U.S. Nuclear Regulatory Commission
Advisory Committee on the Medical Uses of Isotopes

Subcommittee on Training and Experience for All Modalities

Final Report
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CHARGE

The current charge of the subcommittee is to review and evaluate the training and experience requirements for all modalities in 10 CFR Part 35.

On August 20, 2024, the subcommittee received the expanded charge to provide recommendations to the NRC on knowledge topics encompassing the safety related characteristics of emerging medical technologies required for Authorized Users 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 the NRC regulatory requirements.

The subcommittee met several times through September and October of 2024, and then again in February and March of 2025, to discuss the expanded charge and propose recommendations. A pause in the subcommittee discussion was made after the October meeting to review potential conflict of interest (COI) within the subcommittee membership. Following the COI review by the U.S. Nuclear Regulatory Commission (NRC), it was confirmed that the participation of the subcommittee membership in ACMUI activities outweighed any reasonable concern of an appearance of a lack of integrity or impartiality, and the subcommittee membership was authorized to participate in the matters relevant to this charge prior to reconvening in February 2025.

INTRODUCTION

Continuing innovation in the uses of radioisotopes has led to new applications and indications in areas such as gamma knife technology, ophthalmic treatments, diffusing radioactive particle implants, and an increasingly diverse array of diagnostic and therapeutic radiopharmaceuticals. Emerging medical technologies (EMTs) are generally classified under title 10 of the *Code of Federal Regulations* (10 CFR) 35.1000, but development of new radiopharmaceuticals, brachytherapy applications, and other devices utilizing radioactive byproduct material normally regulated under 10 CFR 35.300, 35.400, and 35.600, may also incorporate novel ligand/radioisotope combinations and/or administration methods that may pose additional patient and radiation safety risks and require additional training. This is not limited only to therapeutic applications but also potentially diagnostic applications as well (regulated under 10 CFR 35.100 and 35.200), as an increasing array of diagnostic radioligands are integrated into the clinic.

Training for all medical applications of isotopes requires appropriate classroom and laboratory training in radiation physics and instrumentation, radiation protection, calculations pertaining to the use and measurement of radioactivity, chemistry of byproduct material for medical use, and radiation biology, as well as work experience to provide training in managing and assaying radioactive materials, performing surveys, calibrating and maintaining assay and survey equipment, assaying and preparing doses, managing spills, waste, and contamination, developing safe protocols for radioactive material management, and safely and appropriately delivering radioactive doses to patients.

In addition to these core knowledge areas, there has been increasing complexity around aspects of patient selection, patient and caregiver education, interactions of radioactive material applications with other therapies and interventions, pre- and post-procedure dosimetry, patient monitoring and release, and reporting of adverse reactions and medical events. The subcommittee also recognizes that the authorized user (AU) may not be physically present in some applications (for example, the administration of radiopharmaceuticals) but may be monitoring the dose administration virtually. As such, the independent educational needs of the entire healthcare team are also a consideration that must also be met to ensure the safe utilization of EMTs using radioisotopes.

In this report, we will review the background the current training and experience (T&E) landscape, discuss our recommendations on the acquisition and maintenance of general knowledge base for Authorized Users (AUs) on safety aspects of medical technologies using radioisotopes, expectations for application-specific training for EMTs (including the role of the vendor and implications for “hands-on” and “in-person” training), and considerations for forward planning to address authorization for new technologies.

BACKGROUND

For each medical use modality, 10 CFR Part 35 regulations prescribe the minimum number of hours of classroom and laboratory training, as well as supervised experience for proposed AUs. T&E requirements for EMTs are described in 10 CFR 35.1000 licensing guidance documents. The current regulatory framework for AU training and experience was established in 2002 (67 FR 20249), following a comprehensive overhaul of 10 CFR 35. In the past two decades, the ACMUI has revisited AU T&E requirements a number of times regarding board certification pathways (in years 2002, 2009, and 2023), 10 CFR 35.300 radiopharmaceuticals (in years 2013, 2016, and 2019) and EMTs (in year 2022).

