U.S.NRC
United States Nuclear Regulatory Commission
Protecting People and the Environment

Regulatory Basis for 10 CFR Part 35 Rulemaking on Rubidium-82 Generators, Emerging Technologies, and Other Medical Use of Byproduct Material

U.S. Nuclear Regulatory Commission Public Meeting
Presentation by the U.S. NRC/Agreement State Rulemaking Working Group
August 29, 2023

Where to Find Regulatory Basis Document

Regulations.gov Docket ID NRC-2018-0297

- https://www.regulations.gov/search?filter=nrc-2018-0297

***Federal Register* Citation**

- 88 FR 42654

NRC's Agencywide Documents Access and Management System

- ML23122A356

NRC/Agreement State Rulemaking Working Group

Organization	Working Group Members
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Presentation Outline

- Rulemaking Background
- Regulatory Basis Outline
- Overview of Proposed Changes & Feedback Questions
- Proposed Changes & Feedback Questions
- Early Feedback
- Rulemaking Cost Analysis
- Next Steps
- Questions

Rulemaking Background

- **NRC Rulemaking for 10 CFR Part 35**, "Medical Use of Byproduct Material."

Issues under consideration:

- Challenges associated with licensing Rb-82 generators.
- Challenges associated with licensing existing and future EMTs under the current medical use regulations.
- Other regulatory requirements that may not accommodate new developments in the medical field.

Proposed changes to 10 CFR Part 35 regulations:

- Address calibration and dose measurements for Rb-82 generators.
- Establish risk-informed, performance-based requirements for some existing and future EMTs within applicable subparts in Part 35, and outside of Subpart K (10 CFR 35.1000).
- Allow for additional flexibility and more risk-informed and performance-based requirements.

Rulemaking Background

- SECY-21-0013, "**Rulemaking Plan** to Establish Requirements for Rb-82 Generators and EMTs"
- **Regulatory Basis**

February 2021	RULEMAKING INITIATED via rulemaking plan (SECY-21-0013 - ML20261H562)
January 2022	RULEMAKING PLAN APPROVED (ML22013A266)
February 2022	NRC & Agreement States establish joint WORKING GROUP
November/ December 2022	NRC issues DRAFT REG. BASIS to AGREEMENT STATES & ACMUI REVIEW for comment
July 2023	**REGULATORY BASIS ISSUED for PUBLIC COMMENT (120 days)**

Regulatory Basis Outline

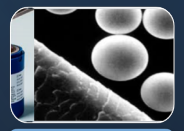
- Background Information and Existing Regulatory Framework
- Regulatory Issues
- Proposed Changes to the Regulations (Appendix A)
- Basis for the Proposed Changes
- Evaluation of Alternatives/Approaches to address the regulatory issues
- Costs and Benefits of Rulemaking and Alternatives
- Cost-benefit Assumptions and Tables (Appendices B, C, and D)

Overview of Proposed Changes

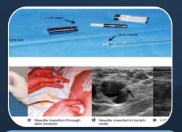
Sr-82/Rb-82 Generator

NorthStar RadioGenix Generator System

RadioMedix™ GeGant Ge-68/Ga-68 Generator System



Y-90 Microspheres



Radioactive Seed Localization

Novoste Beta-Cath Intravascular Brachytherapy System

Gamma Stereotactic RadioSurgery Perfexion and Icon

Gamma Stereotactic RadioSurgery GammaPod

ViewRay™ System Co-60 Radiation Therapy Device

- Proposed Changes are in Appendix A and have been organized by technology.
  - Overall rational for proposed changes.
  - Provides proposed changes organized by subpart and section of Part 35.
  - Includes NRC questions for feedback
- Additional section in Appendix A to address other proposed revisions to 10 CFR 35 (not associated with any one technology).
- Proposed changes are primarily based on the criteria in the EMT licensing guidance.

Overview of Major Proposed Changes

- Major proposed changes include:
  - Requirements for calibration and dosage measurement for strontium-82/rubidium-82 generators.
  - New subpart for microspheres (i.e., "Microsource Manual Brachytherapy").
  - Requiring device-specific training for some generators and EMTs.
  - Specific device components → → → Functional elements of the technologies.
- Note that this rulemaking would not establish regulations for:
  - NorthStar RadioGenix® Mo-99/Tc-99m Generator System.
  - Manual Brachytherapy using diffusing sources.

Appendix A:

Questions for Feedback

- Questions in Appendix A will help inform the proposed rule:
  - Is there enough operating experience to inform regulations for diffusion brachytherapy?
  - Is the effort to establish regulations for less widely used EMTs warranted?
  - Any feedback on the proposed regulatory framework for the new "microsource manual brachytherapy" subpart?
  - Do any EMTs warrant changes to their T&E requirements?

Appendix A:

Commission-directed Questions – "Reconsider T&E for EMTs"

- Additional questions in Appendix A related to T&E for EMTs based on Commission direction in SRM to SECY-20-0005 (ML22027A519):

1. Knowledge topics encompassing the safety-related characteristics of EMTs required for AUs to fulfill their radiation safety-related duties and supervision roles;

2. The methods on how knowledge topics should be acquired; and

3. Consideration for continuing education, vendor training for new medical uses, and training on the NRC regulatory requirements.

Appendix A.1:
Sr-82/Rb-82 and Ge-68/Ga-68 Generators

Proposed changes:

- **Sr/Rb generators continue to be licensed under Subpart D without the need for enforcement discretion.**
- **Ge/Ga generators to be licensed under Subpart D.**
- **Requirements for supervision, T&E, calibration, permissible concentration limits, records, and reporting.**

Question A.1.1: Please provide comments on the need for RSOs to have specific training for all 10 CFR part 35, subpart D generator systems.

If general awareness on radionuclide generators, including their functions and risks, is sufficient, explain why.

Question A.1.2: Please provide comments on whether and how the NRC should allow the completion of dosage measurements after the beginning of an incremental administration for radionuclides other than Rb-82.
- How would such an allowance be bounded?
- What considerations should go into the expansion of this flexibility?

