Please stand by - Public Meeting

Decommissioning Financial Assurance Requirements for Sealed and Unsealed Radioactive Material

Webinar Link (presentation)
Audio: Bridge Number: (877) 910-5948
Passcode: 4930474

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Meeting Logistics

- **Meeting audio is through the bridge line only**
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Decommissioning Financial Assurance Requirements for Sealed and Unsealed Radioactive Material

January 7, 2021

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Agenda

Topic	Speaker
Opening Remarks	Patricia Holahan, Ph.D.
Introduction/Meeting Logistics	Torre Taylor Sarah Lopas, Facilitator
Petition Background/History	Torre Taylor
Technical Discussion (with 15’ break)	All
Decommissioning and Financial Assurance Requirements	Roberto Torres
Agreement State Information	Michelle Beardsley
Options for revising Part 30 Appendix B	Torre Taylor; All
Open Discussion and Questions	All
Summary and Next Steps	Torre Taylor

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Purpose of Meeting

- Topic of Rulemaking
  - Decommissioning financial assurance requirements for sealed and unsealed radioactive material
  - Update to Appendix B/Part 30 to include radionuclides not listed
- Focus of this meeting
  - Discuss approaches for revising Appendix B/Part 30
  - Seek public input
- Status of rulemaking
  - Developing the regulatory basis

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Background and History

- Petition from Organization of Agreement States (OAS) in 2017
- Rulemaking Plan to Commission - December 2019 (SECY-19-0125)
- Commission approved initiation of rulemaking
  - Staff Requirements Memorandum October 2020

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Technical Discussion

- What is financial assurance and how is it determined?
- NRC regulations for financial assurance
- Examples for when decommissioning financial assurance funding plan is needed

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What is financial assurance?

- A guarantee, or other financial arrangement, provided by a licensee that ensures funds for decommissioning will be available when needed. This is in addition to the licensee's regulatory obligation to decommission its facilities.

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When is financial assurance required?

- Two criteria:
  - Radioactive material must have a half life greater than 120 days; AND
  - Licensee must possess it in a quantity greater than the applicable activity threshold in Section 30.35(d) for material in sealed or unsealed form.

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How is financial assurance calculated?

- By using the tables in 10 CFR 30.35(d) - Tables set forth fixed monetary amounts based on order-of-magnitude multiples of the applicable radionuclide values in Appendix B.
- To find the decommissioning funding required, the licensee/regulator compares the license's possession limit for the specific nuclide to the nearest applicable order of magnitude exceeding that possession limit.

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10 CFR 30.35(d) Table

Greater than 10^4 but less than or equal to 10^5 times the applicable quantities of Appendix B to Part 30 in unsealed form.	$1,125,000
Greater than 10^3 but less than or equal to 10^4 times the applicable quantities of Appendix B to Part 30 in unsealed form.	$225,000
Greater than 10^{10} but less than or equal to 10^{12} times the applicable quantities of Appendix B to Part 30 in sealed sources or plated foils.	$113,000

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Examples of Appendix B Values

Material	Microcuries
Americium-241	.01
Carbon-14	100
Cesium-137	10
Cobalt-60	1
Hydrogen-3	1,000
Any alpha emitting	0.01
Any radionuclide other than alpha emitting radionuclides	0.1

