Frequently Asked Questions on the U.S. NRC Proposed Rule, “Reducing Barriers to Medical Use Licensing”

The U.S. Nuclear Regulatory Commission (NRC) staff is planning to update NUREG-1556, Volume 9, Revision 3, “Consolidated Guidance About Materials Licenses: Program-Specific Guidance About Medical Use Licenses,” and Office of Nuclear Material Safety and Safeguards Interim Staff Guidance (NMSS-ISG-03), “Guidance for the Implementation of 10 CFR Part 35 Training and Experience Requirements” (Agencywide Documents Access and Management System Accession No. ML25051A034) to conform with the final rule, “Reducing Barriers to Medical Use Licensing” (Docket ID NRC-2025-1237; RIN 3150-AL50). These updates would be made in a future revision of the guidance rather than concurrently with the final rule. In the interim, the NRC has developed draft guidance that provides answers to Frequently Asked Questions (FAQs) that will be added to NRC’s public website.

TRAINING AND EXPERIENCE

GENERAL TRAINING AND EXPERIENCE

Would “grandfathering” still be allowed for authorized individuals?

Yes. Authorized individuals already authorized for a specific type of use and/or source and/or device under previous guidance do not need to meet the revised criteria for the same type of use and/or source and/or device. The NRC has also made the change from use of the word “grandfathering” to “legacy.”

Based on the proposed definition of physician, what would an individual need to demonstrate they are a physician? How does this differ from the current rule?

To demonstrate they are a physician, the individual would need to have a license by a State or Territory of the United States, the District of Columbia, or the Commonwealth of Puerto Rico to prescribe drugs in the practice of medicine. The individual would no longer need to hold a medical doctor or doctor of osteopathy degree, but could hold another medical degree, such as a foreign medical degree, as long as they hold an active license issued by their State or Territory. To become an authorized user (AU), the physician would still need to meet the training and experience requirements in the applicable subparts of Title 10 of the *Code of Federal Regulations* (10 CFR) Part 35, “Medical Use of Byproduct Material.”

[ML26167A223]

CONTINUING EDUCATION

What would be required under 10 CFR 35.59 for continuing education and experience?

Licensees would need to ensure that all AUs, Radiation Safety Officers (RSOs), Associate RSOs, Authorized Medical Physicists (AMPs), and Authorized Nuclear Pharmacists maintain continuing education and experience relevant to their authorized uses. This includes having education or experience in the type of use within the 7 years preceding the medical use, and receiving instruction on applicable NRC regulations, license conditions, and the licensee's written procedures. These requirements would apply to all medical uses regardless of whether they require a written directive.

If an authorized individual has experience with administration of a source, microsource, device or radioactive drug requiring a written directive or type of use for administration that does not require a written directive in the last 7 years, no additional education or experience for that specific administration would be necessary. However, instruction on any updates to a licensee's written radiation protection procedures, written directive procedures, and license conditions with respect to the use would be required, and a record must be retained in accordance with 10 CFR 35.2059.

Would a licensee need to submit any documentation demonstrating recentness of training when applying to add an authorized individual to a license?

No, licensees would not need to submit any documentation demonstrating recentness of training as part of a license application to the NRC or an Agreement State. However, licensees would need to ensure that individuals have the education and experience as specified in 10 CFR 35.59 prior to first administration.

How would licensees document compliance with continuing education and experience requirements?

Licensees would be required to maintain records of continuing education and training in accordance with 10 CFR 35.2059. The required records would include:

- A list of the topics covered,
- The date of the training or experience, and
- The name(s) of the individual(s) who provided the training.

Records would need to be maintained until the individual is no longer authorized for medical use or listed on the license.

What would happen if an authorized individual has not used a modality in the past 7 years?

If an AU or other authorized individual has not had relevant education or experience in the past 7 years, they would be required to complete refresher training or supervised experience before resuming use. Acceptable continuing education or experience may include the following:

- Successful completion of classroom and laboratory review courses that include radiation safety practices related to the type of medical use for an AU for administrations not requiring a written directive or to the source, microsource, device, or radioactive drug for

administrations requiring a written directive. This review may include various instruction, including online training, as long as the subject matter relates to radiation safety and safe handling of byproduct material for the source, microsource, device, or radioactive drug for administration requiring a written directive or type of use for administrations that do not require a written directive.
- Practical and laboratory experience with patient procedures using radioactive material for the same source, microsource, device, or radioactive drug for administration requiring a written directive or type of use for administrations that do not require a written directive.
- Experience with the device and completion of an in-service review of operating and emergency procedures related to the device.

In addition, the individual would need to receive instruction on the licensee's written radiation protection procedures, regulatory requirements, and licensee-specific procedures with respect to the use. These instructions should be based on current safety practices. The licensee would be responsible for verifying and documenting that the individual has met the continuing education and experience requirements before allowing them to resume medical use activities.

AUTHORIZED USER LICENSING

Would AUs be required to be listed on a license to be authorized for 10 CFR 35.100 or 10 CFR 35.200?

No, AUs would no longer be required to be listed on a license to be authorized for 10 CFR 35.100 or 10 CFR 35.200.

What types of AUs would be required to be listed on a license?

AUs who are approved for uses under 10 CFR 35.300, including those limited to oral administration of sodium iodide I-131 or parenteral administration; 10 CFR 35.490; 35.491; 35.500; 35.600; 35.700; and 35.1000 would be required to be listed on a license.

Would a physician need to meet the training and experience listed in 10 CFR 35.190 or 35.290 before using the material for the uses authorized under 10 CFR 35.100 or 35.200, since they would no longer be required to be listed on a license?