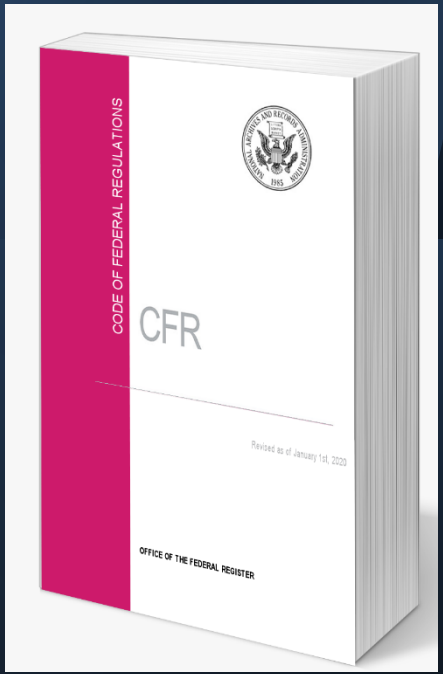
Appendix A.1 (contd.): Sr-82/Rb-82 and Ge-68/Ga-68 Generators

Question A.1.3: The NRC has found that AUs authorized under 10 CFR 35.290, "Training for imaging and localization studies," have sufficient understanding of radionuclide generators, and the NRC is proposing to revise 10 CFR 35.27, "Supervision," to require device-specific training requirements for supervised individuals.

Please provide comments with a rationale on whether Section 35.290 AUs should also be required to have device-specific training for all radionuclide generators for which they supervise the use.

Appendix A.1 Reference Guide

Sr-82/Rb-82 and Ge-68/Ga-68 Generators



Proposed 10 CFR sections to be amended:

35.27, "Supervision"

35.50, "Training for radiation safety officer and associate radiation safety officer"

35.60, "Possession, use, and calibration of instruments used to measure the activity of unsealed byproduct material"

35.63, "Determination of dosages of unsealed byproduct material for medical use"

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

35.290, "Training for imaging and localization studies"

35.2060, "Records of calibrations of instruments used to measure the activity of unsealed byproduct material"

35.2063, "Records of dosages of unsealed byproduct material for medical use"

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

35.3204, "Report and notification for an eluate exceeding permissible molybdenum 99, strontium-82, and strontium-85 concentrations"

Appendix A.2:
Intravascular Brachytherapy Systems

Proposed changes:

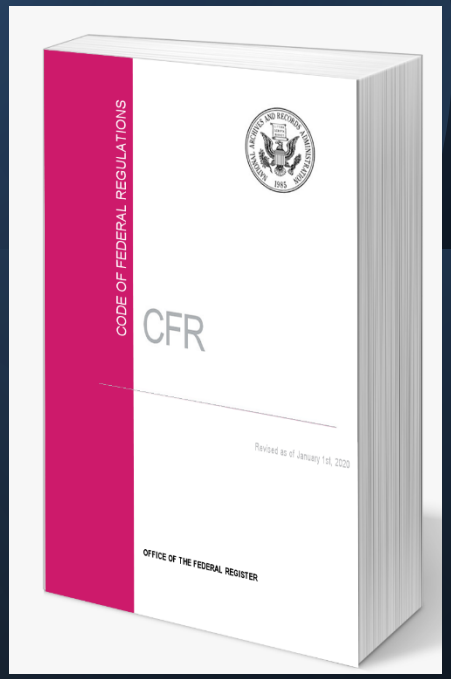
- **IVB to be licensed under Subpart F.**
- **Include similar Subpart H requirements related to T&E, physical presence, operating and emergency procedures, safety precautions, safety procedures and instructions, servicing, and radiation surveys and survey of patients and human research subjects.**
- **WD requirements to include IVB criteria.**

*Question A.2.1: Please provide comments on the sufficiency of the T&E requirements for AUs outlined in the current EMT licensing guidance documents for **IVB**, liquid brachytherapy, and eye applicators.*

Specifically, the NRC is seeking feedback on the knowledge topics encompassing the safety-related characteristics of these EMTs required for AUs to fulfill their radiation safety-related duties and supervision roles; the methods for acquiring knowledge topics; and consideration for continuing education, vendor training for new medical uses, and training on NRC regulatory requirements.

Appendix A.2 Reference Guide

Intravascular Brachytherapy Systems



Proposed 10 CFR sections to be amended:

35.8, "Information collection requirements: OMB approval"

35.12, "Application for license, amendment, or renewal"

35.13, "License amendments"

35.27, "Supervision"

35.40, "Written directives"

35.51, "Training for an authorized medical physicist"

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

35.400, "Use of sources for manual brachytherapy"

35.401, (proposed NEW section)

35.404, "Surveys after source implant removal"

35.405, (proposed NEW section)

35.410, "Safety instruction"

35.415, "Safety precautions"

35.432, "Calibration measurements of brachytherapy sources"

35.492, (proposed NEW section)

35.2605, "Records of installation, maintenance, adjustment, and repair of remote afterloader units, teletherapy units, and gamma stereotactic radiosurgery units"

Appendix A.3:
Liquid Brachytherapy Sources and Devices

Proposed changes:

- **Liquid Brachytherapy to be licensed under Subpart F.**
- **Requirements for definitions, WDs, T&E, possession of sealed sources and brachytherapy sources, labeling, safety instruction and precautions, and reporting.**

Question A.3.1: Please provide comments with a rationale on whether the current definition of manual brachytherapy in 10 CFR 35.2 should be revised to include liquid brachytherapy and exclude microsources or if liquid brachytherapy should be included in the newly proposed subpart I for microsources.

Question A.3.2: The NRC is seeking input on whether the new requirement on contamination control is needed or if the requirements in 10 CFR Part 20, "Standards for Protection against Radiation," are sufficient.

Please provide comments on this proposed requirement and indicate if it should apply to all medical licensees or to a certain subset and why.

Appendix A.3:
Liquid Brachytherapy Sources and Devices

Question A.3.3: The proposed changes discussed in Subpart A ("General Information") of this section would define the term "source leakage" as it relates to liquid brachytherapy. A possible leakage rate could be any leakage from a liquid brachytherapy source that results in a dose that exceeds 0.5 sievert (50 rem) dose equivalent to any individual organ other than the treatment site.

