Final Rule – Medical Use Regulations in 10 CFR 30, 32, and 35

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Protecting People and the Environment

Public Meeting Purpose

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- Assist licensees and permittees with the implementation and application of the new rule.
  - Give a historical framework for changes to the regulations.
  - Explain how the information will be presented.
  - Describe the guidance available and where it can be found
  - Describe the regulatory changes in the new 10 CFR Parts 30, 32, and 35 rule.
  - Discuss changes to the inspection procedures based on the new rule so licensees will know what inspectors consider and look for. The slides on inspections do not include all of a licensee's requirements under Part 35.

Part 35 Rulemaking

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- Amended in its entirety (published April 24, 2002, in 67 FR 20249; with administrative changes published October 9, 2002, in 67 FR 62872).

Part 35 Rulemaking

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- Amended to revise training and experience requirements (published March 30, 2005, in 70 FR 16336).
- Minor amendment to revise 10 CFR 32 and 35 (published August 13, 2007, in 72 FR 45147).
- Minor amendment to revise 10 CFR 57 (published July 14, 2009, in 74 FR 33901).
- Amended 10 CFR 30, 32, and 35 (published July 16, 2018, in 83 FR 33046).

Dates to Note

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August 17, 2017	**Commission final vote (affirmation vote) on final Part 35 rule**
July 16, 2018	- Rule published in the Federal Register - Revised guidance published on NRC medical toolkit website - https://www.nrc.gov/materials/miau/med-use-toolkit.html#guidance
September – December 2018	Three webinar public meeting sessions on the rule – NRC
October – December 2018	Three webinar public meeting sessions on the rule – NRC licensees and MML licensees and permittees
January 14, 2019	**Rule effective for NRC licensees (180 days from date of FR issuance)**
January – March 2019	Multiple webinar public meeting sessions on rule – Agreement States
March 2019	One webinar public meeting session on the rule – Open to all
January 14, 2022	**Rule effective for Agreement States and Agreement State licensees (3 years from effective date of new rule)**

Guidance Documents

U.S.NRC
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- PART 1 – Supplemental Guidance Effective January 2019, for NUREG-1556, Volume 9, Revision 2, Consolidated Guidance About Materials Licenses: Program - Specific Guidance About Medical Use Licenses

- PART 2 – Supplemental Guidance Effective January 2019 for NUREG-1556, Volume 13, Revision 1, Consolidated Guidance About Materials Licenses: Program-Specific Guidance About Commercial Radiopharmacy Licenses

https://www.nrc.gov/docs/ML1817/ML18176A377.pdf

Guidance Documents

U.S.NRC
United States Nuclear Regulatory Commission
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- PART 3 – Medical Use Questions and Answers Effective January 2019, For the Final Rule "Medical Use of Byproduct Material - Medical Event Definitions, Training and Experience, and Clarifying Amendments"

- PART 4 – Comment Resolution for Proposed Guidance on the Proposed Rule "Medical Use of Byproduct Material - Medical Event Definitions, Training and Experience, and Clarifying Amendments"

https://www.nrc.gov/docs/ML1817/ML18176A377.pdf

Major Changes

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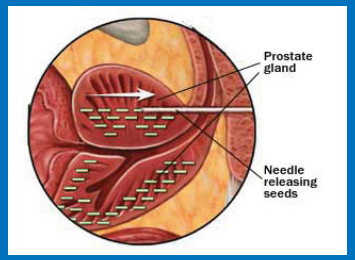
Permanent implant brachytherapy medical event reporting & notification



T&E generic changes for all individuals

PRM-35–20

Molybdenum (Mo) break through measurement frequency and reporting of failed technetium and rubidium generators

Name Associate Radiation Safety Officers on a medical license

Inspection Guidance Documents

U.S.NRC
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IMC 2800	Materials Inspection Program
IP 87127	Radiopharmacy Programs
IP 87130	Nuclear Medicine Programs, Written Directives Not Required
IP 87131	Nuclear Medicine Programs, Written Directives Required
IP 87132	Brachytherapy Programs
IP 87130	Medical Gamma Stereotactic Radiosurgery and Teletherapy Programs

Changes in NRC Inspection Procedures (IP)

U.S.NRC
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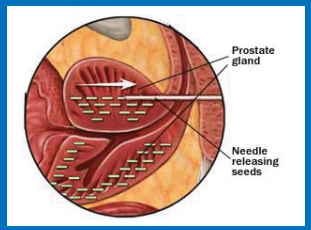
Permanent implant brachytherapy medical event reporting & notification



