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General Comment

The University of Virginia is submitting our comments to NRC-2018-0297 Rubidium-82 Generators, Emerging Technlogies, and Other Medical Use of Byproduct Material.
Mike Welling
UVA RSO

Attachments

UVA response to NRC questions on Part 35 regulatory changes

Generator Systems (See Regulatory Basis Section A.1)

Question 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.

10CFR35.50(d) states: "Has training in the radiation safety, regulatory issues, and emergency procedures for the types of use for which a licensee seeks approval. This training requirement may be satisfied by completing training that is supervised by a Radiation Safety Officer, an Associate Radiation Safety Officer, authorized medical physicist, authorized nuclear pharmacist, or authorized user, as appropriate, who is authorized for the type(s) of use for which the licensee is seeking approval."

As the generator systems should fall under the "use for which the licensee is seeking approval", there seems to be no need to revise subpart D.

Question 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?

10CFR35.63(d) states that the dosage may not be used if it differs from the prescribed dosage by more than 20%. The dosage measurement should be based upon the time all of the radiopharmaceutical is injected. If the injection is incremental, then the time interval needs to be accounted for along with the decay time of the radiopharmaceutical and perform the necessary calculations to ensure the dosage does not differ by more than 20%.

Question 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.

UVA does not agree with the proposal of AUs being required to have device-specific training.

UVA does agree with the 35.27 proposal to require device-specific training for individuals (Nuclear Medicine Technologists) working under an AU's supervision.

The RSO is already required to have this training so there would be ample knowledge between NMTs and RSOs for the proper use of the generators such that the AUs would not be required to have this requirement.

Intravascular Brachytherapy Systems (See Regulatory Basis Section A.2)

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.

Criteria B of Licensing Guidance for TS and SS revision 10.2 section 5.1, should specifically require AUs to get training in calculation of dosage(s) for Y-90 delivery

Question 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.

As long as "liquid brachytherapy" is defined in such a way to ensure it encompasses microsources, then "microsources" could be replaced.

Question 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.

This is not required. 10 CFR 20.1501 "General", requires surveys be performed for "Concentrations or quantities of residual radioactivity" and "The potential radiological hazards or the radiation levels and residual radioactivity detected" and 10 CFR 20.1406 "Minimization of Contamination" states: "licensees, shall to the extent practical, conduct operations to minimize the introduction of residual radioactivity into the site, including the subsurface, in accordance with the existing radiation protection requirements in Subpart B and radiological criteria for license termination in Subpart E of this part".

NUREG-1556 Vol 9, Revision 3 states the following:

8.10.4 Operating and Emergency Procedures

Regulations: 10 CFR 19.11(a)(3), 10 CFR 20.1101,10 CFR 20.1601, 10 CFR 20.1602, 10 CFR 20.1801, 10 CFR 20.1802, 10 CFR 20.1906, 10 CFR 20.2201-2203, 10 CFR 21.21, 10 CFR 35.12, 10 CFR 35.41, 10 CFR 35.75, 10 CFR 35.310, 10 CFR 35.315, 10 CFR 35.404, 10 CFR 35.406, 10 CFR 35.410, 10 CFR 35.415, 10 CFR 35.610, 10 CFR 35.615, 10 CFR 35.3045, 10 CFR 35.3047, 10 CFR 35.3067, 10 CFR Part 37, 10 CFR 37.21(a), 10 CFR 37.45, 10 CFR 37.49

Part 35	Applicability
100	✓
200	✓
300	✓
400	✓
500	✓
600	✓
1000	✓

Criteria: This section summarizes operating and emergency procedures. Many of these procedures are covered in greater detail in other sections of this document. The regulatory requirements are listed above for ease of reference by the applicant. In addition, these procedures must be posted in accordance with 10 CFR 19.11(a)(3).

The licensee must develop, implement, and maintain specific operating and emergency procedures sufficient to ensure compliance with 10 CFR 20.1101(a) and applicable sections in 10 CFR Part 35. Operating and emergency procedures must encompass the scope of the program, which may include the following elements:

- Instructions for opening packages containing licensed material (see Section 8.10.9, "Opening Packages").

