DECOMMISSIONING FINANCIAL ASSURANCE REQUIREMENTS FOR SEALED AND UNSEALED RADIOACTIVE MATERIALS

Regulatory Basis
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Abbreviations and Acronyms

ACMUI	Advisory Committee on the Medical Uses of Isotopes
ADAMS	Agencywide Documents Access and Management System
AEA	Atomic Energy Act of 1954, as amended
Bq	becquerel
CFR	*Code of Federal Regulations*
CRCPD	Conference of Radiation Control Program Directors, Inc.
DFA	decommissioning financial assurance
DFP	decommissioning funding plan
EPAct	Energy Policy Act of 2005
FR	*Federal Register*
Ga	gallium
Ge	germanium
ICRP	International Commission on Radiological Protection
µCi	microcurie
mCi	millicurie
NARM	naturally occurring and accelerator-produced radioactive material
NPV	net present value
NRC	U.S. Nuclear Regulatory Commission
OAS	Organization of Agreement States
PERT	program evaluation and review technique
PRM	petition for rulemaking
Pu	plutonium
SECY	Office of the Secretary of the Commission
SRM	staff requirements memorandum

SSR	Suggested State Regulations for Control of Radiation
U	uranium
WBL	Web-Based Licensing

Definition of Terms (as Used in this Document)

Applicant
Any person, including a current licensee, who submits an application for a license or license amendment to the U.S. Nuclear Regulatory Commission (NRC) or an Agreement State for the use of byproduct material.

Decommission
To remove a facility or site safely from service and reduce residual radioactivity to a level that permits (1) release of the property for unrestricted use and termination of the license or (2) release of the property under restricted conditions and termination of the license (see Title 10 of the *Code of Federal Regulations* (10 CFR) 30.4, “Definitions”).

Decommissioning Funding Plan
A document that contains a site-specific cost estimate for decommissioning, describes the method for assuring funds for decommissioning, describes the means for adjusting both the cost estimate and funding level over the life of the facility, and contains the certification of financial assurance and the signed originals of the financial instruments provided as financial assurance (see 10 CFR 30.35(e)).

Person
Any individual, corporation, partnership, firm, association, trust, estate, public or private institution, group, Government agency other than the Commission or the U.S. Department of Energy, except that the Department shall be considered a person within the meaning of the regulations in this part to the extent that its facilities and activities are subject to the licensing and related regulatory authority of the Commission pursuant to Section 202 of the Energy Reorganization Act of 1974 (88 Stat. 1244), any State or any political subdivision of or any political entity within a State, any foreign government or nation or any political subdivision of any such government or nation, or other entity; and any legal successor, representative, agent, or agency of the foregoing (see 10 CFR 30.4).

Units Conversion Table

Multiply	By	To Obtain
English/Metric Equivalents		
millicurie (mCi)	3.7×10^{7}	becquerel (Bq)
microcurie (μCi)	3.7×10^{4}	becquerel (Bq)
Metric/English Equivalents		
becquerel (Bq)	2.7×10^{-8}	millicurie (mCi)
becquerel (Bq)	2.7×10^{-5}	microcurie (μCi)

Executive Summary

The U.S. Nuclear Regulatory Commission (NRC) is considering revising the table in Appendix B, "Quantities of Licensed Material Requiring Labeling," to Title 10 of the *Code of Federal Regulation*s (10 CFR) Part 30, "Rules of General Applicability to Domestic Licensing of Byproduct Material." The rulemaking would base the NRC's decommissioning funding requirements for radioactive material on the relative risk to public health and safety from different radioisotopes, including naturally occurring and accelerator-produced radioactive material (NARM). The NRC is taking this action in response to a petition for rulemaking (PRM) submitted by the Organization of Agreement States (OAS) on April 14, 2017 (PRM-30-66, "Request of the Organization of Agreement States for the NRC to Amend Appendix B, 'Quantities of Licensed Material Requiring Labeling,' Supersedes ML17123A233" (Agencywide Documents Access and Management System (ADAMS) Accession No. ML17173A063)). In its petition, the OAS requested that the NRC provide specific possession values for NARM radionuclides not currently listed in Appendix B to 10 CFR Part 30, so that licensees using these radionuclides would not have to apply the default values to calculate decommissioning funding requirements or submit an exemption request. Licensees use Appendix B in conjunction with 10 CFR 30.35, "Financial assurance and recordkeeping for decommissioning," and 10 CFR 70.25, "Financial assurance and recordkeeping for decommissioning," to determine the amount of decommissioning financial assurance (DFA) that is needed or whether a decommissioning funding plan is required. If the appendix does not include a particular radionuclide, licensees must use default values that may result in licensees needing more DFA than is warranted based on the risk to public health and safety.

The Commission approved initiation of this rulemaking in the staff requirements memorandum SRM-SECY-19-0125, "Staff Requirements—SECY-19-0125—Petition for Rulemaking and Rulemaking Plan on Decommissioning Financial Assurance Requirements for Sealed and Unsealed Radioactive Material (PRM-30-66; NRC-2017-0159)," dated October 13, 2020 (ADAMS Accession No. ML20287A248). The next step in the NRC's rulemaking process is the development of a regulatory basis that serves as a precursor to the proposed rule. This regulatory basis document summarizes the current regulatory framework, describes the regulatory issues, and evaluates alternatives for revising Appendix B. The regulatory basis also includes cost estimates for the NRC, Agreement States, and industry (i.e., licensees) for each alternative.

The NRC staff is recommending that the agency conduct a rulemaking as described in Alternative 2 of this regulatory basis. Under Alternative 2, the NRC would update Appendix B to 10 CFR Part 30 using the list of radionuclides and possession values from Appendix C, "Quantities of Licensed Material Requiring Labeling," to 10 CFR Part 20, "Standards for Protection Against Radiation." Additionally, the NRC would revise Appendix B to 10 CFR Part 30 to clarify that only radioactive materials with half-lives greater than 120 days are subject to DFA. Finally, the NRC would change the title of Appendix B to reflect its use in determining DFA requirements.

Alternative 2 would provide the fastest regulatory relief to stakeholders that have requested rulemaking and would offer an expeditious solution to the DFA concerns for licensees that currently use or plan to use the unlisted NARM radionuclides, especially in the diagnosis and treatment of diseases. For example, the currently unlisted gallium-68 (Ga-68) radionuclide is vitally important in the early detection and treatment of liver and pancreatic cancers; these types of cancers are hard to diagnose and metastasize quickly through the body. In addition, this

radioactive material provides an effective dose to patients that is significantly lower than that from other radiopharmaceuticals. Thus, at this stage, the staff holds that the qualitative benefits from conducting a rulemaking under Alternative 2 would justify the potential cost impacts to licensees, Agreement States, and the NRC. Alternative 2 would result in projected costs totaling $6.5 million using a 7-percent discount factor and an averted cost of $15 million using the least costly alternative that accomplishes the Commission's directions. Table ES-1 provides the different alternatives with their respective costs. The staff will prepare a regulatory analysis of the qualitative and quantitative costs and benefits that considers public comments received on this regulatory basis for the proposed rule, consistent with NUREG/BR-0058, "Regulatory Analysis Guidelines of the U.S. Nuclear Regulatory Commission."

Table ES-1: Summary Table of Alternatives and Benefits (Costs)

DESCRIPTION	Net Benefits (Costs) in 2021 Dollars		
	Undiscounted	7% NPV	3% NPV
Alternative 1—Status Quo (No Action Taken)	$0	$0	$0
Alternative 2—Update the List of Radionuclides and the Values in the Table in Appendix B to 10 CFR Part 30 (NRC selected)			
NRC Implementation	($518,000)	($468,000)	($495,000)
Alternative 2 NRC	($170,000)	($130,000)	($151,000)
Alternative 2 NRC Averted Cost	$2,115,880	$2,075,601	$2,096,936
Alternative 2 Industry	($4,995,000)	($3,810,000)	($4,438,000)
Alternative 2 Industry Averted Cost	$15,146,546	$13,962,315	$14,589,590
Alternative 2 Agreement States	($2,710,000)	($2,049,000)	($2,398,000)
Alternative 2 Agreement States Averted Cost	$15,775,884	$15,115,132	$15,464,247
Alternative 2 Total Net Benefits (Cost)	$24,645,904	$24,696,030	$24,668,716
Alternative 3—Partially Update Appendix B to 10 CFR Part 30 (Add unlisted NARM radionuclides and other radionuclides not currently listed to the existing table in Appendix B to 10 CFR Part 30)			
NRC Implementation	($518,000)	($468,000)	($495,000)
Alternative 3 NRC	($170,000)	($130,000)	($152,000)
Alternative 3 Industry	($4,995,000)	($3,810,000)	($4,438,000)
Alternative 3 Agreement States	($2,710,000)	($2,049,000)	($2,398,000)
Alternative 3 Total Net Benefits (Cost)	($8,392,000)	($6,457,000)	($7,482,000)
Alternative 4—Develop a New Process for Assessing Decommissioning Funding Costs			
NRC Implementation	($518,000)	($468,000)	($495,000)
Alternative 4 NRC	($222,000)	($169,000)	($197,000)
Alternative 4 Industry	($4,995,000)	($3,810,000)	($4,438,000)
Alternative 4 Agreement States	($2,984,000)	($2,249,000)	($2,637,000)
Alternative 4 Total Net Benefits (Cost)	($8,718,000)	($6,697,000)	($7,767,000)

Alternative 5—Update Appendix B to 10 CFR Part 30 and Develop a New Process for Assessing Decommissioning Funding Costs (Combines Alternative 2 and Alternative 4 - Two rulemakings)			
NRC Implementation	($1,088,000)	($861,000)	($979,000)
Alternative 5 NRC	($392,000)	($259,000)	($326,000)
Alternative 5 Industry	($9,989,000)	($6,717,000)	($8,380,000)
Alternative 5 Agreement States	($5,694,000)	($3,765,000)	($4,741,000)
Alternative 5 Total Net Benefits (Cost)	($17,163,000)	($11,601,000)	($14,427,000)

*Values rounded to the nearest thousand. There may be differences among the tables due to rounding.
*Values in parenthesis, e.g., “()” denote a cost of negative value.

1. Introduction

The U.S. Nuclear Regulatory Commission (NRC) established regulations in Title 10 of the *Code of Federal Regulations* (10 CFR) Part 30, "Rules of General Applicability to Domestic Licensing of Byproduct Material," and 10 CFR Part 70, "Domestic Licensing of Special Nuclear Material," that set forth the technical and financial criteria for decommissioning licensed nuclear materials facilities that use sealed and unsealed radioactive materials. In 10 CFR 30.4, "Definitions," the NRC defines decommissioning as the process whereby a facility or site is safely removed from service and residual radioactivity is reduced to a level that permits (1) release of the property for unrestricted use and termination of the license or (2) release of the property under restricted conditions and termination of the license. Decommissioning activities are initiated when any one of the following events occurs:

- The license expires.
- The licensee has decided to permanently cease operations at the entire site or in any separate building or outdoor area that contains residual radioactivity, such that the building or outdoor area is unsuitable for release in accordance with NRC requirements.
- No principal activities have been conducted at the site for a period of 24 months.
- No principal activities have been conducted for a period of 24 months in any separate building or outdoor area that contains residual radioactivity, such that the building or outdoor area is unsuitable for release in accordance with NRC requirements.