Molybdenum (Mo) break through measurement frequency and reporting of failed technetium and rubidium generators

T&E generic changes for all individuals

PRM-35–20

Name Associate Radiation Safety Officers on a medical license

Roadmap – 10 CFR changes

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30.34

32.72

35.2

35.12

35.13, 35.14, 35.15

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35.40, 35.41

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35.55, 35.190, 35.290,
35.390, 35.392, 35.394, 35.396,
35.490, 35.590, 35.690

35.65

35.204, 35.3204

35.300, 35.390, and 35.396

35.400, 35.500, 35.600

35.433

35.500

35.610

35.655

35.2024, 35.2310, 35.2655

35.3045

Roadmap – Compatibility

30.34 B

32.72 B

35.2 B

35.12 D

35.13, 35.14, 35.15 D

35.24 H&S D

35.40, 35.41 H&S

35.50 B

35.51 B

35.57 B ,(a)(4) D

35.55, 35.190, 35.290, 35.390, 35.392, 35.394, 35.396, 35.490, 35.590, 35.690 B

35.65 D

35.204 H&S, 35.3204 C

35.300, 35.390, and 35.396 B

35.400, 35.500, 35.600 C

35.433 B H&S D

35.500 C

35.610 H&S

35.655 H&S

35.2024, 35.2310, 35.2655 D

35.3045 C

Agreement State Compatibility Categories

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Compatibility Categories A, B, C, D, NRC, or adequacy category Health and Safety (H&S).

Compatibility Category A	those program elements that are basic radiation protection standards and scientific terms and definitions that are necessary to understand radiation protection concepts. An Agreement State should adopt Category A program elements in an essentially identical manner in order to provide uniformity in the regulation of agreement material on a nationwide basis.

Agreement State Compatibility Categories

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Compatibility Category B	those program elements that apply to activities that cross jurisdictional boundaries. These program elements have a particular impact on public health and safety and need to be adopted in an essentially identical manner in order to ensure uniformity of regulation on a nationwide basis..

Agreement State Compatibility Categories

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Compatibility Category C	those program elements that are important for an Agreement State to have in order to avoid conflict, duplication, gaps, or other conditions that would jeopardize an orderly pattern in the regulation of agreement material on a nationwide basis. An Agreement State shall embody the essential objectives of these NRC program elements. The Agreement State program elements may be more restrictive than the NRC program elements provided that the essential objective is met, and the State requirements do not jeopardize an orderly pattern of regulation of agreement material on a nationwide basis.

Agreement State Compatibility Categories

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Compatibility Category D	those program elements that do not meet any of the criteria of Compatibility Categories A, B, or C, or have a particular health and safety role and, thus, do not need to be adopted by Agreement States for purposes of compatibility. An Agreement State has the flexibility to choose whether or not to adopt and implement these program elements that fall within its jurisdiction. However, if an Agreement State chooses to adopt such program elements, they should be adopted in a manner such that 1) they are comparable with those of the NRC,

Agreement State Compatibility Categories

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Compatibility Category D (continued)	2) they do not preclude, or effectively preclude a practice in the national interest without adequate protection of public health and safety, security, or environmental basis related to radiation protection, and 3) they do not preclude, or effectively preclude the ability of the NRC to evaluate the effectiveness of the Agreement State program with respect to the protection of public health and safety

Agreement State Compatibility Categories

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Compatibility Category NRC	those program elements that address areas of regulation that cannot be discontinued when a State enters into an Agreement with the NRC pursuant to the AEA or provisions of Title 10 of the Code of Federal Regulations (CFR). The NRC maintains regulatory authority over these program elements and the Agreement States must not adopt these NRC program elements.

Agreement State Compatibility Categories

U.S.NRC
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Health and Safety	Although not required for compatibility, the State must adopt program elements in this category, that embody the basic health and safety aspects of the NRC's program elements because of particular health and safety considerations.