Yes, a physician would need to meet the training and experience requirements listed in 10 CFR 35.190 or 35.290 before using the material for the uses authorized under 10 CFR 35.100 or 35.200, and the licensee would be responsible for ensuring this. The licensee's management should confirm the training and experience prior to approving the individual in writing to be able to work as an AU in accordance with 10 CFR 35.24(a) and licensees would be required to retain a record of this action for 5 years in accordance with 10 CFR 35.2024. In accordance with 10 CFR 35.24(g)(5), the licensee would be required to provide the RSO sufficient authority, organizational freedom, time, resources, and management prerogative to verify the training and experience of an individual meets 10 CFR 35.190 prior to authorizing use under 10 CFR 35.100 and 35.290 and prior to authorizing use under 10 CFR 35.200. While the NRC would no longer be confirming training and experience during licensing for 10 CFR 35.100 and 35.200 uses, the licensee's process for reviewing physician training and experience, and an individual physician's training and experience, could be verified on inspection.

How could a licensee track who is authorized to use and supervise material under 10 CFR 35.100 and 35.200?

The licensee could create and maintain a separate list of all approved AUs. For example, the licensee could maintain a printed list of the names of the AUs, the uses for which they are approved, and the date of the approval. Licensees would also need to maintain records of training and experience for each AU, which may include using forms like NRC Form 313A, and the verification that AUs meet the training and experience criteria.

Could an individual who is an AU for 10 CFR 35.100 or 35.200 use become the RSO?

Yes. Under 10 CFR 35.50(b)(2), an AU for 10 CFR 35.100 or 35.200 could serve as the RSO for the types of byproduct material use for which they have relevant radiation safety experience. Although the licensee is not required to list the individual as an AU on the license for these uses, the licensee is required to submit an application to have the individual named as the RSO. This application must include sufficient documentation to demonstrate that the individual meets the training and experience requirements for the RSO position.

Based on the proposed changes, what would be needed to support an application for initial approval of an AU for 10 CFR 35.300?

An applicant would use a newly revised NRC Form 313A(AUT) to document:

1. Completion of a 3-year residency in a nuclear medicine or radiation oncology accredited residency program that includes the training and work experience topics listed in 10 CFR 35.390(a)(2) **or**

2. Completion of the alternate pathway of training and work experience topics listed in 10 CFR35.390(a)(2) **or**

3. Documentation that the applicant is certified by an NRC-approved specialty board for 10 CFR 35.390

   AND

   Documentation of supervised clinical case experience which includes administering dosages of radioactive drugs to patients or human research subjects from each of the two categories as required by 10 CFR 35.390(a)(2)(ii)(G)

   AND

   Attestation of the completion of the requirements and the ability for the applicant to independently fulfill radiation safety-related duties.

See Office of Nuclear Material Safety and Safeguards, Interim Staff Guidance, NMSS-ISG-03, Guidance for the Implementation of 10 CFR Part 35 Training and Experience Requirements for more information (ML25051A034).

Based on the proposed changes, what would be needed to support an application for initial approval of an AU for 10 CFR 35.392?

An applicant would use a newly revised NRC Form 313A(AUT) to document:

1. Completion of a 3-year residency in a nuclear medicine or radiation oncology accredited residency program that includes the training and work experience topics listed in 10 CFR 35.392(a)(2), **or**

2. Completion of the alternate pathway of training and work experience topics listed in 10 CFR 35.392(a)(2), **or**

3. Documentation that the applicant is certified by an NRC-approved specialty board for 10 CFR 35.392

   AND

   Documentation of supervised clinical case experience that includes cases involving the oral administration of less than or equal to 1.22 gigabecquerels (33 millicuries) of sodium iodide I-131 as required by 10 CFR 35.392(a)(3)(vi)

   AND

   Attestation of the completion of the requirements and the ability for the applicant to independently fulfill radiation safety-related duties.

See Office of Nuclear Material Safety and Safeguards, Interim Staff Guidance, NMSS-ISG-03, Guidance for the Implementation of 10 CFR Part 35 Training and Experience Requirements for more information (ML25051A034).

Based on the proposed changes, what would be needed to support an application for initial approval of an AU for 10 CFR 35.394?

An applicant would use a newly revised NRC Form 313A(AUT) to document:

1. Completion of a 3-year residency in a nuclear medicine or radiation oncology accredited residency program that includes the training and work experience topics listed in 10 CFR 35.394(a)(2), **or**

2. Completion of the alternate pathway of training and work experience topics listed in 10 CFR 35.394(a)(2), **or**

3. Documentation that the applicant is certified by an NRC-approved specialty board for 10 CFR 35.394

   AND

   Documentation of supervised clinical case experience that includes cases involving the oral administration of greater than 1.22 gigabecquerels (33 millicuries) of sodium iodide I-131 as required by 10 CFR 35.394(a)(3)(vi)

   AND

   Attestation of the completion of the requirements and the ability for the applicant to independently fulfill radiation safety-related duties.

See Office of Nuclear Material Safety and Safeguards, Interim Staff Guidance, NMSS-ISG-03, Guidance for the Implementation of 10 CFR Part 35 Training and Experience Requirements for more information (ML25051A034).

Based on the proposed changes, what would be needed to support an application for initial approval of an AU for 10 CFR 35.396?

An applicant would use a newly revised NRC Form 313A(AUT) to document:

1. Completion of a 3-year residency in a nuclear medicine or radiation oncology accredited residency program that includes the training and work experience topics listed in 10 CFR 35.396(a)(2), **or**

2. Completion of the alternate pathway of training and work experience topics listed in 10 CFR 35.396(a)(2), **or**

3. Documentation that the applicant is certified by an NRC-approved specialty board for 10 CFR 35.396

   AND

   Documentation of supervised clinical case experience as required by 10 CFR 35.396(a)(3)(F)

   AND

   Attestation of the completion of the requirements and the ability for the applicant to independently fulfill radiation safety-related duties.

See Office of Nuclear Material Safety and Safeguards, Interim Staff Guidance, NMSS-ISG-03, Guidance for the Implementation of 10 CFR Part 35 Training and Experience Requirements for more information (ML25051A034).

TRAINING CATEGORIES AND CASES

What changes are proposed for supervised case experience for an AU who wants to only prescribe and orally administer an amount that is less than or equal to 1.22 gigabecquerels (33 millicuries) of sodium iodide I-131?

