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December 1, 2022

Sarah Lopas
U.S. Nuclear Regulatory Commission
Washington, DC 20555–0001

Dear Ms. Lopas,

The OAS Executive Board (Board) appreciates the opportunity to comment on the Nuclear Regulatory Commission (NRC) preliminary regulatory basis for the 10 CFR Part 35 rulemaking to establish requirements for rubidium-82 generators and emerging medical technologies (RCPD-22-010).

After receiving comments from our agreement state partners, the Board has the following comments on the preliminary regulatory basis:

- RSOs and AUs should be required to complete device-specific training on generators.
- RSOs and AUs should be required to complete model-specific training on all 10 CFR Part 35, Subpart H devices.
- For all new modalities that will be added, training requirements of manufacturers should be maintained in line with current guidance documents.

The Board has the additional following comments on the preliminary regulatory basis:

- Whether by regulation, rule, or policy, the NRC should consider developing a structured pathway with defined metrics to have a definitive pathway for determining that a type of medical use of radioactive materials is no longer an emerging technology.
- The NRC should consider scaling back some of the regulatory development for this rulemaking effort. There are a number of medical uses that do not even have a guidance document issued on how those uses should be regulated, such as yttrium-90 disc sources. Developing medical uses should be allowed to be authorized under emerging technologies while the use is still developing which will allow for appropriate regulations to be developed from guidance that may be revised. The Board does appreciate the effort that goes into regulation changes, but implementing regulations for developing medical uses may have unintended consequences, such as having to issue enforcement discretion guidance or process exemption requests for regulations that are no longer applicable as the medical use evolves.
- Section 3.2 includes the statement "Specifically, the regulations in 10 CFR Part 35 currently do not address high dose-rate remote brachytherapy, low dose-rate remote brachytherapy, pulsed dose-rate remote brachytherapy, and gamma stereotactic radiosurgery." This statement is confusing as 10 CFR Part 35, subpart H does address those items.
- If there are no known or proposed uses of liquid brachytherapy, there should not be an effort to develop regulations for that use at this time. Developing regulations based on an inactive, unused product may cause regulations to be developed and implemented that are not applicable to potential future uses, or may cause a regulatory lapse for unknown issues that the regulations would not account for that could be caused by any potential future uses.

- The NRC should consider developing a training and experience pathway for individuals who administer radioactive materials. Many hours of licensing effort are performed annually by each program in the national materials program to add or remove authorized users from a license, and those users may not ever physically use or handle radioactive materials, especially for diagnostic authorized users. A training and experience pathway for individuals who administer radioactive materials, such as potentially requiring those individuals to be a certified nuclear medicine technologist, would improve clarity for licensees as to who can administer unsealed radioactive materials, and could improve patient safety by ensuring those radioactive materials are administered by a trained, certified individual.
- Section 3.3.7 mentions the Akesis Galaxy® unit, but unlike other models listed in Section 3.3.7, there is no mention of that unit in the sub-sections.

Within the preliminary regulatory basis, in Appendix A, there were questions the NRC was specifically requesting for comments. The Board has the following comments to those questions:

Question A.1.1: Do RSOs need device-specific training for all 10 CFR Part 35, Subpart D generator systems, or is general awareness on radionuclide generators, including their functions and risks, sufficient? Please provide a basis for your response.

- Several agreement state partners commented that RSOs should be required to complete device-specific training on generators. Requiring device specific training for RSOs will help ensure that an RSO is adequately able to oversee the safety aspects of each device.

Question A.1.2: The NRC has found that 10 CFR 35.290 AUs have sufficient understanding of radionuclide generators, and the NRC is proposing to revise 10 CFR 35.27 to require device-specific training requirements for supervised individuals. Should 10 CFR 35.290 AUs also be required to have device-specific training for all radionuclide generators for which they supervise the use? Please provide a basis for your response.

- Several agreement state partners commented that AUs should be required to complete device-specific training on generators. Requiring device specific training for AUs will help ensure that radioactive materials which are used under their supervision are used properly. Additionally, the Board supports device-specific training requirements for the actual users of the radioactive materials as most diagnostic AUs do not actually handle or use radioactive materials.

