ADVISORY COMMITTEE ON THE MEDICAL USES OF ISOTOPES

Financial Assurance Requirements for Disposition of Category 1 – 3 Byproduct Material Radioactive Sealed Sources

August 29, 2024

Meeting Handout



Advisory Committee on the Medical Uses of Isotopes TELECONFERENCE AGENDA Thursday, August 29, 2024 2:00 PM – 4:00 PM ET

OPEN SESSION			
	1.	Opening Remarks Mr. Christian Einberg will formally open the meeting.	C. Einberg, NRC
2:00 PM — 4:00PM		Financial Assurance Requirements for Disposition of Category 1-3 Byproduct Material Radioactive Sealed Sources Mr. Richard Green will discuss the ACMUI's draft subcommittee report on its review and recommendations on this regulatory basis document.	R. Green, ACMUI
	2.	Closing and Adjournment Dr. Jadvar will close the meeting.	H. Jadvar, ACMUI



ACMUI Subcommittee on Financial Assurance Requirements for Disposition of Category 1–3 Byproduct Material Radioactive Sealed Sources

Subcommittee Report

Richard L. Green, BSPharm, Chair ACMUI Nuclear Pharmacist August 29, 2024



Financial Assurance Requirements for Disposition of Category 1–3 Byproduct Material Radioactive Sealed Sources

Subcommittee Members

Richard L. Green, BS Pharm (chair) Rebecca Allen, MS Richard Harvey, DrPH Zoubir Ouhib, MS Harvey B. Wolkov, MD

NRC Staff Resource: Daniel Shaw

Charge to Subcommittee

 To review the U.S. Nuclear Regulatory Commission (NRC) staff's draft regulatory basis document on Financial Assurance Requirements for Disposition of Category 1–3 Byproduct Material Radioactive Sealed Sources and provide feedback and recommendations

Regulatory Concerns

- Licensees Unprepared for Costs Associated with Disposition of Some Category 1–3 Sources
- Inadequate Financial Assurance to Support Disposition of Category 1–3 Sources due to Bankruptcy or Other Unforeseen Circumstances
- Lack of Regulatory Incentives to Provide Timely Disposal of Disused Category 1–3 Sources
- Disposition Costs for Some Category 1–3 Sources Borne by the Federal Government/Taxpayers Instead of Licensees

 The U.S. Nuclear Regulatory Commission (NRC) is considering revising the requirements in Title 10 of the Code of Federal Regulations (10 CFR) 30.35, "Financial Assurance and Recordkeeping for Decommissioning." The rulemaking would establish new decommissioning financial assurance (DFA) requirements for the disposition of Category 1–3 byproduct material radioactive sealed sources (RSSs).

Category 1 Sealed Sources, defined

 Category 1 sources, if not safely or securely managed, would be likely to cause permanent injury to a person who handled them or was otherwise in contact with them for more than a few minutes. It would probably be fatal to be close to this amount of unshielded material for a period of a few minutes to an hour. These sources are typically used in radiothermal generators, irradiators, and radiation teletherapy.

Only Categories 1 and 2 for radiation sources are defined by NRC requirements

https://www.nrc.gov/reading-rm/basic-ref/glossary/category-of-radioactive-sources.html

Category 2 Sealed Sources, defined

 Category 2 sources, if not safely or securely managed, could cause permanent injury to a person who handled them or was otherwise in contact with them for a short time (minutes to hours). It could possibly be fatal to be close to this amount of unshielded radioactive material for a period of hours to days. These sources are typically used in industrial gamma radiography, high- and medium-dose rate brachytherapy, and radiography

Only Categories 1 and 2 for radiation sources are defined by NRC requirements

https://www.nrc.gov/reading-rm/basic-ref/glossary/category-of-radioactive-sources.html

Category 3 Sealed Sources, defined

 Category 3 sources, if not safely or securely managed, could cause permanent injury to a person who handled them or was otherwise in contact with them for hours. It could possibly although it is unlikely to—be fatal to be close to this amount of unshielded radioactive material for a period of days to weeks. These sources are typically used in fixed industrial gauges such as level gauges, dredger gauges, conveyor gauges, spinning pipe gauges, and well-logging gauges.

https://www.nrc.gov/reading-rm/basic-ref/glossary/category-of-radioactive-sources.html

- The NRC's regulations in 10 CFR 30.35 require a fixed dollar amount of financial assurance or a decommissioning funding plan (DFP) for licensees possessing byproduct material with a half-life greater than 120 days and at activity levels above certain thresholds.
- However, the thresholds for sealed byproduct material are such that many licensees possessing Category 1–3 byproduct material RSSs are not required to provide financial assurance for decommissioning.