The regulations in 10 CFR 35.392 would still allow approval for the oral administration of less than or equal to 1.22 gigabecquerels (33 millicuries) of sodium iodide I-131. The current requirement for at least 3 supervised clinical cases involving the oral administration of less than or equal to 1.22 gigabecquerels (33 millicuries) of sodium iodide I-131 would be changed.

The regulations in 10 CFR 35.392 would require a sufficient number of cases to allow the supervising AU to evaluate and document the individual's competency in independently performing radiation safety related duties for the medical use for which the individual is requesting AU status. AU radiation safety related duties include radiation safety commensurate with use of byproduct material including all topics listed in 10 CFR 35.392(a)(2)(ii) and

applicable items for oral administration listed in 10 CFR 35.41(b)(1). For most physicians, this will require at least three cases. Physicians could present fewer than three cases if they demonstrate sufficient experience with other therapeutic uses of byproduct material.

An AU applicant would still document this supervised casework on the newly revised NRC Form 313(AUT). Once approved, the AU would be limited to this category of approval.

What changes are proposed for supervised case experience for an AU who wants to only prescribe and orally administer greater than 1.22 gigabecquerels (33 millicuries) of sodium iodide I-131?

The regulations in 10 CFR 35.394 would still allow approval for the oral administration of greater than 1.22 gigabecquerels (33 millicuries) of sodium iodide I-131. The current requirement for at least 3 supervised clinical cases involving the oral administration of greater than 1.22 gigabecquerels (33 millicuries) of sodium iodide I-131 would be changed.

The regulations in 10 CFR 35.394 would require a sufficient number of cases to allow the supervising AU to evaluate and document the individual's competency in independently performing radiation safety related duties for the medical use for which the individual is requesting AU status. AU radiation safety related duties include radiation safety commensurate with use of byproduct material including all topics listed in 10 CFR 35.394(a)(2)(ii) and applicable items for oral administration listed in 10 CFR 35.41(b)(1). For most physicians, this will require at least three cases. Physicians could present fewer than three cases if they demonstrate sufficient experience with other therapeutic uses of byproduct material.

An AU applicant would still document this supervised casework on the newly revised NRC Form 313(AUT). Once approved, the AU would be limited to this category of approval.

What changes are proposed for supervised case experience for an AU who wants to prescribe unsealed byproduct materials that are delivered parenterally?

The staff is proposing to change 10 CFR 35.390(b)(1)(ii)(G)(3), specifically by removing the following text from the regulation, "Parenteral administration 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." The proposed requirement would be "Parenteral administration of any radioactive drug for which a written directive is required." With this proposed change, training for any future radiopharmaceuticals that may be delivered by a parenteral administration pathway would be covered by this regulation.

The current requirement for at least 3 supervised clinical cases involving the parenteral administrations would also be changed. 10 CFR 35.396 would now require a sufficient number of cases to allow the supervising AU to evaluate and document the individual's competency in independently performing radiation safety related duties for the medical use for which the individual is requesting AU status. AU radiation safety related duties include radiation safety commensurate with use of byproduct material including all topics listed in 10 CFR 35.396(a)(2)(ii) and applicable items for parenteral administration listed in 10 CFR 35.41(b)(1). For most physicians, this will require at least three cases. Physicians could present fewer than three cases if they demonstrate sufficient experience with other therapeutic uses of byproduct material.

EMERGING MEDICAL TECHNOLOGIES

GENERAL EMERGING MEDICAL TECHNOLOGIES

Would this rule affect licensing for emerging medical technologies (EMTs) under 10 CFR 35.1000?

The proposed rule would modify Subparts D through H of 10 CFR Part 35 and the new proposed Subpart I to address medical use of EMTs with well-established operational experience, therefore streamlining and standardizing licensing. This rule would not change or affect the regulatory framework for 10 CFR 35.1000 for EMTs that are not specifically addressed in Subparts D through H, and the new proposed Subpart I.

Would licensees be able to use the existing licensing guidance to request authorization for EMTs currently regulated under 10 CFR 35.1000 but that are proposed to be addressed in other subparts?

If the proposed rule becomes effective, licensees would no longer be able to use the existing licensing guidance to apply for licensing under 10 CFR 35.1000 for those technologies that are incorporated into the revised rule. The following EMTs currently licensed under 10 CFR 35.1000 would be incorporated into other subparts of 10 CFR Part 35:

- Subpart D: (1) Germanium-68/Gallium-68 Pharmaceutical Grade Generator (IRE Galli Eo, Eckert & Ziegler).
- Subpart F: (1) NeoVista, Inc's Epi-Rad90 (Sr-90) Ophthalmic System and (2) LV Liberty Vision Y-90 Disc and iWand® Ophthalmic System.
- Subpart H: (1) Akesis GalaxyRTi; (2) Leksell Gamma Knife® Perfexion™; (3) Leksell Gamma Knife® Icon™; (4) Elekta Esprit; (5) Xcision® GammaPod™; (6) Masep Infini; and (7) ViewRay System for Radiation Therapy.
- Subpart I: (1) TheraSphere Y-90 microspheres; (2) SIR-Spheres Y-90 microspheres, and (3) Eye90 microspheres.

Could licensees continue using the criteria in the 10 CFR 35.1000 guidance to meet licensing requirements, or would they need to follow new procedures?

Licensees who obtained a license under 10 CFR 35.1000 prior to the date of publication of the final rule would remain authorized for the uses for which they are authorized under 10 CFR 35.1000. If the licensee received written approval from the Commission to adopt license conditions contained within 10 CFR 35.1000 guidance for compliance with regulations, they could continue to follow their license conditions.

Information on previous and current EMTs can be found on the NRC Medical Uses Licensee Toolkit webpage for Emerging Medical Technologies: https://www.nrc.gov/materials/miau/med-use-toolkit/emerg-licensed-med-tech.

