OFFICE OF NUCLEAR MATERIAL SAFETY AND SAFEGUARDS
INTERIM STAFF GUIDANCE
NMSS-ISG-##

GUIDANCE FOR THE IMPLEMENTATION OF 10 CFR PART 35 TRAINING AND EXPERIENCE REQUIREMENTS

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Prepared by:
Ayoade, Maryann
Flannery, Cindy
Kreuzberger, Charles
Ong, Augustinus*
Shaw, Daniel
Tindle-Engelmann, Elizabeth

U.S. Nuclear Regulatory Commission
Office of Nuclear Material Safety and Safeguards
Washington, DC 20555

*New Hampshire Department of Health & Human Services
Radiological Health Section
29 Hazen Drive
Concord, NH 03301

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ABBREVIATIONS AND ACRONYMS

10 CFR	Title 10 of the *Code of Federal Regulations*
ADAMS	Agencywide Documents Access and Management System
AMP	authorized medical physicist
ANP	authorized nuclear pharmacist
ARSO	associate radiation safety officer
AU	authorized user
AUD	authorized user diagnostic
AUS	authorized user sealed source
AUT	authorized user therapy
Bq	Becquerel
CFR	*Code of Federal Regulations*
Ci	Curie
EMT	emerging medical technologies
FR	*Federal Register*
ISG	interim staff guidance
MML	master materials license
Mo-99	molybdenum-99
NMSS	Office Of Nuclear Material Safety and Safeguards
NRC	U.S. Nuclear Regulatory Commission
OP	ophthalmic physicist
RSC	radiation safety committee
RSO	radiation safety officer
Ra-226	radium-226
Rb-82	rubidium-82
Sr-82	strontium-82
Sr-90	strontium-90
SRM	staff requirements memorandum
SSD	sealed source and devices
Tc-99m	technetium-99m
T&E	training and experience
WBL	web-based licensing
WD	written directive

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1.0 PURPOSE

This document provides guidance for implementing the training and experience (T&E) requirements in Title 10 of the *Code of Federal Regulations* (10 CFR) Part 35, "Medical Use of Byproduct Material." This interim staff guidance (ISG) is intended for use by licensees or applicants who are seeking to add individuals to their license as authorized individuals including authorized users (AUs), radiation safety officers (RSOs), associate radiation safety officers (ARSOs), authorized nuclear pharmacists (ANPs), authorized medical physicists (AMPs), or ophthalmic physicists (OPs).

This ISG also provides criteria for the U.S. Nuclear Regulatory Commission (NRC) staff and Agreement State regulators to evaluate such applications or license amendment requests. It 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, it explains expectations for how these individuals fulfill the T&E requirements.

This ISG:

- identifies the information needed to demonstrate necessary T&E for individuals to be listed as AUs, RSOs, ARSOs, ANPs, AMPs and OPs on an NRC license.
- provides step-by-step instructions for adding authorized individuals on a medical-use license.
- contains information on specialty board certifications recognized by the NRC.
- identifies the information and supporting documentation needed to complete an NRC Form 313A.
- provides completed sample NRC Forms 313A and examples of supporting documents that licensee and applicants may refer to when developing their license requests.
- offers suggested examples of responses for various blocks on the NRC Form 313A series.

As stated in NRC's Medical Policy Statement, NRC regulates the use of radionuclides in medicine to ensure radiation safety of workers and the general public. The NRC does not interfere with medical judgements affecting patients, except when necessary to ensure radiation safety for workers and the general public. When justified by the risk to patients, the NRC will regulate the radiation safety of patients primarily to assure that the use of radionuclides is in accordance with the physician's directions; and, in developing a specific regulatory approach, will consider industry and professional standards that define acceptable approaches of achieving radiation safety.

2.0 APPLICABILITY AND USE

The NRC issues ISGs to clarify or address issues not covered in existing guidance. Guidance is issued by the NRC to describe methods that the NRC staff considers acceptable for implementing and complying with specific parts of the agency's regulations. This ISG is not a substitute for NRC or Agreement State regulations. Therefore, approaches and solutions that differ from those described in this guidance may also be deemed acceptable if they satisfy 10 CFR Part 35 T&E requirements and provide a suitable basis for licensing staff to make the

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necessary determinations for approving individuals as AUs, RSOs, ARSOs, ANPs, AMPs, and OPs. Licensees are free to propose alternative ways of demonstrating compliance with these requirements.

