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December 14, 2023

Maryann Ayoade
U.S. Nuclear Regulatory Commission
Washington, DC 20555–0001

Dear Ms. Ayoade,

The OAS Executive Board (Board) appreciates the opportunity to comment on the regulatory basis for the rulemaking to establish requirements for rubidium-82 generators, emerging technologies, and other medical use of byproduct material (STC-23-049, federal register notice docket number NRC-2018-0297). The Board's comments focused on the questions posed in the regulatory basis document:

Generator Systems Questions

A.1.1: Please provide comments on the need for radiation safety officers to have specific training for all generator systems licensed under 10 CFR part 35, subpart D, ''Unsealed Byproduct Material—Written Directive Not Required.'' If general awareness on radionuclide generators, including their functions and risks, is sufficient, explain why.

> Radiation safety officers should have device specific training to better understand the devices authorized on their license. A general awareness training requirement is insufficient as that requirement would assume that all generators, now and in the future, have the same functionality and risks which is an inappropriate assumption.

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

> Incremental administration of radionuclides could be allowed under the guidance of an authorized user if deemed medically necessary. Bounding of the test should follow the prescription of the authorized user or by a written procedure in a licensee's diagnostic clinical procedures manual.

A.1.3: The NRC has found that AUs authorized under § 35.290, ''Training for imaging and localization studies,'' have sufficient understanding of radionuclide generators, and the NRC is considering revising § 35.27, Supervision,'' to require device-specific training requirements for supervised individuals. Please provide comments with a rationale on whether § 35.290 AUs should also be required to have device-specific training for all radionuclide generators for which they supervise the use.

> Authorized users should have device specific training. It is unclear how supervised individuals, working under the supervision of an authorized user, would receive device-specific training if the supervising authorized user does not have the same level of training.

Intravascular Brachytherapy Systems Question

A.2.1: The NRC is considering adding a new section under subpart F to address the specific training and experience (T&E) requirements to be an AU for IVB and other uses under § 35.401 (liquid brachytherapy, diffusion brachytherapy, and eye applicators). Please provide comments on the sufficiency of the T&E for AUs as outlined in the current EMT licensing guidance documents for IVB, liquid brachytherapy, and eye applicators. Specifically, the NRC is seeking comments on the knowledge topics encompassing the safety-related characteristics of these EMTs required for AUs to fulfill their radiation safety related duties and supervision roles; the methods on how knowledge topics should be acquired; and consideration for continuing education, vendor training for new medical uses, and training on NRC regulatory requirements.

> The Board is unaware of any medical events that have occurred because of inadequate training and experience, so the current training requirements in the licensing guidance appears to be sufficient.

Liquid Brachytherapy Sources and Devices Questions

A.3.1: The NRC has found that the hazards of liquid brachytherapy are similar to those of microsources and microspheres. Please provide comments with a rationale on whether the current definition of manual brachytherapy in § 35.2, ''Definitions,'' should be revised to include liquid brachytherapy and exclude microsources or if liquid brachytherapy should be included in the newly proposed subpart I for microsources.

> Manual brachytherapy should be limited to sealed sources registered with the sealed source and device registry. Liquid brachytherapy should be incorporated into the newly proposed subpart I since the hazards are similar to microsources and microparticles.

A.3.2: The NRC is proposing to add a new § 35.71, ''Contamination control,'' that would require licensees to develop, implement, and maintain procedures addressing contamination control and spill response for the uses authorized on the license. The NRC is seeking input on whether this requirement is needed or if the requirements in 10 CFR part 20, ''Standards for Protection against Radiation,'' are sufficient for contamination control. Please provide comments on this proposed requirement and indicate if it should apply to all medical licensees or to a certain subset and why.

> The requirements in 10 CFR 20 for contamination control are primarily addressed in Subpart E (Radiological Criteria for License Termination) and Subpart J (Precautionary Procedures, mostly for package surveys per 20.1906). 10 CFR part 20 does not adequately address contamination control for medical uses of radioactive materials. Currently, procedures for contamination control are provided during the license application process or reviewed during inspection. If consistency across various licensees is needed, this should be added to Part 35.