Financial assurance is a guarantee or other financial arrangement provided by a licensee to ensure that funds are available for decommissioning when needed (see NUREG-1757, Volume 3, Revision 1, "Consolidated Decommissioning Guidance: Financial Assurance, Recordkeeping, and Timeliness, Final Report," issued February 2012). Thus, the NRC uses decommissioning financial assurance (DFA) requirements to ensure that the decommissioning of licensed nuclear facilities is performed in a safe and timely manner, and to ensure that adequate funds are available to complete decommissioning. The NRC's overall objective with respect to decommissioning is to protect public health and safety and the environment from the use of radioactive materials under its regulatory authority.

To determine the amount of DFA for a given radionuclide with a half-life greater than 120 days, one must multiply the possession value for the radionuclide in 10 CFR Part 30, Appendix B, "Quantities of Licensed Material Requiring Labeling," by 1×10^{5} for unsealed radioactive material in 10 CFR 30.35, "Financial assurance and recordkeeping for decommissioning," and 10 CFR 70.25, "Financial assurance and recordkeeping for decommissioning." In addition, 10 CFR 30.35 provides that for sealed sources, the possession value in Appendix B is multiplied by 1×10^{12}. The regulations in 10 CFR 30.35(a) and 10 CFR 70.25(a) require a license-specific decommissioning funding plan (DFP) to possess a quantity of radionuclides greater than that shown in the corresponding tables in 10 CFR 30.35(d) and 10 CFR 70.25(d). These tables require specific amounts of funding for specified ranges in the quantity of the radionuclide possessed. The funding amounts and quantity ranges in both tables are identical, but 10 CFR 30.35 applies to byproduct material while 10 CFR 70.25 applies to special nuclear material.

The NRC originally established the values in Appendix B to make the possession thresholds match for both licensing and labeling. The labeling values were initially issued in 1963 in Appendix C, "Quantities of Licensed Material Requiring Labeling," to 10 CFR Part 20, "Standards for Protection Against Radiation," and were redesignated in 1993 for decommissioning funding purposes as Appendix B to 10 CFR Part 30 (58 FR 67659, December 22, 1993). Appendix B also includes possession values for radionuclides not specifically listed, which are known as "default" possession values. The default values are set to equal the lowest values of the listed isotopes: 0.01 microcurie (μCi) for alpha emitters like radium-226, and 0.1 μCi for the most restricted nonalpha-emitting isotopes (e.g., iodine-129, strontium-90 or lead-210). As a result, licensees using unlisted radionuclides may be subject to more restrictive DFA requirements regardless of the risk-significance of those radionuclides to public health and safety.

On April 14, 2017, the Organization of Agreement States (OAS) submitted a petition for rulemaking (PRM) to the NRC (PRM-30-66, "Request of the Organization of Agreement States for the NRC to Amend Appendix B, 'Quantities of Licensed Material Requiring Labeling,' Supersedes ML17123A233," ADAMS Accession No. ML17173A063))." In its petition, the OAS requested that the NRC provide specific possession values for naturally occurring and accelerator-produced radioactive material (NARM) radionuclides not currently listed in Appendix B to 10 CFR Part 30 so that licensees using these isotopes would not have to apply the appendix's default values to calculate decommissioning funding requirements.

In SECY-19-0125, "Petition for Rulemaking and Rulemaking Plan on Decommissioning Financial Assurance Requirements for Sealed and Unsealed Radioactive Material (PRM-30-66; NRC-2017-0159)," dated December 17, 2019 (ADAMS Accession No. ML18292A479), the staff sought Commission approval to initiate rulemaking in response to the OAS petition. The Commission approved the initiation of rulemaking in Staff Requirements Memorandum (SRM)-SECY-19-0125, "Staff Requirements—SECY-19-0125—Petition for Rulemaking and Rulemaking Plan on Decommissioning Financial Assurance Requirements for Sealed and Unsealed Radioactive Material (PRM-30-66; NRC-2017-0159)," dated October 13, 2020 (ADAMS Accession No. ML20287A248).

Consistent with the Commission's direction in SRM-SECY-19-0125 and the NRC's rulemaking process, the staff has prepared this regulatory basis, which does the following:

- provides background information on policies, laws, and regulations relative to the issue
- explains how a change in the regulations could resolve the issue
- identifies different approaches that could address the regulatory issue and evaluates the cost and benefits of rulemaking and the alternatives
- provides the scientific, policy, legal, and technical information used to support the evaluation
- explains limitations on the scope and quality of the regulatory basis, such as known uncertainties in the data or methods of analysis
- discusses stakeholder interactions in developing the technical portion of the regulatory basis and stakeholder views, to the extent known

The purpose of this rulemaking is to (1) improve the regulatory framework for NARM by amending Appendix B to 10 CFR Part 30 to align with the NRC's regulatory authority under the Energy Policy Act of 2005 (EPAct) by adding these unlisted radionuclides, (2) risk-inform the NRC's decommissioning funding requirements by aligning the values in Appendix B with the NRC's radiation protection regulations in 10 CFR Part 20, (3) clarify that only radioactive materials with half-lives greater than 120 days are subject to DFA, and (4) clarify the purpose of Appendix B by changing its title. Specific to item 3, the NRC is proposing to update Appendix B to 10 CFR Part 30 using the list of radionuclides and possession values in Appendix C to 10 CFR Part 20.

2. Background and Existing Regulatory Framework

This section briefly discusses the background and existing regulatory framework relative to the DFA requirements for sealed and unsealed radioactive material. Specifically, this section discusses the statutes, regulations, and Commission policies that are relevant to development of this regulatory basis related to DFA requirements.

2.1 Relevant NARM Statutes and Regulations

2.1.1 The Energy Policy Act of 2005

On August 8, 2005, the President signed into law the Energy Policy Act of 2005 (EPAct). Section 651(e) of the EPAct expanded the definition of byproduct material given in Section 11e of the Atomic Energy Act of 1954 (AEA). The expanded definition placed 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 to include any discrete source of radium-226 that is produced for a commercial, medical, or research activity, and any naturally radioactive material other than source material, that the Commission in consultation with the Administrator of the Environmental Protection Agency, the Secretary of the Department of Energy and the Secretary of the Department of Homeland Security and the head of any other appropriate Federal agencies, determines would pose a threat similar to the threat posed by radium-226 to the public health and safety or common defense and security; and is extracted or converted after extraction before, on, or after August 8, 2005 and accelerator-produced radioactive material. This new category of byproduct material is referred to as NARM.

2.1.2 The NARM Rule

On October 1, 2007, the NRC published in the *Federal Registe*r the "Final Rule: Requirements for Expanded Definition of Byproduct Material" (72 FR 55863), which is commonly referred to as the NARM Rule. The purpose of the final rule was to implement the authority that the NRC obtained over NARM through the EPAct. Before enactment of that law, the NRC did not regulate NARM. However, the NRC's definition of occupational dose in 10 CFR Part 20 did include dose contributions from both licensed and nonlicensed radioactive material such as NARM. In addition, the NRC required licensees to consider nondiscrete sources, including radium, during decommissioning activities at sites such as rare-earth processing facilities that were contaminated with source material.

Before the EPAct, Agreement States and some non-Agreement States had regulatory programs for NARM. The law mandated that the NRC use model State standards to the maximum extent

practicable. Thus, the NRC considered the SSRs published by Conference of Radiation Control Program Directors, Inc., (CRCPD)[1] as the model State standard in developing the rule and ensured that all of the NARM radionuclide-specific values were listed in Appendix B to 10 CFR Part 20, "Annual Limits on Intake (ALIs) and Derived Air Concentrations (DACs) of Radionuclides for Occupational Exposure; Effluent Concentrations; Concentrations for Release to Sewerage," and Appendix C to 10 CFR Part 20. However, the NRC did not amend Appendix B to 10 CFR Part 30, which is used in DFA determinations, to include NARM radionuclides.

2.2 NRC Decommissioning Financial Assurance Regulations

2.2.1 Final Rule of 1988

On June 27, 1988, the NRC published in the *Federal Register* its first comprehensive set of regulations addressing the decommissioning of nuclear facilities, "Final Rule: General Requirements for Decommissioning Nuclear Facilities" (53 FR 24018). These regulations were the result of a thorough review over multiple years of issues associated with the decommissioning of nuclear facilities as described in numerous SECY papers and SRMs, contractor reports, *Federal Register* notices, a generic environmental impact statement, public meetings, and comment analysis.[2] The purpose of the rule was to assure that, at the time operations were terminated (including premature closure of nuclear facilities), adequate funds would be available to complete decommissioning in a safe and timely manner. The regulations addressed decommissioning planning needs, timing, funding methods, and environmental review requirements. With regard to DFA for sealed and unsealed radioactive material, the new 10 CFR 30.35 required licensees that possessed and used byproduct material with a half-life greater than 120 days to use the quantities in Appendix C to 10 CFR Part 20[3] to determine whether a DFP was needed. The regulation in 10 CFR 70.25 required licensees that possessed and used unsealed special nuclear material to refer to the quantities in Appendix C to determine whether a DFP was needed.

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[1] The CRCPD is a nonprofit, nongovernmental professional organization dedicated to radiation protection. The CRCPD's mission is to promote consistency in addressing and resolving radiation protection issues, to encourage high standards of quality in radiation protection programs, and to provide leadership in radiation safety and education. As part of this mission, CRCPD compiles the SSRCRs in a dynamic document that is revised and updated on an ongoing basis. The SSRCRs consist of a number of parts that relate to various aspects of radiation regulation.

[2] These documents include (1) January 10, 1978, SECY-78-13, "Recommendations on Course of Action for Establishing Nuclear Facility Decommissioning Requirements" (ADAMS Accession No. ML22063A141); (2) January 31, 1978, SECY-78-13A, "Supplemental Information to SECY-78-13 'Recommendations on Course of Action for Establishing Nuclear Facility Decommissioning Requirements,'" (ADAMS Accession No. ML21252A614); (3) February 17, 1978, SRM-78-13, "Recommendations on Course of Action for Establishing Nuclear Facility Decommissioning Requirements," (ADAMS Accession No. ML22063A473); (4) March 13, 1978, "Advance Notice of Rulemaking for Decommissioning Criteria for Nuclear Facilities" (43 FR 10370); (5) June 22, 1979, "Response to and Partial Denial of Petition for Rulemaking Filed by the Public Interest Research Group, et al. (Docket No. PRM-50-22)," (44 FR 36523) which requested the Commission initiate rulemaking to promulgate regulations for nuclear power plant decommissioning; (6) May 5, 1980, "Proposed Rule: 'Decommissioning of Nuclear Facilities Regulation (10 CFR Parts 30, 40, 50, and 70)'" (45 FR 37011); (7) February 10,1981, "Decommissioning Criteria for Nuclear Facilities: Notice of Availability of Draft Generic Environment Impact Statement" (10 CFR Parts 30, 40, 50, and 70) (46 FR 11666); and (8) February 11, 1985, "Proposed Rule: "Decommissioning Criteria for Nuclear Facilities" (10 CFR Parts 30, 40, 50, 51, 70, and 72) (50 FR 5600).

[3] The NRC redesigned Appendix C to 10 CFR Part 20 as Appendix B to 10 CFR Part 30 as part of the December 22, 1993, amendment of the NRC's regulation, which is discussed in Section 2.2.2.1 of this regulatory basis.

2.2.2 Amendments of Interest

The NRC's decommissioning requirements relative to sealed and unsealed radioactive material have undergone at least 12 amendments since their initial adoption in 1988. The discussion in this regulatory basis focuses on those revisions that pertain to the current rulemaking.