Would licensees that are currently authorized for use of an EMT under 10 CFR 35.1000 need to change anything or apply for a new license under 10 CFR Part 35?

Licensees currently authorized for EMTs under 10 CFR 35.1000 would not need to apply for a new license if the proposed rule becomes effective, provided they are already authorized for the same use under their existing license pursuant to 10 CFR 35.1000.

Individuals already listed on a license for the use of any of the incorporated EMTs in this rule would be considered legacy individuals for that use under the new rule in accordance with 10 CFR 35.57. These individuals would not need to requalify under any new training and experience requirements for the same use as previously authorized.

EXPANSION OF MEDICAL USE GENERATORS

Would licensees need to submit a new license amendment for a generator that was previously licensed under 10 CFR 35.1000?

No. In accordance with the proposed 10 CFR 35.1000(b), licensees may use generators approved for medical use in accordance with the written approval from the Commission in a license or license amendment if the licensee obtained approval under 10 CFR 35.1000 prior to the date of publication of the final rule in the *Federal Register*.

If a licensee already uses a Ge-68/Ga-68 generator under 10 CFR 35.1000, would they need to change their current procedures?

No. In accordance with the proposed 10 CFR 35.1000(b), licensees may use generators approved for medical use in accordance with the written approval from the Commission in a license or license amendment if the licensee obtained approval under 10 CFR 35.1000 prior to the date of publication of the final rule in the *Federal Register*.

However, if the licensee would like to change their authorization to 10 CFR 35.200, the licensee would need to develop, implement, and maintain a written procedure for breakthrough in accordance with the proposed 10 CFR 35.93. This may not be a significant change if the licensee is using the breakthrough limits and testing contained in the current licensing guidance as the limits and tests in the proposed 10 CFR 35.93 are based on the manufacturer's U.S. Food and Drug Administration (FDA) approved generator labeling or nationally recognized standards, such as US Pharmacopeia (USP). In addition, recordkeeping requirements in the proposed 10 CFR 35.93 align with the current licensing guidance.

Would licensees need to apply under 10 CFR 35.1000 for new generator types?

The applicability of the proposed 10 CFR 35.93 depends on the type of generator being introduced. The intent of the proposed 10 CFR 35.93 is to provide flexibility in licensing the medical use of generators under Subparts D and E. If a new generator design emerges that is not specifically addressed in these subparts, licensing under 10 CFR 35.1000 may be required.

Currently, the proposed 10 CFR 35.93 encompasses all existing generator types. Therefore, licensees who begin using a generator they were not previously authorized for would apply for the appropriate "types of use" licensing:

- Use under 10 CFR 35.200 for diagnostic purposes.
- Use under 10 CFR 35.300 for therapeutic purposes.

If the licensee does not already hold authorization for these types of medical use, they would need to submit an application to obtain the necessary approvals.

What training would be required for personnel handling generator eluate?

Licensees would be required to ensure that individuals who elute new or upgraded generators, and those who prepare radioactive drugs using the eluate, receive vendor-provided operational and safety training in accordance with 10 CFR 35.93. This training would include:

- Instruction on measuring and testing the eluate for breakthrough.
- Instruction on processing the eluate with reagent kits.

How would licensees determine acceptable breakthrough limits and testing frequencies under the proposed 10 CFR 35.93?

Pursuant to 10 CFR 35.93, acceptable limits and frequencies would need to be:

- Clearly defined in your facility's written procedures.
- Based on the generator's FDA-approved labeling or a nationally recognized standard such as the USP.

The licensee should review their procedures periodically to ensure they remain current with manufacturer updates or changes in national standards.

CONSOLIDATED SAFETY PRECAUTIONS

Do the 10 CFR Part 20 dose limits apply to patients who cannot be released under 10 CFR 35.75 and are co-located in a room with another patient?

Yes. The proposed rule does not change the provision that dose limits in 10 CFR Part 20, "Standards for Protection Against Radiation," apply to radiation exposure from individuals who have not been released under 10 CFR 35.75. Therefore, if such individuals are co-located, for example, in the same room following different types of administrations, licensees must ensure that exposures to others in the room remain within the applicable Part 20 limits. This may involve managing the duration of co-location, maintaining appropriate distance, and implementing shielding as necessary.

Would patients who cannot be released under 10 CFR 35.75 be required to have a room with a private bathroom?

No. In accordance with the proposed 10 CFR 35.76, licensees would only be required to ensure that patients who have received administrations involving unsealed byproduct material or microsources have access, without leaving the controlled area, to a bathroom that is used exclusively by other individuals who have also received administrations and cannot be released under 10 CFR 35.75.

OPHTHALMIC APPLICATOR SOURCES AND DEVICES

Would an AU authorized under 10 CFR 35.491 be permitted to use Pd-103, I-125, or Ru-106 eye plaques under 10 CFR 35.400?

It would depend on the type of radionuclide used. An AU authorized under 10 CFR 35.491 would be limited to the use of beta-emitting sources for superficial ophthalmic procedures only.

Ru-106 is a beta emitter, and it is typically used to deliver therapeutic doses to intraocular tissues, which exceeds the scope of superficial treatment. For any use of Ru-106 involving deeper tissue penetration, the AU would need to meet the training and experience requirements under 10 CFR 35.490, which authorizes broader use under 10 CFR 35.400.

Pd-103 and I-125 are photon-emitting sources. Any AUs seeking approval to use Pd-103 or I-125 eye plaques for ophthalmic procedures under 10 CFR 35.400 would need to meet the training and experience requirements under 10 CFR 35.490.

What new training would be required under 10 CFR 35.490 and 35.491 for a physician to become authorized to use ophthalmic devices?

Physicians would be required to complete device-specific training in accordance with 10 CFR 35.490 and 35.491 to be authorized for the use of ophthalmic devices, including devices with beta-emitting sources used for superficial radiotherapy. Under the proposed rule, this training:

- Must include instruction in the operation and safety features of the specific ophthalmic device to be used, as well as in the clinical use of the device.
- May be provided by the vendor or device manufacturer or conducted under the supervision of an AU or an AMP authorized for use of the same device for which authorization is being sought.

