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September 9, 2026

Irene Wu
U.S. Nuclear Regulatory Commission
Washington, DC 20555–0001

Dear Ms. Wu,

The OAS Executive Board (Board) appreciates the opportunity to comment on the draft regulation changs to 10 CFR Part 35 proposed by the U.S. Nuclear Regulatory Commission (NRC), published as Docket ID NRC-2025-1237 in the Federal Register dated July 27, 2026, and communicated to Agreement States in STC-26-042. After reviewing the draft regulation changes to 10 CFR Part 35, and after receiving comments from our Agreement State partners, the Board has the following comments:

1. The Board supports including additional regulations which address medical technologies that have previously been regulated under emerging medical technologies (10 CFR Part 35.1000) and have been used for multiple years, are well known by users and regulators, and the radiation risks are well understood. This will add clarity for licensees and ensure a consistent approach is implemented across the National Materials Program. Similarly, the Board supports removing specific regulations for medical technologies which are no longer utilized or have evolved, such as revising the regulations surrounding gamma stereotactic radiosurgery.

2. The proposed definition for 'physician' in 10 CFR Part 35.2 may be too broad. An individual licensed to prescribe drugs in the practice of medicine could potentially be interpreted to include physician assistants and/or nurse practitioners. Physician assistants and nurse practitioners are allowed to prescribe drugs in the practice of medicine but do not have the same residency requirements or training rigor that medical doctors obtain as part of their training and experience.

3. The proposed definition for 'microsource' includes, "…microspheres or microparticles containing **radioactive material** and dispersed…" [emphasis added]. The scope of 10 CFR Part 35 allows for the medical use of byproduct material. The NRC should review the definition and confirm if the use of 'radioactive material' is appropriate or if the definition should be revised to use the term 'byproduct material'.

4. The proposed new regulation in 10 CFR Part 35.2059 leaves a potential gap in records retained by a licensee for determining compliance with regulatory requirements. A licensee may have an authorized user perform medical uses at a licensee's facility and then no longer be authorized to perform medical uses during a licensee's inspection frequency. The licensee would not be required to maintain records of continued education and training, but would be required to demonstrate that an authorized user met the appropriate training and experience requirements. A suggestion would be to require licensees to maintain records for at least 5 years after the last medical use by the authorized user to ensure a licensee maintains records of continuing education records for at least the period of years that would be the longest inspection frequency for medical licensees.

5. For the proposed training and experience requirements in 10 CFR Part 35.790(a)(1), it is not clear if the 3 years of residence training in diagnostic radiology and 1 year of interventional radiology in a residency or fellowship program can be obtained concurrently of if those residencies are required to be separate and distinct.

6. The proposed addition of 10 CFR Part 35.24(g)(5) is a good addition for licensees that have an independent radiation safety officer. However, for licenses where the radiation safety officer is also an authorized user, this could create a conflict of interest where the radiation safety officer is reviewing and approving their own training and experience.

7. The proposed changes to 10 CFR Part 35.13(b) no longer require a licensee to apply for and receive a license amendment before it permits anyone to work as an authorized user for medical use of byproduct materials for 35.100 uses or 35.200 uses. It is assumed this change is in part because of the Standard General License framework found in the proposed rulemaking NRC-2025-1205. However, there are a number of authorized users performing work with medical byproduct materials under 35.200 that do not fall under the Standard General License framework, such as authorized users for positron emission tomography (PET) and authorized users for mobile medical licensees. These authorized users now fall into a gray area where they are not regulated by the proposed Standard General License framework and are not required to be listed on a license by the proposed 10 CFR 35.13(b). There needs to be clarity added to the proposed regulation for licensees and regulators regarding PET and mobile medical authorized users.

8. By removing the requirement for medical facilities to apply for and receive a license amendment before it permits anyone to work as an authorized user for 35.100 and 35.200 uses, the burden of determining compliance is shifted from a licensing task to an inspection task. Time needed to adequately perform routine inspections will substantially increase, especially for larger medical facilities. Additionally, Agreement States that have separate licensing and inspection groups will be required to dedicate resources to train inspectors on how to adequately review training and experience documentation that was previously reviewed by license reviewers.