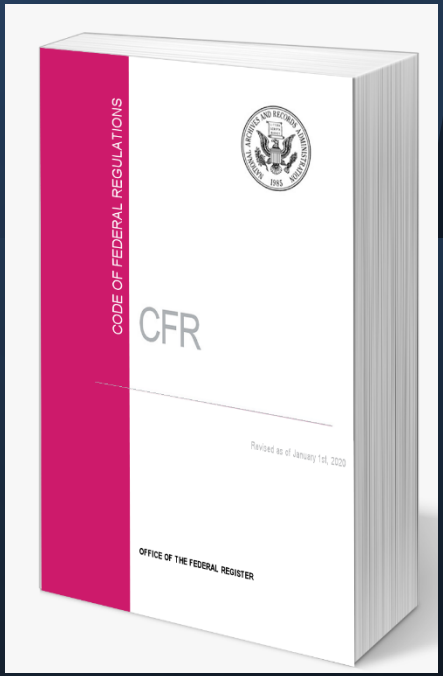
Please comment on whether this limit is appropriate and explain why or why not. What types of limits for liquid brachytherapy device leakage should the NRC consider (e.g., activity-based, dose-based, external to the patient)?

REFER TO Question A.2.1: Please provide comments on the sufficiency of the T&E requirements for AUs outlined in the current EMT licensing guidance documents for IVB, ***liquid brachytherapy****, and eye applicators.*

Specifically, the NRC is seeking feedback on the knowledge topics encompassing the safety-related characteristics of these EMTs required for AUs to fulfill their radiation safety-related duties and supervision roles; the methods for acquiring knowledge topics; and consideration for continuing education, vendor training for new medical uses, and training on NRC regulatory requirements.

Appendix A.3 Reference Guide

Liquid Brachytherapy Sources & Devices



Proposed 10 CFR sections to be amended:

35.2, "Definitions"

35.8, "Information Collection Requirements: OMB approval"

35.13, "Application for license, amendment, or renewal"

35.40, "Written directives"

35.41, "Procedures for administrations requiring a written directive"

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

35.67, "Requirements for possession of sealed sources and brachytherapy sources"

35.69, "Labeling of vials and syringes"

35.71, "Contamination control"

35.400, "Use of sources for manual brachytherapy"

35.401, (proposed NEW section)

35.410, "Safety instruction"

35.415, "Safety precautions"

35.492, (proposed NEW section)

35.3067, "Report of a leaking source"

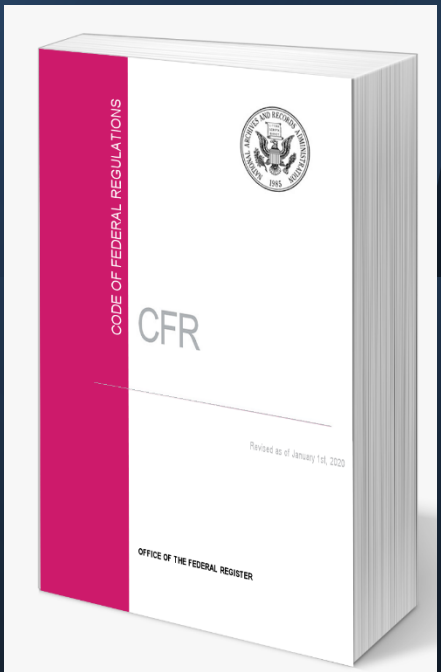
Appendix A.4:
Radioactive Seed Localization

Proposed changes:

- **Radioactive Seed Localization to be licensed under Subpart G.**
- **Requirements for definition, supervision, T&E, suppliers for sealed sources or devices, possession of sealed sources and brachytherapy sources, records, and medical event reporting.**

Appendix A.4 Reference Guide

Radioactive Seed Localization



Proposed 10 CFR sections to be amended:

35.2, "Definitions"

35.8, "Information Collection Requirements: OMB approval"

35.27, "Supervision"

35.49, "Suppliers for sealed sources or devices for medical use"

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

35.500, "Use of sealed sources and medical devices for diagnosis."

35.501, (proposed NEW section)

35.504, (proposed NEW section)

35.506, (proposed NEW section)

35.510, (proposed NEW section)

35.515, (proposed NEW section)

35.532, (proposed NEW section)

35.591, (proposed NEW section)

35.2024, "Records of authority and responsibilities for radiation protection programs"

35.2026, "Records of radiation protection program changes"

35.2406, "Records of brachytherapy source accountability"

35.2432, "Records of calibration measurements of brachytherapy sources"

35.3045, "Report and notification of a medical event"

Appendix A.5:
Ophthalmic (Eye) Applicator Sources and Devices

Proposed changes:

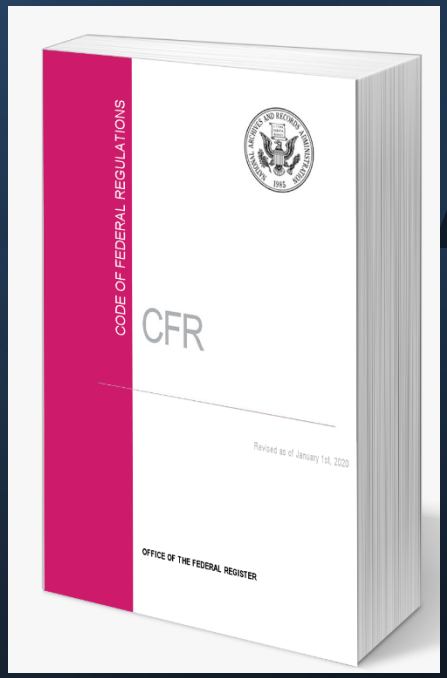
- **Ophthalmic (Eye) Applicator Sources and Devices to be licensed under Subpart F.**
- **Address T&E for use of unique devices, operation, and use; and a different type of radionuclide.**
- **Requirements for WDs, T&E, safety precautions, physical presence, ophthalmic sources, and records.**

*REFER TO Question A.2.1: Please provide comments on the sufficiency of the T&E requirements for AUs outlined in the current EMT licensing guidance documents for IVB, liquid brachytherapy, and **eye applicators**.*

Specifically, the NRC is seeking feedback on the knowledge topics encompassing the safety-related characteristics of these EMTs required for AUs to fulfill their radiation safety-related duties and supervision roles; the methods for acquiring knowledge topics; and consideration for continuing education, vendor training for new medical uses, and training on NRC regulatory requirements.