Roadmap – Qs and As

U.S.NRC
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1	14	27	40	53	66
2	15	28	41	54	67
3	16	29	42	55	68
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5	18	31	44	57	70
6	19	32	45	58	71
7	20	33	46	59	72
8	21	34	47	60	73
9	22	35	48	61	74
10	23	36	49	62	75
11	24	37	50	63	
12	25	38	51	64	
13	26	39	52	65	

Road Map – Corresponding IP changes

U.S.NRC
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30.34

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35.13, 35.14, 35.15

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35.40, 35.41

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35.55, 35.190, 35.290, 35.390, 35.392, 35.394, 35.396, 35.490, 35.590, 35.690

35.65

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35.400, 35.500, 35.600

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35.2024, 35.2310, 35.2655

35.3045

General Topics

U.S.NRC
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- Generators
- Associate RSO & Ophthalmic Physicist
- Emerging Technologies
- Notification
- Manual Brachytherapy
- Training & Experience
- Diagnostic medical uses
- 10 CFR 35.300 Radiopharmaceuticals
- Sealed Source & Device Registry
- Vendor Training
- Gamma Knife Source Exchange

Generators and labeling

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

30.34 B

32.72 B

35.2

35.12

35.13, 35.14, 35.15

35.24

35.40, 35.41

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Generators

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

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9	22	35	48	61	74
10	23	36	49	62	75
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13	26	39	52	65	

10 CFR Part 30.34

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- Intended primarily for the commercial nuclear pharmacy, it directs the licensee to Part 35 [35.204(a), 35.3204] for:
  - when to perform the breakthrough test
  - records to keep
  - when to report the results

IP 87127

U.S.NRC
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- The inspector should –
  - determine that the licensee is aware of the notification requirement in 10 CFR 35.3204 to notify NRC of a generator elution that exceeds the limits.
  - verify that the licensee knows
    - when to perform the breakthrough test;
    - the records that they are supposed to keep; and
    - when to report the results of breakthroughs.

10 CFR 32.72

U.S.NRC
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- The applicant has to commit to the labeling requirements.
- The licensee has to satisfy the labeling requirements.
- Removes the requirement for the board certified nuclear pharmacist to provide an attestation statement with a copy of the certificate.

IP 87127 – No change

- The inspector should be aware that if the licensee labelling is not in accordance with their license commitment, then a violation can now be cited to the rule.

10 CFR 35.204 & 35.3204

U.S.NRC
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- Breakthrough has to be measured for each elution of Mo-99/Tc-99m generator.
- Breakthrough in excess of regulatory limits need to be reported to NRC and the generator distributor.
- Information that has to be reported and reporting time frame is provided.

Permissible concentration (breakthrough regulatory limits)	
Mo/Tc generator	**0.15 µCi of Mo-99 per mCi of Tc-99m**
Sr/Rb generator	0.02 **µCi** of Sr-82 per mCi of Rb-82 chloride
	0.2 **µCi** of Sr-85 per mCi of Rb-82 chloride

IP 87127 & IP 87130

U.S.NRC
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- That the inspector should discuss with the licensee about measuring for breakthroughs in excess of the regulatory limits, and when to report to the NRC and the generator distributor.
- Note that the licensee must:
  - Make a telephone notification to the NRC Operations Center and the distributor within 7 calendar days after discovering the breakthrough.
  - Submit a written report to the NRC within 30 days of this discovery.

Associate RSO & Ophthalmic Physicist

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

30.34

32.72

35.2 B

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35.13, 35.14, 35.15

35.24 H&S D

35.40, 35.41

35.50 B

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35.400, 35.500, 35.600

35.433 B H&S D

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35.2024, 35.2310, 35.2655 **D**

35.3045

Associate RSO & Ophthalmic Physicist

U.S.NRC
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13	26	39	52	65	

10 CFR 35.2 and 35.24

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- Added two new definitions:
  - Associate Radiation Safety Officer (ARSO)
  - Ophthalmic physicist
- Revised the Preceptor definition - add ARSO.
- Introduced provisions to appoint an ARSO.
- Clarified requirements for licensee, RSO, and ARSO.

IP 87130, IP 87131, IP 87132, IP 87133

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- The inspector should:
  - check if the licensee has any ARSOs.
  - verify that the ARSOs are knowledgeable about their duties and tasks.
  - Verify that the ARSOs duties and tasks match the uses for which they are authorized.
  - note that anyone can be assigned duties and tasks, but the duties and tasks for the ARSO need to be assigned in writing.

IP 87130, IP 87131, IP 87132, IP87133

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- The inspector should also be aware that:
  - Only the RSO has full responsibility for the Radiation Protection Program.
  - In the documented absence of the RSO, the ARSO cannot assume RSO responsibilities unless the licensee designates the ARSO as a temporary RSO.

