U.S. Nuclear Regulatory Commission (NRC)
Advisory Committee on the Medical Uses of Isotopes (ACMUI)

Subcommittee Review and Comments on

Guidance for the Implementation of 10 CFR Part 35 Training and Experience Requirements

Final Report

Submitted: July 3, 2024

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Charge

On February 2, 2024, the ACMUI Chair expanded the charge of the Training and Experience (T&E) for all modalities subcommittee to include a review of the staff's draft training and experience implementation guidance. A joint NRC / Agreement State working group has drafted this guidance in accordance with Commission Direction.

Background

Per Commission direction in the Staff Requirements Memorandum to SECY-20-0005, "Staff Requirements – SECY-20-0005 – Rulemaking Plan for Training and Experience Requirements for Unsealed Byproduct Material (10 CFR Part 35)" (Agencywide Documents Access and Management System Accession Number ML22027A519), the staff has developed guidance for implementing the T&E requirements in 10 CFR Part 35, "Medical Use of Byproduct Material." This guidance aims to clarify the roles and responsibilities of individuals subject to T&E requirements, and it outlines the information needed to demonstrate the necessary T&E for individuals being listed on the license. Additionally, the guidance explains expectations for how these individuals fulfill the T&E requirements. The guidance also provides criteria for the NRC staff and Agreement State regulators to evaluate applications or license amendment requests from licensees or applicants who are seeking to add individuals to their license as authorized individuals including authorized users, radiation safety officers, associate radiation safety officers, authorized nuclear pharmacists, authorized medical physicists, or ophthalmic physicists. The NRC staff utilized information from different sources, including NUREG-1556, Volume 9, Consolidated Guidance About Materials Licenses: Program-Specific Guidance About Medical Use Licenses, frequently asked questions from the NRC's Medical Toolkit, and information based on questions received from stakeholders, to develop this guidance. *With this guidance, the NRC is not recommending or instituting changes to the current training and experience requirements in 10 CFR Part 35*.

It was noted that, due to ongoing medical rulemakings, the NRC staff prepared this guidance as interim staff guidance, as some training and experience requirements could change in the near future. Once the NRC is closer to promulgating these medical rulemakings the NRC staff will decide on the best vehicle to transmit this guidance (e.g., include as part of existing licensing guidance in NUREG-1556, Volume 9, or issue it as its own standalone guidance document).

General Comments:

1. The general opinion of the subcommittee members was that the guidance document was well developed, and effectively outlined the process to list individuals as AUs, RSOs, ARSOs, ANPs, AMPs, and OPs on an NRC license.
2. Presentation of the required hours (divided into classroom/laboratory and supervised work experience hours) and/or number of cases/supervised clinical casework required to meet regulatory requirements for each T&E element should be presented in tabular format (perhaps as an appendix) as a more accessible resource.
3. Example T&E case scenarios should be made available that outline common situations; for example:
    a. an interventional radiologist seeking to be listed as an AU for liver microsphere applications,
    b. a medical physicist taking on the role of RSO at a new institution,
    c. a radiation oncologist 10 years out of training seeking to be listed as an AU for permanent seed implant brachytherapy or radiopharmaceutical therapy,
    d. a community radiologist engaged in a solely diagnostic nuclear medicine imaging practice (without dedicated nuclear medicine fellowship or dual 16-month diagnostic radiology – nuclear medicine pathway in residency) and now wants to participate in theranostics.

Specific Comments on the Guidance:

1. Section 2.0 Applicability and Use, page 2, add "for the medical use of byproduct material" after "applicants and licensees," and noted that the extensive listing of subtopics of 10 CFR Chapter 1 Part 35 may not be additive.
2. Section 4.1.2 Roles and Responsibilities, page 6, under Radiation Safety Committee (RSC), add a statement about how and when 35.1000 technologies are required to have RSC participation.
3. Section 4.1.2 Roles and Responsibilities, page 7, under Radiation Safety Officer (RSO), add "but are not limited to" to the statement "Typically, these duties and responsibilities include, but are not limited to, the following:"
4. Section 4.1.2 Roles and Responsibilities, page 7, under Radiation Safety Officer (RSO), add hyperlink to 10 CFR 35.24. (https://www.ecfr.gov/current/title-10/chapter-I/part-35/subpart-B/section-35.24)
5. Section 4.1.2 Roles and Responsibilities, page 9, under Associate Radiation Safety Officer (ARSO), clarify in the third bullet that the appointment of the ARSO as a temporary RSO is maintained by the licensee within the institution rather than a submittal of a license amendment to the regulator. This clarification should include references to the temporary RSO requirements in 10 CR 35.24(c) and the notification requirements in 10CFR 35.14(b)(2).

6. Section 4.3.2.4 Device-Specific Training, page 17, the guidance stated that the training is not required to be specific to the model of the device; this is inconsistent with other guidances that require specific training for new devices and applications. Even though an AU/AMP may be otherwise qualified, they should have training in the use of and emergency procedures for the model of device or byproduct material application for which authorization is sought.
    a. It is later noted that model specific training may be required under some cases under 10 CFR 35.610, but this would only apply to use of sealed sources in remote afterloader units, teletherapy units and gamma stereotactic radiosurgery units, and there are many other byproduct material uses/devices that are not covered under 10 CFR 35.610.
    b. Section 5.1 of the microsphere licensing guidance (ML21089A364) also requires AUs to have training with the specific microsphere product for which the AU is seeking authorization. Clarification of this point in the guidance is recommended.
7. Section 4.3.2.4 Device-Specific Training, page 17; remove the sentence "This element must be completed in-person with the device," and provide guidance as to when and what devices/applications require in-person/"hands-on" training.
8. Section 4.5.1 Adding New Authorized Individuals, page 20, word missing, corrected to "Guidance on preparing amendment requests and notifications can be found **in** the NUREG-1556 Volume 9, Revision 3."

Respectfully submitted on May 22nd, 2024,
Subcommittee on Training and Experience for all modalities
Advisory Committee on the Medical Use of Isotopes (ACMUI),
U.S. Nuclear Regulatory Commission

The ACMUI unanimously approved this report as presented during its public meeting on June 5, 2024.