Appendix A.5 Reference Guide

Ophthalmic (Eye) Applicator Sources and Devices



Proposed 10 CFR sections to be amended:

35.8, "Information Collection Requirements: OMB approval"

35.40, "Written directives"

35.50, "Training for Radiation Safety Officer and Associate Radiation Safety Officer"

35.51, "Training for an authorized medical physicist"

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

35.400, "Use of sources for manual brachytherapy"

35.401, (proposed NEW section)

35.415, "Safety precautions"

35.433, "Strontium-90 sources for ophthalmic treatments"

35.492, (proposed NEW section)

35.2433, "Records of decay of strontium-90 sources for ophthalmic treatments"

Appendix A.6:
Gamma Stereotactic Radiosurgery and Photon Emitting Teletherapy Units

Proposed changes:

- **Restructure Subpart H to focus on functional elements and objectives of technologies.**
- **Address major design and engineering changes in technologies.**
- **Requirements for definitions, license amendments, WDs, T&E, safety procedures/instructions and precautions, full calibration measurements, periodic spot checks, and records.**

Question A.6.1: Please provide comments on the need for model-specific training for radiation safety officers for certain 10 CFR part 35, subpart H devices. If model-specific training is needed, how should the NRC determine which devices would require such training?

Appendix A.6:
Gamma Stereotactic Radiosurgery and Photon Emitting Teletherapy Units

Question A.6.2: Current NRC requirements in 10 CFR Part 35, Subpart H, focus on components critical to patient and facility safety for the use of these devices. The proposed changes to Subpart H focus on elements rather than specific components.

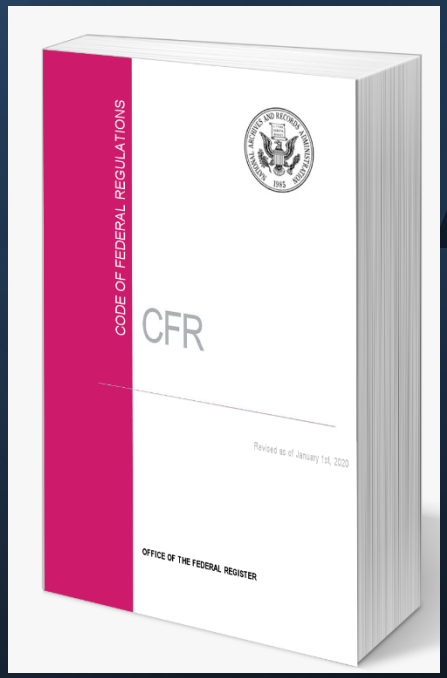
Please provide comments on other elements that should be considered.

Question A.6.3: Please provide comments on what types of objective tests the NRC should require for full calibration measures for 10 CFR Part 35, Subpart H, devices? Additionally, what functional elements should be considered critical to safety?

Question A.6.4: Please provide comments on what types of objective tests the NRC should require for periodic spot-checks for 10 CFR Part 35, Subpart H, devices. Additionally, what functional elements should be considered critical to safety?

Appendix A.6 Reference Guide

Gamma Stereotactic Radiosurgery & Photon Emitting Teletherapy Units



Proposed 10 CFR sections to be amended:

35.2, "Definitions"

35.8, "Information collection requirements: OMB approval"

35.12, "Application for license, amendment, or renewal"

35.13, "License amendments"

35.40, "Written directives"

35.41, "Procedures for administrations requiring a written directive"

35.50, "Training for Radiation Safety Officer and Associate Radiation Safety Officer"

35.51, "Training for an authorized medical physicist"

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

35.610, "Safety procedures and instructions for remote afterloader units, teletherapy units, and gamma stereotactic radiosurgery units"

35.615, "Safety precautions for remote afterloader units, teletherapy units, and gamma stereotactic radiosurgery units"

35.632, "Full calibration measurements on teletherapy units"

35.633, "Full calibration measurements on remote afterloader units"

35.635, "Full calibration measurements on gamma stereotactic radiosurgery units"

35.642, "Periodic spot-checks for teletherapy units"

35.643, "Periodic spot-checks for remote afterloader units"

35.645, "Periodic spot-checks for gamma stereotactic radiosurgery units"

35.690, "Training for use of remote afterloader units, teletherapy units, and gamma stereotactic radiosurgery units"

35.2642, "Records of periodic spot-checks for teletherapy units"

35.2643, "Records of periodic spot-checks for remote afterloader units"

35.2645, "Records of periodic spot-checks for gamma stereotactic radiosurgery units"

Appendix A.7:
Microsource Manual Brachytherapy

Proposed changes:

- **New subpart in Part 35, Subpart I, with new sections (e.g., 10 CFR 35.700) for Microsource Manual Brachytherapy.**
- **New title for type of use and new definition for these sources.**
- **Requirements to distinguish between current manual brachytherapy technologies and microsource manual brachytherapy.**
- **Mirrored regulatory structure in Subparts F and H, and criteria in current microspheres licensing guidance.**

Question A.7.1: The NRC is considering defining a "microsource" in 10 CFR 35.2 as microparticles and microspheres. What types of radiation (such as alpha, beta, gamma) should be covered by the definition of "microsource"? Please include comments and a rationale for whether 1) microspheres should be limited to specific types of radiation or certain energies, 2) microsources should be limited to sealed sources with a SS&D registry, 3) unsealed microsources should be required to have a SS&D registry, and 4) any additional changes are needed to the current regulations for microsource brachytherapy that would increase flexibility for future microsource brachytherapy.

Appendix A.7:
Microsource Manual Brachytherapy

Question A.7.2: The NRC is considering defining "physiological equilibrium" in 10 CFR 35.2 to include stasis or other states of equilibrium. Please comment on what should be included in physiological equilibrium or identify other considerations for physiological stop points.

Question A.7.3: As the complexity of the medical use of byproduct material increases, use of teams in medical care is becoming more common. Please provide comments on the fundamental elements of a successful team-approach program..

Question A.7.4: For microsource manual brachytherapy, please provide comments and a rationale for whether the before-implant written directive should specify the dose or activity.

Question A.7.5: For microsource manual brachytherapy, please provide comments and a rationale for whether the after-implant written directive should specify the activity administered or the dose delivered to the treatment site.

Appendix A.7:
Microsource Manual Brachytherapy

Question A.7.6: As required by Section 35.41 for determining whether a medical event has occurred (as defined in Section 35.3045), please comment on whether and why the NRC should require calculating and documenting the activity administered or the activity or dose specifically delivered to the treatment site. By what deadline (e.g., number of hours or days) should this determination be made?

Question A.7.7: For microsource manual brachytherapy, please comment on whether the NRC should require post-treatment imaging to confirm that the treatment was delivered in accordance with the written directive. Why or why not? What other mechanisms are available to confirm that the treatment was delivered in accordance with the written directive?

Question A.7.8: Please identify any tasks that would require an AMP for the use of microsphere manual brachytherapy and identify whether and how the NRC should revise the T&E requirements for AMPs.