10 CFR 35.50

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- Added Associate Radiation Safety Officer.
- Permit ARSO to provide written attestation.
- Permit new AU to be RSO on new license.
- Permit authorized individuals (AU, AMP, ANP) to use authorized status be RSO on a different license for same uses for which the individual is authorized.

Records – 10 CFR 35.2024

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- Added the record retention time for documents appointing an ARSO.

10 CFR 35.433

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- Added ophthalmic physicist to individuals who are required to perform certain task.
- Clarified the training needed to be an ophthalmic physicist.
- Clarified expected duties of AMP and ophthalmic physicist for Strontium-90 sources used for ophthalmic treatments.

IP 87132

U.S.NRC
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- The inspector should verify that the AMP or ophthalmic physicist is performing the tasks as required.

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Questions?

- Generators
- Associate RSO & Ophthalmic Physicist

Emerging Technologies

U.S.NRC
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Protecting People and the Environment

30.34

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35.12 D

35.13, 35.14, 35.15

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35.2024, 35.2310, 35.2655

35.3045

Qs & As Emerging Technologies

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10 CFR 35.12

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- Clarified information required for 10 CFR 35.1000 medical uses application
  - Additional aspects needed for radiation safety not in or different from requirements in the regulations
  - Identification and commitment to meet appropriate existing requirements.

IP 87130, IP 87131, IP 87132, IP 87133

U.S.NRC
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- The inspector should:
  - Review the guidance for emerging technologies that are authorized on the license.
  - Verify that the licensee is meeting the commitments made in the license application.

Notification

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35.13, 35.14, 35.15 D

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35.40, 35.41

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35.2024, 35.2310, 35.2655

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Qs & As Notification

U.S.NRC
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10 CFR 35.13 & 35.14

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- Added notification/termination provision for the ophthalmic physicist.
- Added amendment requirement before an individual works as a ARSO or before the RSO can assign duties and task to an ARSO beyond the current authorization.
- Added notification provision for certain manual brachytherapy sources.
- Removed notification attestation statement.

IP 87130, IP 87131, IP 87132, IP 87133

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- The inspector should:
  - Be aware if an ARSO or an ophthalmic physicist permanently discontinues performance of duties under the license or has a name change, and whether NRC was notified within 30 days.
  - verify that the licensee has notified NRC within 30 days of receiving the new brachytherapy sources, if the manufacturer and model numbers are different for manual brachytherapy.

10 CFR 35.15

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- Up dating a reference to 10 CFR 35.13 to conform to the changes paragraph numbering in 10 CFR 35.13.
- Exempted Type A broad scope licensees from needing to notify NRC when permitting an ophthalmic physicist to working as an ophthalmic physicist.

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Questions?

- Emerging Technologies
- Notification

Manual Brachytherapy

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35.13, 35.14, 35.15

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35.40, 35.41 H&S

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35.55, 35.190, 35.290, 35.390, 35.392, 35.394, 35.396, 35.490, 35.590, 35.690

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35.2024, 35.2310, 35.2655

35.3045 C

Qs & As Manual Brachytherapy

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1	14	27		40	53	66		
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10	23	36		49	62	75		
11	24	37		50	63			
12	25	38		51	64			
13	26	39		52	65			

10 CFR 35.40

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- Clarified permanent implant brachytherapy written directive (WD) components:
  - Still includes AU signature and dating before administration.
  - Requiring the total source strength in the pre-implantation portion of the WD.
  - Deleting the total dose from the post-implantation portion of the WD added total number of sources and date.
  - Deleting the requirement to include dose.
  - Requiring completion of the post-implantation portion of the WD before the patient leaves the post-treatment recovery area.

10 CFR 35.40

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What is a **post-treatment recovery area**?

The term **post-treatment recovery area** as used in 10 CFR 35.40 means the area or place where a patient recovers immediately following the brachytherapy procedure before being released to a hospital intensive care unit or patient room or in the case of an outpatient treatment, released from the licensee's facility.

IP 87132

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- The inspector should:
  - Verify that the licensee has the appropriate components of the WD and that they are being completed for all permanent implant brachytherapy procedures.
  - Be aware that an AU must sign the WD after completion of the pre-implantation portion of the document (**but before the administration begins**).
  - Be aware that the current date must also be entered both before the administration begins and after implantation, but before the patient leaves the post-treatment recovery area.