With the rapid development of novel radiopharmaceuticals in the late 2010s, stakeholders expressed concerns with the perceived burden of T&E requirements for AUs. NRC staff engaged stakeholders, the ACMUI, and Agreement States, and explored options to reduce the regulatory burden for physicians seeking to become AUs while preserving training critical to radiation safety. This led NRC staff to submit a rulemaking proposal in 2020 (SECY-20-0005) to modify the T&E requirements in 10 CFR 35, Subparts D and E for unsealed byproduct material. A primary driver for this proposal was to establish high-level radiation safety training criteria in advance of the expected arrivals of new, complex radiopharmaceutical therapies and eliminate the case-by-case approval of individual physicians as AUs on radioactive byproduct materials licenses. The rulemaking would have eliminated the alternate pathway for unsealed byproduct material and required physician AUs to be certified by an NRC-recognized specialty board. Medical specialty boards seeking NRC recognition would have needed to demonstrate that their certification processes meet NRC requirements for T&E. However, in 2022, the Commission voted against this rulemaking plan and approved maintaining the status quo.

In 2022, the Commission approved initiation of a medical rulemaking (SECY-21-0013, “Rulemaking Plan to Establish Requirements for Rubidium-82 Generators and Emerging Medical Technologies (Rb-EMT”) that would move many EMTs from being regulated via licensing guidance under 10 CFR 35.1000 to other sections of Part 35. This rulemaking would, in part, codify T&E requirements (that are currently in licensing guidance) for AU physicians for these technologies. In 2023, the NRC staff published a draft regulatory basis for this rulemaking. The emerging medical technologies rulemaking remains in the proposed rule phase.

One effect of moving T&E requirements from licensing guidance into the regulations in 10 CFR 35 is that these requirements will necessarily become less flexible. As a result, the NRC staff are assessing ways to make the existing EMT T&E requirements more generic, in order to apply them to a broader range of technologies (including future technologies), instead of having a customized set of T&E requirements for each 10 CFR 35.1000 licensing guidance document. The subcommittee’s current charge to review knowledge topics for EMTs is connected to the Rb-EMT rulemaking in an effort to identify consistent T&E elements for AUs.

DISCUSSION

Acquisition and Maintenance of General Knowledge Base for Safety Aspects of Medical Technologies Using Radioisotopes

Prior to becoming an AU, the core requirements of 10 CFR Part 35 must be met for the class of applications (10 CFR 35.59 and 35.190, 35.290, 35.390, 35.392, 35.394, 35.396, 35.490, 35.590, or 35.690)

While the final review and approval of AUs are primarily the responsibility of the NRC and Agreement States, the subcommittee strongly feels that the acquisition of general safety content and continuing education should primarily be the responsibility of the medical boards such as the American Board of Radiology and the American Board of Nuclear Medicine; accreditation councils such as the Accreditation Council for Graduate Medical Education and the Commission on Accreditation of Medical Physics Education Programs; and professional societies that are actively engaged in the training and certification of AUs, Radiation Safety Officers (RSOs), Associate RSOs (ARSOs), Authorized Nuclear Pharmacists (ANPs), Authorized Medical Physicists (AMPs), and Ophthalmic Physicists (OPs). Professional societies that are engaged in radiation safety educational development may include but are not limited to:

- Society of Nuclear Medicine and Medical Imaging (SNMMI)
- American Society for Radiation Oncology (ASTRO)
- American Association for Physicists in Medicine (AAPM)
- American College of Nuclear Medicine (ACNM)
- American College of Medical Physics (ACMP)
- American Society for Medical Dosimetry (ASMD)
- American College of Radiation Oncology (ACRO)
- American Pharmacists Association (APhA) APhA-APPM Nuclear Pharmacy Practice Special Interest Group (SIG)
- Health Physics Society (HPS)
- American College of Radiology (ACR)
- Radiological Society of North America (RSNA)
- American Society of Nuclear Cardiology (ASNC)
- American Brachytherapy Society (ABS)
- American Radium Society (ARS)

Safety educational development is an area of active engagement by the professional societies. For example: SNMMI and ACNM are circulating a joint practice guideline for the use of radiopharmaceuticals, ASTRO has been developing their “safety white paper”, and ABS is developing training objectives for radiopharmaceutical practice. The ACR has partnered with multiple societies to develop practice parameter guidelines for a range of diagnostic and therapeutic applications involving radioisotopes, which are regularly updated in collaboration with multiple societies including SNMMI, ACNM, ASTRO, ABS, and ARS.