This requirement would ensure that physicians not only meet the general training and experience standards but also demonstrate competence in the safe and effective use of the specific device they intend to use in clinical practice.

How would this proposed rule affect recordkeeping requirements under 10 CFR 35.2433?

This proposed rule would update the terminology in 10 CFR 35.2433 by replacing “strontium-90 sources” with “beta-emitting sources.” This change would ensure that recordkeeping requirements remain applicable to a broader range of radionuclides without altering the scope or intent of the regulation.

MICROSOURCE BRACHYTHERAPY (NEW SUBPART I)

Why is NRC proposing a new Subpart for microsource use?

Microsource brachytherapy is a type of cancer treatment that uses tiny radioactive particles, like yttrium-90 (Y-90) microspheres, implanted directly into the body. These particles are very small and behave differently than traditional radiation sources. The NRC determined that microsources have unique properties that should be addressed through a specific regulatory framework separate from traditional sealed sources.

How would this proposed rule affect licensing for TheraSphere® and SIR-Spheres® Y-90 microspheres?

This proposed rule would establish a dedicated subpart for microsource brachytherapy, Subpart I, “Microsource Brachytherapy.” Y-90 microspheres licensing, including licensing for TheraSphere® and SIR-Spheres® would now be licensed under Subpart I, instead of Subpart K to 10 CFR Part 35.

What new procedures would applicants be required to submit for microsource use that were not required under the Y-90 microspheres licensing guidance?

Applicants would be required to develop, implement, and maintain written procedures that address the licensee’s response to abnormal situations while using microsources (e.g., spills, equipment failures, and emergent conditions that affect the administration of microsources) in accordance with the new proposed 10 CFR 35.710(b). Appendix N, “General Topics for Safe Use of Radionuclides and Model Emergency Procedures,” of NUREG-1556, Volume 9, Revision 3, contains guidance for responding to some types of emergencies, such as spills.

Would this rule revise medical event reporting for microsource brachytherapy for events caused by shunting?

No. The requirements for shunting and medical event reporting for microsource brachytherapy would remain essentially the same compared to the NRC licensing guidance for Y-90 microspheres. Shunting would continue to be excluded from medical event reporting if properly evaluated prior to administration in accordance with the manufacturer’s instructions as set forth in its FDA product approval.

This rule would amend 10 CFR 35.2 to include a definition for shunting that would distinguish shunting from other types of medical events. This rule would codify the shunting exclusion and medical event criteria directly into Part 35 regulations, making them more explicit and standardized for all microsource brachytherapy (not just Y-90 microspheres).

What are the key differences between the proposed rule for microsource brachytherapy and the licensing guidance for Y-90 microspheres regarding the written directive?

The new proposed 10 CFR 35.40(b)(5) would align microsource brachytherapy with manual brachytherapy, incorporating similar flexibility for written directives as that used in the current Y-90 microspheres licensing guidance, and provide AUs flexibility to modify the written directive after administration based on medical judgment. The proposed 10 CFR 35.40(b)(5) would continue to require both a pre-administration and post-administration component for written directives for permanent manual brachytherapy and would now explicitly include microsource brachytherapy. Specifically, the written directive would be required to include:

- Before administration: treatment site, radionuclide, and total source strength or prescribed dosage.

- After administration (before the patient leaves the recovery area): treatment site, number of sources and total source strength or activity administered, and the date.

Additionally, the proposed 10 CFR 35.40(b)(5) would update the criteria for reporting medical events to exclude cases where emergent patient conditions prevent the completion of the administration as originally planned, thereby reducing unnecessary reporting. See the medical event FAQ for more information. Lastly, model information would no longer be required to be

included in the written directive and only the prescribed dosage could be listed on the written directive.

What are the key differences between the proposed rule for microsource brachytherapy and the licensing guidance for Y-90 microspheres regarding brachytherapy source accountability?

Under 10 CFR 35.406, brachytherapy source accountability requirements do not apply to licensees using microsources under Subpart I. Microsources, including Y-90 microspheres, are treated as unsealed byproduct material under Subpart I, and § 35.406 applies only to manual brachytherapy sources (sealed sources). However, licensees must still comply with security and control of material contained in 10 CFR 20.1801 and 20.1802, similar to controls for unsealed byproduct material.

Would there be any changes in the requirements for leak testing, inventory, and waste disposal for microsource brachytherapy?

No. The requirements for leak testing and inventory (10 CFR 35.67) and waste disposal (10 CFR 35.92) for microsource brachytherapy (including Y-90 microspheres) would not change beyond that described above for brachytherapy source accountability. This rule would codify the current criteria in the Y-90 licensing guidance, as described below.

- Licensees are not required to perform leak tests of microsources due to the small size and large number of current known microsources, which makes leak testing impractical.
- Licensees are not required to conduct semi-annual physical inventories due to the expected short half-lives of current known microsources (e.g., Y-90 has a half-life of approximately 64 hours) and the fact that microsources are not managed as individual, discrete sources.
- Waste from microsource administrations must be handled as radioactive waste and contaminated materials and items from patient rooms must be managed in accordance with 10 CFR 35.76.
- Licensees may use decay-in-storage prior to disposal for microsources with a physical half-life of 275 days or less, in accordance with the changes proposed in 10 CFR 35.92.

From what entities would medical licensees be able to acquire microsources?

Licensees would only be able to use microsources obtained from entities licensed under 10 CFR 32.72 or 32.74 or used under an active FDA-approved Investigational Device Exemption (IDE), in accordance with 10 CFR 35.700.

What documentation would an applicant or licensee need to support an application for initial approval of an AU for 10 CFR 35.790?