Question A.2.1: Are the T&E requirements for AUs outlined in the current EMT licensing guidance documents for IVB, liquid brachytherapy, diffusing sources brachytherapy, and eye applicators sufficient? Please provide a basis for your response. Specifically, the NRC is seeking feedback on the knowledge topics encompassing the safety-related characteristics of these EMTs required for AUs to fulfill their radiation safety-related duties and supervision roles; the methods on how knowledge topics should be acquired; and consideration for continuing education, vendor training for new medical uses, and training on NRC regulatory requirements.

- From a performance-based point of view, the T&E requirements appear to be sufficient as there does not appear to be a number of medical events that have occurred because of insufficient AU training and experience. Manufacturer and/or vendor training would appear to be the most efficient method to receive training as a manufacturer and/or vendor would have the best insight as to how their radioactive materials should be used safely.

Question A.3.1: Should the definition of manual brachytherapy be revised to include liquid brachytherapy and exclude microsources? Or, because hazards of microsources are similar to liquid brachytherapy, should

liquid brachytherapy be included in the newly proposed 10 CFR Part 35, Subpart I, "Microsource Manual Brachytherapy"? Please provide a basis for your responses.

- The definition of manual brachytherapy should be revised to exclude microsources. However, that exclusion may require a new definition of 'microsource' to provide clarity for future medical uses. A new definition of microsource might exclude liquid brachytherapy by definition. Even though the hazards of liquid brachytherapy are most similar to microsources, it may make sense to include liquid brachytherapy with the manual brachytherapy regulations.

Question A.3.2: Are the T&E requirements for AUs outlined in the current EMT licensing guidance documents for IVB, liquid brachytherapy, diffusing sources brachytherapy, and eye applicators sufficient? Specifically, the NRC is seeking feedback on the knowledge topics encompassing the safety-related characteristics of these EMTs required for AUs to fulfill their radiation safety-related duties and supervision roles; the methods on how knowledge topics should be acquired; and consideration for continuing education, vendor training for new medical uses, and training on NRC regulatory requirements. Please provide a basis for your responses.

- This question appears to be nearly identical to question A.2.1 and the Board has the same response as above.

Question A.5.1: What radiation safety issues should be considered if manual brachytherapy using alpha-emitting diffusing sources were added to 10 CFR Part 35, Subpart F?

- Assuming that alpha-emitting diffusing sources are permanently implanted sources, the radiation safety issues should include patient dose rate to account for dose rate from daughter products after radioactive materials have diffused through the body; source assay to ensure administered amounts are implanted in accordance with the written directive; acceptable dose to surrounding tissue or other organs if there are multiple metabolic pathways for diffusing sources to spread through a body; contamination control; patient instructions to minimize exposures to members of the public.

Question A.5.2: Are calibration requirements in 10 CFR 35.432, "Calibration measurements of brachytherapy sources," sufficient for diffusing sources? Please provide a basis for your response.

- There are too many unknowns, including isotopes, how alpha-emitting diffusing sources are implanted, and how these sources will bio-distribute throughout a body, to adequately answer this question.

Question A.5.3: Are the T&E requirements for AUs outlined in the current EMT licensing guidance documents for IVB, liquid brachytherapy, diffusing sources brachytherapy, and eye applicators sufficient? Please provide a basis for your response. Specifically, the NRC is seeking feedback on the knowledge topics encompassing the safety-related characteristics of these EMTs required for AUs to fulfill their radiation safety-related duties and supervision roles; the methods on how knowledge topics should be acquired; and consideration for continuing education, vendor training for new medical uses, and training on NRC regulatory requirements.

- This question appears to be nearly identical to question A.2.1 and the Board has the same response as above.

Question A.6.1: Are the T&E requirements for AUs outlined in the current EMT licensing guidance documents for IVB, liquid brachytherapy, diffusing sources brachytherapy, and eye applicators sufficient? Please provide a basis for your response. Specifically, the NRC is seeking feedback on the knowledge topics encompassing the safety-related characteristics of these EMTs required for AUs to fulfill their radiation safety-related duties and supervision roles; the methods on how knowledge topics should be acquired; and

consideration for continuing education, vendor training for new medical uses, and training on NRC regulatory requirements.

- This question appears to be nearly identical to question A.2.1 and the Board has the same response as above.