2.2.2.1 Amendments to 10 CFR Part 20

On May 21, 1991, the NRC published the "Final Rule: Standards for Protection Against Radiation" (56 FR 23360). The purpose of the rule was to modify the NRC's primary radiation protection regulations in 10 CFR Part 20 to reflect scientific developments since their issuance in 1957 (22 FR 548; January 29, 1957) by the Atomic Energy Commission (the NRC's predecessor agency) and subsequent amendments in the 1960s and 1970s (25 FR 8595, September 7, 1960; 25 FR 10914, November 17, 1960; and 35 FR 6425, April 22, 1970). These earlier versions of 10 CFR Part 20 were based upon the recommendations of the National Committee on Radiation Protection and Measurements in National Bureau of Standards Handbook 52, "Maximum Permissible Amounts of Radioisotopes in the Human Body and Maximum Permissible Concentrations in Air and Water," dated March 20, 1953, and Handbook 59, "Permissible Dose from External Sources of Ionizing Radiation," dated January 8, 1957, that were incorporated into International Commission on Radiological Protection (ICRP) Publication 2, "Report of Committee II on Permissible Dose for Internal Radiation (1959)," issued 1960. After years of research into the biological effects of ionizing radiation, it was determined that some of the early concepts of radiation protection created over-conservativeness in the regulation of radioactive material. The 1991 amendments to 10 CFR Part 20 adopted the updated and more risk-informed basic tenets of radiation protection in ICRP Publication 26, "Recommendations of the International Commission on Radiological Protection," adopted January 17, 1977, and ICRP Publication 30, "Limits for Intakes of Radionuclides by Workers," issued 1979–1988.[4]

The 1991 amendments revised the values in Appendix C to 10 CFR Part 20. The revised appendix lists µCi quantities for 757 radionuclides. However, with regard to DFA requirements for sealed and unsealed radioactive materials, the final rule amended 10 CFR 30.35 and 10 CFR 70.25 as follows:

> … paragraph (a) is amended by revising the references to "appendix C to 10 CFR part 20" and "appendix C" to read "appendix C to §§ 20.1–20.601 of 10 CFR part 20"; paragraph (d) is amended by revising the three references to "appendix C of the part 20" to read "appendix C to §§ 20.1–20.601 of 10 CFR part 20"; and by adding a note at the end of the section to read as follows:

[4] ICRP Publication 30 was published in four parts and several supplements. These publications are: (1) "ICRP, 1979. Limits for Intakes of Radionuclides by Workers. ICRP Publication 30 (Part 1). Ann. ICRP 2 (3-4)"; (2) "ICRP, 1979. Limits for Intakes of Radionuclides by Workers. ICRP Publication 30 (Supplement to Part 1). Ann. ICRP 3 (1-4)"; (2) "ICRP, 1980. Limits for Intakes of Radionuclides by Workers. ICRP Publication 30 (Part 2). Ann. ICRP 4 (3-4)"; (3) "ICRP, 1981. Limits for Intakes of Radionuclides by Workers. ICRP Publication 30 (Part 3). Ann. ICRP 6 (2-3)"; (4) "ICRP, 1982. Limits for Intakes of Radionuclides by Workers. ICRP Publication 30 (Supplement B to Part 3). Ann. ICRP 8 (1-3)"; (5) "ICRP, 1982. Limits for Intakes of Radionuclides by Workers. ICRP Publication 30 (Index). Ann. ICRP 8 (4)"; and (6) "ICRP, 1988. Limits for Intakes of Radionuclides by Workers: An Addendum. ICRP Publication 30 (Part 4). Ann. ICRP 19 (4)." These publications are referenced collectively in the condensed reference formats as "ICRP Publication 30 (1988)" in this document.

> … Note: Appendix C of §§ 20.1–20.601 of 10 CFR part 20 applies for the purpose of estimating decommissioning costs regardless of whether the licensee adopts 10 CFR 20.1001–20.2401 or continues to use 10 CFR 20.1–20.601.

As a result, the values in Appendix C to 10 CFR 20.1–20.601 continued to be based upon biokinetic models described in ICRP Publication 2 (1959). The NRC's proposed, "Standards for Protection Against Radiation" (50 FR 51992, December 20, 1985, and 51 FR 1092, January 9, 1986) indicated in the statements of consideration that the NRC determined that it was not necessary to conform the values in Appendix C to 10 CFR 20.1–20.601 that were used for decommissioning cost determinations with the revised values in Appendix C to 10 CFR 20.1001-20.2401.

2.2.2.2 Origin and Basis of Appendix B to 10 CFR Part 30

On December 22, 1993, the NRC published a final rule, "Standards for Protection Against Radiation; Removal of Expired Material." The rule made a number of minor conforming amendments to the NRC's standards for protection against radiation that were published on May 21, 1991 (56 FR 23360). It removed the text of the superseded standards and conformed references in the new 10 CFR Part 20. With regard to DFA, the NRC redesignated Appendix C to 10 CFR 20.1–20.601 as Appendix B to 10 CFR Part 30. In turn, it revised 10 CFR 30.35 and 10 CFR 70.25 to eliminate references to "Appendix C to 10 CFR Part 20" and to insert references to "Appendix B to 10 CFR Part 30."

As a result, the Appendix B to Part 30 values continued to be based upon ICRP Publication 2. The NRC decided not to conform the Appendix B values to ICRP Publications 26 and 30 during the 1991 revision of 10 CFR Part 20. The NRC had determined that its experience with the values in Appendix C to 10 CFR Part 20 over 30 years had shown that the values were generally adequate to determine the level of funding assurance required for decommissioning and, therefore, retained them.

2.2.2.3 Origin and Basis of the 120-Day Half-Life Criterion

In the February 11, 1985, in its proposed rule, "Decommissioning Criteria for Nuclear Facilities" (50 FR 5600), the NRC indicated that funding plans would be required for licensees authorized to use sealed and unsealed byproduct material with a half-life greater than 120 days. Commenters on the proposed rule supported this criterion. For example, Mallinckrodt, Inc., which is one of the largest manufacturers of radiopharmaceuticals in the United States, referred to this criterion as a "prudent decision" that would provide "safe and timely decommissioning of byproduct material facilities." The Agreement State of Rhode Island noted that "medical licensees would be largely unaffected [by the addition of DFP requirements] because they generally do not utilize unsealed byproduct material containing radionuclides with a half-life greater than 120 days" (see NUREG-1221, "Summary, Analysis, and Response to Public Comments on Proposed Amendments to 10 CFR Parts 30, 40, 50, 51, 70, and 72, Decommissioning Criteria for Nuclear Facilities," issued June 1988 (ADAMS Accession No. ML18073A149)).

The statements of consideration for the proposed rule did not provide a specific rationale for the 120-day threshold. Rather, the section entitled "Mechanisms for Requiring Financial Assurance," stated, "The amounts (of financial assurance) for materials licensees were chosen based primarily on data in NUREG/CR-1754 and on licensing experience." The data in NUREG/CR-1754, "Technology, Safety and Costs of Decommissioning Reference Non-Fuel-Cycle Nuclear Facilities," issued February 1981(ADAMS Accession No. ML20008E869), indicated that if a licensee is limited to the use of very short-lived radionuclides, then its facilities do not require a major decommissioning effort.

The greater than 120-day half-life criterion is consistent with the agency's regulation of low-level waste disposal through onsite decay-in-storage. The NRC previously had two decay-in-storage license conditions: one was for medical licensees and the other for nonmedical licensees. Both license conditions authorized decay-in-storage for waste containing radioactive material with half-lives less than or equal to 120 days, provided that the radioactive material was held for a minimum of 10 half-lives and additional conditions were met.[5]

Thus, the statements of consideration for the proposed rule, the data in NUREG/CR-1754, and the NRC's licensing experience with decay-in-storage support the 120-day half-life criterion for DFA for byproduct material. The data in NUREG/CR-1754 and the NRC's licensing experience indicate that (1) radioactive materials with very short half-lives do not require a major decommissioning effort, and (2) radioactive materials with half-lives less than or equal to 120 days will completely decay in a few years.

2.2.2.4 10 CFR Part 70 Licensees

The NRC describes financial assurance for licensees possessing special nuclear material in 10 CFR 70.25. Special nuclear material generally means plutonium, uranium(U)-233, uranium enriched in the isotope 233 or in the isotope 235, or any other material the Commission determines to be special nuclear material, but it does not include source material. A table of amounts of financial assurance for decommissioning by quantity of material appears in 10 CFR 70.25(d). This table refers to "applicable quantities of appendix B to part 30" but does not limit consideration to radionuclides of special nuclear material with a half-life greater than 120 days. The only special nuclear material radionuclides contained in the current Appendix B to 10 CFR Part 30 are plutonium (Pu)-239, uranium (natural), uranium-233, and uranium-234--uranium-235.

2.3 The Existing Regulatory Framework

Either the NRC or an Agreement State regulates the Nation's use of radioactive materials, including by applying the requirements for DFA. The following sections describe these regulatory processes for determining the need for a DFP, the basis for establishing the decommissioning funding level, and the role of the Agreement States in the process.

[5] See the NRC letter dated June 4, 1981, to all of its medical and academic licensees on decay-in-storage before disposal (ADAMS Accession No. ML20136E300), and Appendix E to NUREG-1556, Volume 20, "Consolidated Guidance About Materials Licenses: Guidance About Administrative Licensing Procedures, Final Report," issued December 2000 (ADAMS Accession No. ML010250252). For additional information on NRC's decay-in-storage rulemakings, see the discussions at 10 CFR Part 35.92 in 51 FR 36951 and 67 FR 20299.

2.3.1 NRC Regulatory Program

As stated in Section 1, the NRC's regulations in 10 CFR 30.35 and Appendix B to 10 CFR Part 30 are used together to determine the amount of DFA required for unsealed and sealed byproduct material. The regulations in 10 CFR 70.25 and Appendix B to 10 CFR Part 30 are used together to determine the amount of DFA required for unsealed special nuclear material. As noted in 10 CFR 30.35(a)(1) and 10 CFR 70.25(a)(2), DFPs must be submitted when radionuclide concentrations exceed 1×10^{5} times the applicable quantities listed in the table in Appendix B to 10 CFR Part 30. Individuals with licenses authorizing the possession and use of sealed sources or plated foils at quantities 1×10^{12} times the values in the table in Appendix B to 10 CFR Part 30 must also submit DFPs. The NRC gives additional details about these criteria in 10 CFR 30.35(d) and 10 CFR 70.25(d).

The table in Appendix B to 10 CFR Part 30 includes default possession values for radionuclides not specifically listed. The default possession values are equal to the lowest values listed in Appendix B for specific alpha-emitting and gamma- and beta-emitting radionuclides.

2.3.2 Agreement State Regulatory Program

Section 274 of the AEA authorizes the NRC to enter into agreements with individual States, known as Agreement States, providing them the authority and responsibility for administering a regulatory program for the safe use of radioactive materials within their borders. For the duration of such agreements, the Agreement States have the authority to regulate the materials covered by the agreement for the protection of public health and safety and the environment from radiation hazards. The Agreement States are required to adopt regulations in accordance with the compatibility category designation assigned to each NRC regulation, as discussed in NRC Management Directive 5.9, "Adequacy and Compatibility of Program Elements for Agreement State Programs," dated April 26, 2018 (ADAMS Accession No. ML18081A070). Appendix B to 10 CFR Part 30 is designated as Compatibility Category B, which means that the Agreement States will be required to adopt requirements that are essentially identical to those in the NRC's regulations, including the requirements for DFA for sealed and unsealed radioactive material. Other provisions, 10 CFR 30.35(a), (b), (e), and (g), relating to decommissioning funding are classified and Category Health & Safety (H&S). Category H&S are not required for purposes of compatibility. However, the State must adopt program elements in this category, that embody the basic H&S aspects of the NRC's program elements. These sections are not planned to be revised as a part of this rulemaking.