10 CFR 35.3045

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- Revises the definition of a ME for permanent implant brachytherapy:
  - The total source strength for inside and outside the treatment site compared with post-implantation written directive.
  - The wrong radionuclide.
  - The wrong individual or human research subject.
  - Sealed source(s) directly delivered to the wrong treatment site.
  - A leaking sealed source resulting in a dose that exceeds 0.5 Sv (50 rem) to an organ or tissue.

10 CFR 35.3045

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What does **discontiguous** mean?

- **Discontiguous** in general terms is used to describe things that are not contiguous in space, things that are not adjacent or touching, and things that have a gap in between or are disconnected or separate.
- As it relates to the ME criteria in 10 CFR 35.3045 for PIB, discontiguous means a location that is not physically adjacent to or touching the treatment site.

IP 87132

U.S.NRC
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- The inspector should be aware of the main changes to the ME reporting requirements for permanent implant brachytherapy:
  - Addition of a separate section for PIB medical events.
  - A criterion involving total source strength administered differing by 20% or more from the total source strength documented in the post-implantation WD.
  - A criterion for the difference between the total source strength implanted outside the treatment site exceeding 20 percent of the total source strength documented in the post-implant portion of the WD.

IP 87132

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- The inspector should be aware of the main changes to the ME reporting requirements for permanent implant brachytherapy (continued):
  - Including a dose threshold for the leaking sealed source criterion.
  - Addition of a criterion for sealed source(s) implanted directly into a location discontiguous from the treatment site, as defined in the post-implantation portion of the WD.
  - Addition of a criterion for administration of the wrong radionuclide.

IP 87132

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- The inspector should:
  - Determine if a licensee knows about the new ME criteria for permanent implant brachytherapy.
  - assess the licensee's ability to effectively identify and respond to different types of MEs.
  - verify that licensee staff is aware of the person within the organization:
    1. To whom they should report a ME or treatments that may have resulted in MEs; and
    2. Who is responsible for reporting MEs to the NRC.

IP 87132

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- If during the inspection a previously unidentified ME is identified, the inspector should:
  - Remind the licensee of the need to comply with the reporting requirements in 10 CFR 35.3045.
  - Follow the applicable NRC guidance (Management Directive 8.10, “NRC Medical Event Assessment Program”).
  - Notify NRC regional management as soon as possible if this is the case, to ensure that appropriate guidance is given and matters are reviewed before completing the inspection.

IP 87132

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- For cases where sources may be implanted in a location other than the treatment site, the inspector should be aware that:
  - It is a reportable ME if a source was directly delivered to location discontiguous from the treatment site as documented in the post-implant WD.
  - It is not a reportable ME if the sources were removed before the post-implantation portion of the WD was completed, and if the total activity in the treatment site in the post implant WD include only those seeds implanted in the treatment site.

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- For cases where sources may have migrated to a location outside of the treatment site, the inspector should be aware that:
  - It is not a reportable ME if the sources that were implanted correctly migrate outside the treatment site.
- The inspector should be aware that for errors in calculating the source or total source strength:
  - It is encouraged that the licensee check calculations and assay a portion of their seeds. It is only a reportable ME if the total source strength administered differs by 20% from that documented in the post-implant WD.

10 CFR 35.41

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- All licensees must have procedures to determine if a medical event occurred.
- Permanent implant brachytherapy licensees must have procedures to determine within 60 days:
  - The total source strength outside treatment site compared to total source strength in post implant written directive.
  - That if a patient was not available within the 60 days, the licensee must document the reason for the unavailability.

IP 87130, IP 87131, IP 87132, IP 87133

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- The inspector should:
  - verify the licensee's implementation of its written procedures for determining if a ME, as defined in 10 CFR 35.3045, has occurred.
  - be aware that licensees can have a diagnostic ME even though a WD is not required.

IP 87132

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- The inspector should also sample selected brachytherapy cases and determine if the licensee implements actions to verify that:
  - They determined if a ME occurred in accordance with 10 CFR 35.3045; AND
  - For permanent implant brachytherapy, a determination of the total source strength administered outside of the treatment site compared to that documented in the post-implantation portion of the WD, was performed within 60 calendar days from the date of the implant, unless a written justification of patient unavailability is documented.

IP 87132

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- If a patient is not available within the 60-day time limit and the licensee is unable to determine whether 80% or more of the sources are implanted within the treatment site:
  - the inspector should note that the licensee is required to provide a written justification that explains why the patient was unavailable.