Question A.7.1: Should model-specific training for RSOs only be required for certain 10 CFR Part 35, Subpart H devices? Please provide a basis for your response. If so, how should it be determined which devices would require model-specific training?

- Model-specific training for RSOs should be required for all types of 10 CFR Part 35, subpart H devices to ensure adequate oversight over the radiation safety program.

Question A.7.2: The proposed changes to 10 CFR Part 35, Subpart H, focus on elements rather than specific components. Current NRC requirements in 10 CFR Part 35, Subpart H are focused on components that are critical to patient and facility safety for the use of these devices. The proposed changes shift to a focus on elements and objectives rather than specific components. What other elements should be considered, if any? Please provide a basis for your response.

- The items listed in the preliminary regulatory basis (source output, source collimation, source position, source attenuation, patient safety, and facility safety) appear to be sufficient.

Question A.7.3: What types of objective tests should the NRC require to be completed for full calibration measures for 10 CFR Part 35, Subpart H devices? Additionally, what functional elements should be considered critical to safety? Please provide a basis for your response.

- Objective tests listed in the preliminary regulatory basis document appear to be sufficient. An additional catch-all regulation could be included, such as ‘any tests required by the device manufacturer’. This question might be better asked of current 10 CFR 35, Subpart H device manufacturers to ensure the regulation encompasses the correct critical safety tests.

Question A.7.4: What types of objective tests should the NRC require to be completed for periodic spot-checks for 10 CFR Part 35, Subpart H devices? Additionally, what functional elements should be considered critical to safety? Please provide a basis for your response.

- Objective tests listed in the preliminary regulatory basis document appear to be sufficient. An additional catch-all regulation could be included, such as ‘any tests required by the device manufacturer’. This question might be better asked of current 10 CFR 35, Subpart H device manufacturers to ensure the regulation encompasses the correct critical safety tests.

Question A.8.1: The proposed changes to bring 10 CFR Part 35, Subpart K, microspheres into the regulatory framework include defining a “microsource” in 10 CFR 35.2 as microparticles and microspheres. What types of radiation (such as alpha, beta, gamma) should be covered by the definition of “microsource”? Should microspheres be limited to specific types of radiation or certain energies? Should microsources be limited to sealed sources with an SS&D registry? Are there any additional changes needed to the current regulations for microsource brachytherapy that would create added flexibility for future microsource brachytherapy? Please provide a basis for your responses.

- Including ‘microparticle’ as part of the microsource definition is vague and could lead to inconsistent use across the national materials program. The definition would be better with a limit in particle size (i.e. no larger than X um or something similar) to provide a definitive definition. Alternatively, something less definitive such as ‘a solid source that cannot be assayed or measured independently prior to administration’ would provide a more consistent approach for the national materials program. The types of radiation should be inconsequential to the definition of

microsource and the definition should rely more on physical characteristics to delineate microsources from manual brachytherapy sources. Similarly, microspheres should not be limited to specific types of radiation. Microsources should be limited to sealed sources with an SS&D registry.

Question A.8.2: The proposed changes to bring microsphere EMTs into the regulatory framework include defining "physiological equilibrium" to include stasis or other states of equilibrium in 10 CFR 35.2. What should be included in physiological equilibrium or other considerations for physiological stop points? Please provide a basis for your response.

- This question might be better asked of current microsphere manufacturers or medical users of microspheres as the definition includes 'other states of equilibrium **based on a medical determination**' [emphasis added].

Question A.8.3: As the complexity of the medical use of byproduct material increases, use of teams in medical care is becoming more common. What are the fundamental elements of a successful team-approach program? Please provide a basis for your response.

- Inclusion of a medical physicist in microspheres administration can help provide successful administrations of microspheres.

Question A.8.4: For microsource manual brachytherapy, should the written directive require the dose or activity? Please provide a basis for your response.

- The written directive could be flexible enough to include either the dose or total activity as currently described in the microspheres licensing guidance.

Question A.8.5: For microsource manual brachytherapy, should the written directive specify the activity administered or should it specify the activity or dose delivered to the treatment site? Please provide a basis for your response.

- The written directive should specify the activity or dose delivered to the treatment site. Activity administered is not specific enough to evaluate if a medical event has occurred.