- The Commission approved initiation of this rulemaking in Staff Requirements Memorandum (SRM) SECY-16-0115, "Staff Requirements - SECY-16-0115—Rulemaking Plan on Financial Assurance for Disposition of Category 1 and 2 Byproduct Material Radioactive Sealed Sources," dated December 8, 2021.
- 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 establishing financial assurance requirements.
- This regulatory basis also includes a cost benefit analysis that considers impacts to the NRC, Agreement States, and industry (i.e., licensees) for each alternative.

Current Exemptions

- Licensees subject to 10 CFR Parts 50, 52, 72, 76 and 10 CFR Part 70, Subpart H, would be exempt from this rulemaking for the facilities and activities covered under those licenses.
- These licensees are already required to prepare a decommissioning plan and demonstrate sufficient financial assurance for decommissioning these facilities, including the disposition of any Category 1-3 byproduct material RSSs.

Cost / Impact Considerations

- NRC Implementation
- NRC Operations
- Agreement States Implementation
- Agreement States Operations
- Industry Implementation
- Industry Operations
- Other Government (DOE/NNSA) Operations

- Alternative 1—The Status Quo
- Alternative 2—Financial Assurance Based on Device Type and Disposition Pathway
- Alternative 3—Fixed Financial Assurance Based on Source Category
- Alternative 4—Financial Assurance Determined by a Parametric Formula
- Alternative 5—Financial Assurance Based on a Decommissioning Funding Plan
- Alternatives 6a, 6b (NRC Selected) and 6c—Hybrid Approach (Combines Alternatives 2, 3 and 5)

- 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 the baseline from which the staff evaluated the five other alternatives.

• Alternative 2—Financial Assurance Based on Device Type and Disposition Pathway

Alternative 2 Advantages

- Leverages extensive information collected and analyzed by the NRC staff to assign realistic DFA requirements across a broad range of devices
- Links DFA requirements to radiological risk, as represented by the 10 CFR Part 37 and IAEA Code of Conduct risk-based categories.
- Simple implementation for many licensees possessing sources or devices that are assigned a fixed DFA amount.
- Provides a DFA estimate tailored to the final disposition scenario for some devices (i.e., disposal through the DOE/NNSA or a commercial LLW disposal facility).
- Reduces risks associated with under- or over payment of DFA by tailoring required DFA amounts to estimated disposition costs.
- More accurately estimates DFA requirements compared to Alternative 3, which assigns a fixed DFA amount based on source category alone.
- Imposes less burden on licensees and regulatory staff than Alternative 5, which requires a DFP from each licensee.

Alternative 2 Disadvantages

- Has greater complexity than other alternatives and would result in greater regulatory costs for NRC, Agreement States, and licensees compared to the staff's recommended alternative (Alternative 6b).
- Would require additional education and training efforts during initial implementation.
- Includes fixed amounts and equations used to calculate DFA that would become outdated over time and require periodic updates.
- Bases fixed DFA amounts on averages for groups of devices that may not accurately represent the dispositioning cost for all individual cases.

• Alternative 3—Fixed Financial Assurance Based on Source Category

Alternative 3 Advantages

- Ties DFA requirements directly to radiological risk, as represented by the 10 CFR Part 37 and IAEA Code of Conduct risk-based categories.
- Simple implementation.
- For licensees electing to use the fixed DFA amounts in table 2, would result in less regulatory burden for both licensees and regulatory staff.

Alternative 3 Disadvantages

- Does not link DFA requirements directly to the cost of source dispositioning, so the specified DFA amounts will significantly over- or under-estimate actual costs for many disposition scenarios.
- Would expect many licensees to opt for a DFP in instances where the DFA amount is overestimated, increasing burden on licensees and regulators.
- Increased regulatory risk that the DFA amount will be inadequate to provide for device disposition (in cases where the fixed DFA value is an underestimate).
- Includes fixed DFA amounts that would become outdated over time and require periodic updates.