A.3.3: The NRC is considering amending § 35.2 to define the term ''source leakage'' as it relates to liquid brachytherapy. For example, a possible leakage rate could be any leakage from a liquid brachytherapy source that results in a dose exceeding 0.5 Sievert (50 rem) dose equivalent to any individual organ other than the treatment site. Please comment on whether this limit is appropriate and explain why or why not. What types of limits for liquid brachytherapy device leakage should the NRC consider (e.g., activity-based, dose-based, external to the patient)?

A term for source leakage should be provided, but care should be exercised in choosing the name of the of the definition to prevent confusion with definition of 'sealed source'. A leakage rate that results in a dose exceeding 0.5 Sievert (50 rem) dose equivalent seems high as that would be the limit for a medical event, and may exceed the threshold for an abnormal occurrence should the patient be a minor and the total effective dose equivalent exceed 50 mSv (5 rem). An activity-based limit would be the easiest for a licensee to determine if leakage occurred, and then after leakage had been determined, a dose to the affected tissue could be determined.

Gamma Stereotactic Radiosurgery and Photon Emitting Teletherapy Unit Questions

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

Radiation safety officers should have device specific training to better understand the devices authorized on their license. This should apply to all devices.

A.6.2: Current NRC requirements in 10 CFR part 35, subpart H, are focused on components critical to patient and facility safety for the use of these devices. The proposed changes to subpart H focus on elements and objectives rather than specific components. Examples of elements include source output, source collimation, source position, source attenuation, patient safety, and facility safety. Please provide comments on other elements that should be considered.

The Board agrees that the proposed changes should focus on elements and objectives to ensure the regulations are not so specific that they are not applicable to contemporary devices.

A.6.3: Please provide comments on what types of objective tests the NRC should require for full calibration measures for 10 CFR part 35, subpart H devices. What functional elements should be considered for safety?

Regulations for full calibration measurements should include common elements for all devices, such as source positioning, source output, etc. It may be useful to include a catch-all regulation such as 'any tests deemed necessary by the device manufacturer' to allow for flexibility with future devices.

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

Regulations for periodic spot-checks should include common elements for all devices, such as source positioning, timer accuracy, etc. that has the potential for variability or being disabled between treatments would have a detrimental effect on patient care should those items be problematic. It may be useful to include a catch-all regulation such as 'any tests deemed necessary by the device manufacturer' to allow for flexibility with future devices.

Microsource Manual Brachytherapy

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

1) Microspheres should not be limited to specific types of radiation or certain energies.

2) Microsources should be limited to sealed sources with a Sealed Source and Device registry.

3) Unsealed microsources should not be required to have a Sealed Source and Device registry as unsealed sources aren't sealed sources. An unsealed microsource should be considered as unsealed materials used under 10 CFR 35.100, 35.200, or 35.300.

4) The Board is unaware of any limitations in the current regulations that are preventing use of microsource brachytherapy.

A.7.2: The NRC is considering defining ''physiological equilibrium'' in § 35.2 to include stasis or other states of equilibrium. Please provide comments on what should be included in a definition of physiological equilibrium or identify other considerations for physiological stop points.

The Board supports including this definition but have no comments on what should be included beyond patient stasis.

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

Fundamental elements of a successful team approach should include the implementation of an authorized medical physicist as part of the team. A nuclear medicine technologist may not have the equivalent training or experience that an authorized medical physicist could provide.

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

The before-implant written directive should specify the activity. This would eliminate any differences between implementation (i.e. dose to tumor versus dose to tissue/organ) and help promote a consistent approach to medical procedures.

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

The after-implant written directive should the activity administered for comparison to the before-implant written directive. The dose delivered to the treatment site provides more value to the physician in determining if the treatment is effective.

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

The requirements for determining if a medical event has occurred should begin with calculating and documenting the activity administered. Once it has been determined that the activity administered is different than what was expected, the licensee can determine the activity not delivered to the treatment site and calculate the dose to the surrounding tissue to determine if a medical event occurred. § 35.3045 currently has no deadline for determining whether a medical event has occurred. § 35.41(b)(6) requires a determination of total source strength administered outside of the treatment site to be evaluated within 60 days and this number could be used for consistency; however, 60 days may be too long due to the half-life of Y-90.

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

Post-treatment imaging may not be appropriate depending on the isotope and activity used for treatment. Post-treatment imaging should only be required if necessary to ensure a microsource treatment was delivered correctly.