9. The Board supports increasing the decay-in-storage limit to 275 days in the proposed changes to 10 CFR Part 35.92(a). The Board also supports retaining the financial assurance requirements and thresholds in 10 CFR Part 30 to remain unchanged as part of this rulemaking. The financial assurance requirements and thresholds will prevent a medical licensee from accumulating large amounts of radioactive waste without a proper plan for decommissioning and disposal of radioactive waste.

10. The proposed removal to 10 CFR Part 35.80(b) eliminates some of the clarity found in that regulation. Removal of the regulation could imply that mobile medical services may have byproduct materials delivered to a client location which would not be in accordance with 10 CFR Part 30.41.

11. The proposed training requirements in 10 CFR Part 35.396 is a significant decrease in the training and experience required for those potential authorized users. Currently, the regulations require an authorized user to be a physician who 1) is an authorized user under 35.390; 2) is an authorized user under 35.490 or 35.690; or 3) is certified by a medical specialty board whose certification process has been recognized by the Commission. The current 10 CFR Part 35.396(a) ends with those acceptable authorized user descriptions and then 10 CFR Part 35.396(b) includes additional description of training and experience the proposed authorized user needs to obtain. The proposed 10 CFR Part 35.396 includes an 'or' after 35.396(a) and allows for an 80-hour training and experience pathway for proposed authorized users. The addition of 'or' after 35.396(a) is a significant decrease in required training and experience for those proposed authorized users. Additionally, there is no discussion within the proposed rule explaining why there is a significant decrease in the required training and experience for proposed 35.396 authorized users and how that decrease will maintain current radiation safety and patient safety standards.

12. The full calibration measurements for remote afterloader units includes a reference to NRC-approved or Agreement State-approved manufacturer procedures, specifically in 10 CFR Part 35.633(d). However, the periodic spot-checks for remote afterloader units includes a reference to manufacturer instructions accepted by the NRC with no reference to Agreement States in 10 CFR Part 35.643(b)(2). Although this proposed regulation is compatibility H&S, it should include the potential for manufacturer instructions accepted by Agreement States so it does not appear that a licensee would be required to obtain NRC approval for procedures if they are not under NRC jurisdiction.

13. The full calibration measurements for gamma stereotactic radiosurgery units includes a reference to NRC-approved or Agreement State-approved manufacturer procedures, specifically in 10 CFR Part 35.635(d). However, the periodic spot-checks for gamma stereotactic radiosurgery units includes a reference to manufacturer instructions accepted by the NRC with no reference to Agreement States in 10 CFR Part 35.645(a)(2). Although this proposed regulation is compatibility H&S, it should include the potential for manufacturer instructions accepted by Agreement States so it does not appear that a licensee would be required to obtain NRC approval for procedures if they are not under NRC jurisdiction.

14. The proposed changes to 10 CFR Part 35.3047 include the phrase 'reasonable effort' to 35.3047(a)(2). Additional guidance or clarification is needed as 'reasonable effort' could easily be interpreted differently between different entities.

15. The training and experience training requirements in 10 CFR Part 35 focus on the authorized user who prepares the prescription (written directive or a diagnostic clinical procedures manual) and not necessarily the individual how directly handles radioactive materials. The training and experience for the individuals administering diagnostic, therapeutic, and theranostic radiopharmaceuticals are vague and undefined in that those individuals are working under the supervision of the authorized user. The NRC should take this opportunity to define the training and experience requirements of the individuals who are actually administering radioactive materials.

Specific requests for comments

1. The NRC is proposing to revise the definition of "teletherapy" in § 35.2 to clarify that it refers to external beams of ionizing radiation are delivered from an external source without stereotactic guidance. However, the NRC is also considering removing the specific reference to stereotactic guidance or adding additional clarifying language to further expand the definition. As such, the NRC is seeking comments on examples of teletherapy uses and whether the NRC would need to further revise the definition of teletherapy to ensure these teletherapy uses are included. Please provide the basis for your response.

   OAS Board Response: The Board agrees with adding the language 'without stereotactic guidance to deliver a therapeutic dose to a treatment site' to ensure that there is a delineation between teletherapy treatments and gamma stereotactic radiosurgery treatments.