In our discussions with the NRC staff, it was noted that the NRC cannot “endorse” or preferentially favor a training pathway, but we would recommend that the NRC evaluate whether educational materials or a program “meets requirements” for initial certification with a technology or application. As the NRC itself is not in the position to develop and disseminate initial and ongoing educational content, a mechanism must be in place for the NRC staff to validate whether an existing training program meets minimum specifications. It will likely be necessary that the NRC will have to develop a range of training scenarios for initial certification

that will depend on the time that has elapsed since professional training was completed by the prospective AU, as well as, which training pathway the prospective AU initially completed. This is in keeping with the request for “case scenarios” in the recent ACMUI T&E for All Modalities subcommittee report (https://www.nrc.gov/docs/ML2418/ML24185A268.pdf).

The subcommittee recognizes the role for ongoing continuing medical education (CME) in supporting quality of care and radiation safety. In terms of CME, the subcommittee recognizes that professional societies are actively developing and providing CME for practitioners administering existing and EMTs through recorded, virtual, and in-person offerings. The AU will need to maintain records of their CME. We recommend that professional societies develop guidelines for CME minimum contact hours; we would also recommend that the NRC explore the need to define minimum CME requirements for AUs.

Verification of ongoing T&E and CME must follow applicable state, local, and certification board requirements, as well as the authority of the hospital or practice clinical credentialing program. Credentialing is a process where medical facilities grant healthcare professionals (such as physicians, non-physician mid-level providers, medical physicists, nurses, medical dosimetrists, and medical technologists) the ability to practice medicine and supportive services in their clinical sites. Credentialing and maintenance of associated privileges is not regulated by the NRC. These credentialing programs may add additional requirements or increased training/CME contact hours over those recommended by the NRC and/or professional societies. AUs should receive information on medical events related to the domains of radioactive byproduct material with which they practice via vendors and professional societies, and review of these materials should be documented; additionally, if a licensee has a violation associated with a medical event related to the use of radioactive byproduct material, this should trigger the need for additional remediation/corrective action and CME and/or additional training for that AU.

Application-Specific Knowledge Base Training for Emerging Medical Technologies and the Role of Vendor Training

In addition to the core knowledge areas covered above, the practical knowledge base for EMTs must include application-specific content and documentation of training on:

- Patient assessment and eligibility
- Patient and caregiver education on the procedure and radiation safety (verbally and in writing)
- How to develop site-specific protocols for administration and use of the medical technology
- Radiation safety and quality control for all aspects of the procedure including ordering, preparation, administration, and disposal of contamination/waste (if present)
- Components of the written directive for therapeutic administrations
- Pre-procedure assay/dosimetry
- Role of post-procedure dosimetry
- Patient monitoring, discharge instructions, and release, including management of procedural events such as extravasations
- Follow-up protocols for therapeutic interventions
- Reporting of adverse reactions and medical events
- Aspects of supervision of the healthcare team, including relevant NRC regulatory requirements

New 10 CFR 35.1000 as well as 10 CFR 35.200, 35.300, 35.400, and 35.600 applications may have very complex indications and patient selection criteria that will require additional training, as well as ongoing assessment needs due to changes in patient clinical condition. Therapeutic radiopharmaceuticals can have very different radiation protection needs due to different radioisotopes or pathways for excretion. Radiation safety protocols may vary widely due to state, local, and hospital/practice requirements, and AUs need to be able to address these effectively. Follow-up protocols and reporting of adverse reactions/medical events are critical for EMTs as there will generally be limited or no long-term data on toxicities or unexpected radiation safety issues, and AUs must stay up to date on information as it becomes available.