Question A.8.6: Section 35.41 of 10 CFR Part 35 requires procedures to determine if a medical event, as defined in 10 CFR 35.3045, has occurred. Should the NRC require calculating and documenting the activity administered, or activity or dose specifically delivered to the treatment site? If so, by what timeframe (e.g., 48 hours, 7 days, etc.) should this determination be made? Please provide a basis for your response.

- The current criteria for a medical event should be applied to microsphere and microsource procedures.

Question A.8.7: Is there any task that would require an AMP for the use of microsphere manual brachytherapy? If so, would there be any need to change the T&E requirements for AMPs? Please provide a basis for your response.

- AMPs should be involved in calculating or reviewing the calculation of the dose to the treatment and other sites, prepare or directly supervise the dose for administration, and perform or directly supervise the pre- and post- administration measurements for microsphere and microsource administrations. The T&E requirements would have to be evaluated to determine if the current specialty board certifications are adequate and appropriate, or if additional subspecialties would be adequate and appropriate, such as an AMP with a specialty in diagnostic imaging or nuclear medicine.

Question A.8.8: What types of use should be permitted under a new subpart for microsource manual brachytherapy? Should the use of microsources be limited to the use(s) approved in the SS&D registry? Please provide a basis for your response.

- Microsources should be limited to uses approved by an SS&D registry. A comprehensive safety evaluation by requiring an SS&D sheet would build confidence that the new materials could be used safely and would be licensed in a consistent manner across the national materials program.

Question A.8.9: The proposed changes to bring microspheres into the regulatory framework include establishing safety procedures and instructions. These changes are based on current licensing guidance for Y-90 microspheres and expected new uses of microsources. Are there other items that should be included in a new requirement for safety procedures in instructions for microsource manual brachytherapy? Please provide a basis for your response.

- The current licensing guidance for microspheres appears to be adequate for proposed new regulations, but a review of medical events that have occurred throughout the national materials program should be conducted to ensure there are no common issues that could be eliminated by additional regulations or requirements.

Question A.8.10: The proposed changes to bring microspheres into the regulatory framework include establishing safety precautions. These changes are based on current licensing guidance for Y-90 microspheres and expected new uses of microsources. Are there other items that should be included in a new requirement for safety precautions for microsource manual brachytherapy? Please provide a basis for your response.

- This question appears to be nearly identical to question A.8.9 and the Board has the same response as above.

Question A.8.11: The current licensing guidance for Y-90 microspheres requires that an AU 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 prior to completing these three hands-on patient cases if a proposed AU cannot complete patient cases prior to authorization. The reason this conditional approval was originally added to the guidance was there were limited Y-90 microsphere licensees and AUs to provide training to future AUs. As there has been a significant increase in the use of Y-90 microspheres, is there still a need for conditional approval for Y-90 microspheres? Should the NRC continue to allow this pathway for all microspheres and microsources AUs? Please provide a basis for your responses.

- Due to the increase in licensees authorized for microsphere use and authorized users that are authorized to administer microspheres, a conditional authorized user pathway does not seem to be needed for microspheres at this point. It is not yet clear if microsources will be as widely used as microspheres, so it is impossible to determine if that pathway will be needed for authorized user certification.

Question A.8.12: The current licensing guidance for Y-90 microspheres has 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. Are there any additional topics or specific

T&E areas that are not currently listed in the licensing guidance that should be considered? Are there any topics or specific T&E areas that should be removed? Is 80 hours 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? Please provide a basis for your responses.

- As noted in question A.8.3, a team approach is often used for administering microspheres. The current training and experience requirements in the microspheres licensing guidance appears to be adequate for microsphere, but including additional team members such as an AMP could increase the oversight over microsphere and microsource use, improve patient administration, and decrease medical events.

Question A.8.13: The current licensing guidance for Y-90 microspheres provides a pathway for interventional radiologists and physicians that meet the T&E requirements in 10 CFR 35.390 and 10 CFR 35.490 to become AUs for Y-90 microspheres use. This pathway does not require any additional classroom and laboratory training or specific work experience for these physicians besides demonstration of successfully completed training in the operation of the delivery system, safety procedures, and clinical use (including hands-on patient cases) for the type of Y-90 microsphere for which the physician seeks authorization. Should additional classroom and laboratory training topics or specific work experience be required for these physicians to become AUs for all microspheres or other types of microsources in 10 CFR Part 35, Subpart I? If so, what additional training and work experience should be considered? Please provide a basis for your responses.