- Instructions for using licensed material, operating therapy treatment devices, and performing routine maintenance on devices containing sealed sources, according to the manufacturer's written recommendations and instructions and in accordance with regulatory requirements (see Section 8.10.7, "Installation, Maintenance, Adjustment, Repair, and Inspection of Therapy Devices Containing Sealed Sources"). There may be sources and devices containing NARM that do not have SSD registration certificates. If these legacy sources or devices have manufacturers' recommendations or instructions, they should be followed. These devices and sources are, however, subject to the standard leak test provisions included in materials licenses.

- Instructions for conducting area radiation level and contamination surveys (see Section 8.10.12, "Area Surveys").

Response from Applicant: No response required.

8.10.5 Spill/Contamination Procedures

Regulations: 10 CFR 20.1101

Part 35	Applicability
100	✓
200	✓
300	✓
400	
500	
600	
1000	✓

Criteria: Before using licensed material, the licensee must develop, document, and implement a radiation protection program that includes proper response to spills of licensed material.

Discussion: The radiation protection program that licensees are required to develop, document, and implement in accordance with 10 CFR 20.1101, must include provisions for responding to spills or other contamination events to prevent the spread of radioactive material. Appendix N of this NUREG contains model emergency response procedures, including model spill procedures. Spill procedures should address all types and forms of licensed material used and should be posted in restricted areas where licensed materials are used or stored. The instructions should specifically state the names and telephone numbers of persons to be notified (e.g., RSO, staff, State and local authorities, and the NRC, when applicable). Additionally, the instructions should contain procedures for evacuation of the area, and containment of spills and other releases, as well as appropriate methods for reentering and decontaminating facilities (when necessary).

Response from Applicant: Provide the following statement:

"We have developed and will implement and maintain written procedures for safe response to spills of licensed material in accordance with 10 CFR 20.1101."

Reference:

- NCRP Report No. 65, "Management of Persons Accidentally Contaminated with Radionuclides," 1980

As these issues are addressed in licensing and verified during inspections, there is no reason to create new regulations.

Question 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)?
UVA agrees with this proposal as it was defined in the licensing guidance for I-125 Iotrex for GliaSite radiation therapy system use:
"Source leakage" for the Iotrex™ implanted in the GliaSite® RTS means leakage of I-125 that results in a dose that exceeds 0.5 Sv (50 rem) dose equivalent to any individual organ other than the treatment site (based on definition of a medical event).

Gamma Stereotactic Radiosurgery and Photon Emitting Teletherapy Units (See Regulatory Basis Section A.6)

Question 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?
We agree that there is a need for model-specific training for radiation safety officers involved in Gamma Stereotactic Radiosurgery and/or Photon Emitting Teletherapy Units. We believe a focus on emergency sub-systems, radiation safety procedures, and regulatory issues specific to a particular model device would likely be of significant help in equipping an RSO with information required to maintain a radiation safety program including these devices. As noted in the Specific Requests for Comments of this proposed rule change, the design of gamma stereotactic radiosurgery have changed significantly since requirements were established in 2002, with several models of units appearing in the clinic. Other photon emitting therapy devices have also been released subsequent to 2002 (for instance, 60Co-based MRI therapy systems). Devices from different manufacturers have differing designs, differing emergency sub-systems, and differing radiation safety devices (such as number, style, and location of emergency stop controls, etc.). One of the responsibilities of an RSO is to maintain oversight of the radiation program, a working understanding of the emergency subsystem expected behavior, radiation safety systems of the device and treatment room, and regulatory issues would provide an RSO with information critical to understanding how to provide this oversight.

We believe this training should be specific to devices based on their Sealed Source and Device (SS&D) certificate (i.e. a new training would be required to use a device with a new SS&D certificate). Specifically for Gamma Stereotactic Radiosurgery devices we support training requirements for RSOs following the model found in the current Leksell Gamma Knife® Perfexion™ and Leksell Gamma Knife® Icon™ Licensing Guidance, Revision 1, January 2019. We believe this training should be provided by the manufacturer or by an Authorized Medical Physicist or Authorized User who is listed on a current radioactive materials license with authorization for the same device for which the RSO is requesting authorization.

Question 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.

We support the change in focus from specific components to elements and objectives. We also agree that components and objectives should include source output, source collimation, source position, patient safety, and facility safety. We would also suggest the following:

- Patient positioning system / treatment bed position
- Integrity of patient immobilization mount / connection to treatment device

We have some question about the meaning of the proposed element, "source attenuation" and how this would differ from the element "source output". The sources of a modern Gamma Stereotactic System cannot be measured individually in a clinic setting and are 60Co sources based on a known design. The physics of the attenuation of the sources is fixed, so to us it is not clear what this element is getting at.

