



**American College
of Radiology™**

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Secretary, U.S. Nuclear Regulatory Commission
Washington, DC 20555-0001
ATTN: Rulemakings and Adjudications Staff

Subject: (Docket ID NRC-2018-0297) Rubidium-82 Generators, Emerging Technologies, and Other Medical Use of Byproduct Material, Draft Regulatory Basis; Comments of the American College of Radiology

The American College of Radiology (ACR)—a professional association representing over 41,000 diagnostic radiologists, interventional radiologists, nuclear medicine physicians, radiation oncologists, and medical physicists—appreciates the opportunity to provide comments to the U.S. Nuclear Regulatory Commission (NRC) addressing the July 3, 2023, *Federal Register* notice of the draft regulatory basis on “Rubidium-82 Generators, Emerging Technologies, and Other Medical Use of Byproduct Material.” The purpose of the planned “emerging medical technologies” (EMT) rulemaking is to enable oversight of mature or similar EMTs via regulation instead of via guidance. The NRC’s regulatory basis and corresponding questions indicate additional subtopics under NRC consideration that may also be included in the EMT rulemaking.

General ACR Comments and Recommendations

Training and experience (T&E)— The T&E criteria in 10 CFR §35 for authorized personnel are foundational to NRC’s ability to protect public health and safety. Authorized Users (AUs), Authorized Medical Physicists (AMPs), Radiation Safety Officers (RSOs) and other authorized personnel must be sufficiently qualified to fulfill their radiation safety responsibilities.

Guidance familiarity preservation — The rulemaking should, where practical, implement in regulation the requirements previously iterated via licensing guidance that are familiar to licensees and training programs. NRC should only modify EMT requirements when necessary or if reducing unnecessary administrative burden.

Grandfathering — If any T&E requirements are added or changed as part of this rulemaking, existing Authorized Users (AUs) should be explicitly “grandfathered” to avoid patient care disruptions and licensee, physician, or regulatory agency burdens.

Additional 10 CFR §35 opportunities not addressed in the regulatory basis — This rulemaking could also be used to reduce licensee administrative burden. Examples include:

- Removing authorized personnel preceptor attestation requirements. These attestations are redundant with documentation of T&E completion.

- Removing 24-hour/“next calendar day” timing for Medical Event (ME) notifications in §35.3045(c) and §35.3045(e) unless circumstances require “next calendar day” intervention by the regulator or recipient. §35.3045(e) regulatory notifications are nonadditive to conventional physician-patient communication and medical intervention, and §35.3045(c) early notifications to NRC/Agreement States should only be required when immediate NRC action is needed to protect health and safety. The 15-day reporting timeframe required under §35.3045(d) for the substantive ME report is adequate for any nonurgent ME communications.
- Alternatively, §35.3045(e) should be modified in the following manner:
 - Changing the 24 hours after event discovery (or as soon as possible thereafter) to “next calendar day” after event discovery (or as soon as possible thereafter). This would provide marginally more time during standard business hours for the licensee to ensure an accurate and appropriate §35.3045(e) notification.
 - Removal of the “referring physician” from the required language at §35.3045(e). There may not be an external referring provider with therapeutic procedures or self-referred procedures. Moreover, a referring physician is unlikely to be significantly familiar with NRC regulations and the purpose of §35.3045(e) notifications. Finally, §35.3045(e) has been justified historically by NRC as existing to inform the patient of case data being collected by a government agency—§35.3045(e) notifications are not, and should not be construed as, medical communications.

Radiation Safety Committee (10 CFR 35.24) — The ACR supports removing the existing requirement at §35.24(f) for a “representative of the nursing service” on licensees’ radiation safety committees, as discussed in the regulatory basis. Outpatient/freestanding facilities may not have onsite nursing services, and licensees can optionally add member(s) to their committee beyond the minimum requirements at §35.24(f). Additionally, the ACR agrees with NRC that radiation safety committees should have AU representatives for each §35.1000 EMT on the facility’s license, in addition to AU representatives for each mature/normalized medical use on the license (however, this could be the same AU representing multiple uses).

Procedures for Administrations Requiring a Written Directive (10 CFR 35.41) — The described mandate for annual AU re-training on administrative procedures related to writing, reviewing, or signing Written Directives (WDs) seems unnecessarily prescriptive and counterproductive for NRC’s performance-based regulatory principles when universally applied to all AUs regardless of need. NRC should instead consider freely offering educational resources via the *Medical Uses Licensee Toolkit* webpage for licensees and healthcare professionals interested in voluntarily accessing such content. NRC could also consider a more targeted re-training requirement based on a procedure volume metric—e.g., lack of use of a modality requiring a written directive for a consecutive 24-month period could require “re-privileging” with a case supervised by another AU or the vendor (i.e., recency of training requirements).