- This question appears to be similar to question A.8.12 and the Board has the same response as above.

Question A.8.14: The current licensing guidance for Y-90 microspheres provides pathways for interventional radiologists and physicians that meet the T&E requirements in 10 CFR 35.390 and 35.490 to become AUs for Y-90 microspheres use. Is there a need for additional pathways for other types of physicians to become AUs for use of microspheres or other types of microsources? Please provide a basis for your response.

- There does not appear to be a need for additional pathways for current authorized users to be certified for microspheres and microsources.

Question A.9.1: Due to the increased number and complexity of EMTs, should the NRC require continuing education for AUs? If so, what should the continuing education entail, what should be the frequency at which it should be acquired, and how should knowledge topics be acquired? Please provide a basis for your responses.

- The NRC should not require continuing education but should rely on other regulatory bodies, such as the state medical boards or the Joint Commission, to maintain those requirements.

Question A.9.2: Do AUs for 10 CFR 35.200 need device-specific training on radionuclide generators? If so, what should the scope of the training include? Should the training be specific to the radionuclide generator for which they are supervising the use? Please provide a basis for your response.

- Yes, device-specific training should be required for all AUs and users of radionuclide generators. The training should be provided by the manufacturer and encompass all radiological safety aspects of the generators. This training should be specific to the make and model of the generator.

Question A.9.3: Do physicians authorized for full use under 10 CFR 35.300 need additional new T&E to fulfill their radiation safety-related duties and supervision roles due to expected emerging therapeutic radiopharmaceuticals? Do these 10 CFR 35.300 AUs need additional training on regulatory requirements

for emerging therapeutic radiopharmaceuticals? If so, what should the scope of the T&E include? Should these AUs be required to have any specific training (such as vendor training on clinical use and safety procedures), prior to use for the first time, or have continuing education? Please provide a basis for your response.

- If there are known, unique hazards that will exist based on expected emerging therapeutic radiopharmaceuticals, then the training requirements should encompass communicating those hazards so AUs and staff that administer radiopharmaceuticals can adequately manage those hazards.

Question A.9.4: Is the current AU T&E requirement for use of sealed sources and medical devices for diagnosis in 10 CFR 35.590 (i.e., 8 hours of classroom and laboratory training in basic radionuclide handling techniques specifically applicable to the use of the device authorized under 10 CFR 35.500, as well as device-specific training in the use of the device) appropriate for future emerging sealed sources and medical devices containing sealed sources? If AUs for 10 CFR 35.500 need additional new training and work experience topics due to future emerging sealed sources and medical devices containing sealed sources for diagnosis, what should the scope of the training include? Please provide a basis for your response.

- Similar to the answer for question A.9.3, if there are known, unique hazards that will exist based on expected emerging sealed sources and medical devices for diagnosis, then the training requirements should encompass communicating those hazards so AUs and staff that handle sealed sources and medical devices for diagnosis can adequately manage those hazards.

Question A.9.5: Are there specific changes that are needed to secure consoles, keys, and passwords for remote afterloader units, teletherapy units, and GSR units that should be considered based on the changes in technology? If so, what changes are suggested? Please provide a basis for your response.

- Changes that could be made to the regulations could be to make the regulations less specific. For example, for an HDR that doesn't utilize a console key, instead of requiring the console key to be stored securely, the regulation could be changed to something like 'a licensee shall ensure that only authorized individuals have access to HDR unit controls.'

Question A.9.6: What types of doors or entry controls are acceptable to maintain security of licensed material while not interfering with patient care? (Should a physical door be required or are other entry controls such as lasers acceptable?) Please provide a basis for your response.

- A physical door should be required to control entry and maintain security of HDR/teletherapy/GSR units. Lasers will serve to detect entry but do not delay access the way a physical door does. A physical door is also often used as part of security requirements needed to be in compliance with 10 CFR Part 37.

Thank you again for the opportunity to comment on this draft regulatory basis document.

Sincerely,

Steve Seeger

Steve Seeger, Chair
Organization of Agreement States

TN Division of Radiological Health
1301 Riverfront Parkway, Suite 206
Chattanooga, TN 37402