Question 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?

For full calibration measurements we suggest adopting the tests as outlined in the report of AAPM Task Group 178[1] on Gamma Stereotactic Radiosurgery, tables VII-VIII. (Please note that the consensus recommendations in the AAPM task group report categorize tests a bit differently from current NRC regulations. Instead of a single full-calibration category, they are split into annual QA and acceptance/commissioning tests. We support a recategorization of these tests to match the recommendations in the consensus task group report).

Question 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?

For periodic spot checks we suggest adopting the tests as outlined in the report of AAPM Task Group 178[1] on Gamma Stereotactic Radiosurgery, tables III-V. (However note that in table III we recommend the Focus Precision test be performed on at least a monthly basis as enforced by the Gamma Knife control system).

[1] Petti, P.L., Rivard, M.J., Alvarez, P.E., Bednarz, G., Daniel Bourland, J., DeWerd, L.A., Drzymala, R.E., Johansson, J., Kunugi, K., Ma, L., Meltsner, S.G., Neyman, G., Seuntjens, J.P., Shiu, A.S. and Goetsch, S.J. (2021), Recommendations on the practice of calibration, dosimetry, and quality assurance for gamma stereotactic radiosurgery: Report of AAPM Task Group 178. Med. Phys., 48: e733-e770. https://doi-org.proxy1.library.virginia.edu/10.1002/mp.14831

Microsource Manual Brachytherapy (See Regulatory Basis Section A.7)

Question 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) Microsource should include all types of radiation (no limitations)
2) No
3) No, all information can be acquired through FDA
4) No

Question 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.
Due to the possibility of stasis especially with spheres and the possibility of stasis as smaller subsections of the liver are treated, stasis and other states of equilibrium should be included in the definition. This is a doctor decision, and it should be left to the treating physician to determine states of equilibrium on a case-by-case basis.

Question 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.
Each team should consist of the treating physician or physicians, along with properly trained physics/ radiation protection oversight, along with properly trained technologists and nurses. Training should include specific microsource procedure training, radiation safety, and proper departmental procedures. UVA has been working this way for 10 years and it has worked well in helping prevent misadministrations. Each team member has defined roles during the procedure. A multi-specialty checklist keeps all of the team members engaged and includes multiple short timeouts to ensure the treatment happens with the intended activity dose and in the intended target.

Question 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.
Due to lack of pre-volumetric dosimetry planning a before-implant written directive should specify activity. However, having absorbed dose information available for the physicians can be helpful to avoid miscommunications.

Question 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.

To keep the written directive consistent, the after-implant written directive should also be activity.

Question 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?
To keep consistent, the medical event should be reported in activity. The deadline should continue to be within the next calendar day from discovery of the event.

Question 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?
Yes, post-treatment imaging should be used to confirm the treatment was delivered. This is the only way to confirm that the dose was truly delivered to the written directive area. Volumetric imaging is recommended when possible. We are not aware of any other mechanisms that are available.

Question 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.
A physics check that would be similar to that done in external beam therapy. This would be more important as pre-volumetric dose treatment planning software becomes available. This should include activity dose and dose to treatment site calculations. The physicist is in a good position to be able to spot errors through all parts of planning and treatment. Training requirements should not be changed.

Question 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.
No limit should be made due to the possibility of new microsources and unique delivery systems will come out in the future.

Question A.7.10: Please comment on why any new requirements for microsource manual brachytherapy should or should not be limited to permanent implants.
If any new requirements for microsources are created, they should not be limited to permanent implants. For microsource accountability, especially in the case of non-permanent implants.

Question 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
No, these are captured in other sub-sections of the regulations already.

Question 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
No, these are captured in other sub-sections of the regulations already. Patients are released in accordance with RG 8.39.

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
The three cases should be required, there are more AU's available to observe now and if one cannot be found, the manufacturer can provide the necessary guidance.

Question 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?
This training should still be required. This is needed to ensure proper understanding of the calculation process of determining dose and activity needed to treat along with the radiation safety needed in case of emergency. This should be supervised by either a current AU, a qualified medical physicist, or RSO.