Appendix A.7:
Microsource Manual Brachytherapy

Question A.7.9: Please comment on what types of use should be permitted for microsource manual brachytherapy, including whether the use should be limited to that approved in the sealed source and device registry. Please comment on why unsealed microsources without a unique delivery system should or should not be allowed.

Question A.7.10: Please comment on why any new requirements for microsource manual brachytherapy should or should not be limited to permanent implants.

Question A.7.11: The potential changes to bring microspheres into the regulatory framework include establishing safety procedures and instructions. These changes are based on current licensing guidance for Y-90 microspheres and expected new uses of microsources. Please identify and comment on other items that should be included in a new requirement for safety procedures and instructions for microsource manual brachytherapy.

Appendix A.7:
Microsource Manual Brachytherapy

Question A.7.12: The potential changes to bring microspheres into the regulatory framework include establishing safety precautions. These changes are based on current licensing guidance for Y-90 microspheres and expected new uses of microsources. Please identify and comment on other items that should be included in a new requirement for safety precautions (controls) for microsource manual brachytherapy.

Appendix A.7:
Microsource Manual Brachytherapy

Question A.7.13: The current licensing guidance for Y-90 microspheres states that an AU should successfully complete training in the operation of the delivery system, safety procedures, and clinical use for the specific type of Y-90 microsphere for which authorization is sought.

The guidance specifies that clinical use training to support unsupervised use should include at least three hands-on patient cases for each type of Y-90 microsphere requested, conducted in the physical presence of an AU who is authorized for the type of Y-90 microsphere for which the individual is seeking authorization.

The guidance allows conditional approval of an AU before completing these three hands-on patient cases if a proposed AU cannot complete patient cases before authorization. This conditional approval was originally added to the guidance because there were limited Y-90 microsphere licensees and AUs to train future AUs. As the use of Y-90 microspheres has increased significantly, please comment on the continued need for conditional approval for Y-90 microsphere AUs.

Indicate why the NRC should or should not continue to allow this pathway for all microsphere and microsource AUs.

Appendix A.7:
Microsource Manual Brachytherapy

Question A.7.14: The NRC is seeking input on the 80 hours of classroom and laboratory training for interventional radiologists pursuing AU status for Y-90 microsphere and other microsource uses.

The NRC in the current EMT licensing guidance for Y-90 microspheres includes a pathway for interventional radiologists to become AUs for Y-90 microspheres use. This pathway requires the interventional radiologist to demonstrate that they have 80 hours of classroom and laboratory training in specific topics and specific work experience important to radiation safety, in addition to demonstrating that they have sufficient clinical interventional radiology and diagnostic radiology experience. Please comment on why 80 hours is or is not an appropriate amount of time to ensure that these topics are adequately covered.

Who should supervise the work experience to ensure that the future AUs have adequate radiation safety knowledge and why?

Appendix A.7:
Microsource Manual Brachytherapy

Question A.7.15: The NRC in the current licensing guidance for Y-90 microspheres provides a pathway for interventional radiologists and physicians who meet the T&E requirements in 10 CFR 35.390 and 10 CFR 35.490 to become AUs for Y-90 microsphere use.

This pathway does not require any additional classroom and laboratory training or specific work experience for these physicians besides demonstration of successfully completed training in the operation of the delivery system, safety procedures, and clinical use (including hands-on patient cases) for the type of Y-90 microsphere for which authorization is sought. Please identify and comment on any additional classroom and laboratory training topics or specific work experience that should be required for these physicians to become AUs for all microspheres or other types of microsources in Subpart I.

What additional training and work experience should be considered, if any, and why?

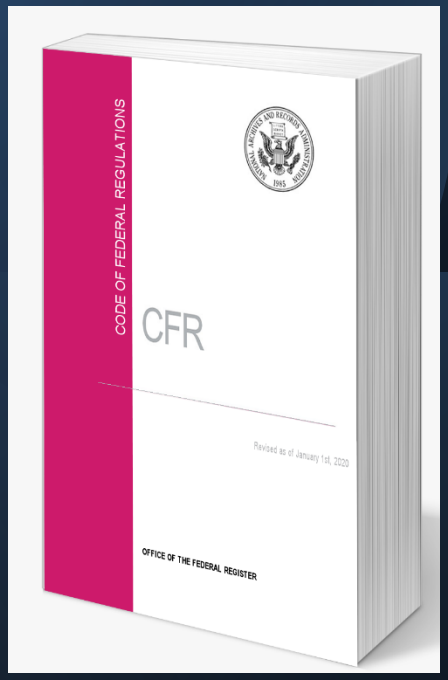
Appendix A.7:
Microsource Manual Brachytherapy

Question A.7.16: The NRC in the current licensing guidance for Y-90 microspheres provides pathways for interventional radiologists and physicians that meet the T&E requirements in 10 CFR 35.390 and 10 CFR 35.490 to become AUs for Y-90 microsphere use. Please comment on whether and why the NRC should or should not provide additional pathways for other types of physicians to become AUs for use of microspheres or other types of microsources.

Question A.7.17: In most circumstances, are AUs the individuals administering Y-90 microspheres? Is it appropriate for other individuals to administer microsources under the supervision of an AU? Why or why not?

Appendix A.7 Reference Guide

Microsource Manual Brachytherapy



Proposed 10 CFR sections to be amended:

35.2, "Definitions"
35.8, "Information collection requirements: OMB approval"
35.12, "Application for license, amendment, or renewal"
35.13, "License amendments"
35.14, "Notifications"
35.24, "Authority and responsibilities for the radiation protection program"
35.27, "Supervision"
35.40, "Written directives"
35.41, "Procedures for administrations requiring a written directive"
35.50, "Training for Radiation Safety Officer and Associate Radiation Safety Officer"
35.51, "Training for an authorized medical physicist"
35.57, "Training for experienced Radiation Safety Officer, teletherapy or medical physicist, authorized medical physicist, authorized user, nuclear pharmacist, and authorized nuclear pharmacist"
35.59, "Recentness of training"
35.60, "Possession, use, and calibration of instruments used to measure the activity of unsealed byproduct material"
35.63, "Determination of dosages of unsealed byproduct material for medical use"
35.67, "Requirements for possession of sealed sources and brachytherapy sources"
35.69, "Labeling of vials and syringes"

NEW SUBPART I to establish the requirements for microsource manual brachytherapy. At a minimum, this subpart would address requirements for the safe use of microsource manual brachytherapy.