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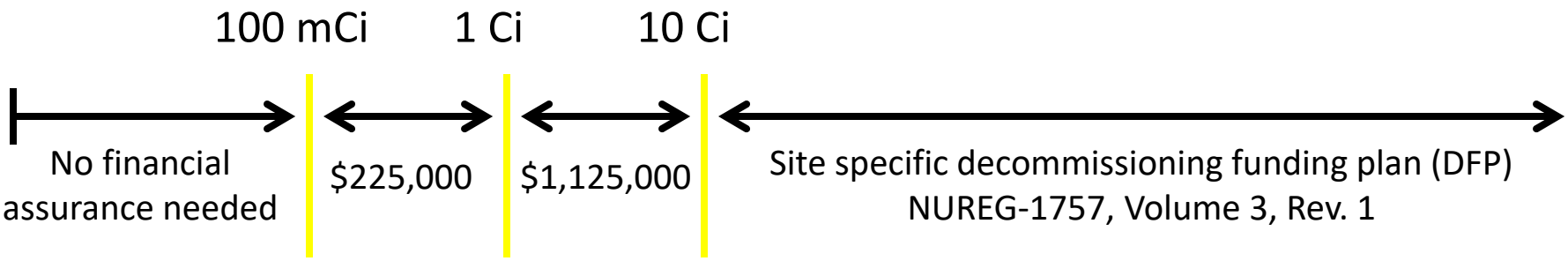
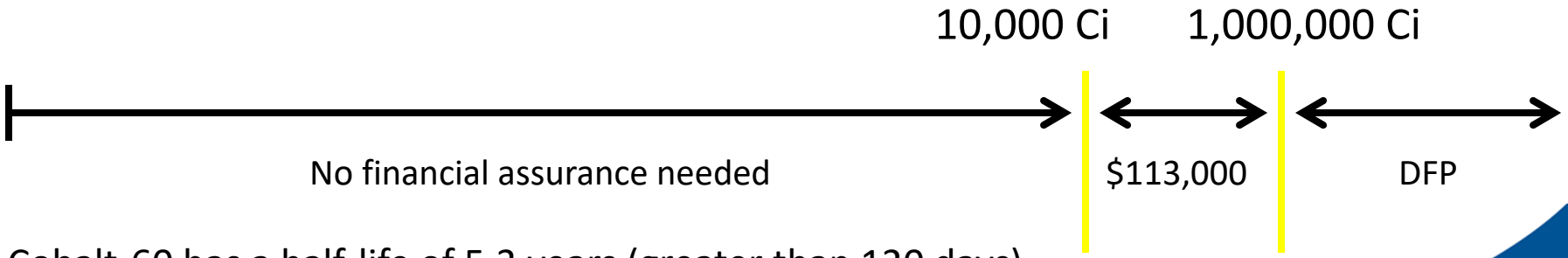
C-14 Unsealed: 10 CFR 30.35



Carbon-14 has a half-life of 5,730 years (greater than 120 days).

Co-60 Sealed: 10 CFR 30.35



Cobalt-60 has a half-life of 5.3 years (greater than 120 days).

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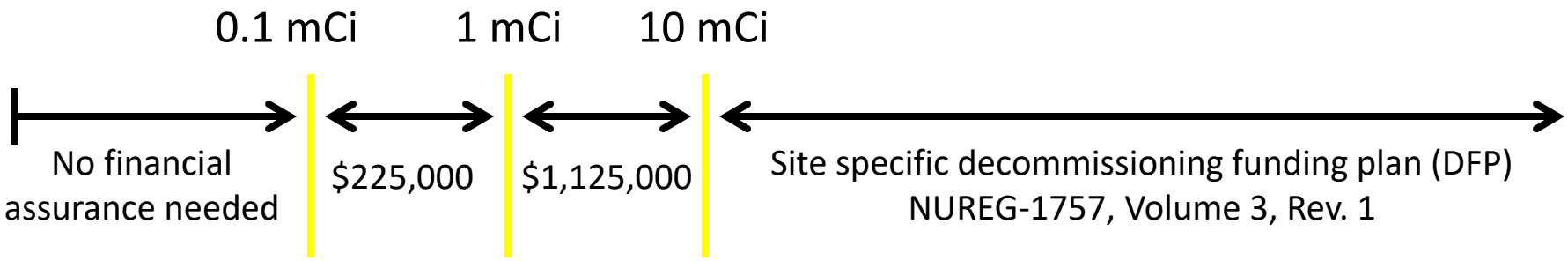
Ge-68 Unsealed: 10 CFR 30.35



Germanium-68 has a half life of 270.95 days (greater than 120 days).

Germanium-68/Gallium-68 generator (100 mCi of Ge-68), used in medical diagnosis, would require a site-specific decommissioning funding plan.

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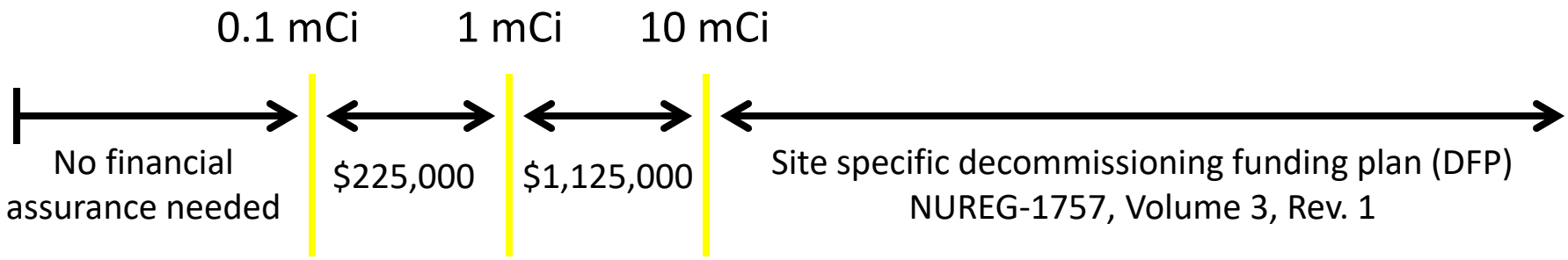
Lu-177m Unsealed: 10 CFR 30.35



Lutetium-177m has a half life of 161 days (greater than 120 days).