Applicants and staff should use this ISG in addition to the existing applicable guidance (e.g., NUREG-1556, Volume 9, Revision 3, etc.) until it is superseded or incorporated in other guidance or rulemaking. NRC staff intends to update guidance on the implementation of 10 CFR Part 35 T&E requirements when the rulemaking to establish requirements for Rubidium (Rb)-82 generators and emerging medical technologies (EMT) is completed. At the time of issuance of this ISG, the Rb-82 generators and EMT rulemaking is expected to be finalized in 2027.

An individual who accesses an electronic version of this guidance document can navigate by clicking on the hyperlinks for each section listed in the Table of Contents. Hyperlinks also appear throughout the guidance to enable the reader to go directly to reference material or sections of the rule.

Certain States, called Agreement States, have entered into agreements with the NRC that give them the authority to license and inspect byproduct, source, and special nuclear materials, in quantities not sufficient to form a critical mass, which are used or possessed within their borders. Any licensee or applicant, other than a Federal entity, that wishes to possess or use licensed material in one of these Agreement States should contact the responsible officials in that State for guidance on implementing these regulations.

Some sources of basic information about T&E for use by applicants and licensees include the following:

- 10 CFR 35.2, 35.12, 35.13, 35.14, 35.24, 35.26, 35.27 35.50, 35.51, 35.55, 35.57, 35.59, 35.190, 35.290, 35.390, 35.392, 35.394, 35.396, 35.490, 35.491, 35.590, 35.690
- NUREG-1556, Volume 9, Revision 3 "Consolidated Guidance About Materials Licenses: Program-Specific Guidance About Medical Use Licenses"
- NUREG-1516, "Management of Radioactive Material Safety Programs at Medical Facilities"
- Medical Uses Licensee Toolkit
- NRC Forms 313A series
- Specialty Board Certification Recognized by the NRC Under 10 CFR Part 35
- Final Rule "Medical Use of Byproduct Material—Medical Event Definitions, Training and Experience, and Clarifying Amendments," published as a final rule on July 16, 2018 (83 FR 33046)
- Final Rule "Medical Use of Byproduct Material," published as a final rule on April 24, 2002 (67 FR 20250)
- SECY-20-0005: "Rulemaking Plan for Training and Experience Requirements for Unsealed Byproduct Material (10 CFR Part 35)"
- SRM-SECY-20-0005: "Rulemaking Plan for Training and Experience Requirements for Unsealed Byproduct Material (10 CFR Part 35)"

3.0 BACKGROUND

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The NRC's regulations require that individuals complete T&E criteria to be authorized for the medical use of byproduct material and to independently fulfill the radiation safety-related duties of an AU, RSO, ARSO, ANP, AMP and OP.

The T&E requirements have evolved over the years in response to changes in medical practice, and to ensure that access to patient care is not affected by changes in the medical arena. In SRM-SECY-20-0005, "Rulemaking Plan for Training and Experience Requirements for Unsealed Byproduct Material (10 CFR Part 35)," the Commission directed the staff to develop implementation guidance to clarify the roles and responsibilities of individuals subject to T&E requirements and to clarify how individuals will fulfill these requirements. Guidance on medical T&E criteria found in NUREG-1556, Volume 9, Revision 3 "Consolidated Guidance About Materials Licenses: Program-Specific Guidance About Medical Use Licenses, Final Report." is periodically updated concurrent with any regulatory changes. However, in the interim until the next rulemaking, and given the types of questions that NRC and Agreement State staff routinely receive regarding T&E requirements, the NRC staff has determined that supplemental guidance would benefit individuals applying for authorized individual status and that this ISG should address the following in response the Commission's direction:

- expectations for individuals that are subject to the T&E requirements (e.g., supervision)
- training, including equivalency of hours, recentness of training, and vendor- and device-specific training; preceptors and their role in T&E requirements
- multiple authorizations (e.g., AUs or AMPs who can also serve as RSOs)
- completing NRC Form 313A series and supporting documentation

4.0 GUIDELINES

To ensure high levels of safety, medical use licensees are required to have highly qualified and experienced personnel who are knowledgeable about the technical and administrative safety requirements. The following guidelines are designed to help individuals who are interested in becoming an AU, AMP, OP, ANP, RSO, or ARSO.