10 CFR **Sections under new Subpart I: 700, 704, 706, 710, 715, and 790**

35.2060, "Records of calibrations of instruments used to measure the activity of unsealed byproduct material"35.2643, "Records of periodic spot-checks for remote afterloader units"
35.2063, "Records of dosages of unsealed byproduct material for medical use"
35.2310, "Records of safety instruction"
35.2404, "Records of surveys after source implant and removal"
35.2406, "Records of brachytherapy source accountability"
35.2710, (proposed NEW section)
35.3045, "Report and notification of a medical event"

Appendix A.8:
Other 10 CFR Part 35 Changes

Proposed changes:

- **Procedures for breakthrough testing and reporting for novel radionuclide generators.**

Question A.8.1: Industry is evaluating various novel radionuclide generators. Some novel radionuclide generators may be used to compound therapeutic dosages of unsealed byproduct material. The NRC is considering a requirement for licensees to perform breakthrough testing on novel radionuclide generators and report instances when breakthrough exceeds a defined limit. Since breakthrough limits for some novel radionuclide generators have not been established by the United States Pharmacopeia, please explain why it would or would not be sufficient for licensees to develop, implement, and maintain procedures for breakthrough testing and reporting for novel radionuclide generators.

Appendix A.8:
Other 10 CFR Part 35 Changes

Proposed changes:

- **T&E for AUs and ANPs utilizing novel radionuclide generators.**
- **AMP involvement in Manual Brachytherapy.**

Question A.8.2: Please comment on the type of T&E that should be required for AUs utilizing novel radionuclide generators and the type of T&E for authorized nuclear pharmacists utilizing novel radionuclide generators.

Question A.8.3: Please comment on why current structure for AMP involvement in 10 CFR Part 35, Subpart F, "Manual Brachytherapy," is or is not sufficient. If not sufficient, what specific tasks or skills should be performed by an AMP for manual brachytherapy?

Appendix A.8:
Other 10 CFR Part 35 Changes

Proposed changes:

- **Requirements for definition of a physician, defining treatment regimen for patient release, Radiation Safety Committee, supervision, WDs, T&E and recentness of training, patient release, record keeping, medical event reporting, and safety procedures/instructions/precautions.**

Question A.8.4: Due to the increased number and complexity of EMTs, please comment on why the NRC should or should not require continuing education for AUs. If continuing education should be required, what should it entail, at what frequency should it be acquired, and how should knowledge topics be acquired?

Question A.8.5: Please comment on the need for AUs for 10 CFR 35.200 to have device-specific training on radionuclide generators. If device-specific training is needed, what topics should the training include? Please explain why the training should or should not be specific to the radionuclide generators for which the AUs are supervising the use.

Appendix A.8:
Other 10 CFR Part 35 Changes

Question A.8.6: Please comment and provide a rationale for whether physicians authorized for full use under 10 CFR 35.300, "Use of unsealed byproduct material for which a written directive is required," need additional T&E to fulfill their radiation safety related duties and supervision roles because of expected emerging therapeutic radiopharmaceuticals. Please comment on why additional training is or is not needed on regulatory requirements for emerging therapeutic radiopharmaceuticals. If needed, what should the scope of the T&E include?

What specific training should these AUs be required to have (e.g., vendor training on clinical use and safety procedures) prior to first-time use, if any? Why should they be required or not required to have continuing education?

Appendix A.8:
Other 10 CFR Part 35 Changes

Question A.8.7: Please comment on why the current AU T&E requirements for use of sealed sources and medical devices for diagnosis in 10 CFR 35.590 (i.e., 8 hours of classroom and laboratory training in basic radionuclide-handling techniques specifically applicable to the use of the device authorized under 10 CFR 35.500, as well as device-specific training in the use of the device) are or are not appropriate for emerging sealed sources and medical devices containing sealed sources.

If AUs for 10 CFR 35.500 need additional training and work experience on emerging sealed sources and medical devices containing sealed sources for diagnosis, what topics should be covered?

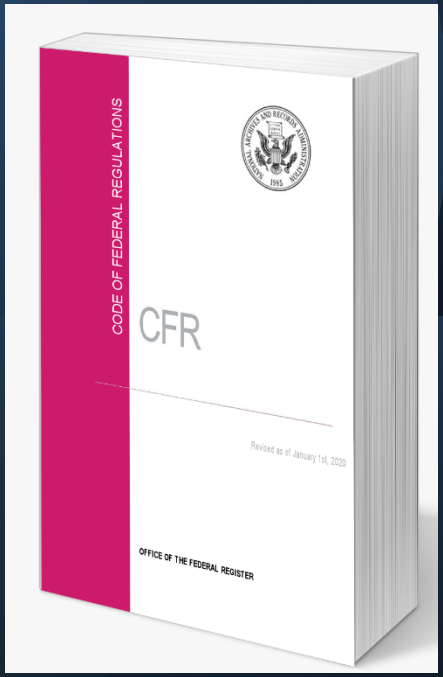
Appendix A.8:
Other 10 CFR Part 35 Changes

Question A.8.8: Please comment on any specific changes that are needed to secure consoles, keys, and passwords for remote afterloader units, teletherapy units, and GSR units because of changes in technology.

Question A.8.9: Please comment on the types of doors or entry controls that would be acceptable to maintain security of licensed material while not interfering with patient care. For example, why should a physical door be required, or why are other entry controls such as lasers acceptable?

Appendix A.8 Reference Guide

Other 10 CFR Part 35 Changes



Proposed 10 CFR sections to be amended:

35.2, "Definitions"

35.24, "Authority and responsibilities for the radiation protection program"

35.27, "Supervision"

35.40, "Written directives"

35.41, "Procedures for administrations requiring a written directive"

35.59, "Recentness of training"

35.75, "Release of individuals containing unsealed byproduct material or implants containing byproduct material"

35.190, "Training for uptake, dilution, and excretion studies"

35.290, "Training for imaging and localization studies"

35.392, "Training for the oral administration of sodium iodide I-131 requiring a written directive in quantities less than or equal to 1.22 gigabecquerels (33 millicuries)"

35.394, "Training for the oral administration of sodium iodide I-131 requiring a written directive in quantities greater than 1.22 gigabecquerels (33 millicuries)"

35.396, "Training for the parenteral administration of unsealed byproduct material requiring a written directive"

35.590, "Training for use of sealed sources and medical devices for diagnosis"

35.610, "Safety procedures and instructions for remote afterloader units, teletherapy units, and gamma stereotactic radiosurgery units"

35.615, "Safety precautions for remote afterloader units, teletherapy units, and gamma stereotactic radiosurgery units"

35.2075, "Records of the release of individuals containing unsealed byproduct material or implants containing byproduct material"

35.3045, "Report and notification of a medical event"

The Organization of Agreement States

Comments on DRAFT REGULATORY BASIS

- Indicated support of the proposed training requirements.
- Recommended NRC should consider scaling back some of the regulatory development for this rulemaking effort.
- Recommended that NRC consider developing a T&E pathway for individuals who administer radioactive materials.
- Recommended that NRC consider developing a structured pathway with defined metrics for determining that a type of medical use of radioactive materials is no longer an emerging technology.