2. As part of this rulemaking package, the NRC has developed guidance to clarify that the physical presence of an AU for the medical use of byproduct is not required under § 35.11(b)(1). 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. As indicated, the NRC has developed guidance to clarify that there is no requirement regarding the location of the AU during the use. The current compatibility category of § 35.11(b) is category C, allowing Agreement States to be more restrictive and potentially require the physical presence of an AU. The NRC has received concerns from industry stakeholders that § 35.11(b) raises transboundary concerns as medical networks have grown and many cross state lines, such that the regulation should be compatibility category B. In addition, the industry stakeholders have expressed concerns that requiring an AU to be physically present or within a specified location of the medical use limits access to treatments in rural areas. As such, the NRC is considering changing this regulation to be compatibility category B. The NRC is requesting specific comments on the appropriate compatibility category for § 35.11(b).

   OAS Board response: the compatibility for 10 CFR Part 35.11(b) should remain compatibility C. The physical presence requirements for authorized users do not have particular impact on public health and safety that would be necessary to designate that regulation as compatibility B. Agreement States should retain the flexibility of compatibility C should any given State want to be more restrictive than the federal regulation. Administrations of radioactive materials only occur in one jurisdiction, so there is no concern with transboundary issues.

3. The NRC is proposing to establish specific criteria in § 35.63 to allow incremental administrations to be performed using direct infusion systems, including a criterion that calls for the administered radioisotope to have a half-life of less than three minutes. These provisions are designed to accommodate the unique characteristics of isotopes such as Rb-82, which cannot be practically measured using traditional methods due to their rapid decay and automated delivery systems. The NRC is seeking feedback on whether the proposed three-minute timeframe is appropriate or if a higher threshold would be beneficial for a current or expected future medical use and if so, what length half-life would be appropriate (for example, 5 minutes or 10 minutes). Please provide the basis for your response.

   OAS Board response: the three-minute timeframe appears to be appropriate but could be increased based on other isotopes (such as carbon-11 or nitrogen-13) as long as the infusion system includes a means to accurately determine the dose administered to patients.

4. The NRC is proposing to change § 35.92(a) to allow licensees to hold byproduct material with a physical half-life of less than or equal to 275 days, instead of 120 days, to allow licensees to hold Lu-177m and Co-57 flood sources for decay-in-storage. The NRC is seeking feedback on whether an even longer half-life limit would be beneficial for medical use in this context. Specifically, the NRC is considering increasing the physical half-life beyond 275 days if there is a radioisotope used in medicine that could benefit from such an increase without causing a significant increase in risk. Please comment on whether increasing the half-life limit beyond 275 days would provide a meaningful benefit to medical licensees. If you believe a longer limit would be appropriate, indicate what specific half-life (for example, 300 days or 365 days) you recommend and explain the medical use which would benefit from your recommendation. In addition, describe any safety or operational considerations the NRC should evaluate if the limit is extended further.

   OAS Board response: the Board supports increasing the decay-in-storage half-life threshold to 275 days.

5. The NRC is proposing to change the definition of "physician" in § 35.2 to expand eligibility for individuals to become AUs. This change is intended to allow those who meet training and experience requirements and are fully licensed to practice medicine in the United States, but whose primary medical qualification is not titled MD or DO, such as foreign-trained physicians, to be eligible to become AUs. The NRC is considering whether the clause specific to prescribing drugs should be removed or additional qualifying language should be added to this definition in the final rule. In particular, the NRC is seeking feedback on whether removing additional language or adding additional qualifying language, such as "fully licensed to practice medicine independently," is needed in this definition to ensure individuals defined as physicians have adequate training and experience to perform tasks allowed under 10 CFR part 35. Please provide the basis for your response.

   OAS Board response: the current training and experience requirements are developed based on authorized users attending and successfully passing training and education which includes a residency program. The proposed regulation changes would allow other medical professionals to prescribe radioactive materials who do not have the same training and experience as required by the current regulations.

6. The NRC is proposing to remove the requirement for a written directive for a diagnostic administration of sodium iodide I-131 in quantities greater than 1.11 megabecquerels (30 microcuries). The requirement was historically established to reduce the potential for unintended thyroid irradiation associated with irreversible thyroid uptake and to help prevent wrong-patient or wrong-procedure administrations. The NRC is seeking feedback on whether eliminating this written directive requirement could raise any safety concerns or otherwise affect patient protection beyond risks associated with diagnostic administrations. In particular, the NRC seeks input on whether current clinical practices of patient identification, procedure verification, and pregnancy screening provide sufficient assurance that diagnostic administration of sodium iodide I-131 are performed safely without the need for a written directive. The NRC is also seeking feedback on whether the removal of this requirement would reduce unnecessary administrative burden on licensees while maintaining adequate protection of patients. Please provide the technical or operational basis for your response, including any relevant experience, data, examples from clinical practices, or information on current institutional practices used to verify patient identity and the intended procedure.

