND QUALITY ASSURANCE PROGRAM APPROVALS AND GOVERNMENT AGENCIES LICENSED BY THE NRC

63. The authority citation for part 171 is revised to read as follows:

Authority: Sec. 7601, Pub. L. 99–272, 100 Stat. 146, as amended by sec. 5601, Pub. L. 100–203, 101 Stat. 1330 as amended by sec. 3201, Pub. L. 101–239, 103 Stat. 2132, as amended by sec. 6101, Pub. L. 101–508, 104 Stat. 1388, as amended by sec. 2903a, Pub. L. 102–486, 106 Stat. 3125 (42 U.S.C. 2213, 2214); and as amended by Title IV, Pub. L. 109–103, 119 Stat. 2283 (42 U.S.C. 2214; sec. 301, Pub. L. 92–314, 86 Stat. 227 (42 U.S.C. 2201w); sec. 201, Pub. L. 93–438, 88 Stat. 1242, as amended (42 U.S.C. 5841); sec. 1704, 112 Stat. 2750 (44 U.S.C. 3504 note); sec. 651(e), Pub. L. 109–58, 119 Stat. 806–810 (42 U.S.C. 2014, 2021, 2021(b), 2111).

62. In § 171.5, the definition of *Byproduct material* is revised to read as follows:

§ 171.5 Definitions.

* * * * *

Byproduct material means—

(1) Any radioactive material (except special nuclear material) yielded in, or made radioactive by, exposure to the radiation incident to the process of producing or using special nuclear material;

(2)(i) Any discrete source of radium-226 that is produced, extracted, or converted after extraction, before, on, or after August 8, 2005, for use for a commercial, medical, or research activity; or

(ii) Any material that—

(A) Has been made radioactive by use of a particle accelerator; and

(B) Is produced, extracted, or converted after extraction, before, on, or after August 8, 2005, for use for a commercial, medical, or research activity; and

(3) Any discrete source of naturally occurring radioactive material, other than source material, that—

(i) The Commission, in consultation with the Administrator of the Environmental Protection Agency, the Secretary of Energy, the Secretary of Homeland Security, and the head of any other appropriate Federal agency, determines would pose a threat similar to the threat posed by a discrete source of radium-226 to the public health and safety or the common defense and security; and

(ii) Before, on, or after August 8, 2005, is extracted or converted after extraction for use in a commercial, medical, or research activity.

* * * * *

63. In § 171.16, paragraph (d), in the table, Schedule of Materials Annual Fees and Fees for Government Agencies Licensed by NRC, paragraph 3.B. is revised, and new categories 3.R. and 3.S. and corresponding fees are added to read as follows:

§ 171.16 Annual Fees for Reactor Licenses and Fuel Cycle Licenses and Materials Licenses, Including Holders of Certificates of Compliance, Registrations, and Quality Assurance Program Approvals and Government Agencies Licensed by the NRC.

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SCHEDULE OF MATERIALS ANNUAL FEES AND FEES FOR GOVERNMENT AGENCIES LICENSED BY NRC

Category of materials licenses	Annual fees[1 2 3]
* * * * * * *	
3. Byproduct material:	
* * * * * * *	
B. Other licenses for possession and use of byproduct material issued under part 30 of this chapter for processing or manufacturing of items containing byproduct material for commercial distribution. This category also includes licenses for repair, assembly, and disassembly of products containing radium-226	
Application	8,200
* * * * * * *	
R. Possession of items or products containing radium-226 identified in 10 CFR 31.12 which exceed the number of items or limits specified in that section.[14]	
1. Possession of quantities exceeding the number of items or limits in 10 CFR 31.12(a)(3), (4), or (5) but less than or equal to 10 times the number of items or limits specified	1,600
2. Possession of quantities exceeding 10 times the number of items or limits specified in 10 CFR 31.12(a)(3), (4), or (5)	2,500
S. Licenses for production of accelerator-produced radionuclides	10,200
* * * * * * *	

* * * * * * *

[1] Annual fees will be assessed based on whether a licensee held a valid license with the NRC authorizing possession and use of radioactive material during the current fiscal year. However, the annual fee is waived for those materials licenses and holders of certificates, registrations, and approvals who either filed for termination of their licenses or approvals or filed for possession only/storage licenses before October 1, 2004, and permanently ceased licensed activities entirely by September 30, 2004. Annual fees for licensees who filed for termination of a license, downgrade of a license, or for a possession only license during the fiscal year and for new licenses issued during the fiscal year will be prorated in accordance with the provisions of § 171.17. If a person holds more than one license, certificate, registration, or approval, the annual fee(s) will be assessed for each license, certificate, registration, or approval held by that person. For licenses that authorize more than one activity on a single license (e.g., human use and irradiator activities), annual fees will be assessed for each category applicable to the license. Licensees paying annual fees under Category 1A(1) are not subject to the annual fees for Category 1C and 1D for sealed sources authorized in the license.

[2] Payment of the prescribed annual fee does not automatically renew the license, certificate, registration, or approval for which the fee is paid. Renewal applications must be filed in accordance with the requirements of parts 30, 40, 70, 71, 72, or 76 of this chapter.

[3] Each fiscal year, fees for these materials licenses will be calculated and assessed in accordance with § 171.13 and will be published in the Federal Register for notice and comment.

* * * * * * *

[14] Persons who possess radium sources that are used for operational purposes in another fee category are not also subject to the fees in this category. (This exception does not apply if the radium sources are possessed for storage only.)

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Dated at Rockville, Maryland, this 20th day of July, 2006.

For the Nuclear Regulatory Commission.

Annette L. Vietti-Cook,

Secretary for the Commission.

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