An applicant would use a newly developed NRC Form 313A(AUM) to document:

- Completion of a 3-year residency in a diagnostic radiology accredited residency program and 1 year of interventional radiology in an accredited residency or fellowship program

AND

- Completion of training and experience requirements which include:

- Classroom and laboratory training listed in § 35.790(2)(i)(A)-(D)
- Work experience listed in § 35.790(a)(2)(ii)(A)-(D)
- Work experience listed in § 35.790(a)(2)(iii)(A)-(C) for each type of microsource use requested

AND

- Attestation of the completion of the requirements and the ability for the applicant to independently fulfill radiation safety-related duties

  OR

- Documentation that the applicant is an AU under § 35.390, 35.396, or 35.490

AND

- Documentation of training and work experience in device operation, safety procedures, and clinical use for the type(s) of microsource for which authorization is sought. This training must include three hands-on cases including work experience as described in paragraphs § 35.790(a)(2)(ii) and (iii) for the type of microsource for which authorization is sought.
- Attestation that the individual has satisfactorily completed the above-listed requirements.

REVISIONS TO SUBPART H OF 10 CFR PART 35 DUE TO EMERGING MEDICAL TECHNOLOGIES

Would a medical physicist need safety training if they only operate a unit authorized under 10 CFR 35.600 for calibration?

Yes. If the medical physicist operates a unit for calibration they would need vendor operational and safety training in accordance with proposed changes to 10 CFR 35.690(d). If the medical physicist only checks calibration which is performed by another staff member, the medical physicist would not need the training. However, the staff member who performs the calibration would.

If a licensee makes patient-specific masks for treatments, would the licensee need to perform drills of emergency procedures for each mask?

No. The licensee would not be required to perform drills for each individual mask. Instead, emergency procedure drills should be conducted for each *type* of immobilization device to ensure that staff are trained to quickly and safely remove a patient from the radiation source in the event of an abnormal situation.

What does "immediately available" mean for the AU during continuation of treatment?

"Immediately available" under 10 CFR 35.615 means the AU must be able to respond without delay to any situation that may arise during the patient administrations. The AU does not have to respond in person but should be able to evaluate the situation to provide supervision and support in the case of an abnormal situation or an unexpected interruption.

What would licensees be required to do if the treatment is unexpectedly interrupted and needs to be re-initiated?

If there is an unexpected interruption requiring operator re-initiation, both the AU and AMP would need to evaluate the situation to ensure the treatment is being delivered in accordance with the treatment plan and written directive prior to re-initiation. The AU would not need to be physically present but should have enough information to evaluate the situation as necessary prior to initiation. This could include confirming immobilization and localization is correct if the interruption was related to patient movement.

Who would be required to be physically present during the continuation of the treatment?

The AMP and appropriate staff who are trained in emergency response and are necessary in accordance with written procedures pursuant to 10 CFR 35.610(a)(4) to be physically present for the continuation of treatment. For example, if the procedure required per 10 CFR 35.610(a)(4) has the radiation therapist, AMP, and one additional trained individual responding to remove a patient in an abnormal situation, these individuals would need to be physically present during the continuation of the treatment.

For modalities that do not have physically present requirements, who is required to be present during administration?

The current regulation in 10 CFR 35.11(b)(1) permits licensees to allow individuals who are not AUs to perform certain tasks under the supervision of an AU who is named on the license or permit. For modalities that do not specify requirements for certain individuals to be physically present during administration, the use of byproduct material may be performed by an individual under the supervision of an AU in accordance with 10 CFR 35.27. This provision to all uses of byproduct material that do not have explicit physical presence requirements, such as diagnostic and therapeutic unsealed byproduct material, manual brachytherapy, and microsphere brachytherapy.

Under this regulation, the licensee instructs the supervised individual in the licensee's written radiation protection procedures, procedures for administrations requiring a written directive, applicable regulations, and license conditions related to the use of byproduct material. The supervised individual is required to follow the instructions of the supervising AU for medical uses of byproduct material, as well as the licensee's written radiation protection procedures, written directive procedures, and all applicable regulations and license conditions. Unless otherwise specified by regulation or license conditions, the AU is not required to be physically present or onsite during the administration, provided that the supervised individual is able to follow the AU's instructions in accordance with 10 CFR 35.27, including licensee's written radiation protection procedures, which should include response to an emergency or a spill involving the byproduct material.

What should a licensee do if they wish to use an EMT before a nationally recognized body has developed published protocols for full calibration or spot checks?

In place of committing to following licensing conditions listed in the 10 CFR 35.1000 licensing guidance which were developed using manufacturer calibration and spot check instructions, licensees could use NRC-approved manufacturer protocols listed on the NRC Medical Use

Toolkit website under the Emerging Medical Technologies page. If a protocol is not listed for the technology the licensee desires to use, the licensee can include it with their application and the NRC or Agreement State will review it to ensure it contains appropriate full calibration measurements as required in 10 CFR 35.632, 35.633, or 35.635 or spot check measurements as required in 10 CFR 35.633 or 35.635, similar to the review the NRC conducts for 10 CFR 35.1000 licensing guidance licensing conditions.

What does it mean when the NRC refers to "NRC-accepted manufacturer instructions" in the context of proposed 10 CFR 35.645?

Under the proposed performance-based revisions to 10 CFR 35.645, licensees would no longer be required to follow a fixed list of mechanical and safety checks (like testing helmet microswitches, trunnion centricity, emergency timing circuits, and intercom systems) as previously outlined in the regulation. Instead, licensees could follow procedures written by an AMP and either nationally recognized standards or NRC-accepted manufacturer instructions.

NRC-accepted manufacturer instructions are written procedures developed by the manufacturer that have been reviewed and confirmed by the NRC to include appropriate procedures and acceptable tolerance limits for required spot checks and calibrations. These procedures will be approved by the NRC if they contain instructions to check necessary systems and components as required per regulation and contain clear tolerance limits for licensee use. This is similar to the process the NRC used to develop licensing condition recommendations contained in current 10 CFR 35.1000 guidance for technologies before nationally recognized bodies, such as American Association of Physicists in Medicine (AAPM), had published protocols. Both AAPM task group reports and medical physicist practice guidelines (MPPGs) are considered published protocols from a nationally recognized body.