2.4 Requests for Revisions to the NRC's Regulations

2.4.1 NRC Advisory Committee on the Medical Uses of Isotopes

Many of the unlisted radionuclides are used in the diagnosis and treatment of diseases. The unlisted radionuclides germanium (Ge)-68/gallium (Ga)-68 are of particular concern to those in the medical field. Radiopharmaceuticals labeled with Ga-68 have been proven to be effective in the

early diagnosis and treatment of neuroendocrine tumors, including cancers of the prostate, liver, and pancreas. These types of cancers are difficult to diagnose and can spread through the body quickly. As a result, Ge-68/Ga-68 generators[6] are vitally important in the early detection and treatment of these types of cancers. In addition to their enhanced diagnostic capabilities, Ga-68-labeled radiopharmaceuticals provide a lower effective dose to patients when compared to other radiopharmaceuticals. They also are less expensive and more accessible when compared to other diagnostic tools and therapies used in cancer treatment.

Because of the importance of Ge-68/Ga-68 generators in the diagnosis and treatment of liver and pancreatic cancers, the Advisory Committee on the Medical Uses of Isotopes (ACMUI) issued the "Germanium-68 (Ge-68) Decommissioning Funding Plan (DFP) Final Report," and addendum, dated August 12, 2015 (ADAMS Accession No. ML15231A047). In the report, the ACMUI concluded that the restrictive aspects of a DFP for Ge-68/Ga-68 generators that arise from the current 10 CFR Part 30 regulations were preventing or deterring the use of promising Ga-68 diagnostic imaging agents for patients. The ACMUI also noted that patients treated with Ga-68 radiopharmaceuticals would receive nearly a five-fold reduction in effective dose when compared to other radiopharmaceuticals. Thus, the ACMUI recommended that the NRC address the DFP concerns relative to Ge-68/Ga-68 generators.

The NRC staff agreed with the ACMUI report that the DFP requirement could impede or limit patient access to the radiopharmaceuticals developed from Ge-68/Ga-68 generators and that a DFP is not necessary to ensure the safe decommissioning of facilities that use the generators. By memoranda dated July 29, 2016, (ADAMS Accession No. ML16082A415) and July 13, 2017 (ADAMS Accession No. ML17075A487), the NRC established a process for granting exemptions to the DFP requirements. The NRC staff issued guidance for the exemption that would relieve a licensee from the requirement for a DFP for the possession and use of Ge-68/Ga-68 radiopharmaceutical generators when certain conditions are met. The guidance allowed exemptions only from the DFP requirement, and only for licensees using Ge-68/Ga-68 generators. Specifically, the exemption guidance provided that licensees could possess up to 19 Ge 68/Ga 68 generators with $1.125 million in DFA. In addition, the exemption guidance provided that the licensees would maintain and submit for NRC review a legally binding agreement that ensured that the Ge-68/Ga-68 generators will be returned to the manufacturer or distributor at the end of use in order to qualify for the DFA certification option.

The NRC created this exemption process to provide a pathway until it could address the issue generically through rulemaking, as stated in the July 2016 memorandum. The rulemaking recommended in this regulatory basis document would provide a regulatory solution.

2.4.2 Organization of Agreement States Petition—PRM-30-66

As mentioned above, in PRM-30-66, the OAS requested that the NRC provide specific possession values for NARM radionuclides that are not currently listed in Appendix B to 10 CFR Part 30 so that licensees using these isotopes, especially medical licensees, would not have to apply the

[6] A Ge-68/Ga-68 radiopharmaceutical generator is a device used to extract the positron-emitting isotope Ga-68 from a source of decaying Ge-68. The parent isotope Ge-68 has a half-life of 271 days, which serves as the basis for DFA because it has a half-life greater than the 120-day criterion, while the daughter isotope, Ga-68, has a half-life of only 68 minutes. Because of its short half-life, in-hospital generator production of Ga-68 is the optimal production method.

appendix's default values to calculate decommissioning funding requirements. The OAS asserted the following:

- Without possession values for the unlisted radionuclides, regulators are forced to evaluate new products against the default criteria and apply overly burdensome financial assurance obligations or evaluate case-by-case exemptions.

- Patient health and safety are being compromised due to delays in licensing important diagnostic and therapeutic products that use radionuclides not listed in the table in 10 CFR Part 30, Appendix B.

- These licensing obstacles could discourage development of new products, diminishing the possibility of new innovative and beneficial options in both medical and industrial applications.

- Rather than issuing exemptions on a case-by-case basis, the more appropriate way to address the inconsistency in Appendix B is to amend it to add appropriate radionuclides and their corresponding activities.

On August 23, 2017, the NRC published a *Federal Register* notice of docketing (82 FR 39971) and requested comments on issues raised in the petition. The comment period ended on December 6, 2017, and the agency received 20 comment letters (ADAMS Package Accession No. ML18038A879). Fifteen commenters explicitly supported rulemaking, and one commenter requested a generic exception that only rulemaking can provide. No commenters opposed rulemaking, but one letter, while supporting a rulemaking for medical licensees, indicated that rulemaking could result in exempting industrial uses from AEA regulation under the guise of a medical purpose. Five commenters identified 10 radionuclides whose uses have been adversely affected by not being listed in Appendix B to 10 CFR Part 30.

2.4.3 SECY-19-0125 and Associated SRM-SECY-19-0125

The NRC staff sought Commission approval to initiate rulemaking in response to the OAS petition. The rulemaking would involve a revision to Appendix B to 10 CFR Part 30 and could involve a revision to 10 CFR 30.35 and 10 CFR 70.25. As discussed in SECY-19-0125, the rulemaking would do the following:

- Replace the listings and values in Appendix B to 10 CFR Part 30 with those of Appendix C to 10 CFR Part 20 for isotopes with a half-life greater than 120 days.

- Develop a new methodology for assessing DFA requirements and developing site-specific DFPs based on decommissioning risk factors.

- Amend the title to the table in Appendix B to 10 CFR Part 30 to reflect its current use for DFA as opposed to labeling.

- Remove all radionuclides with a half-life of 120 days or less from the table in Appendix B to 10 CFR Part 30 since these radionuclides are not considered when assessing DFA requirements and developing site-specific DFPs.

- Examine the merits of creating a new category for isotope generators that provides an engineered confinement greater than in unsealed form but less than that of a sealed source.

In SRM-SECY-19-0125, the Commission approved the initiation of rulemaking in response to PRM-30-66 to provide specific possession values for radionuclides that are not currently listed in Appendix B to 10 CFR Part 30 and the publication of the staff's proposed *Federal Register* notice announcing the determination on this petition. The NRC published a *Federal Register* notice on November 27, 2020 (85 FR 75959), announcing that the agency would consider the issues raised in PRM-30-66 through the NRC's rulemaking process.

2.4.4 Other Stakeholder Requests

The NRC held a public meeting on January 7, 2021, to gain stakeholder input on the regulatory approaches for DFA requirements for sealed and unsealed radioactive material (see ADAMS Package Accession No. ML21026A339).

At the public meeting, the NRC discussed regulatory issues related to the current DFA requirements and specific radionuclides that are not listed in Appendix B to 10 CFR Part 30. The NRC specifically discussed the following:

- Potential rulemaking options for updating Appendix B to 10 CFR Part 30, including developing a new risk methodology for calculating new Appendix B values or updating the Appendix B values using the values currently listed in Appendix C to 10 CFR Part 20.

- An option to create a separate category within 10 CFR 30.35(d) for radiopharmaceutical generators, given the engineering confinement of generators.

In general, the meeting participants supported the rulemaking option, noting that updating Appendix B to 10 CFR Part 30 to include radionuclides not currently listed would help with DFA funding by eliminating the need to use default values as is currently required. The participants noted that the NRC needs to address DFA funding for Ge-68/Ga-68 generators as soon as possible, given that current funding requirements for these radionuclides are excessive when compared to their relative risk to public health and safety based on their engineering design. Several commenters supported a separate category for Ge-68/Ga-68 generators within 10 CFR 30.35(d), with one commenter suggesting that the NRC evaluate conducting a direct final rule for these items. Commenters also noted that financial assurance requirements related to lutetium-177m also need to be addressed soon, given the likelihood that there will be an increase in its use upon approval of new medical treatments.

Participants did not express a strong preference for either of the potential rulemaking options but said that a faster update to Appendix B to 10 CFR Part 30 would be helpful. Several commenters noted that updating Appendix B with values from Appendix C to 10 CFR Part 20 would not help provide lower DFA funding overall because some values could decrease while other values could increase; therefore, the overall amount of required funding may not change. In addition, one commenter noted that updating Appendix B with the values in Appendix C to 10 CFR Part 20 would enable its facility to use more radionuclides in its research without changing the decommissioning funding amounts, given the use of the "unity rule" in 10 CFR 30.35(a).

3. Statement of Regulatory Concerns

This section examines the regulatory concerns that are to be addressed as a part of this rulemaking to provide specific possession values for NARM radionuclides and other radionuclides that are not currently listed in Appendix B to 10 CFR Part 30 for DFA requirements for sealed and unsealed byproduct material.

3.1 Unaligned Appendix B Values and Radionuclide Listings

The current values in Appendix B to 10 CFR Part 30 are not aligned with the NRC's primary radiation protection regulations in 10 CFR Part 20. Appendix B is based upon the radiation principles from ICRP Publication 2 (1959), while the values in Appendix C to 10 CFR Part 20 are based upon the more risk-informed principles in ICRP recommendations (ICRP Publication 26) and methodologies (ICRP Publication 30).

In addition, the current listing of radionuclides in Appendix B to 10 CFR Part 30 is not well-aligned with the NRC's regulatory authority under the EPAct. The EPAct amended the definition of byproduct material to include NARM radionuclides and provided the NRC authority over this new category of byproduct material. However, the NRC has not updated Appendix B to 10 CFR Part 30 to add NARM radionuclides and their possession values.

3.2 Applying the Generic Default Values in Appendix B to 10 CFR Part 30

The application of the generic default possession values in Appendix B to 10 CFR Part 30 for the DFA determinations of unlisted NARM radionuclides is not warranted based on risk to public health and safety. First, the types and quantities of byproduct material originally found in Appendix B to 10 CFR Part 30 were not developed to determine decommissioning funding. Rather, the values were initially derived from exceptions to labeling requirements such that certain small quantities of byproduct material could be released into the sanitary sewerage or buried in soil for disposal (58 FR 67657, December 22, 1993). Second, the default values were based upon the radiation protection principles in ICRP Publication 2 (1959) that were not risk-informed by research into the biological effects of ionizing radiation. Third, the default values are generic and do not reflect isotope-specific possession values and their associated radiological, chemical, and physical properties. Fourth, the generic default values are set to equal the most restrictive values of the nonrisk-assigned isotopes: 0.01 µCi for alpha emitters like radium-226, and 0.1 µCi for the most restrictive values of nonalpha-bearing isotopes (iodine-129, strontium-90 or lead-210)

For example, for an unsealed nonalpha-emitting isotope, a licensee possessing more than 0.1 millicurie (mCi) but less than 1 mCi would be required under 10 CFR 30.35(d) to provide $225,000 in DFA. To possess more than 1 mCi of the radionuclide, a licensee would be required to provide $1,125,000 in DFA, and a DFP would be required to possess more than 10 mCi. However, if the NRC revised Appendix B to 10 CFR Part 30 to adopt the values in Appendix C to 10 CFR Part 20, the minimum possession threshold for DFA or a DFP would increase 100-fold for NARM isotopes Ge-68, gold-195, sodium-22, and cobalt-57. Thus, the application of these generic default possession values creates regulatory burdens by requiring licensees to provide decommissioning funding that is not risk-informed by the isotope-specific possession values.