A.7.8: Please identify any tasks that would require an authorized medical physicist for the use of microsphere manual brachytherapy and identify whether and how the NRC should revise the training and experience requirements for authorized medical physicists in § 35.51, ‘‘Training for an authorized medical physicist.’’

Tasks for an authorized medical physicist should include performing the measurements to determine the microsphere activity.

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

Radioactive materials that are determined to be a sealed source, regardless of physical size, should be limited to those approved in the sealed source and device registry. Other radioactive materials should be considered as unsealed radioactive materials. It is unclear on how the delivery system affects the radioactive materials and the regulations should be developed based on the radioactive materials and not the delivery system.

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

Any new requirements for microsource manual brachytherapy should not be limited to permanent implants so that the new regulations would not prohibit future uses that have yet to be developed.

A.7.11: The NRC is considering establishing minimum safety procedures for microsources and requiring instructions to assure adequate protection of public health and safety. These changes are based on current EMT licensing guidance for yttrium-90 (Y–90) microspheres and expected new uses of microsources. Please identify and comment on other items that should be included in a new requirement for safety procedures and instructions for microsource manual brachytherapy.

Safety procedures and instructions (presumably patient instructions) should provide guidance on how to ensure public dose limits are not exceeded.

A.7.12: The NRC is considering establishing minimum safety precautions (controls) to assure adequate protection of public health and safety. These considerations are based on current EMT licensing guidance for Y–90 microspheres and expected new uses of microsources. Please identify and comment on other items that should be included in a new requirement for safety precautions (controls) for microsource manual brachytherapy.

The Board has no comment or answer for this question.

A.7.13: The NRC is seeking input on the need for continued conditional approval for AUs of Y–90 microspheres. The current licensing guidance for Y–90 microspheres states that an AU should successfully complete training in the operation of the delivery system, safety procedures, and clinical use for the specific type of Y–90 microsphere for which authorization is sought. The guidance specifies that clinical use training to support unsupervised use should include at least three hands-on patient cases for each type of Y–90 microsphere requested, conducted in the physical presence of an AU who is authorized for the type of Y–90 microsphere for which the individual is seeking authorization. The guidance allows conditional approval of an AU before completing these three hands-on patient cases if a proposed AU cannot complete patient cases before authorization. This conditional approval was originally added to the guidance because there were limited Y–90 microsphere licensees and AUs to train future AUs. As the use of Y–90 microspheres has increased significantly, please comment on the continued need for conditional approval for Y–90 microsphere AUs. Indicate why the NRC should or should not continue to allow this pathway for all microspheres and microsources AUs.

It appears that there is a sufficient number of licensees authorized for Y-90 microspheres with a sufficient number of authorized users such that the conditional approval pathway could be discontinued.

A.7.14: The NRC is seeking input on the 80 hours of classroom and laboratory training for interventional radiologists pursuing AU status for Y–90 microsphere and other microsource uses. The NRC in the current EMT licensing guidance for Y–90 microspheres includes a pathway for interventional radiologists to become AUs for Y–90 microspheres use. This pathway requires the interventional radiologist to demonstrate that they have 80 hours of classroom and laboratory training in specific topics and specific work experience important to radiation safety, in addition to demonstrating they have sufficient clinical interventional radiology and diagnostic radiology experience. Please comment on why 80 hours is or is not an appropriate amount of time to ensure these topics are adequately covered. Who should supervise the work experience to ensure the future AUs have adequate radiation safety knowledge and why?

Requiring 80 hours of training is consistent with the required hours of training for other medical uses. The supervision of work experience could be completed by another authorized user qualified and licensed for those medical uses, by the manufacturer representative, or a combination of those individuals.

A.7.15: The NRC is seeking input on classroom and laboratory training topics for physicians seeking AU status for all microspheres or other types of microsources. The NRC, in the current EMT licensing guidance for Y–90 microspheres, provides a pathway for interventional radiologists and physicians that meet the training and experience requirements in §§ 35.390 and 35.490 to become AUs for Y–90 microspheres use. This pathway does not require any classroom and laboratory training or specific work experience for these physicians besides demonstration of successfully completed training in the operation of the delivery system, safety procedures, and clinical use (including hands-on patient cases) for the type of Y–90 microsphere for which authorization is sought. Please identify and comment on any additional classroom and laboratory training topics or specific work experience that should be required for these physicians to become AUs for all microspheres or other types of microsources in subpart I. What additional training and work experience should be considered, if any, and why?