Patient Release (10 CFR 35.75) — The current “per release” NRC implementation of §35.75 accommodates multiple administrations via conservative public dose overestimations when §35.75(b) patient instructions are followed. Real-world data, including past studies funded by the NRC, demonstrate that the existing requirements protect patients’ family members and other members of the public. The NRC should not change to a “per regimen” approach for fractionated radiopharmaceutical therapies as this level of granularity would unnecessarily increase clinical, personnel, and financial burden and reduce patient access.

Responses to Targeted NRC Questions

To address NRC's questions, the ACR collected feedback from a wide variety of stakeholders. The breadth of NRC's regulatory basis combined with the specificity of the questions created unique challenges to feedback collection, with some ACR members expressing concern about the unclear intent. To improve the quality of public feedback, the NRC could consider developing and publishing an Advanced Notice of Proposed Rulemaking (ANPRM) prior to the future EMT Notice of Proposed Rulemaking (NPRM). The ANPRM would enable the stakeholder community to better predict real-world effects of the preliminary regulatory concepts, both positive and unintentionally negative, and provide more information to NRC staff prior to drafting the future NPRM.

Section A.1 – Generator Systems

Q: A.1.1 through A.1.3:

ACR: General awareness of disparate generator systems, including Rb-82 generators, is adequate and the knowledge subtopics mentioned in the regulatory basis are currently provided in the relevant training programs. The current guidance requirements do not need to substantially change in transition into regulation, except to eliminate unnecessary burden with respect to hands-on training in generator elution by prospective AUs, who will likely not need this process training in practice.

Section A.6 – Gamma Stereotactic Radiosurgery and Photon Emitting Teletherapy Units

A.6.1.1 through A.6.4:

ACR: The current requirements in Subpart H or EMT licensing guidance referenced by these questions are appropriate. If necessary, NRC could reassess process-focused requirements (i.e., §35.604 through §35.657) to determine if any regulatory language should be modified to better accommodate EMT use.

Section A.7 – Microsource Manual Brachytherapy

Q: A.7.1: Comment on microsource definition.

ACR: Either the new "microsource" definition should be limited to alpha- and beta-emitters—or if gamma decay is included, Tc-99m-MAA should be clearly excluded to avoid enforcement confusion. However, in general, the radiation safety-related considerations with microspheres are effectively similar to unsealed material uses.

Q: A.7.2: Comment on what should be included in a definition of physiological equilibrium or identify other considerations for physiological stop points.

ACR: "Physiological equilibrium" means "a stable, balanced, or unchanging state in response to external and/or internal inputs." However, physiologic equilibrium, as defined by stasis or reflux within the target vessel, is not the only stop/end point to consider. Complete administration of the dose should be included if this end point is undefined elsewhere. Regulatory language should not be so narrow as to preclude the practice of medicine. Instead, NRC should require relevant licensees to have written procedures specifying reasonable procedure stop points.

Q: A.7.3: Comment on the fundamental elements of a successful team-approach program.

ACR: Medical team components other than the licensee's authorized personnel is a practice of medicine consideration. This will vary substantially from licensee to licensee; however, such teams can consist of the following generalizable roles:

- AU (may or may not also administer)—overall supervisory responsibilities with respect to radiological materials use.

- Administering physician, who may or may not also serve as the AU—responsible for safe and effective technical performance of the procedure.
- Medical physicist—safety/dosimetry/measurement responsibilities.
- RSO, who may or may not also be the team’s medical physicist—licensee-wide regulatory/radiation protection compliance duties.
- Assistive supervised personnel (if applicable)—assists during procedure, attends to patient needs, reads administration checklist, etc.
- Other supervised personnel (if applicable)—receive product from manufacturer, dispose undelivered product, may perform post-procedure PET or SPECT imaging, etc.

Q: A.7.4: Comment on whether the pre-implant written directive should specify the dose or activity.

Q.A.7.5: Comment on whether the after-implant written directive should specify the activity administered or the dose delivered to the treatment site.

Q: A.7.6: Comment on calculating/documenting the activity administered or the activity or dose specifically delivered to the treatment site and by what deadline?