Would licensees still be required to check treatment table retraction mechanisms for Gamma Stereotactic Radiosurgery (GSR)?

Yes. Treatment table retraction mechanisms for GSRs should be checked as part of the operability and availability of retraction devices appropriate to the unit. Licensees would ensure the operability and availability of all retraction and emergency response equipment required to implement procedures required in 10 CFR 35.610(a)(4) to separate a patient from the source in an abnormal situation as quickly as possible.

If a localization device such as a frame is found not to be functioning appropriately during a spot check required under proposed 10 CFR 35.647(b)(1), could a licensee still use the unit with another localization device that is functioning appropriately?

Yes. The licensee could still use the unit with another localization device that is functioning appropriately. The licensee could not use the localization device that is not functioning appropriately until it is repaired and found to be functioning appropriately.

RB-82 GENERATORS

Would licensees need to amend their licenses to continue using Rb-82 generators under the proposed rule?

No. Rb-82 generators would remain licensed under 10 CFR 35.200. The proposed rule would not change their licensing pathway but would replace the need for enforcement discretion with clear, codified requirements. However, licensees would need to update their procedures and records to comply with the new general requirements in 10 CFR 35.93, 35.2093, and 35.2310.

How would the rule codify training criteria in EGM-13-003?

The proposed rule would codify the expectations for training outlined in Enforcement Guidance Memorandum (EGM) 13-003 and expand their applicability. Unlike EGM-13-003, which is limited to Rb-82 generators, the proposed rule would apply to all radionuclide generators.

Key proposed changes include:

- Training requirements would be formally integrated into regulation under 10 CFR 35.93, with documentation requirements specified in 10 CFR 35.2093 and 35.2310.
- Training for any radionuclide generator and associated equipment would be required prior to first use of a new generator or existing generator.
- Instruction on elution, breakthrough testing, dose calibrator calibration, and safety procedures would be required.

OTHER TOPICS

WRITTEN DIRECTIVE

With the removal of the written directive requirement for administration of sodium iodide I-131 greater than 1.11 megabecquerels (MBq) (30 microcuries (µCi)), what Subpart would include the uptake and diagnostic use of sodium iodide I-131 fall?

If this proposed rule is adopted, the requirement for a written directive for diagnostic administrations of sodium iodide I-131 exceeding 1.11 MBq (30 µCi) would be removed. As a result, the uptake and diagnostic use of sodium iodide I-131would fall under Subpart D, Unsealed Byproduct Material, Written Directive Not Required. Specifically, 10 CFR 35.100 and 10 CFR 35.200 would govern the use of unsealed byproduct material for uptake, dilution, excretion, imaging, and localization studies, which would include diagnostic uses of sodium iodide I-131. These sections would allow for the use of such materials without a written directive.

Would physicians who are already authorized for 10 CFR 35.300 uses need additional training to be authorized for diagnostic use of sodium iodide I-131?

No. Physicians already authorized for 10 CFR 35.300 uses would not need additional training to be authorized for diagnostic use of sodium iodide I-131. Their existing authorization includes the necessary qualifications for diagnostic uses covered under 10 CFR 35.190(c) and 35.290(c).

With the removal of the requirement for a written directive for administrations of sodium iodide I-131 greater than 1.11 MBq (30 µCi), would medical event reporting, patient release, and other safety regulations still apply?

Yes. The removal of the written directive requirement for administrations of sodium iodide I-131 greater than 1.11 MBq (30 µCi) would not exempt licensees from complying with provisions related to radiation safety, such as patient release criteria (10 CFR 35.75), radiation surveys

(10 CFR 35.70), instrument calibration (10 CFR 35.60), and dosage determination (10 CFR 35.63). Additionally, medical event reporting requirements (10 CFR 35.3045) would continue to apply when applicable, such as in cases of significant deviation from prescribed dosage or wrong-patient administration.

When would an AU be required to sign the two-part written directive required for permanent implant brachytherapy?

An AU would be required to sign and date the pre-implantation portion of the written directive before the administration begins, as would be required under 10 CFR 35.40(a). For permanent implant brachytherapy, a second signature would be required after the administration but before the patient leaves the post-treatment recovery area, as specified in 10 CFR 35.40(b)(5)(ii). This post-implantation portion would document the actual number of sources, total source strength or activity administered, and the date.

Under the proposed 10 CFR 35.3045(a)(2), a medical event for permanent implant brachytherapy would include incidents where the total source strength or activity administered outside the treatment site exceeds 20% of what is documented in the post-implantation portion of the written directive. By requiring the AU to sign this portion after the procedure, the proposed regulation would ensure that medical event evaluations are based on the final, AU-approved administration. This clarification would help prevent unnecessary medical event reports when changes are clinically justified and properly documented.

REPORTING EMBRYO/FETUS EVENTS

If a licensee made a reasonable effort to determine a patient's pregnancy status but pregnancy could not be reasonably excluded prior to administration, and the licensee then later learns the patient was pregnant at the time of the administration and determines that the dose to the embryo/fetus was greater than 50 millisievert (mSv) (5 roentgen equivalent man (rem)) dose equivalent, would the licensee be required to report this under 10 CFR 35.3047?

No. If the licensee made a reasonable effort to determine the pregnancy status of the patient (prior to the administration), but pregnancy could not be reasonably excluded, the event would not be reportable under proposed 10 CFR 35.3047(a)(2).

What is meant by "reasonable effort to determine a patient's pregnancy status" and what is an example of a licensee making reasonable effort to determine a pregnancy status and being unable to be reasonably exclude the pregnancy prior to administration if a patient is actually pregnant?