IP 87132

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- The inspector should be aware that for source positioning determination:
  - The requirement in 10 CFR 35.41(b)(6) is for the determination to be made within 60 calendar days from the date the implant was performed. This is a performance based requirement and does not specifically direct licensees as to how the objectives are to be achieved.

IP 87132

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- The inspector should also be aware that for cases where there is no treatment planning software or post-implant imaging was not performed for permanent implant brachytherapy procedures:
  - Using treatment planning software or post-implant imaging are not explicitly required. The requirements in 10 CFR 35.41 are performance based.
  - NRC believes that the use of both is likely necessary to outline the treatment site and make the determination of implanted source positioning to decide whether a ME has occurred.

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Questions?

- **Manual Brachytherapy**

Training & Experience

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30.34

32.72 B

35.2

35.12

35.13, 35.14, 35.15

35.24

35.40, 35.41

35.50 B

35.51 B

35.57 B ,(a)(4) D

35.55, 35.190, 35.290, 35.390, 35.392, 35.394, 35.396, 35.490, 35.590, 35.690 B

35.65

35.204, 35.3204

35.300, 35.390, and 35.396

35.400, 35.500, 35.600

35.433

35.500

35.610

35.655

35.2024, 35.2310, 35.2655

35.3045

Qs & As Training and Experience

U.S.NRC
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1	14	27	40	53	66
2	15	28	41	54	67
3	16	29	42	55	68
4	17	30	43	56	69
5	18	31	44	57	70
6	19	32	45	58	71
7	20	33	46	59	72
8	21	34	47	60	73
9	22	35	48	61	74
10	23	36	49	62	75
11	24	37	50	63	
12	25	38	51	64	
13	26	39	52	65	

10 CFR 35.51

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- Require AMP to be board certified by board recognized under 10 CFR 35.51.

Training and Experience

U.S.NRC
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- Removed written attestation from board certification pathway requirements.
- Revised written attestation statement
  - …is able to independently fulfill the radiation safety-related duties as …
- Permits residency program directors to provide written attestation under certain conditions.

10 CFR 32.72

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- The applicant has to commit to the labeling requirements.
- The licensee has to satisfy the labeling requirements.
- Removes the requirement for the board certified nuclear pharmacist to provide an attestation statement with a copy of the certificate.

10 CFR 35.57

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- Grandfathered RSO's and AMP's must meet requirements in 10 CFR 35.50(d) or 35.51(c), for materials or uses not authorized earlier.
- Grandfathered individuals board certified on or before October 24, 2005 by boards listed in regulation for materials and uses performed before this date.

IP 87130, IP 87131, IP 87132, IP 87133 – No change

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- The inspector should continue to:
  - Discuss the radiation safety training to ensure that appropriate training was actually received by these grandfathered individuals.
  - Also verify that RSOs and AMPs understand the radiation protection requirements associated with their assigned activities.

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Questions?

- **Training & Experience**

Diagnostic medical uses

U.S.NRC
United States Nuclear Regulatory Commission
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30.34

32.72

35.2

35.12

35.13, 35.14, 35.15

35.24

35.40, 35.41

35.50

35.51

35.57

35.55, 35.190, 35.290, 35.390, 35.392, 35.394, 35.396, 35.490, **35.590**, 35.690 **B**

35.65 D

35.204, 35.3204

35.300, 35.390, and 35.396

35.400, 35.500, 35.600

35.433

35.500

35.610

35.655

35.2024, 35.2310, 35.2655

35.3045

Qs & As Diagnostic medical uses

U.S.NRC
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1	14	27	40	53	66
2	15	28	41	54	67
3	16	29	42	55	68
4	17	30	43	56	69
5	18	31	44	57	70
6	19	32	45	58	71
7	20	33	46	59	72
8	21	34	47	60	73
9	22	35	48	61	74
10	23	36	49	62	75
11	24	37	50	63	
12	25	38	51	64	
13	26	39	52	65	

10 CFR 35.65

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- Clarified medical use does not include calibration, transmission and reference sources except as authorized under 10 CFR 35.500.
- Bundled or aggregated sources with activities greater than maximum single source activities in 35.65 is not permitted under 10 CFR 35.65.
- Clarified when sources do not have to be listed on license.

10 CFR 35.590

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- Authorizes an AU for imaging uses for medical use of sealed sources and medical devices for diagnosis.