The Advisory Committee on the Medical Uses of Isotopes

Comments on DRAFT REGULATORY BASIS

- Scope of rulemaking is ambitious, but reasonable; and should be limited to products that are in broader use because time and clinical experience are needed to understand the technology and safety issues before codifying requirements.
  - Recommended not moving the Gammapod™ and the ViewRay™ System into 10 CFR Part 35, Subpart H.
  - Recommended not moving diffusing brachytherapy sources into 10 CFR Part 35, Subpart F.
- Recommended creating a contamination control requirement for IVB and diffusing sources
- Recommended that the NRC revise the licensing process for ophthalmic applicator systems. Specifically, NRC should comprehensively reevaluate the requirements for ophthalmic applicator systems licensed under 10 CFR Part 35, Subpart F and Subpart K.

Rulemaking Cost Analysis

NRC staff developed a preliminary cost analysis for the rulemaking and options.

- NRC rulemaking costs.
- Agreement State and Licensee rulemaking participation costs (includes WG member).
- NRC, Agreement State, and licensee implementation of the rule (developing compatible regs, submitting and reviewing revised procedures).
- Averted costs related to inspection of Rb-82 generators and EMT licensing actions.

Cost Analysis:

Where to Focus

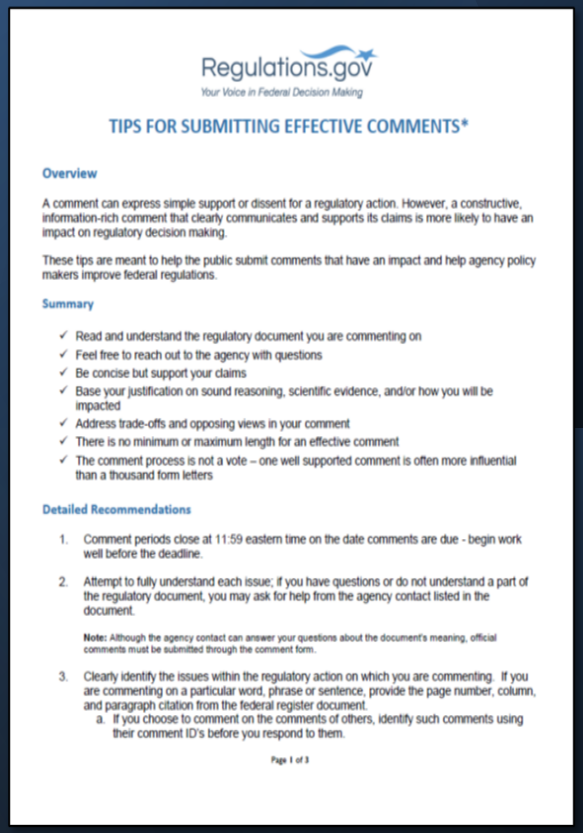
Section 8, "Cost/Impact Considerations"

- Contains "Analysis Assumptions" and description of Agreement State costs and averted costs
- Table 5 is a summary table of costs for each of the four alternatives
- Table 6 is a breakdown of the Alternative 4 rulemaking costs for NRC/AS/Licensees

Appendix B, "Data Tables"

- Table 7 is EMT licensing assumptions (i.e., how many EMTs NRC has licensed to date, how many similar technologies we expect to license in future, and how many hours we could save on initial license and amendment applications)
- Table 8 shows data for each alternative

How to Submit Comments



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TIPS FOR SUBMITTING EFFECTIVE COMMENTS*

Overview

A comment can express simple support or dissent for a regulatory action. However, a constructive, information-rich comment that clearly communicates and supports its claims is more likely to have an impact on regulatory decision making.

These tips are meant to help the public submit comments that have an impact and help agency policy makers improve federal regulations.

Summary

- ✓ Read and understand the regulatory document you are commenting on
- ✓ Feel free to reach out to the agency with questions
- ✓ Be concise but support your claims
- ✓ Base your justification on sound reasoning, scientific evidence, and/or how you will be impacted
- ✓ Address trade-offs and opposing views in your comment
- ✓ There is no minimum or maximum length for an effective comment
- ✓ The comment process is not a vote – one well supported comment is often more influential than a thousand form letters

Detailed Recommendations

1. Comment periods close at 11:59 eastern time on the date comments are due - begin work well before the deadline.
2. Attempt to fully understand each issue; if you have questions or do not understand a part of the regulatory document, you may ask for help from the agency contact listed in the document.

   Note: Although the agency contact can answer your questions about the document's meaning, official comments must be submitted through the comment form.
3. Clearly identify the issues within the regulatory action on which you are commenting. If you are commenting on a particular word, phrase or sentence, provide the page number, column, and paragraph citation from the federal register document.
   a. If you choose to comment on the comments of others, identify such comments using their comment ID's before you respond to them.