Lutetium-177 (half life of 6.647 days), used in medical treatment, sometimes contains Lutetium-177m (half life of 161 days) that will require a site-specific decommissioning funding plan.

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What is an "Agreement State"?

- Agreement States are States that enter into an agreement with the NRC to maintain a program that is adequate to protect public health and safety, and the environment, and is compatible with the NRC's program
- The regulations included in this rulemaking are a matter of both adequacy and compatibility with the Agreement States.

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Agreement State Compatibility with NRC Regulations

- Table in 10 CFR 30.35(d)
  - Compatibility D: Not required for the purpose of compatibility; however, required for adequacy.

- Appendix B of 10 CFR Part 30
  - Compatibility B: The State program element should be essentially identical to that of NRC.

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Where do we go from here?

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Alternative Approaches for Setting Appendix B Values

- Alternative 1: Develop a new methodology based on risks and costs of decommissioning a facility where the subject radionuclide is used
  - Apply to radionuclides already listed as well as the new additions

- Alternative 2: Reconstitute Appendix B with values for labeling from Appendix C in 10 CFR Part 20

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Pros and Cons for Alternative #1

Develop new risk methodology

Pros	Cons
More risk informed possession values	Likely to result in Appendix B values that are less conservative than Part 20 Appendix C's labeling values
Greater savings on decommissioning financial assurance costs for greatest number of affected licensees	Longer rulemaking due to the need for developing new risk methodology
Allows values to be set for unlisted nuclides with uses not now foreseen	

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Pros and Cons for Alternative #2
Update with values from Appendix C

Pros	Cons
Likely to result in more conservative Appendix B possession values compared to Alternative 1	Possession values for Appendix B radionuclides would be less risk-informed
Sixty-seven radionuclides in Appendix B would increase 10-fold; another eleven would increase 100-fold: may result in the need for less decommissioning funding	Likely to result in less decommissioning financial assurance cost savings compared to Alternative 1
Anticipate rulemaking taking less time to complete	Will result in smaller Appendix B values for key radionuclides (e.g., Am-241, Cd-109k, Pu-239, U-233, U-234, U-235, Zr-93)

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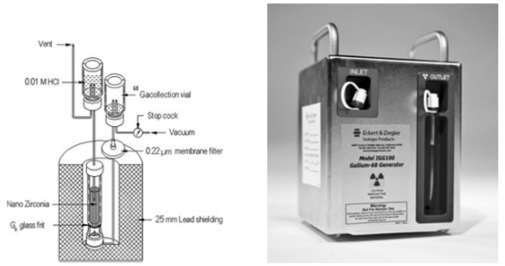
Comment on Petition

Add new category in Section 30.35 for radiopharmaceutical generators

- More engineered confinement than unsealed material but less than sealed sources
- Typically returned to an M&D
- Typically no need for extensive site decontamination or decommissioning

Ge-68/Ga-68 Generator



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Questions on Technical Discussion

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Decommissioning Financial Assurance Requirements Public Meeting

15 minute Break

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Questions for Discussion

1. Is it a higher priority to update Appendix B with Appendix C/Part 20 values versus developing a new risk-methodology based on decommissioning risk?

2. If we develop a new risk-methodology, what factors should we consider in setting values for radionuclides?

3. Would a 10-fold reduction in Appendix B values increase any licensee's decommissioning funding requirement for americium-241, cadmium-109, plutonium-239, uranium-233, -234, and -235, or zirconium-93?

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Questions for Discussion

4. What other benefits would be gained using one alternative over the other (new risk methodology vs. using values in Appendix C/Part 20)?

5. Is one option more resource intensive than the other for the Agreement States or for licensees?

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Questions for Discussion

6. If we develop a new category in Section 30.35 for radiopharmaceutical generators, how should we define them?
   - What factors should we consider in setting requirements for engineered confinement?

7. Are there other regulatory requirements (NRC, state, other Federal agencies) that we need to consider?

8. What costs/benefits should be considered?
   - Information about types and number of licensees; number of administrations per year, etc.