ACR: (Answer to above three questions). There are varying opinions on documentation of dose versus activity or both in the pre-procedure microsource manual brachytherapy WD for NRC regulatory purposes. However, all agree the AU must have flexibility to make patient-specific, appropriate, dynamic modifications at the time of delivery and to record those modifications in a post-procedure-modified WD. NRC must avoid situations in which providers are obligated to report as “MEs” physician-intended deviations for the optimization of patient care.

Regarding deadline—please see ACR’s prior general comment/recommendation regarding removal of “next day” notification requirements for any nonurgent MEs that do not require immediate intervention by NRC to protect public health and safety.

Q: A.7.7: Comment on whether NRC should require post-treatment imaging to confirm that the treatment was delivered in accordance with the WD.

ACR: Post-treatment imaging is typically performed. This allows the most accurate assessment of dose and screening for off-target delivery. NRC regulations should not require this imaging for demonstrating WD compliance, as this would be duplicative of medically standard practices and procedure guidelines/practice parameters.

Q: A.7.8: Identify any tasks that would require an AMP for the use of microsphere manual brachytherapy and identify whether and how the NRC should revise the T&E for AMPs in §35.51.

ACR: The current task and T&E requirements (in regulation or licensing guidance) referenced by this question are appropriate and adequate.

Q: A.7.9: 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. Comment on why unsealed microspheres without a unique delivery system should/should not be allowed.

ACR: The efficiency/timing of sealed source and device registration compared to FDA regulatory pathways and other healthcare-relevant regulations is unclear, and the ACR would defer to manufacturers and the ACMUI on whether this should be a requirement for use under the new subpart.

Absent further information regarding microspheres “without unique delivery systems,” we assume such future products would be administered in a manner akin to unsealed material requiring a written directive. If accurate, unsealed microspheres “without unique delivery systems,” should therefore be

regulated accordingly under §35.300. By comparison, currently available Y-90 microspheres have specialized delivery systems.

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

ACR: It is unclear how the differentiation of permanent versus non-permanent microspheres would change NRC's practical regulatory approach.

Q: A.7.11: Comment on items (other than items from current licensing guidance) that should be included in a requirement for safety procedures/instructions for microsource manual brachytherapy.

ACR: The NRC should consider providing educational resources, programs, and monitoring device recommendations directly to transportation entities and mortician practices regarding patient death prior to decay of external dose from the body to 10 CFR §20 levels. The agency provides and refers to guidance exclusively for licensees, but such a death may occur at home or in a healthcare/hospice facility unaffiliated with the licensee.

Q: A.7.12: Comment on other items (beyond existing EMT licensing guidance) that should be included in a new requirement for safety precautions (controls) for microsource manual brachytherapy.

ACR: The general sense is that current licensing guidance-iterated requirements should be preserved in the new regulation without unnecessarily adding new requirements that are unfamiliar to healthcare professionals, licensees, manufacturers, and training programs. Further information from NRC on angio suite protections would be more appropriate for NUREG-1556 or even a Regulatory Issue Summary (RIS) rather than regulatory language.

Q: A.7.13: Seeking input on the need for continued conditional approval for AUs of Y-90 microspheres.

ACR: Despite its maturity as a modality, Y-90 microsphere brachytherapy use is currently expanding into smaller and rural communities where simulated case experience for physicians under manufacturer supervision is likely still beneficial. Therefore, the flexibility should remain with a defined period for completion of proctored cases, as removing it would put patients in rural areas at a disadvantage.

NRC could consider implementing a date- or circumstance-based trigger in the regulatory language for when a conditional pathway would be eliminated as an option. This approach could enable a planned future change in regulation without requiring an additional rulemaking to make the change, and the expired pathway could be removed from the CFR whenever 10 CFR §35 is subsequently reopened. This approach of including "expiration dates" in the regulatory language of transitional requirements is commonly used by HHS agencies.

Q: A.7.14: Comment on why 80 hours is or is not an appropriate amount of time to ensure topics are adequately covered. Who should supervise the work experience to ensure future AUs have adequate radiation safety knowledge and why?

ACR: The current requirements, including the guidance's flexibility of the 80-hour pathway for any diagnostic radiologists and interventional radiologists who are not already AU-eligible for §35.300 and §35.400 uses, are appropriate for Y-90 microspheres. NRC should consider further clarifying to what degree the 80 classroom and laboratory hours enabled for these radiologists can be addressed via prior training for other microspheres under the proposed future Subpart I. The supervisor issue was addressed in the previous question.

Q: A.7.15: 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 microspheres in subpart I. What additional training and work experience should be considered, if any, and why?

ACR: The current work experience requirements in Y-90 licensing guidance do not need to change in the new regulatory language.