3.3 Processing Exemption Requests

As discussed above, the NRC currently has granted licensee-requested exemptions for medical licensees that use Ge-68/Ga-68 generators under certain conditions. These exemptions were approved in advance of pending rulemaking to generically resolve the issue. By providing a regulatory solution through rulemaking, the NRC would create a more stable framework for use by regulators, applicants, and licensees.

If the NRC does not complete this rulemaking, then the Ge-68/Ga-68 exemption process would be retracted, and consideration of exemption requests would revert to case-by-case reviews. In addition, since many of these unlisted radionuclides are used in the medical field, if the NRC does not pursue this rulemaking, many users of these unlisted isotopes are likely to submit numerous requests for exemptions to the DFA requirements, especially if the half-lives of these unlisted radionuclides are 120 days or less. The time and cost impacts from processing numerous exemption requests from DFA requirements on a case-by-case basis for the radionuclides with a half-life of 120 days or less would be very burdensome for the NRC and the Agreement States. In addition, to the extent that the agency frequently issues similar exemptions, the NRC could be viewed as not following its own regulations.

3.4 Reviewing Plans for Unlisted Radionuclides

Some licensees are choosing to submit DFPs under 10 CFR 30.35 instead of using the exemption process for Ge-68/Ga-68 generators. The DFP requirements in 10 CFR 30.35(e) were intended for major facilities possessing large quantities of radioactive material with half-lives greater than the 120-day criterion because they require a significant decommissioning effort. The 10 CFR 30.35(e) requirements, however, were not intended for the types and quantities of radioactive material typically used by medical licensees, because such licensees normally use radionuclides with short half-lives that do not pose a significant risk to public health and safety. Although medical licensees possess smaller quantities of radioactive material, they may develop facility-specific decommissioning cost estimates under 10 CFR 30.35(e). Some licensees pursue this option if they can demonstrate through a DFP that a lower amount of financial assurance is needed as compared to that required using the default possession values in Appendix B to 10 CFR Part 30. In addition, some licensees may find the submission of a DFP more efficient and effective than the exemption submission and approval process.

The review and approval of DFA under 10 CFR 30.35(e) is resource intensive for both the licensee and the regulatory agency. The DFPs must contain, among other things, a detailed cost estimate for an independent contractor to perform decommissioning activities so that the site meets the requirements for unrestricted use and a certification that financial assurance in the amount of the cost estimate has been provided. The licensee must resubmit the DFP every 3 years with adjustments as necessary to account for changes in costs and the extent of contamination. Even if a medical licensee possesses only one unlisted NARM radionuclide that requires a DFP, the plan must cover all radionuclides at the site, whether or not the aggregated total quantity of these other radionuclides would have required a DFP. Thus, this creates an unwarranted regulatory burden because the level of detail in the DFP would be unnecessary based upon the relative risk to public health and safety when only one well-defined device, such as a Ge-68/Ga-68 generator, is triggering the DFP requirements.

3.5 Revising 10 CFR 30.35 with a New Methodology and Category for Generators

In SECY-19-0125, the NRC staff discussed possibly developing a new methodology for determining DFA and creating a separate category in 10 CFR 30.35 for radiopharmaceutical generators. Five commenters on the OAS petition commented that Ge-68/Ga-68 generators should have a separate category within 10 CFR 30.35, and the DFA funding amounts should be lower than those currently required. Additionally, several stakeholders at a public meeting on this subject (see Section 7) also supported a separate category for these generators. However, the stakeholders at the public meeting supported updating Appendix B to 10 CFR Part 30 on a faster schedule than would be needed to develop a new decommissioning funding methodology and a separate category for generators.

3.6 Unaligned Appendix Title and Purpose

Appendix B to 10 CFR Part 30 is titled "Quantities of Licensed Material Requiring Labeling." This title is not consistent with its intent and purpose. Appendix B is used solely for the purpose of calculating the required amounts of DFA. In addition, this title is the same as that of Appendix C to 10 CFR Part 20. Thus, this could potentially cause confusion about the appropriate appendix for labeling requirements and the appropriate appendix for decommissioning requirements.

3.7 Unaligned Listing of Isotopes and Decommissioning Criteria

The current NRC regulations in 10 CFR 30.35 and 10 CFR 70.25 document the criteria for determining the amount of DFA required by licensees. DFA considerations only apply for radionuclides with a half-life greater than 120 days. However, the table in Appendix B to 10 CFR Part 30, which is used for calculating DFA costs, includes radionuclides with a half-life of 120 days or less. The disconnect between the criteria in 10 CFR 30.35 and the list of radionuclides in the table in Appendix B to 10 CFR Part 30 can lead to confusion about which radionuclides need to be considered when determining DFA requirements.

4. Evaluation of Rulemaking Alternatives

In SRM-SECY-19-0125, the Commission directed the staff to initiate rulemaking in response to the OAS petition requesting specific possession values for radionuclides that are not currently listed in Appendix B to 10 CFR Part 30. The staff considered multiple alternatives, including changes in the guidance as appropriate, to address the issues raised in the petition, while maintaining adequate protection of public health and safety. This section summarizes the five alternatives that the NRC considered.

4.1 Alternative 1—The Status Quo

The status quo considers no changes to the current process for assessing a licensee's DFA requirements. The status quo is considered to be the baseline from which the staff evaluated the four other alternatives.

4.2 Alternative 2—Update the List of Radionuclides and the Values in Appendix B to 10 CFR Part 30 Table (NRC Selected)

The NRC would revise the current table in Appendix B to 10 CFR Part 30 using the radionuclides and quantities from Appendix C to 10 CFR Part 20, including additional radionuclides not currently named in Appendix B to 10 CFR Part 30. These include radionuclides associated with industrial technologies and current and emerging medical uses. In addition, the NRC would remove all radionuclides with a half-life of 120 days or less from the appendix since these radionuclides are not considered when developing DFA. Finally, the default values would be set to equal the lowest values of the listed radionuclides: 0.001 µCi for alpha-emitting radionuclides like U-235, and 0.01 µCi for the most restricted nonalpha-emitting radionuclides (e.g., iodine-129, strontium-90 or lead-210). By making these changes, licensees, the NRC staff, and the Agreement States would have an up-to-date table with more risk-informed values for use when assessing DFA. Appendix B to this document contains an updated version of the table.

Actions associated with this alternative do not affect the current decommissioning funding costs outlined in 10 CFR 30.35(d) but do change the funding thresholds for some radionuclides. Based on the current cost criteria, changes to the table would decrease costs associated with 18 radionuclides but would increase costs for others, especially alpha emitters. This approach to rulemaking does not provide flexibility for incorporating additional radionuclides in the future. Additional rulemaking actions would be required if the NRC wishes to add radionuclides to the table in the future.

Table 1 lists the advantages and disadvantages considered by the NRC for this alternative.

Table 1: Advantages and Disadvantages of Alternative 2

Advantages
• satisfies the petitioner's request and Commission direction through a simple approach • provides a more up-to-date and risk-informed table (ICRP 26/30 vs. ICRP 2) • adds to the table specific radionuclides associated with industrial technologies and current and emerging medical uses (e.g., Ge-68, sodium-22, silicon-32, titanium-44, cobalt-57, thulium-170, and lutetium-177 (metastable)) • removes over 130 radionuclides with a half-life $\leq$120 days • decreases decommissioning costs for about 18 radionuclides by changing thresholds • does not need lengthy analysis or contractor assistance
Disadvantages
• is not site specific or scenario specific • does not address specific issues related to decommissioning costs (10 CFR 30.35(d) or 10 CFR 70.25(d)) • increases decommissioning costs for a few radionuclides (primarily alpha-emitting isotopes) by changing thresholds • does not provide an option for adding new NARM radionuclides created in the future without additional rulemaking

Pursuing this alternative would result in a more up-to-date and risk-informed Appendix B to 10 CFR Part 30 for use in the development of DFA without requiring significant time and

resources. For these reasons, the NRC recommends this alternative as the method to pursue for this rulemaking.

4.3 Alternative 3—Partially Update Appendix B to 10 CFR Part 30 (Add Unlisted NARM Radionuclides and Other Radionuclides Not Currently Listed to the Existing Table in Appendix B)

The NRC would add only the unlisted NARM radionuclides and other radionuclides listed in the table in Appendix C to 10 CFR Part 20 to the table in Appendix B, 10 CFR Part 30. The agency would not change the values for the radionuclides already listed in Appendix B to 10 CFR Part 30.

The advantage of this alternative is that it would satisfy the request in the OAS petition to update Appendix B to 10 CFR Part 30 to include the unlisted NARM radionuclides. However, this alternative would result in DFA requirements in the same table being based on multiple ICRP methodologies. The values in the current Appendix B to 10 CFR Part 30 are based upon the methodology of radiation protection in ICRP Publication 2 (1959) and do not address annual limits on intake or derived air concentrations. The values in the current Appendix C to 10 CFR Part 20 are based on the methodologies in ICRP Publication 26 (1977) and ICRP Publication 30. For this reason, the NRC is not recommending this alternative.

Table 2 lists the advantages and disadvantages considered by the NRC for this alternative.

Table 2: Advantages and Disadvantages of Alternative 3

Advantages
• simple, straightforward approach that satisfies the petitioner's request • values for the unlisted radionuclides would be added based upon ICRP Publications 26 and 30, which would update and risk-inform the table
Disadvantages
• is not site specific or scenario specific • does not provide an option for adding new radionuclides without further rulemaking • does not address specific issues related to decommissioning costs (10 CFR 30.35(d) or 10 CFR 70.25(d)) • would result in mixed radiation protection methodologies for assessing internal dose in the table because the current values in Appendix B to 10 CFR Part 30 are based upon the dose methodology in ICRP Publication 2 and the values of the NARM radionuclides to be added would be based upon ICRP Publications 26 and 30 • would require significantly greater NRC and Agreement State resources to develop and implement the new requirements when compared to Alternative 2 • initial costs associated with establishing a DFP would likely be significantly greater than those required under Alternative 2

4.4 Alternative 4—Develop a New Process for Assessing Decommissioning Funding Costs

As noted in SECY-19-0125, the NRC also intended to consider developing a new methodology based on decommissioning risk factors. This alternative involves eliminating the use of specific

tabulated values and establishing a new framework for determining decommissioning funding costs. Although this approach goes beyond the specific scope of the OAS petition, it would provide licensees with a more up-to-date and risk-informed approach for developing DFA based on their individual, site-specific needs. This approach would be flexible enough to be modified as needed to address potential changes associated with a licensee's business interests.

The amount of time and resources required to develop and implement this alternative would be greater than the previous alternatives considered. This approach would require a minimum of approximately 15 months[7] to develop the technical basis associated with this approach and additional time to implement the new methodology and obtain contractor support. Depending on how this approach is implemented, there may be additional burden on the NRC, particularly regional staff, who would have to review and approve each licensee's initial DFP. The NRC would also have to perform periodic reviews to confirm that the approved funding plan is still adequate, as well as address any changes that the licensee may wish to implement. These additional burdens could also impact the Agreement States that implement similar programs for their licensees.