> Authorized users and physicians that meet the training and experience requirements in §§ 35.390 and 35.490 should have adequate classroom and laboratory training and would not need further training in those topics.

A.7.16: The NRC is seeking input on the pathways for physicians to become AUs for use of microspheres and other types of microsources. The NRC in the current EMT licensing guidance for Y–90 microspheres provides pathways for interventional radiologists and physicians that meet the training and experience requirements in §§ 35.390 and 35.490 to become AUs for Y–90 microsphere use. Please comment on whether and why the NRC should or should not provide additional pathways for other types of physicians to become AUs for use of microspheres or other types of microsources.

> The pathways in the current microspheres licensing guidance appears to be adequate with no additional pathways needed.

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

> Yes, it appears that in most circumstances that the authorized user is the individual administering Y-90 microspheres. Individuals authorized to prescribe and administer pharmaceuticals in the practice of medicine may be appropriate to administer microsources under the direct supervision of an authorized user but would need additional training for preparing and handling radioactive materials.

Other Part 35 Changes: Novel Radionuclide Generators

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

> Breakthrough testing and limits should be developed by the generator manufacturer and not by individual medical licensees.

Other Part 35 Changes: Training and Experience

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

Training should be generator-specific for the radiological hazards with a focus patient safety, including how to properly ensure breakthrough has not occurred prior to medical use.

A.8.3: Please comment on why the current structure for authorized medical physicist involvement in 10 CFR part 35, subpart F, ‘‘Manual Brachytherapy,’’ is or is not sufficient. If not sufficient, what specific tasks or skills should be performed by an authorized medical physicist for manual brachytherapy?

Medical physicists should be involved with confirming source output, confirming source positioning within applicators, and confirming treatment planning software is working appropriately.

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

Continuing education is required for medical board certification and should remain in that area of expertise. Device specific training for new medical uses, new devices, or major changes to existing devices using radioactive materials for medical purposes should be required for authorized users.

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

Authorized users should have device specific training. Topics for the training should at least include worker safety precautions, patient safety precautions, breakthrough monitoring, how doses are assayed, proper storage, and proper shipping procedures.

A.8.6: Please comment and provide a rationale for whether physicians authorized for full use under § 35.300 need additional T&E to fulfill their radiation safety-related duties and supervision roles because of expected emerging therapeutic radiopharmaceuticals. Please comment on why additional training is or is not needed on regulatory requirements for emerging therapeutic radiopharmaceuticals. If needed, what topics should the T&E include? What specific training should these AUs be required to have (e.g., vendor training on clinical use and safety procedures) prior to first-time use, if any? Why should they be required or not required to have continuing education?

If the radioactive materials or physical form for an emerging medical use has unique properties, then additional training should be required.

A.8.7: Please comment on why the current AU T&E requirements for use of sealed sources and medical devices for diagnosis in § 35.590 (i.e., 8 hours of classroom and laboratory training in basic radionuclide handling techniques specifically applicable to the use of the device authorized under § 35.500, as well as device-specific training in the use of the device) are or are not appropriate for emerging sealed sources and medical devices containing sealed sources. If AUs for § 35.500 need additional training and work experience on emerging sealed sources and medical devices containing sealed sources for diagnosis, what topics should be covered?

The Board is unaware of any medical events that have occurred because of inadequate training and experience, so the current training requirements in the licensing guidance appears to be sufficient.

Other Part 35 Changes: Security and Controls

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

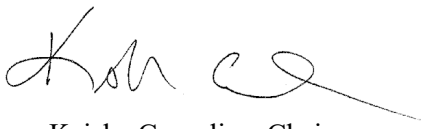
> § 35.610(a)(1) is not a prescriptive regulation for security purposes and is written such that licensees have the flexibility to secure consoles, keys, and passwords in a method that is most appropriate for their facility.

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

> Other entry controls such as lasers may be acceptable to ensure sources retract to a shielded or secure position during patient treatment. Entry controls that do not form a physical barrier, like a door, may not be sufficient to prevent access to radioactive materials.

Once again, the Board appreciates this opportunity to comment. We are available should you have any questions or need clarifications to our responses.

Sincerely,



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