Q: A.7.16: Comment on if NRC should or should not provide additional pathways for other types of physicians (i.e., non-IRs, non-NM, and non-radiation oncologists) to become AUs for use of microspheres or other types of microspheres.

ACR: Any physician, regardless of specialty, who completes the requisite T&E requirements should continue to be AU-eligible. To our knowledge, beyond the radiological subspecialties, such as diagnostic radiology, nuclear radiology, interventional radiology, nuclear medicine, and radiation oncology, or specific cardiological subspecialties (e.g., nuclear cardiology), there are no other medical specialties with training program requirements that would be relevant to NRC T&E criteria for microsphere manual brachytherapy, such as Y-90 microspheres.

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

ACR: This varies based on institutional policies and practices. As with most any medical uses, it is generally appropriate for other individuals other than the AU to administer microspheres under appropriate AU supervision—e.g., a non-AU IR administering Y-90 microspheres under the supervision of a nuclear medicine physician, nuclear radiologist, or radiation oncologist AU on the license. The availability of this option is also necessary for AU training purposes.

Section A.8 – Other Part 35 Changes

Q: A.8.2: 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 (ANPs).

ACR: Appropriate AUs and other authorized personnel should be able to adequately serve their responsibilities with additional vendor-provided training, or with training by a provider with the current privileging, specific to the novel generator technology in question. For AUs, NRC could eliminate hands-on generator elution training, which typically involves arrangements with nuclear pharmacies and time away from physician training.

Q: A.8.3: Comment on current structure for authorized medical physicist (AMP) involvement in 10 CFR part 35, subpart F, “Manual Brachytherapy.”

ACR: The current regulatory structure for AMPs involved in Subpart F uses is sufficient.

Q: A.8.4: 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?

ACR: Generally, continuing education is already a de facto requirement for practicing AUs as part of continuing certification (formerly maintenance of certification) in their respective specialty. Moreover, vendor training is typically provided when a healthcare institution adopts any new, higher risk patient care technologies with unique medical use characteristics, including NRC-regulated EMTs. The added value of NRC regulatory requirements for AU continuing education after a given EMT has been adopted

is questionable and less flexible for meeting evolving professional needs than if the agency were to defer to initial board certification and continuing certification.

Q: A.8.5: Comment on the need for AUs for §35.200 to have device-specific training on radionuclide generators.

ACR: In general, many/most diagnostic-only AUs do not have a practical need for device-specific training on §35.200 generator technologies, as it is atypical for them to be supervising generator uses in non-academic practice settings. Therefore, these specific requirements could be removed to reduce the administrative burden for programs and trainees. Larger healthcare facility licensees with on-premises generator technologies could be required to provide/secure additional training for all newly added AUs. As mentioned previously, hands-on training for prospective AUs with generator elution should ideally be eliminated.

Q: A.8.6: Comment whether physicians authorized for full use under §35.300 need additional T&E because of expected emerging therapeutic radiopharmaceuticals.

ACR: The current requirements under §35.300 are sufficiently broad to provide minimum regulatory requirements for AU-eligibility for radiopharmaceutical therapy EMTs. Generally, EMTs with substantially different use characteristics will be introduced into healthcare facilities with vendor-provided training. Depending on the EMT, NRC could require a minimum number of simulated cases from the vendor, though this may or may not be required for EMTs that have characteristics akin to other unsealed therapies used at the facility.

Subsection Re: Cumulative Effects of Regulation (CER)

Q1 through Q5: How should NRC provide sufficient time to implement the new proposed requirements, including changes to programs and procedures?

ACR: Depending on the degree of deviation from current regulatory or licensing guidance requirements made by the future rulemaking, NRC should provide a two-year-minimum transition period for the effective date in NRC/non-Agreement States and an additional grace period for Agreement State compatibility. However, if substantial changes are made to AU T&E that would necessitate changes in AU eligibility, training programs, vendor-provided training requirements, or licensee policies and procedures, the transition period should be extended an additional three years minimum.

The ACR appreciates the NRC staff's consideration of medical community comments on the EMT regulatory basis. As mentioned, possible impacts of the future EMT rulemaking may be challenging for stakeholders to predict due to the scope of potential changes, and the NRC may benefit from releasing an ANPRM for public comment prior to drafting the future NPRM. For questions, please contact Gloria Romanelli, JD, ACR Senior Director, Legislative and Regulatory Relations, at gromanelli@acr.org; or Michael Peters, ACR Senior Government Affairs Director, at mpeters@acr.org.

Sincerely,



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