• Alternative 4—Financial Assurance Determined by a Parametric Formula

Alternative 4 Advantages

- Ties DFA requirements to radiological risk, as represented by the 10 CFR Part 37 and IAEA Code of Conduct risk-based categories. Increases parametric factors for sealed sources with increasing radiological risk.
- Has parametric factors based on key variables that drive disposal costs.
- Methodology is relatively simple to use and relies on source activity and disposal options provided by the applicant or licensee.
- Has parametric factors based on recent (2023) disposal cost estimates (albeit for a limited group of Category 1–3 RSSs and devices).
- DFA requirements are adjustable over time by adjusting the parametric factors (e.g., parameters can be adjusted to reflect increased disposition costs based on changes in the consumer price index (CPI) or disposal rate schedules).

Alternative 4 Disadvantages

- Selection of parameter values was based on a limited data set and the NRC staff was unable to validate the parametric model for device types dissimilar from those used to develop the model. Consequently, the parametric formula could significantly over- or under-estimate disposition costs for some types of devices.
- Has greater complexity than other alternatives and would result in greater regulatory costs for NRC, Agreement States, and licensees compared to the staff's recommended alternative (Alternative 6b).
- Requires periodic review and update of parametric factors by the regulator (e.g., labor, transportation, and disposal costs may change frequently), which would result in increased burden on licensees and regulators, as resources would be needed to periodically review each license, update the DFA calculation, and adjust the associated DFA amounts.
- Would require additional education and training efforts during initial implementation.
- Parameter values based on commercial disposal estimates and limited actual device disposal experience.

• Alternative 5—Financial Assurance Based on a Decommissioning Funding Plan

Alternative 5 Advantages

- Provides an accurate assessment of DFA requirements for source/device disposition that considers a licensee's unique circumstances.
- Adaptable to the diverse types of licensees/uses for Category 1–3 byproduct material RSSs.
- Adjustable over time and can be updated as licensees add or remove sources/devices from the license, or to account for changing disposition costs.
- May provide a cost savings for some licensees (e.g., if a fixed DFA amount specified by the NRC represents an overestimate).

Alternative 5 Disadvantages

- Would result in the highest implementation costs for the NRC, Agreement States, and licensees compared to the other alternatives, due to the need for initial preparation/review and periodic updates to DFPs for all affected licensees.
- Imposes unnecessary burden on licensees and regulators if RSS/device disposition costs can be adequately estimated through another method, such as a fixed DFA amount.

• Alternatives 6a, 6b (NRC Selected) and 6c—Hybrid Approach (Combines Alternatives 2, 3 and 5)

Alternative 6b Advantages

- For all variations, leverages extensive information collected and analyzed by the NRC staff to assign realistic fixed DFA amounts for many common RSSs and devices.
- All variations link DFA requirements to radiological risk, as represented by the 10 CFR Part 37 and IAEA Code of Conduct risk-based categories.
- All variations provide a simple approach using fixed DFA amounts for most affected licensees, while requiring DFPs in more complex scenarios in which disposition costs are expected to vary significantly.
- All variations result in lower costs for licensees, the NRC, and Agreement States compared to Alternatives 2 through 5 (i.e., Alternative 6c has the lowest costs, followed by Alternative 6b and Alternative 6a).
- Alternative 6b is informed by radiological risk by focusing on sources subject to 10 CFR Part 37 physical protection requirements.
- All variations provide licensees that are eligible to use the fixed DFA values with the flexibility to prepare a DFP if they so choose.

Alternative 6b Disadvantages

- Uses fixed DFA amounts that would become outdated over time and require periodic updates.
- Does not include some features of Alternative 2, such as a DFA estimate tailored to the final disposition scenario for some devices (i.e., disposal through the DOE/NNSA or a commercial LLW disposal facility).
- Bases fixed DFA amounts on averages for groups of devices that may not accurately represent the dispositioning cost for all individual cases.

This Regulatory Basis does the following

- Provides background information on policies, laws, and regulations related 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 the 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 and views, to the extent known.

Requiring financial assurance for the disposition of these Category 1- 3 byproduct material RSSs would do the following:

- Help ensure affected licensees are prepared for RSS disposition and facilitate timely disposition of disused RSSs.
- Ensure adequate financial resources are available to support RSS disposition in the event of unforeseen circumstances, such as licensee bankruptcy.
- Help ensure dispositioning costs for Category 1–3 RSSs are borne by those who receive the associated economic benefits.
- Address recommendations on this issue provided by the Government Accountability Office (GAO), the interagency Radiation Source Protection and Security Task Force, and other groups.