Question 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?
Additional training in Lung shunt, and activity to radiation dose calculation training should be specified to ensure the treating physicians have a clear understanding of what they are treating the patient with.

Question 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
No, no other pathways are needed.

Question 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?

1) Yes.
2) Yes, as long as the AU is present in the room. This supervision is identical to radiotherapy injections being performed in a Nuclear Medicine Department.

Other Part 35 Changes: Novel Radionuclide Generators (See Regulatory Basis Section A.8)
Question 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.
Each licensee should not be responsible for designating the breakthrough testing and results for new radionuclides being used, this should be done by the FDA, US Pharmacopeia or any other nationally recognized expert. The goal of regulations and guidance is to ensure the proper use of radionuclides throughout the US. If each licensee would create their own testing of new radionuclides, it would create a conundrum for the patients and public as to what is safe for use.

Other Part 35 Changes: Training and Experience (See Regulatory Basis Section A.8)
Question 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.
As stated in question A.1.3, the AU should not be required for the training of these generators while the individuals working under their supervision and the RSO should be required to have the proper training. If an ANP is providing the radionuclide for injection, then they should also have the proper training.

Question 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?
UVA sees no reason to include AMPs in 10 CFR Part 35, Subpart F as the work is being done under the supervision of an AU and the duties of a Therapeutic Medical Physicist has been defined by the following:
AAPM: AMERICAN ASSOCIATION OF PHYSICISTS IN MEDICINE (aapm.org)

Clinical Service & Consultation

Many medical physicists are heavily involved with responsibilities in areas of diagnosis and treatment, often with specific patients. These activities take the form of consultations with physician colleagues. In radiation oncology departments, one important example is the planning of radiation treatments for cancer patients, using either external radiation beams or internal radioactive sources. An indispensable service is the accurate measurement of the radiation output from radiation

sources employed in cancer therapy. In the specialty of nuclear medicine, physicists collaborate with physicians in procedures utilizing radionuclides for delineating internal organs and determining important physiological variables, such as metabolic rates and blood flow. Other important services are rendered through investigation of equipment performance, organization of quality control in imaging systems, design of radiation installations, and control of radiation hazards. The medical physicist is called upon to contribute clinical and scientific advice and resources to solve the numerous and diverse physical problems that arise continually in many specialized medical areas.

Department of Veterans Affairs: 2023-05141.pdf (govinfo.gov)
Proposed National Standard of Practice for Therapeutic Medical Physicists
Therapeutic Medical Physicists (TMPs) assure the safe and effective use of radiation in radiation oncology. TMPs perform or oversee the scientific and technical aspects of radiotherapy procedures necessary to achieve this objective. In the clinical setting, this involves the use of ionizing or nonionizing radiation in the planning and delivery of radiotherapy treatments. TMPs collaborate with radiation oncologists and monitor equipment to ensure each patient's safety.

Question 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 regarding EMTs should not be a regulatory requirement of AUs. Radiation safety use of EMTs is the responsibility of the RSO and need to be the one ensuring safety actions are in place. This should also be part of the annual radiation safety training that is required to be provided to the Nuclear Medicine Technologists.
Question 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.
See answer in question A.1.3, A.8.2 and A.8.4 above
Question 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?
As stated in previous questions, the Nuclear Medicine Technologists and RSOs should be required to have the specific training for these types of use. These individuals can ensure the regulatory requirements are being met and can educate the AUs as necessary.

Question 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?

These training requirements should be the same as radionuclide generators, the individuals working under the AUs supervision and the RSO should be required to have the device-specific training. The AU may be educated by these individuals as necessary.

Other Part 35 Changes: Security and Controls

Question 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.

There seems be nothing needed as 35.610 states:

(a) A licensee shall—

(1) Secure the unit, the console, the console keys, and the treatment room when not in use or unattended;

(2) Permit only individuals approved by the authorized user, Radiation Safety Officer, or authorized medical physicist to be present in the treatment room during treatment with the source(s);

Each licensee is responsible for ensuring safety of the units at all times.

Question 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?

This should not be stated in a rule, this should be left up to the licensee and regulator to determine if the security in place meets the requirement of 20.1801, 20.1802, Part 35 and Part 37. There is enough guidance documentation regarding security that further rulemaking is not necessary.