IP 87130

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- The inspector should:
  - Be aware that some licensees may not recognize that use of calibration, transmission, or reference sources during imaging procedures meets the definition of medical use.
  - Be aware that AUs for imaging studies are also authorized for use of medical devices for diagnosis.
  - Verify that the use is under the supervision of an AU if using these sources on patients or human research subjects.

IP 87130

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- The inspector should:
  - Be aware that calibration, transmission, or reference sources that are used in accordance 10 CFR 35.500, and are not bundled to result in an activity greater than that specified in 10 CFR 35.65, do not have to be listed on the license.
  - Verify that the licensee is not bundling or aggregating sources.

10 CFR 35.300 Radiopharmaceuticals

U.S.NRC
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30.34
32.72
35.2
35.12
35.13, 35.14, 35.15
35.24
35.40, 35.41
35.50
35.51
35.57
35.190, 35.290, 35.390, 35.392, 35.394, 35.396, 35.490, 35.590, 35.690
35.65
35.204, 35.3204
35.300, 35.390, and 35.396 B
35.400, 35.500, 35.600
35.433
35.500
35.610
35.655
35.2024, 35.2310
35.3045

Qs & As 10 CFR 35.300 Radiopharmaceuticals

U.S.NRC
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10 CFR 35.300, 35.390 & 35.396

- Clarified that 10 CFR 35.300 only applied to materials listed in 10 CFR 35.390.
- Revised listing of materials in 10 CFR 35.390 for parenteral uses by the primary emission needed for the particular medical use (i.e., is primarily used for … emission).

10 CFR 35.300, 35.390 & 35.396

10 CFR 35.300

Current Rule reads:

– A licensee may use any unsealed byproduct material prepared for medical use and for which a written directive is required that is—

- New Rule reads:
  – A licensee may use any unsealed byproduct material identified in § 35.390(b)(1)(ii)(G) prepared for medical use and for which a WD is required that is—

10 CFR 35.300, 35.390 & 35.396

10 CFR 35.390(1)(ii)(G) categories for 3 cases

Current Rule reads:

1. Oral ≤ 1.22 GBq (33 mCi) of NaI I-131 WD;
2. Ora > 1.22 GBq (33 mCi) of NaI I-131 WD;
3. Parenteral of any beta emitter, or a photon- emitting radionuclide with a photon energy less than 150 keV, for which a WD is required; and/or
4. Parenteral administration of any other radionuclide, for which a WD is required;

10 CFR 35.300, 35.390 & 35.396

10 CFR 35.390(1)(ii)(G) categories for 3 cases

- New Rule reads:
  - A licensee may use any unsealed byproduct material identified in § 35.390(b)(1)(ii)(G) prepared for medical use and for which a WD is required that is —
  - (1) the same as current rule.
  - (2) the same as current rule.
  - (3) Parenteral administration of any radioactive drug that contains a radionuclide that is primarily used for its electron emission, beta radiation characteristics, alpha radiation characteristics, or photon energy of less than 150 keV, for which a written directive is required

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Questions?

- Diagnostic Medical Uses
- 10 CFR 35.300 Radiopharmaceuticals

Sealed Source & Device Registry

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

30.34

32.72

35.2

35.12

35.13, 35.14, 35.15

35.24

35.40, 35.41

35.50

35.51

35.57

35.55, 35.190, 35.290, 35.390, 35.392, 35.394, 35.396, 35.490, 35.590, 35.690

35.65

35.204, 35.3204

35.300, 35.390, and 35.396

35.400, 35.500, 35.600 B

35.433

35.500

35.610

35.655

35.2024, 35.2310, 35.2655

35.3045

Qs & As Sealed Source & Device Registry

U.S.NRC
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Protecting People and the Environment

1	14	27	40	53	66
2	15	28	41	54	67
3	16	29	42	55	68
4	17	30	43	56	69
5	18	31	44	57	70
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8	21	34	47	60	73
9	22	35	48	61	74
10	23	36	49	62	75
11	24	37	50	63	
12	25	38	51	64	
13	26	39	52	65	

10 CFR 35.400, 35.500 & 35.600

- Clarifies that use includes uses under the appropriate medical use that is not explicitly listed in the Sealed Source and Device Registry (SSDR).
- Requires the use to be in accordance with radiation safety conditions and limitations in SSDR.
- Differentiated between use requirements for sources and devices containing sources.