Initial costs associated with establishing a DFP would likely be greater, as licensees would have to develop plans that incorporate the details associated with the site-specific criteria for determining decommissioning funding costs. For many licensees, however, this approach could result in long-term cost savings, as costs for developing and maintaining this type of plan plus the costs for performing actual cleanup activities could be less than $113,000, the minimum value provided in 10 CFR 30.35(d) for sealed sources.

Table 3 lists the advantages and disadvantages considered by the NRC for this alternative.

Table 3: Advantages and Disadvantages of Alternative 4

Advantages
• addresses decommissioning funding issues • more accurate assessment of decommissioning costs (10 CFR 30.35(d) and 10 CFR 70.25(d)) • adaptable to different types of licensees/uses (e.g., generators, nondispersible) • adjustable over time (e.g., licensees change function; decommissioning costs change) • cost savings for some licensees
Disadvantages
• significant contractor costs • possible increase in resources for some licensees associated with developing and maintaining a DFP • at least 15 additional months would be needed to develop the technical basis • would require significantly greater NRC and Agreement State resources to develop and implement the new requirements when compared to Alternative 2

[7] The staff based the estimate of 15 months on the time needed for a contract to be put in place, the contractor to conduct the technical analysis, and the staff to evaluate the contractor's analysis.

This alternative would result in a more risk-informed approach for determining decommissioning funding costs and allow for added flexibility to address differences among licensees and changes over time. However, the NRC staff determined that developing a new approach would require significant time, effort, and resources. Based on internal discussions, comments received on the petition, and stakeholder input provided during the public meeting, the NRC staff concluded that this approach also goes beyond the petitioner's request of updating Appendix B to include unlisted NARM radionuclides not currently included in the table and would not provide the fast regulatory relief to licensees as requested. For these reasons, the NRC is not recommending this alternative.

4.5 Alternative 5—Update Appendix B to 10 CFR Part 30 and Develop a New Process for Assessing Decommissioning Funding Costs (Combines Alternative 2 and Alternative 4 - Two rulemakings)

This alternative considers combining Alternatives 2 and 4 into a multistep rulemaking process. The NRC would update the values in Appendix B to 10 CFR Part 30 as outlined in Alternative 2, developing a more up-to-date and risk-informed table of values for use in assessing decommissioning funding costs. This addresses the concerns outlined in the petition and the direction provided by the Commission. The NRC then would investigate a more modern, risk-informed approach for developing and maintaining an up-to-date DFP, with contractor assistance and input from the public.

Table 4 lists the advantages and disadvantages considered by the NRC for this alternative.

Table 4: Advantages and Disadvantages of Alternative 5

Advantages
• provides the same advantages identified for Alternatives 2 and 4 • addresses specific issues identified in SECY-19-0125 and issues related to decommissioning costs • provides quick resolution to the initial issues raised in the petition • provides licensees with the flexibility to use either the table or a site-specific approach
Disadvantages
• has the same disadvantages identified for Alternatives 2 and 4 • requires a longer timeframe to complete the final rule

Pursuing this alternative would result in a more up-to-date and risk-informed Appendix B to 10 CFR Part 30, while also developing a process for developing site-specific DFPs. However, this approach would require the approval of a second rulemaking, while stakeholders want a faster resolution to the request to provide specific radionuclide possession values. This alternative would also require two separate rulemakings and take longer to complete. For these reasons, the NRC is not recommending this alternative.

5. Basis for Proposed Changes

This section explains the proposed changes to NRC regulations and discusses the technical rationale and assumptions used to support those changes. This section also discusses how the proposed changes could resolve the issues identified in Section 3 of this regulatory basis.

5.1 Proposed Changes

The recommended rulemaking alternative is to replace the entire Appendix B to 10 CFR Part 30 with the information from Appendix C to 10 CFR Part 20 except for radionuclides with a half-life of less than or equal to 120 days. The NRC would change the title of Appendix B to align with its decommissioning purpose.

5.2 Benefits of the Rulemaking

5.2.1 A More Risk-Informed Regulation

A risk-informed approach to regulatory decisionmaking represents a philosophy whereby risk insights are considered, together with other factors, to establish requirements that better focus licensee and regulatory attention on issues commensurate with their importance to public health and safety. This approach to regulation reduces unnecessary conservatism in regulation. The rulemaking would advance the NRC's commitment to maintain up-to-date regulations by aligning the NRC's DFA requirements with more risk-informed possession values in Appendix B to 10 CFR Part 30. The Appendix B values are currently based on radiation principles associated with ICRP Publication 2 (1959) that did not consider risk. The rulemaking would update the values in Appendix B using the values in Appendix C to 10 CFR Part 20. The Appendix C values reflect a more recent understanding of radionuclide biokinetics by incorporating the methodologies in ICRP Publication 26 (1977) and ICRP Publication 30. It would provide a more risk-informed alternative to the generic default values that result in decommissioning funding requirements that are not commensurate with anticipated decommissioning costs and associated risks to public health and safety. Thus, a rulemaking would ensure that the DFA requirements reflect more up-to-date radiation protection principles.

5.2.2 Reduces or Eliminates Exemption Requests

The rulemaking would reduce or eliminate the need for licensees to submit exemption requests for some unlisted radionuclides. In turn, the NRC and the Agreement States would no longer need to perform time-consuming and resource-intensive exemption evaluations on a case-by-case basis for some unlisted NARM radionuclides.

The impact on Ge-68/Ga-68 generators is a good example of how this regulatory change would affect licensees. Ge-68, a NARM radionuclide with a half-life of 271 days, exceeds the 120-day half-life criterion. Because Ge-68 is not currently listed in Appendix B to 10 CFR Part 30, the default possession value of 0.1 µCi is used to determine DFA and DFP requirements. In the current 10 CFR 30.35(a), DFA and DFP requirements apply to radionuclides with a half-life greater than 120 days in quantities exceeding 1×10^5 times the applicable quantities set forth in Appendix B for unsealed sources and quantities exceeding 1×10^{12} times the applicable quantities set forth in Appendix B for sealed sources. In addition, 10 CFR 30.35(b) provides that a licensee can chose to either submit a DFP according to 10 CFR 30.35(e) or submit a DFA certification in the amount prescribed by 10 CFR 30.35(d).

Since Ge-68/Ga-68 generators are not considered a sealed source, the unsealed source value would be applied. Thus, 0.1 µCi or 0.0001 (1×10^{-4} mCi) multiplied by 1×10^5 results in a DFA limit of 10 mCi. Because each new Ge-68/Ga-68 generator has 50 mCi of Ge-68, the possession of one generator would subject a licensee to DFP requirements in accordance with

10 CFR 30.35(a)(1). In addition, one new Ge-68/Ga-68 generator at 50 mCi of Ge-68 per generator exceeds the 10 mCi limit for DFA certification under 10 CFR 30.35(d) of $1.125 million. Therefore, the current regulations would not allow Ge-68/Ga-68 generator licensees the option of submitting a DFA certificate under 10 CFR 30.35(d).

If the NRC updates the value in Appendix B to 10 CFR Part 30 to 10 µCi, the value from Appendix C to 10 CFR Part 20, then the DFA limit for Ge-68/Ga-68 generators increases to 1,000 mCi (10 µCi or 0.01 mCi (1×10^{-2}) multiplied by 1×10^{5} for unsealed sources). As a result, licensees with 50 mCi of Ge-68 in each Ge-68/Ga-68 generator could possess up to 20 generators at a time before being subjected to the DFP requirements in 10 CFR 30.35(a)(1). In addition, according to 10 CFR 30.35(d), licensees possessing one or two Ge-68/Ga-68 generators (50 to 100 mCi of Ge-68) could provide a $225,000 DFA certificate and not submit a DFP; licensees possessing 3 to 20 generators (>100 to 1,000 mCi) could provide a $1.125 million DFA certificate without being required to develop a DFP. However, this applies only if the licensee does not possess additional radionuclides with half-lives greater than 120 days that would have to be considered under the unity rule as discussed in 10 CFR 30.35(a).

Thus, the proposed revisions to Appendix B to 10 CFR Part 30 would provide greater regulatory flexibility than the current regulations; the 200-mCi limit for Ge-68/Ga-68 generators discussed in the ACMUI report described in Section 2.4.1 above; and the NRC exemption guidance also described in Section 2.4.1. The proposed revisions would allow licensees to possess up to 20 generators before reaching the threshold of $1.125 million in DFA and would not require NRC review and approval of generator return agreements as one condition required for approving a site-specific exemption request. Therefore, the proposed rulemaking would reduce or eliminate exemption approval processing delays for the use of the unlisted Ge-68 and other NARM radionuclides that are important in the diagnosis and treatment of diseases, especially cancer.

5.2.3 Addresses Emerging Technologies

The rulemaking would remove unnecessary decommissioning-related barriers to licensing Ga-68 imaging and other emerging medical and industrial technologies that use or plan to use the unlisted NARM radionuclides. Adding unlisted radionuclides in a single comprehensive rulemaking minimizes the need for additional rulemakings in the future when new applications are developed for radionuclides that are not included in the current Appendix B to 10 CFR Part 30.

5.2.4 Alignment of Title and Purpose

Changing the title of Appendix B to 10 CFR Part 30 would eliminate any confusion between Appendix B to 10 CFR Part 30 and Appendix C to 10 CFR Part 20, differentiating between which regulation should be used for labeling requirements and which regulation should be used for decommissioning funding requirements. Both appendices are titled “Quantities of Licensed Material Requiring Labeling.” The rulemaking would retitle the table in Appendix B to 10 CFR Part 30 to reflect its purpose for determining DFA. The staff proposes to title 10 CFR Part 30, Appendix B, “Quantities of Licensed Material Used to Assess Financial Assurance for Decommissioning.”

5.2.5 Alignment of Listing of Radionuclides and Decommissioning Criteria

The rulemaking would align the listing of radionuclides with the decommissioning technical basis and criteria in 10 CFR 30.35 that require the amount of DFA to be determined for a given radionuclide with a half-life greater than 120 days, multiplied by the value in Appendix B to 10 CFR Part 30 for the radionuclide. Removing radionuclides with a half-life of 120 days or less is consistent with the technical basis that such radionuclides would completely decay in a few years and do not pose significant decommissioning concerns.

Some radioactive materials licensed under 10 CFR Part 70 have a half-life less than or equal to 120 days. Appendix C to 10 CFR Part 20 contains 12 radionuclides for plutonium that are licensed under 10 CFR Part 70. Seven of these radionuclides have half-lives greater than 120 days, four have half-lives less than 11 hours, and the last radionuclide, Pu-237, has a half-life of 45.2 days. As a part of the rulemaking, the NRC staff plans to include the seven plutonium radionuclides with half-lives greater than 120 days into the revised Appendix B to 10 CFR Part 30. The NRC staff does not recommend including the four radionuclides with half-lives less than 11 hours (Pu-234, Pu-235, Pu-243, and Pu-245) in the revised table in Appendix B to 10 CFR Part 30, because they will undergo a minimum of 10 half-lives within 5 days of creation/possession and will not require special consideration for decommissioning planning. The remaining radionuclide of plutonium considered (Pu-237) has a half-life of 45.2 days and has been used in environmental tracer studies. Pu-237 is produced by bombarding uranium targets with 27 megaelectron volts of helium ions using a cyclotron, and the primary decay mode is by electron capture to neptunium-237. While 10 CFR Part 70 does not explicitly exclude this radionuclide from DFA consideration, Appendix B to 10 CFR Part 30 will include the target material and decay products. Accordingly, the NRC staff recommends excluding Pu-237 from the table in Appendix B to 10 CFR Part 30 to retain a consistent methodology for revision of Appendix B (i.e., including only radionuclides with half-lives greater than 120 days).