A "reasonable effort to determine pregnancy status" should be consistent with standard medical care for the patient, such as asking the patient for pregnancy status and the licensee performing a blood or urine pregnancy test 24 hours prior to the administration of the radiopharmaceutical. However, there are situations where pregnancy cannot be reasonably excluded, even after such efforts. For instance, the patient may deny the possibility of being pregnant and the gestational age of the embryo/fetus may be too early for detection by standard testing methods, or the patient may have a medical condition (e.g., amenorrhea, hormonal imbalance, or recent miscarriage) that interferes with the accuracy of pregnancy tests. The

licensee should document in the patient's charts their efforts to determine pregnancy to show reasonable effort was made prior to administration.

MEDICAL EVENTS

What are some examples of emergent patient conditions that could prevent completion of administration as planned?

Examples of emergent patient conditions that could prevent completion of administration as planned include, but are not limited to, vascular spasms, sudden changes in vital signs (e.g., hypotension, arrhythmia), loss of consciousness, seizure that stops treatment that cannot be restarted, or acute allergic reactions.

What are examples of events not resulting from patient intervention or emergent patient conditions that prevent completion of administration as planned that are excluded from reporting under 10 CFR 35.3045(a)?

Examples include administration to the wrong treatment site due to a dislodged localization device or underdose due to spills caused by expected patient movement unrelated to emergent patient conditions. Patient stretching or sneezing would be considered expected patient movement that a localization device should prevent causing a medical event.

What are some examples of events that are caused by a leak or defect in administration kit or supplies?

Examples include defects in Luer locks used in radiopharmaceutical administration, leaks in the tubing connections in a Y-90 microsphere administration kit, and bent catheters mistakenly used in microsphere administration.

DECAY-IN-STORAGE

What types of radioactive materials can be held for decay-in-storage under the proposed rule?

Licensees would be able to hold unsealed byproduct material for decay-in-storage if the material has a physical half-life of 275 days or less in accordance with the changes proposed to 10 CFR 35.92. This includes commonly used radionuclides such as lutetium-177m (Lu-177m) and cobalt-57 (Co-57), which are excluded under the 120-day limit in the current rule. Under the proposed rule, these materials could be stored onsite until they decay to background radiation levels, provided the licensee has space and could meet all other applicable requirements to ensure the material is controlled safely.

It is important to note that this does not relieve licensees from complying with other applicable Federal or State requirements related to waste.

How long can radioactive material be stored under the proposed decay-in-storage provision?

The requirements in the proposed 10 CFR 35.92 do not specify how long material may be stored, but the material cannot be disposed of until the licensee determines that its radioactivity cannot be distinguished from the background radiation level with an appropriate radiation detection survey meter set on its most sensitive scale and with no interposed shielding. The actual storage time will depend on the radionuclide's decay characteristics and the material's initial activity. If the licensee wishes to dispose of the material sooner, the licensee could dispose of the material using any disposal pathway allowed under 10 CFR Part 20, Subpart K.

LICENSING FOR HUMAN RESEARCH

Would a license be required to conduct research involving human research subjects?

Yes. Entities that want to conduct research involving human research subjects must have a medical use license. If a licensee is already approved for a certain type of medical use, the licensee could conduct research under that same license or approval. Licensees would be required to ensure they obtain review and approval for the research from an "Institutional Review Board" and obtain "informed consent" as defined and described in the Federal Policy for the Protection of Human Subjects (Federal Policy) and follow all other Federal and local requirements regarding the research.

MOBILE MEDICAL LICENSEES

What are mobile medical licensees required to do under the proposed rule?

Mobile medical licensees would remain subject to radiation safety regulations that apply to all licensees. For example, mobile medical licensees would still be required to perform radiation surveys in accordance with 10 CFR 20.1501. This includes evaluating radiation levels and identifying potential hazards at the client's location. Instruments used to measure the activity of unsealed byproduct material and microsources must be properly calibrated as required by 10 CFR 35.60.

Additionally, licensees would be required to maintain constant control and surveillance of licensed material in unrestricted areas, as mandated by 10 CFR 20.1802. This ensures that byproduct material is not left unattended or unsecured during mobile operations. Furthermore, mobile medical licensees would still be required under 10 CFR 35.80 to obtain a letter signed by a client's management that permits the use of byproduct material at the client's address and clearly delineates the authority and responsibility of the licensee and the client. Mobile medical licensees would be required to retain this letter in accordance with 10 CFR 35.2080.

RADIATION SAFETY COMMITTEE

Which licensees would be required to have a Radiation Safety Committee in accordance with 10 CFR 35.24(f)?

Licensees authorized for two or more different types of uses of byproduct material under Subparts E, F, H, I, and K of this part which require a written directive, or two or more types of

units under Subpart H of this part, would be required to establish a Radiation Safety Committee (RSC). Therefore, licensees who are authorized for two different therapeutic uses; such as radiopharmaceutical therapy, manual brachytherapy, microsources, or a use under Subpart H or K of 10 CFR Part 35, would be required to have an RSC. However, if a licensee is authorized for two different types within the same modality, such as two types of microsources, two types of manual brachytherapy, or two types of radiopharmaceuticals, or is authorized for only one type of unit under Subpart H or one type of use under Subpart K that requires a written directive, then the licensee would not be required to establish an RSC. This would hold true even if the licensee is also authorized for additional uses that do not require a written directive.

MAINTENANCE OF RECORDS

Would licensees still be required to maintain records if 10 CFR 35.55 is being removed?

Yes. Medical licensees would still be required to maintain records in accordance with 10 CFR 30.51.

Paperwork Reduction Act

This document provides voluntary guidance for implementing the mandatory information collections in 10 CFR Part 35 that are subject to the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 et. seq.). These information collections were approved by the Office of Management and Budget (OMB), under control number 3150-0010. Send comments regarding this information collection to the FOIA, Library, and Information Collections Branch, Office of the Chief Information Officer, Mail Stop: T6-A10M, U.S. Nuclear Regulatory Commission, Washington, DC 20555-0001 or by email to Infocollects.Resource@nrc.gov, and to the OMB reviewer at OMB Office of Information and Regulatory Affairs (3150-0010), Attn: Desk Officer for the Nuclear Regulatory Commission, 725 17th Street, NW, Washington, DC 20503.

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