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Next Steps

- Develop regulatory basis
  - Evaluate input from public meeting
- Sixty day public comment period
  - Notice in the *Federal Register* – December 2021
- Follow rulemaking in www.regulations.gov under Docket ID: NRC-2017-0031

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References

- Organization of Agreement State Petition; April 17, 2017 - ML17173A063
- Comments on petition – ML18038A879
- Federal Register notice closing petition
  - 85 FR 75959; November 27, 2020

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References

- 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); December 17, 2019 (ML18292A434)
- SRM-SECY-19-0125, October 13, 2020 (ML20287A248)

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References

References for Agreement State Information and Compatibility

- Management Directive 5.9, “Adequacy and Compatibility of Program Elements for Agreement State Programs
- Management Directive 5.6, "Integrated Materials Performance Evaluation Program (IMPEP)"
- Agreement State Program Policy Statement, dated October 18, 2017 (82 FR 48535)
- State Agreement Procedure SA-200 (ML20183A325)
- NUREG 1350, Vol. 32 "2020-2021 Information Digest" (ML20282A632) Appendix L, P. L-1

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References

- NUREG-1757, "Consolidated Decommissioning Guidance," (ML063000243, ML063000252, and ML12048A683)

- Energy Policy Act of 2005, H.R. 6, 109th Cong. (2005)

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Background Slides

OAS Petition

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Petition Background

Regulatory burden on Germanium-68 generators

- Small, enclosed, lead-lined. Contain a solid resin column with 50-100 mCi of insoluble Ge-68 ($T^{1/2}$ 271 days), which decays to Gallium-68 ($T^{1/2}$ 68 mins.)
- FDA-approved for diagnostic imaging of neuroendocrine tumors (e.g., liver and pancreatic cancers)
  - Significantly higher resolution permits much earlier detection and surgical excision of tumors;
  - Nearly five-fold reduction in patient dose compared to In-111 technology.
- Generators are typically returned to the manufacturer/distributor when depleted, typically every 12 months
- Citing costs of the DFP requirement, only a few major medical centers and radiopharmacies provide Ge-68 technology.

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Radionuclides with Half-Lives Greater Than 120 Days Proposed by Commenters for Listing in Appendix B

Radionuclides Specifically Proposed By Commenters for Listing in Part 30 Appendix B	Listed in Part 20 Appendix C?
Actinium-227	Yes (0.001 microcuries)
Aluminum-26	Yes (10 microcuries)
Cobalt-57	Yes (100 microcuries)
Germanium-68	Yes (10 microcuries)
Lutetium-177m	Yes (10 microcuries)
Sodium-22	Yes (10 microcuries)
Rhenium-184m	Yes (10 microcuries)
Silicon-32	Yes (1 microcurie)
Thorium-228	Yes (0.001 microcuries)
Titanium-44	Yes (1 microcurie)

Background Slides

CURRENT NRC REGULATIONS

Decommissioning Funding Requirements

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Current NRC Regulations

- Under § 30.35:
  - Possessing an unsealed radionuclide in a quantity more than 1,000 times the Appendix B value requires decommissioning financial assurance;
  - Possessing an unsealed quantity greater than 100,000 times the Appendix B value requires a decommissioning funding plan (DFP);
  - DFPs require a comprehensive decommissioning cost estimate and updates every three years;
    - May not be necessary for licensees using small quantities in engineered containers returned to manufacturer/distributor (M&D) after use.

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Current NRC Regulations (cont'd)

- Appendix B possession values are used with 10 CFR 30.35 to determine how much decommissioning funding a licensee must provide to possess a given radionuclide in a sealed or unsealed form.
- Section 30.35 sets forth tables requiring fixed amounts of decommissioning funding that increase with the quantity of a nuclide the licensee is allowed to possess.
- The smaller the Appendix B value for a radionuclide, the less of it the licensee is allowed to possess without having to provide decommissioning financial assurance.
- A licensee with a radionuclide not listed on Appendix B must use a very restrictive default value to determine the decommissioning funding amount required to possess the unlisted nuclide at the limit allowed by the license.
- Material possessed in a sealed form requires much less financial assurance. Most medical uses require material in an unsealed form.

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Current NRC Regulations (Cont'd)

- If the license's possession limit exceeds the quantity for which Section 30.35 prescribes the maximum $1,125,000 fixed amount of financial assurance, the licensee must submit a decommissioning funding plan (DFP) based on the expected actual cost of decommissioning. DFPs
  - Must provide an amount of financial assurance based on a comprehensive estimate of the cost of decommissioning a facility using the maximum quantity allowed by the license;
  - Must cover all nuclides used at a facility, even if none of the other nuclides would otherwise require decommissioning funding;
  - May not be necessary for licensees using small quantities in engineered containers returned to manufacturer/distributor (M&D) after use.

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Background Information

AGREEMENT STATE COMPATIBILTY CATEGORIES

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Compatibility Categories of Regulations

A	B	C
State regulation needs to be identical	State regulation needs to be essentially identical	State regulation needs to meet essential objective of regulation
D	**H&S**	**NRC**
Not required compatibility	Needs to meet health and safety objective	States cannot adopt regulations

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