Summary

- The NRC staff recommends Alternative 6b as the method to pursue for this rulemaking. The staff chose this alternative because it provides the best balance between ensuring funds are available for RSS disposition and the associated regulatory burden borne by the NRC, Agreement States, and industry.
- The staff's recommended alternative (6b) would result in an updated, risk-informed approach that best addresses the direction provided by the Commission in SRM-SECY-16-0115 and the regulatory concerns identified by the NRC staff.

Subcommittee Comments

General Comments:

1. The general opinion of the subcommittee members was that the regulatory basis document was well developed, and effectively outlined the regulatory alternatives.

2. The subcommittee supports the recommendation that the agency conduct rulemaking as described in Alternative 6b of this regulatory basis.

3. A historical review of how financial assurance requirements have changed prior to the current regulations in place would be helpful.

4. A table of examples would be helpful to licensees and regulators.

Specific Comments on the Regulatory Basis Document:

1. A definition should be provided for a "self shielded irradiator"

Subcommittee Comments

- As representatives of the medical community, we feel this regulatory basis will help licensees to plan and to make full weighted financial decisions as they contemplate acquiring new technology and sealed sources.
- We all thought of our respective medical facilities and spoke with our colleagues regarding this topic. We all agreed that our facilities had some initial work prepared for disposition cessation activities, but additional focus would be appropriate.

Implementation Timeline & Process

- The estimated compliance date for the rule is 2028, by which time *NRC licensees* must comply.
- Agreement States will have 3 years to promulgate the rule.
 - The NRC assumes implementation to be spread evenly over the period 2028–2030 (one-third of total Agreement State licensees will implement the rule in each of the years 2028, 2029, and 2030).
- These dates will be subject to approval of the proposed rule and final rule.
 - The public will have another opportunity to comment after the proposed rule is issued.

- Am-241 americium-241
- Am/Be americium/beryllium
- BLS U.S. Bureau of Labor Statistics
- Bq becquerel
- CFR Code of Federal Regulations
- Ci curie
- Co-60 cobalt-60
- CPI Consumer Price Index

- CRCPD Conference of Radiation Control Program Directors, Inc.
- Cs-137 cesium-137
- DFA decommissioning financial assurance
- DFP decommissioning funding plan
- DOE U.S. Department of Energy
- ECB engineered concrete barrier
- FR Federal Register
- FTE full-time equivalent

- FY fiscal year
- GAO Government Accountability Office
- GTCC greater than Class C
- H&S Health and Safety
- IAEA International Atomic Energy Agency
- ISMP Integrated Source Management Portfolio
- LLW low-level waste
- mCi millicurie

- NIOSH National Institute for Occupational Safety and Health
- NNSA National Nuclear Security Administration
- NSTS National Source Tracking System
- NPV net present value
- NRC U.S. Nuclear Regulatory Commission
- OAS Organization of Agreement States
- ORS Office of Radiological Security
- OSRP Off-Site Source Recovery Program

- PERT program evaluation and review technique
- RSS radioactive sealed source
- SCATR Source Collection and Threat Reduction
- SECY Office of the Secretary of the Commission
- SRM staff requirements memorandum
- U.S.C. United States Code
- WBL Web-Based Licensing
- WCS Waste Control Specialists

U.S. Nuclear Regulatory Commission (NRC)

Advisory Committee on the Medical Uses of Isotopes (ACMUI)

Draft Report

Subcommittee Review and Comments on

Financial Assurance Requirements for Disposition of Category 1–3 Byproduct Material Radioactive Sealed Sources

Submitted: August 8th, 2024

Subcommittee Membership

Richard L. Green, BS Pharm (Chair)

Rebecca Allen, MS

Richard Harvey, DrPH

Zoubir Ouhib, MS

Harvey B. Wolkov, MD

NRC Staff Resource: Daniel Shaw

<u>Charge</u>

On April 8, 2024, the ACMUI Chair created a subcommittee to update the regulations in 10 CFR 30.35 that deal with financial assurance for Category 1 and Category 2 material. The Financial Assurance Requirements for Disposition of Category 1–3 Byproduct Material Radioactive Sealed Sources subcommittee's charge is to review and comment on the NRC staff's regulatory basis document. A joint NRC / Agreement State working group has drafted this document in accordance with Commission Direction.

Background

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Respectfully submitted on August 8th, 2024,

Subcommittee on Financial Assurance Requirements for Disposition of Category 1–3 Byproduct Material Radioactive Sealed Sources

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U.S. Nuclear Regulatory Commission (NRC)