Appendix C to 10 CFR Part 20 includes 11 radionuclides for uranium. Six of these radionuclides have half-lives greater than 120 days, and the NRC staff recommends including these six radionuclides into a revised Appendix B to 10 CFR Part 30. Five uranium radionuclides have half-lives less than 120 days; the NRC staff recommends excluding them (U-230, U-231, U-237, U-239, and U-240) from the revised table in Appendix B to 10 CFR Part 30 because they are source material and are regulated under 10 CFR Part 40, “Domestic licensing of source material,” not 10 CFR Part 70. Thus, the staff recommends that 10 CFR 70.25 include the decommissioning technical basis and criteria that require DFA for radionuclides with a half-life greater than 120 days, revising as follows [emphasis added]:

> (a)(2) A specific license authorizing the possession and use of unsealed special nuclear material *of half-life greater than 120 days* and in quantities exceeding 1×10^5 times the applicable quantities set forth in appendix B to part 30. A decommissioning funding plan must also be submitted when a combination of isotopes is involved if R divided by 1×10^5 is greater than 1 (unity rule), where R is the sum of the ratios of the quantity of each isotope to the applicable value in appendix B to part 30.

(b)	Each applicant for a specific license authorizing possession and use of unsealed special nuclear material *of half-life greater than 120 days*, in quantities specified in paragraph (d) of this section, shall either—

6. Backfitting and Issue Finality Analysis

The rulemaking would update the values in Appendix B to 10 CFR Part 30 that are used to calculate DFA for byproduct material licenses in accordance with 10 CFR 30.35 (10 CFR Part 30 licenses) and for unsealed special nuclear material licenses in accordance with 10 CFR 70.25 (10 CFR Part 70 licenses). There are no backfitting or issue finality provisions in 10 CFR Part 30. Although 10 CFR Part 70 contains backfitting provisions, they are not applicable to the provisions in 10 CFR 70.25. The proposed regulatory changes do not impose modifications of or additions to the systems, structures, components, or design of facilities, nor would they require licensees to modify the procedures or organization required to design, construct, or operate facilities. Thus, the proposed changes are not backfits. As a result, no backfit analysis is required for this rulemaking.

7. Stakeholder Involvement

Stakeholders have had several opportunities for involvement in this planned rulemaking. Stakeholders, including the Agreement States, could comment on the OAS petition, as well as participate in a public meeting on this topic on January 7, 2021. The rulemaking process will provide future opportunities for public engagement.

In addition, the Agreement States participated in the development of this regulatory basis. In accordance with Management Directive 5.3, “Agreement State Participation in Working Groups,” dated June 22, 2016 (ADAMS Accession No. ML18073A142), the staff provided early opportunities for Agreement State engagement on this rulemaking. A representative from the OAS served on the working group that assisted in developing the regulatory basis, and an OAS representative is on the rulemaking steering committee. Additionally, the Agreement States had an opportunity to review a draft of this regulatory basis and provide comments. The OAS Board, as well as the Agreement States of Arkansas and Wisconsin, provided specific comments.

The NRC considered these comments in developing this regulatory basis, as described below:

- Wisconsin supported Alternative 2 and indicated that the rulemaking should ease regulatory burden while protecting public health. As this supports the current recommendation, the staff did not revise the regulatory basis.

- Arkansas recommended that the staff amend 10 CFR 70.25 to specifically include the 120-day half-life criterion to ensure consistency across the regulations. The NRC agreed and revised this regulatory basis accordingly.

- The OAS Board supported Alternative 5 because it would provide prompt resolution of the petition issue (Alternative 2) combined with a modern, risk-informed resolution (Alternative 4). As discussed in Section 4 of this regulatory basis, the NRC is recommending Alternative 2 because it would result in a more up-to-date and risk-informed

approach to DFA without requiring significant time and resources. At this time, the NRC cannot justify the additional resources to conduct Alternative 4 (as part of Alternative 5). After receiving public comment on this regulatory basis, the staff will consider whether its recommended alternative remains advantageous from a safety and cost basis.

In addition, the OAS Board questioned whether Alternative 2 would provide sufficient regulatory relief for Ge-68/Ga-68 generators. In consideration of this comment, the NRC expanded the discussion of the benefits of this rulemaking in Section 5.2.2 of this regulatory basis. Adding Ge-68 to the list of radionuclides in 10 CFR Part 30, Appendix B, directly addresses the issue with these generators that was the subject of the original petition and eliminates the need for DFPs in many cases. While further relief could be contemplated—such as by considering generators akin to sealed sources for purposes of DFA—this is outside the scope of the recommended rulemaking alternative. The OAS Board confirmed that this expanded discussion of the benefits addressed their technical questions with Alternative 2.

The staff will consider comments received from stakeholders on this regulatory basis in the development of the proposed rule.

8. Cost/Impact Considerations

This section discusses cost and other impacts related to the rulemaking for DFA requirements for sealed and unsealed radioactive material. This section discusses potential impacts on three groups: (1) the NRC, (2) the Agreement States, and (3) licensees. The analyses presented in this section are based on the NRC staff's preliminary assessment. The staff will carry out a more detailed cost/impact evaluation as part of the regulatory analysis developed in accordance with NUREG/BR-0058, Revision 5, "Regulatory Analysis Guidelines of the U.S. Nuclear Commission, Draft Report for Comment," issued April 2017, during the proposed rule phase of the rulemaking.

8.1 Applicability

Under 10 CFR 30.35 and 10 CFR 70.25, certain specific NRC licensees authorized for use or possession of byproduct, source, or special nuclear material are subject to DFA requirements. According to Appendix L to NUREG-1350, Volume 32, "2020–2021 Information Digest," issued October 2020 (ADAMS Accession No. ML20282A632), the total number of materials licenses issued by the NRC and the Agreement States is 18,664. The total number of radioactive material licenses under NRC jurisdiction is 2,209 (12 percent of total licensees), and the total under Agreement State jurisdiction is 16,455 (88 percent of total licensees). Based upon a search of NRC's Web-Based Licensing (WBL) system, 175 (8 percent of 2,209) of the NRC radioactive material licensees are, or have recently been, subject to 10 CFR 30.35 or 10 CFR 70.25 financial assurance requirements. By extrapolating based on the number of licenses in the Agreement States, the NRC estimates that 1,304 Agreement State licenses are or have recently been subject to financial assurance requirements. Therefore, 1,479 total licensees may be subject to financial assurance requirements. The types of licensees that are subject to financial assurance requirements include those authorized under a broad scope license and those authorized for medical, industrial, research, nuclear pharmacy, and manufacturer and distributor uses.

8.2 Analysis Assumptions

The estimates used in developing the cost estimates are based on a composite of a search of the WBL database and pending financial assurance licensing actions (as these will not be reflected in WBL). The staff subtracted the number of licenses issued under 10 CFR Part 40 in this search from the total number of licenses, since the rulemaking would not apply to 10 CFR Part 40 licensees. The estimates for Agreement State licensees are based on the ratio of the number of licensees under NRC jurisdiction. The cost estimates use only 38 of the current 39 Agreement States. The Wyoming Agreement State assumed the regulation of only uranium recovery from the NRC. Therefore, the State of Wyoming does not have jurisdiction over licensees that would be impacted by this rulemaking and was not included in the cost estimate.

The cost estimates cover several actions that would have to be done by the NRC, the Agreement States, and licensees. The NRC and the Agreement States would have to notify licensees of the rulemaking and the need for licensees to (1) review their licensed programs for any changes to the amount of required financial assurance or the need for a DFP and (2) review revised or new financial assurance estimates or DFPs. There are various mechanisms for DFPs, such as letters of credit, surety bonds, self-guarantee, and statements of intent, all of which carry different requirements and costs to put in place.

Many of the NRC licensees that are, or have recently been, subject to 10 CFR 30.35 or 10 CFR 70.25 financial assurance requirements (175 based on a search of WBL) are large radioactive materials programs such as broad scope licensees, nuclear pharmacies, researchers, manufacturers, and irradiators. These licensees will not see any impact on their DFA or DFPs based on the proposed rule. Based on this analysis, the NRC estimates that it would need to notify 60 licensees about the final rule. Of these 60, the NRC estimates that 40 licensees would need to review their financial assurance and may need to revise their financial assurance funding or DFP. For ease of calculations, the NRC used a ratio of 1 NRC licensee to 10 Agreement State licensees to estimate the number of actions for the Agreement States (rather than 12 percent to 88 percent as noted above). For industry calculations, the number of industry actions is the sum of the number of NRC actions and Agreement State actions.

8.3 Affected Entities

The affected entities are the NRC, the Agreement States, and licensees.

8.3.1 NRC

Based upon a 7-percent discount rate, the NRC estimates that the NPV projected cost of rulemaking would be approximately ($467,970). NRC implementation consists of completing the proposed and final rules and developing and issuing licensing guidance to comply with the new requirements. Additionally, the NRC would incur a NPV projected cost of approximately ($129,601) to review licensee revisions to DFA estimates or DFPs. The total NRC NPV projected cost is ($597,571).

8.3.2 Agreement States

The Agreement States will have 3 years to adopt the regulatory changes. The NRC estimates that the NPV cost of this rulemaking to the Agreement States is approximately ($2,049,132) for

Agreement State rulemaking and associated changes, assuming a 7-percent discount rate. The Agreement States would also need to review licensee revisions to DFA estimates or DFPs. This rulemaking cost may be lower if the Agreement States choose to incorporate the regulatory changes by reference or by using other legally binding requirements (i.e., license conditions).

8.3.3 Licensees

Assuming a 7-percent discount rate, the NRC estimates that the rule would incur a NPV cost to licensees of approximately ($3,810,315). Those costs would be incurred mainly during the review of its licensed programs and submission of necessary revisions to their DFA or DFPs. Additionally, some licensees may need to submit DFA estimates or DFPs for NRC or Agreement State review.

8.3.4 Tribal Nations

The NRC does not expect the rule to affect any Tribal Nations.

8.4 Summary of Alternatives and Cost

Appendix B to this regulatory basis tabulates the assumptions and inputs by alternative for each affected entity. Appendix C summarizes Alternatives 2–5 and shows the costs for each alternative for the NRC, the Agreement States, and industry. Table 5 summarizes the estimated costs for each alternative.

The NRC is recommending Alternative 2. Under Alternative 2, the NRC plans to update Appendix B to 10 CFR Part 30 by replacing the values in the appendix with the values from Appendix C to 10 CFR Part 20. Additionally, the NRC would exclude all radionuclides with a half-life of 120 days or less from the appendix because these radionuclides are not considered when applying DFA requirements. Finally, to clarify the purpose of Appendix B, the NRC would also change the title of the appendix to reflect its use in determining DFA requirements.