4.1 Authorized Individuals and Other Individuals Involved in Implementing the Program

REGULATORY REQUIREMENTS:

10 CFR 35.2, 35.12, 35.24, 35.26, 35.27, 35.50, 35.51, 35.55, 35.57, 35.59, 35.190, 35.290, 35.390, 35.392, 35.394, 35.396, 35.400, 35.490, 35.491, 35.690

OTHER REFERENCES:

- NUREG-1516, "Management of Radioactive Material Safety Programs at Medical Facilities"
- NUREG-1556, Volume 9, Revision 3 "Consolidated Guidance About Materials Licenses: Program-Specific Guidance About Medical Use Licenses," Section 8.7, "Item 7: Individual(s) Responsible for the Radiation Safety Program and Their Training and Experience"

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- NUREG-1556, Volume 9, Revision 3 "Consolidated Guidance About Materials Licenses: Program-Specific Guidance About Medical Use Licenses," Section 8.7.1, "Radiation Safety Officer (RSO) and Associate Radiation Safety Officers (ARSOs)"
- NUREG-1556, Volume 9, Revision 3 "Consolidated Guidance About Materials Licenses: Program-Specific Guidance About Medical Use Licenses," Figure 8-2, "Licensing Examples of Potential Radiation Safety Officer (RSO) and Associate Radiation Safety Officer (ARSO) Arrangements"
- NUREG-1556, Volume 9, Revision 3 "Consolidated Guidance About Materials Licenses: Program-Specific Guidance About Medical Use Licenses," Appendix I, "Radiation Safety Officer Duties, Responsibilities, and Delegation"

EXPLANATION:

An authorized individual is a person (i.e., an AU, AMP, ANP, RSO, ARSO, or OP as defined in 10 CFR 35.2)–

- with T&E that meets the applicable regulatory training requirements in 10 CFR Part 35 and has been reviewed and approved by the NRC or Agreement States; or

- identified as an authorized individual on an NRC or Agreement State radioactive materials medical use license or permit (that authorizes the medical use of byproduct material) or nuclear pharmacy license or permit (that authorizes the medical use or the practice of nuclear pharmacy) and is able to independently fulfill specific radiation safety-related duties.

Although the regulations in 10 CFR 35.2 do not specifically define the term "authorized individual," it defines each specific type of authorized individuals (AU, AMP, ANP, RSO, ARSO, and OP) that may be listed on a license or permit. The term "authorized individual" is generally used to refer to these specific individuals.

4.1.1 Purpose of an Authorized Individual

An authorized individual is responsible for ensuring that radioactive materials are handled and used safely and in accordance with NRC and Agreement State regulations, and the terms and conditions of the license or permit. An authorized individual is also responsible for carrying out the applicable duties and functions associated with the license or permit.

An authorized individual may have multiple authorizations and may serve as more than one type of authorized individual (Section 4.5, "Authorized individuals Seeking to Become an RSO/ARSO Under a Current or New License").

4.1.2 Roles and Responsibilities

The regulations in 10 CFR 35.24 provide the requirements for the authority and responsibilities for the licensee's radiation protection program, including the licensee's management, the RSO, and other personnel that have a role in the radiation protection program (i.e., ARSOs, AUs, AMPs, ANPs, OPs, and members of the Radiation Safety Committee (RSC) if an RSC is required).

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Licensees are responsible for their radiation protection programs and the conduct of licensed activities. Each authorized individual has a role and is responsible for implementing certain aspects of the radiation protection program in accordance with the authorizations on the approved license or permit. Section 8.7, "Item 7: Individual(s) Responsible for the Radiation Safety Program and Their Training and Experience," of NUREG-1556, Volume 9, Revision 3, includes a detailed description of the responsibilities of the licensee and licensee management, as well as the roles and responsibilities of each authorized individual.

Licensee and Licensee Management

- The licensee is responsible for the conduct of licensed activities and the licensee's management has the ultimate responsibility for the radiation protection program.

- Licensees shall have management oversight in place to ensure that licensed activities are in accordance with the regulations and the licensee's procedures. The regulations in 10 CFR 35.2 define "management" as the chief executive officer or other individual that has the authority to manage, direct, or administer the licensee's activities, or those persons' delegate or delegates. The responsibilities and duties of management are included in certain other regulations in 10 CFR Part 35 (e.g., 10 CFR 35.12, 35.24, 35.26).

- Licensee management can delegate tasks or duties, but not the responsibility, to a management delegate.

- Licensee management must approve requests (in writing) for a license application, renewal, or amendment before submittal to the NRC of: (i) any individual before allowing that individual to work as an RSO or ARSO, AU, ANP, AMP, or OP; and (ii) radiation protection program changes that do not require a license amendment and are permitted under 10 CFR 35.26.

- The licensee's management must appoint an RSO, who agrees, in writing, to be responsible for implementing the radiation protection program. Licensee management must provide the RSO sufficient authority, organizational freedom, time, resources, and management prerogative to communicate with personnel and direct personnel regarding NRC regulations and license provisions, including: (i) identifying radiation safety problems; (ii) initiating, recommending, or providing corrective actions; (iii) stopping unsafe operations; and (iv) verifying the implementation of corrective actions. Although not required, the licensee's management may appoint one or more ARSOs to support the RSO.