IP 87132, IP 87133 – No change

- The inspector should be aware that the licensee now has more flexibility as they are now required to use material that they are licensed for in accordance with the radiation safety conditions and limitations in the SSDR.

Vendor Training

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30.34
32.72
35.2
35.12
35.13, 35.14, 35.15
35.24
35.40, 35.41
35.50
35.51
35.57
35.55, 35.190, 35.290, 35.390, 35.392, 35.394, 35.396, 35.490, 35.590, 35.690
35.65
35.204, 35.3204
35.300, 35.390, and 35.396
35.400, 35.500, 35.600
35.433
35.500
35.610 H&S
35.655
35.2024, 35.2310, 35.2655
35.3045

Qs & As Vendor Training

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10 CFR 35.610

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- Requires vendor training of 10 CFR 35.600 medical use devices when there are upgrades that affect the operational and safety of the unit.
- Vendor training must be by the vendor or someone certified by the vendor.

IP 87132, IP 87133

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- The inspector should:
  - Verify that operational and safety training was provided by the device manufacturer (or by an individual certified by the manufacturer) before the first use for patient treatment of a new unit, or an existing unit with a manufacturer upgrade that affected the operation and safety of the unit.
  - Be aware that the requirement to provide vendor operational and safety training is for all individuals, including AUs, AMPs, operators, and others that need to know how the new unit operates and understand how the upgrades affect safety and operations.

Records – 10 CFR 35.2310

- Clarifies the information that must be recorded for
  - Information for the operational and safety instructions for 10 CFR 35.610.

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IP 87132, IP 87133 – No Change

- The inspector should be aware that the review of records in accordance with 10 CFR 35.2310 should now be of the vendor operational and safety instructions, and not just the safety instructions.

Gamma Knife Source Exchange

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30.34

32.72

35.2

35.12

35.13, 35.14, 35.15

35.24

35.40, 35.41

35.50

35.51

35.57

35.55, 35.190, 35.290, 35.390, 35.392, 35.394, 35.396, 35.490, 35.590, 35.690

35.65

35.204, 35.3204

35.300, 35.390, and 35.396

35.400, 35.500, 35.600

35.433

35.500

35.610

35.655 H&S

35.2024, 35.2310, **35.2655 D**

35.3045

Qs & As Gamma Knife Source Exchange

U.S.NRC
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Protecting People and the Environment

1	14	27	40	53	66
2	15	28	41	54	67
3	16	29	42	55	68
4	17	30	43	56	69
5	18	31	44	57	70
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7	20	33	46	59	72
8	21	34	47	60	73
9	22	35	48	61	74
10	23	36	49	62	75
11	24	37	50	63	
12	25	38	51	64	
13	26	39	50	65	

10 CFR 35.655

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- Clarifies in the title that the section is addressing full-inspection servicing.
- Retains 5 year frequency for teletherapy units.
- Changes frequency for gamma stereotactic units to 7 years.

IP 87133

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- The inspector should verify that:
  - Each teletherapy unit and gamma stereotactic radiosurgery unit was fully inspected and serviced during each source replacement.
  - The interval between each full-inspection servicing shall not exceed 5 years for each teletherapy unit or 7 years for each gamma stereotactic radiosurgery unit.

Records – 10 CFR 35.2655

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- Clarifies the information that must be recorded for
  - Information for full-inspection servicing for teletherapy units and gamma stereotactic radiosurgery units.

IP 87133 – No change

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- The inspector should verify that the licensee is aware of the change to the full-inspection and service interval for gamma stereotactic radiosurgery units and is maintaining a record of the full-inspection servicing.

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Questions?

- Sealed Source & Device Registry
- Vendor Training
- Gamma Knife Source Exchange

Questions?

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Acronym

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- ANP – Authorized Nuclear Pharmacist
- AMP – Authorized Medical Physicist
- ARSO – Associate Radiation Safety Officer
- AU – Authorized User
- Ga – Gallium
- Ge – Germanium
- IMC – Inspection Manual Chapter
- IP – Inspection Procedures
- ME – Medical Event
- Mo – Molybdenum

Acronym

- PIB – Permanent Implant Brachytherapy
- PRM – Petition for Rulemaking
- Rb - Rubidium
- RSO – Radiation Safety Officer
- Sr – Strontium
- SSDR – Sealed Source and Device Registry
- WD – Written Directive
- Tc – Technetium