As noted above, simply understanding the role of the AU in a new application may be insufficient, as the administration/use of the technology may require the direct involvement of a range of other specialties including— Certified Nuclear Medicine Technologists (CNMT), Registered Nurses (RN), RSOs, and Authorized Medical Physicists (AMP). Understanding of NRC regulatory requirements for these roles must also be required for the AU. As such—

- The educational needs of the entire healthcare team, including the licensee/administrator, CNMT, RN, RSO, and AMP (if available/applicable), must also be met to ensure the safe utilization of EMTs using radioisotopes.

- The AU must have a clear understanding of the roles and limitations of each member of the healthcare team, and a documented plan for how they would interact with these members when physically present and when monitoring remotely.

Pre-procedure assays and dose calibration methodology are generally well established, and application-specific training should be provided. However, post-procedure dosimetry protocols are not well established for many radiopharmaceutical applications and may not be clear for

EMTs. This topic is an area of ongoing research and discussion, and the subcommittee recommends that post-treatment dosimetry should be performed, when possible (and applicable), following professional society recommendations.

- Proper equipment for assaying and dosimetry must be in place for pre-procedure and post-procedure (where applicable) assessments, and the AU (and CNMT, AMP, RN, etc. as applicable) should be trained in their use.

For EMTs and new radiopharmaceutical applications, the application vendor has a significant role in recommending and providing the appropriate knowledge and technical training for the safe and effective use of their technology. Vendor training should cover all aspects of how to correctly use the new device/drug. Training should also include contraindications to use and remind trainees not to modify/substitute aspects of the device or procedure without the approval of the manufacturer.

It is the recommendation of this subcommittee that hands-on training should be expected for any new therapeutic device/drug, or for any therapeutic application that has a unique delivery platform. This means that the prospective user would have to conduct mock use or supervised patient use of the device/drug using the actual device/drug or a model device that incorporates all practice aspects of the new technology. Any training must include opportunities for the prospective AU to ask questions about the training material and process and receive answers in real time. The trainer (vendor and/or current AU) must be able to directly assess prospective AU learning in the context of the training prior to unsupervised clinical implementation.

Additionally, it is the recommendation of this subcommittee that the trainer (either a vendor representative or an AU for the new technology) must be physically present ("in-person") for the training of the prospective user and their team, even in situations where the standard-of-care administration or use of the technology may be performed with the AU supervising remotely.

The NRC should encourage licensees to include information in annual refresher training for appropriate individuals (AUs, CNMTs, etc.) regarding medical events involving radiopharmaceuticals or devices used by the licensee. We recommend that information on known medical events should also be included in initial training for a new device/drug application.

Forward Planning to Address New Technologies

For any new therapeutic device/drug (such as we have seen in the licensing guidance for new versions of Y-90 microspheres or novel ocular therapy applicators), training requirements will generally be addressed under 10 CFR 35.1000 with licensing guidance and ACMUI commentary/review. A new application that would normally fall under 10 CFR 35.300 or 35.400 that has unique considerations from other applications in that class (for example, the diffusing radioactive particle applicator Alpha DaRT (https://www.nrc.gov/docs/ML2202/ML22021B298.pdf) can be licensed instead under 10 CFR 35.1000. For a new parenteral/oral radiopharmaceutical application that would normally be under 10 CFR 35.300, regulation via 10 CFR 35.1000 licensure can be considered if, for example, a novel form of administration or co-administration is involved or if a novel targeting ligand with unique biological properties is used.

SUBCOMMITTEE RECOMMENDATIONS

1. Core knowledge base topics should be supplemented with application-specific content for existing and future EMTs incorporating radioactive byproduct materials.

2. The NRC should enable the relevant professional societies to develop curricula for initial training and should explore how best to evaluate these curricula on an ongoing basis and how these curricula may be incorporated into an efficient licensing process.

3. The NRC should explore the need to define minimum CME requirements for AUs.

4. Training for new therapeutic devices/drug or any therapeutic application that has a unique delivery platform should be both hands-on and in-person with a vendor representative and/or an AU for the new technology prior to unsupervised clinical implementation.

5. The NRC should encourage inclusion of information on known medical events in annual refresher training for drugs/devices used by the licensee, and in initial training for a new drug/device application.

Respectfully submitted, March 10, 2025
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The ACMUI unanimously approved this report as presented during its public meeting on April 7, 2025.