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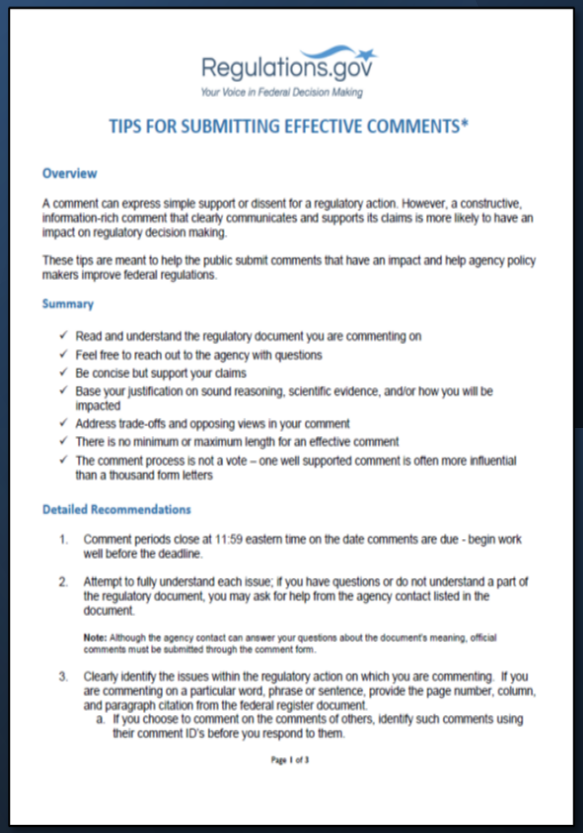
- Available from Regulations.gov at: https://downloads.regulations.gov/FS-2018-0053-0007/content.pdf
- This information is also available from the page for submitting comments on the proposed rule: https://www.regulations.gov/commenton/NRC-2018-0297-0001
- Frequently Asked Questions (FAQs) on commenting are available at: https://www.regulations.gov/faq

How to Submit Comments



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Ways You Can Submit Comments:

- **Regulations.gov**: comment form for the proposed rule on docket NRC–2018–0297

or

- **Email**: Rulemaking.Comments@nrc.gov

or

- **Mail**: Secretary, U.S. Nuclear Regulatory Commission, Washington, DC 20555-0001, ATTN: Rulemakings and Adjudications Staff

- **Comment period closes on October 31, 2023**

Next Steps

10 CFR Part 35 Rb-82/EMT Rulemaking Timeline

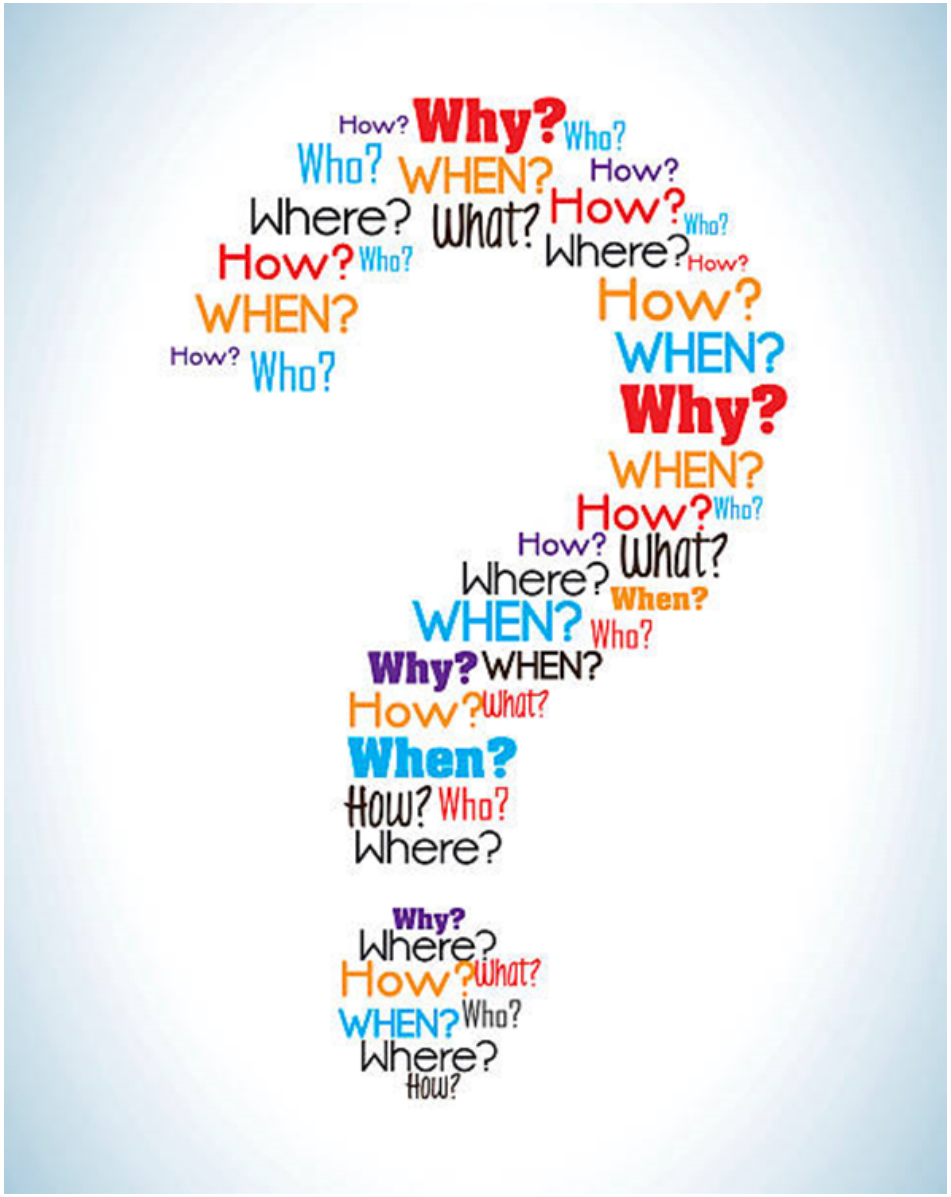
REGULATORY BASIS		Delay ⟺	PROPOSED RULE & DRAFT GUIDANCE	FINAL RULE & GUIDANCE
July 2023 Public Comment period (120 days)	**August 2023** NRC Public Meeting (comments & feedback)		**Early-Mid 2026** Public Comment Period & NRC Public Meeting	**Early-Mid 2027**

Questions?

Contact Us:

medicalquestions.resource@nrc.gov

Medical Uses Licensee Toolkit | NRC Public Website



Acronyms

- ACMUI – Advisory Committee on the Medical Uses of Isotopes
- AMP – Authorized Medical Physicist
- AU – Authorized User
- CFR – Code of Federal Regulations
- EMT – Emerging Medical Technologies
- FR – *Federal Register*
- Ge-68/Ga-68 – Germanium-68/Gallium-68
- OAS – Organization of Agreement States
- Rb-82 – Rubidium-82
- RSO – Radiation Safety Officer
- SECY – Commission Papers (staff written)
- Sr-82 – Strontium-82
- SRM – Staff Requirements Memorandum
- SS&D – Sealed Source and Device
- STC – State and Tribal Communications
- T&E – Training and Experience
- WD – Written Directive
- Y-90 – yttrium-90