Table 5: Alternatives and Benefits (Costs)

DESCRIPTION	Net Benefits (Costs) in 2021 Dollars		
	Undiscounted	7% NPV	3% NPV
Alternative 1—Status Quo (No Action Taken)	$0	$0	$0
Alternative 2—Update the List of Radionuclides and the Values in the Table in Appendix B to 10 CFR Part 30 (NRC selected)			
NRC Implementation	($518,000)	($468,000)	($495,000)
Alternative 2 NRC	($170,000)	($130,000)	($151,000)
Alternative 2 NRC Averted Cost	$2,115,880	$2,075,601	$2,096,936
Alternative 2 Industry	($4,995,000)	($3,810,000)	($4,438,000)
Alternative 2 Industry Averted Cost	$15,146,546	$13,962,315	$14,589,590
Alternative 2 Agreement States	($2,710,000)	($2,049,000)	($2,398,000)
Alternative 2 Agreement States Averted Cost	$15,775,884	$15,115,132	$15,464,247
Alternative 2 Total Net Benefits (Cost)	$24,645,904	$24,696,030	$24,668,716

DESCRIPTION	Net Benefits (Costs) in 2021 Dollars		
	Undiscounted	7% NPV	3% NPV
Alternative 3—Partially Update Appendix B to Part 30 (Add unlisted NARM radionuclides and other radionuclides not currently listed to the existing table in Appendix B to 10 CFR Part 30)			
NRC Implementation	($518,000)	($468,000)	($495,000)
Alternative 3 NRC	($170,000)	($130,000)	($151,000)
Alternative 3 Industry	($4,995,000)	($3,810,000)	($4,438,000)
Alternative 3 Agreement States	($2,710,000)	($2,049,000)	($2,398,000)
Alternative 3 Total Net Benefits (Cost)	($8,392,000)	($6,457,000)	($7,482,000)
Alternative 4—Develop a New Process for Assessing Decommissioning Funding Costs			
NRC Implementation	($518,000)	($468,000)	($495,000)
Alternative 4 NRC	($222,000)	($169,000)	($197,000)
Alternative 4 Industry	($4,995,000)	($3,810,000)	($4,438,000)
Alternative 4 Agreement States	($2,984,000)	($2,249,000)	($2,637,000)
Alternative 4 Total Net Benefits (Cost)	($8,718,000)	($6,697,000)	($7,767,000)
Alternative 5—Update Appendix B to 10 CFR Part 30 and Develop a New Process for Assessing Decommissioning Funding Costs (Combines Alternative 2 and Alternative 4 - Two rulemakings)			
NRC Implementation	($1,088,000)	($861,000)	($979,000)
Alternative 5 NRC	($392,000)	($259,000)	($326,000)
Alternative 5 Industry	($9,989,000)	($6,717,000)	($8,380,000)
Alternative 5 Agreement States	($5,694,000)	($3,765,000)	($4,741,000)
Alternative 5 Total Net Benefits (Cost)	($17,163,000)	($11,601,000)	($14,427,000)

*Values rounded to the nearest thousand. There may be differences among the tables due to rounding.
*Values in parenthesis, e.g., "()" denote a cost of negative value.

The rulemaking for DFA requirements for sealed and unsealed radioactive material would have a projected cost of approximately $6.5 million over a 15-year period for the recommended alternative, Alternative 2. The majority of costs to the NRC, the Agreement States, and industry would be incurred during the first year of implementation of the final rule. The costs to the industry would include licensees having to review their current DFA or DFPs for any needed revisions to be in compliance with the final rule. Some licensees may need to obtain DFA or submit a DFP as a result of these changes. The NRC and the Agreement States would have to review any new or revised DFA estimates or DFPs. In the long run, however, the rulemaking would save resources and reduce costs, since fewer licensees would need to use default values for determining the amount of DFA or to seek exemptions. The NRC is requesting feedback from the public on this document to assist in identifying the overall cost that may result from the proposed rule to amend 10 CFR Part 30.

9. Uncertainty Analysis

The NRC completed a Monte Carlo sensitivity analysis for this regulatory analysis using the specialty software @Risk®. The Monte Carlo approach answers the question, "What distribution of net benefits results from multiple draws of the probability distribution assigned to key variables?"

9.1 Uncertainty Analysis Assumptions

As this regulatory analysis uses estimates of values that are sensitive to licensees' unique situations, the staff analyzed the variables that have the greatest amount of uncertainty. To perform this analysis, the staff used a Monte Carlo simulation analysis using the @Risk® software program. This was done to determine the robustness of the costs and net benefits of the rulemaking. The NRC examined how anticipated savings change due to uncertainties associated with the NRC's analytical assumptions and input data shown in Appendix B to this document.

9.2 Uncertainty Analysis Inputs

The probability distributions chosen to represent the different variables in the analysis were bounded by the range-referenced input and the NRC staff's professional judgment. When defining the probability distributions for use in a Monte Carlo simulation, summary statistics are used to characterize the distributions. These summary statistics include the minimum, most likely, and maximum values of a program evaluation and review technique (PERT) distribution. The staff used the PERT distribution to reflect the relative spread and skewness of the distribution defined by the three estimates—the minimum, most likely, and maximum. Figure 1 provides the probability distribution function and the descriptive statistics of the inputs used in the uncertainty analysis. Appendix B to this document shows the inputs.

9.3 Uncertainty Analysis Results

Figure 1 depicts the results of the uncertainty analysis of Alternative 2 net costs using a 7-percent discount rate. This figure displays the histogram of the incremental net cost for rulemaking to resolve the identified issues. The uncertainty analysis graph shows that the Alternative 2 mean net cost is ($6.5 million) in 2021 dollars with a 90-percent confidence level that the costs are between ($13.1 million) and ($2.57 million) using a 7-percent discount rate. Note that there will be differences in totals due to the software used to perform the uncertainty analysis.

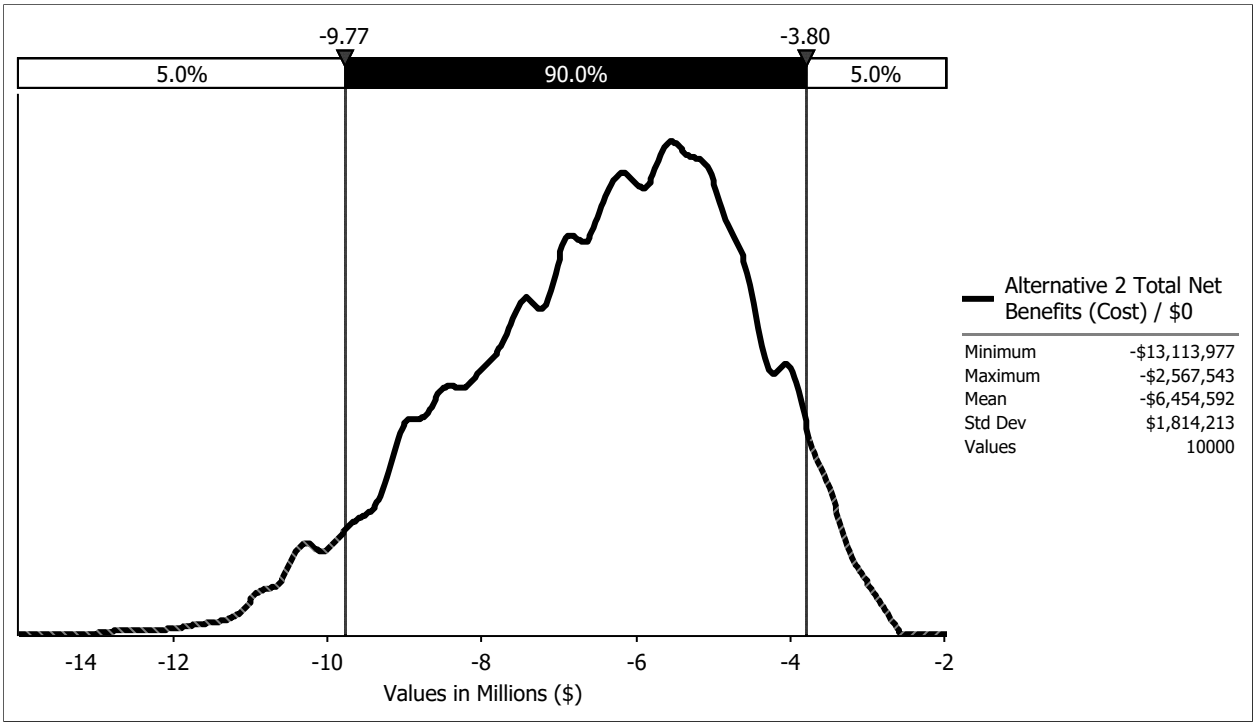

Figure 1: Incremental Net Costs for Alternative 2 (7-Percent Discount Rate)

9.4 Sensitivity Analysis

In addition to estimating the probability distributions for the net benefits of the rule, the staff used Monte Carlo simulation to conduct a sensitivity analysis to determine the variables that have the greatest impact on the resulting net costs. Variables shown to have a large effect on the resulting net benefits may deserve more attention and scrutiny than variables shown to have a small or minimal effect.

Figure 2 shows a tornado diagram that identifies the key variables whose uncertainty drives the largest impact on net benefits for this recommended alternative. Figure 2 ranks the variables based on their contribution to cost uncertainty.

The estimate that has the greatest variation in the Alternative 2 overall results is the licensee labor rate. The uncertainty in this variable would result in a change to the mean of ($5.8 million), a difference in costs that ranges between ($3.8 million) to ($9.6 million) with a 90-percent confidence level.

The estimate that has the second greatest variation in the Alternative 2 overall results is the number of licensees revising their decommissioning plans. The uncertainty in this variable would result in a change to the mean of ($1.5 million), a difference in costs that ranges between ($5.7 million) to ($7.2 million) with a 90-percent confidence level.

The estimate that has the third greatest variation in the Alternative 2 overall results is the number of hours required per DFP. The uncertainty variable would result in a change to the mean of ($0.7 million), a difference in costs that ranges from ($6.1 million) to ($6.8 million) with a 90-percent confidence level.

The estimate that has the fourth greatest variation in the Alternative 2 overall results is the number of industry licensees with revised financial assurance mechanism values. The uncertainty variable would result in a change to the mean of ($0.6 million), a difference in costs that ranges from ($6.2 million) to ($6.8 million) with a 90-percent confidence level. The remainder of the variables result in small or minimal effect on the costs.

Figure 2: Alternative 2 Cost Drivers (7-Percent Discount Rate)

10. Rulemaking Cost Justification

This regulatory basis supports a rulemaking to update Appendix B to 10 CFR Part 30 to include more risk-informed values for the existing radionuclides by using the values provided in Appendix C to 10 CFR Part 20, adding radionuclides not currently included, and clarifying that only materials containing radionuclides with half-lives greater than 120 days are subject to DFA and a DFP. Updating the table would lead to aggregated cost savings that would exceed the projected cost of this one-time rulemaking. For example, the current generic bounding estimate for the cost of a license exemption is $278,000, consisting of an estimated $188,000 for the licensee's development and submittal of a license exemption request and an estimated $90,000 for the NRC's review. As of July 2019, the NRC staff had processed seven DFP exemption requests for Ge-68/Ga-68 generators at a cost of approximately $1.95 million ($278,000 × 7 DFP exemption reviews). The rulemaking would avert the cost of all such exemptions in the future. In addition, the NRC has conducted 24 DFP reviews as of December 2021. Fewer of these DFP reviews would be needed after the recommended rulemaking. In addition, the Agreement States regulate 87 percent of the materials licensees in the United States. Therefore, the NRC projects that the averted regulatory costs from reduced exemptions and fewer DFP reviews across the National Materials Program would far exceed the one-time rulemaking cost of $6.5 million.

This rulemaking, in the NRC staff's view, would also have a number of additional benefits to licensees, the NRC, and the Agreement States. The proposed changes to Appendix B to 10 CFR Part 30 that are incorporated into this rulemaking will provide a more risk-informed method for determining the need for DFA. This includes aligning Appendix B to 10 CFR Part 30 with the NRC's regulatory authority under the EPAct and the more up-to-date radiation protection standards in 10 CFR Part 20. The addition of radionuclides not previously included will also reduce the need to use default values that, as noted in the OAS petition, are often considered overly burdensome.