OAS Board response: based on the potential harm that could occur with wrong administrations of iodine-131, all authorized users should be identified on a radioactive materials license, and diagnostic use of iodine-131 greater than 30 microcuries should continue to require a written directive.

7. The NRC is proposing to remove prescriptive requirements for specific numbers of classroom and laboratory training hours and work experience hours for physicians who have completed residency training in specialties where radiation safety and the clinical use of byproduct material are inherently integrated into the curriculum. This proposed rule identifies diagnostic radiology, nuclear medicine, and radiation oncology as specialties that would not need to complete these prescriptive training hours for training related to uptake, dilution, excretion, imaging, and localization studies. The NRC is seeking feedback on whether these residency programs do and would continue to include sufficient training in these areas, without the prescriptive hour requirements, as the NRC considers whether to remove or maintain the current requirements.

   OAS Board response: the Board supports removing prescriptive hour requirements for authorized users that complete residency training in diagnostic radiology, nuclear medicine, or radiation oncology.

8. In addition, the NRC is proposing to keep the current training hours requirements for physicians who completed fellowship but is considering removing these training hours requirements provided the fellowship curriculum sufficiently integrates radiation safety and the clinical use of byproduct material to ensure the physician can independently fulfill radiation safety-related duties as an AU for medical use. Thus, the NRC is seeking feedback on whether any fellowship curriculum sufficiently integrates radiation safety and the clinical use of byproduct material to ensure the physician can independently fulfill radiation safety-related duties as an AU for medical use, and on any potential considerations of including fellowship training in addition to residency training for meeting the training and experience requirements in subparts D through H of 10 CFR part 35. Please provide the basis for your response.

   OAS Board response: the Board does not have a comment for this item.

Regulatory flexibility analysis

1. The NRC is seeking public comment on the potential impact of this proposed rule on small entities. The NRC particularly desires comment from licensees who qualify as small businesses, specifically as to how the proposed regulation will affect them and how the regulation may be tiered or otherwise modified to impose less stringent requirements on small entities while still adequately protecting the public health and safety and common defense and security. Comments on how the regulation could be modified to take into account the differing needs of small entities should specifically discuss:

   a. The size of the business and how the proposed regulation would result in a significant economic burden upon it as compared to a larger organization in the same business community;

   b. How the proposed regulation could be further modified to take into account the business's differing needs or capabilities;

c. The benefits that would accrue, or the detriments that would be avoided, if the proposed regulation was modified as suggested by the commenter;

d. How the proposed regulation, as modified, would more closely equalize the impact of NRC regulations as opposed to providing special advantages to any individuals or groups; and

e. How the proposed regulation, as modified, would still adequately protect the public health and safety and common defense and security.

OAS Board response: the proposed regulations in 10 CFR Part 35 appear to adequately allow small entities to safely administer radioactive materials for medical use. Consideration should always be given to rural communities to ensure those populations have access to medical care.

Cumulative Effects of Regulation

1. The NRC is proposing an effective date that will be 30 days after the date of publication of a final rule. Does this provide sufficient time to implement the proposed requirements? Please provide a rationale for your response.

   OAS Board response: the proposed regulations are not wildly different than the guidance used to regulate current medical uses. However, many licensees may need to update multiple procedures and documents such as written directive to incorporate newer nomenclature such as the change from microspheres to microsources. Additional time may be needed to ensure licensees have an adequate amount of time to make adjustments to their radiation protection programs.

2. Are there unintended consequences related to this rulemaking and how should they be addressed? Please provide a rationale for your response.

   OAS Board response: the Board believes the unintended consequences are identified in the comment items above.

3. Please comment on the NRC's cost and benefit estimates in the regulatory analysis that supports this proposed rule.

   OAS Board response: the Board does not have a comment for this item.

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

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