- The licensee is responsible for ensuring that individuals working under the supervision of an AU or ANP have or are provided adequate T&E in accordance with 10 CFR 35.27 (see Section 4.2, "Supervision").

- Licensees may contract for medical use services, including those involving patient services. However, the licensee should not assume that, by hiring a contractor (e.g., consultant) to provide certain services, it has satisfied all regulatory requirements or that it has transferred responsibility for the licensed program to the contractor. Licensee management should ensure that adequate mechanisms for oversight are in place to

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determine that the radiation protection program, including the training of contractor staff, is effectively implemented by the appropriate individuals.

Radiation Safety Committee (RSC)

- Not all licensees are required to have an RSC. Licensees that are authorized for two or more different types of uses of byproduct material under 10 CFR Part 35 Subparts E, F, and H, or two or more types of units under Subpart H are required under 10 CFR 35.24(f) to establish an RSC to oversee all uses of byproduct material permitted by the license. Membership in the committee must include an AU for each type of use permitted by the license, the RSO, a representative of the nursing service, and a representative of management who is neither an AU nor the RSO. The committee may include other members the licensee considers appropriate.

- If the licensee is not required under 10 CFR 35.24(f) to create an RSC, but still decides to establish this committee, then the RSC functions as management directs, and it's duties are as assigned.

Radiation Safety Officer (RSO)

- A licensee is required to have an RSO who has been appointed by licensee management and agrees in writing to be responsible for implementing the radiation protection program in accordance with 10 CFR 35.24. The licensee must provide the RSO sufficient authority, organizational freedom, time, resources, and management prerogative to perform his or her duties. Additionally, the RSO must have a sufficient commitment from management to fulfill the duties and responsibilities specified in 10 CFR 35.24 to ensure that radioactive materials are used in a safe manner.

- The RSO identified on a license or permit is responsible for overseeing and ensuring the safe operation of the licensee's entire radiation protection program, and that radiation safety activities are being performed in accordance with licensee-approved procedures and regulatory requirements. The NRC requires the name of the RSO to be listed on the license to ensure that licensee management always has a responsible, qualified person identified and that the named individual knows of their designation as RSO.

- Every license is limited to one RSO, but there may be more than one ARSO, or more than one temporary RSO in accordance with 10 CFR 35.24.

- If the RSO is placed in the licensee management structure and meets the criteria of "management" as defined in the regulations in 10 CFR 35.2, then actions of the RSO may be considered actions of management. However, if the licensee has a RSC, the RSO is prohibited by 10 CFR 35.24(f) from serving as the management representative on the committee.

- The RSO, with written agreement from licensee management, may delegate or assign duties and tasks to each ARSO that are limited to the types of use for which the ARSO is listed on the license, but shall not delegate the authority or responsibilities for implementing the radiation protection program (10 CFR 35.24(b)).

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- An AU, AMP, or ANP listed on a license or permit may be designated and can serve as the RSO or ARSO on the license if the individual has experience with the radiation safety aspects of similar types of byproduct material use for which that individual will have RSO responsibilities or ARSO duties and tasks and as required by 10 CFR 35.24.

- A nuclear medicine technologist can be an RSO if he or she has successfully completed all of the T&E requirements in 10 CFR 35.50 and agrees, in writing, to be responsible for implementing the radiation protection program.

- The RSO is often directly employed by the licensed facility. However, the NRC allows authorized individuals who are not directly employed by the licensee, such as consultants, to fill the role of RSO or to provide support to the facility RSO. To fulfill the duties and responsibilities, the RSO should be onsite periodically to conduct meaningful, person-to-person interactions with licensee staff, commensurate with the scope of licensed activities, to satisfy the requirements of 10 CFR 35.24.

- A licensee must apply for and receive approval via a license amendment, before an individual can begin duties as a permanent RSO for an existing license in accordance with 10 CFR 35.13. A licensee may also appoint individuals as temporary RSOs under the license for up to 60 days each year without prior NRC approval in accordance with 10 CFR 35.14. A license amendment is not needed for a temporary RSO to begin performing the duties of the RSO, but the licensee must notify the NRC no later than 30 days after permitting a qualified individual to function as the temporary RSO. To be so appointed, an individual must either be qualified to be an RSO or be an AMP, ANP, or AU identified on the licensee's license and have experience with the radiation safety aspects of similar types(s) of use(s) of byproduct material for which the individual will have RSO responsibilities. If necessary, for complete radiation safety coverage of activities conducted under the license, the licensee may simultaneously appoint more than one temporary RSO to be responsible for assigned program areas.

- The RSO is responsible for the day-to-day oversight of the entire radiation safety program and has independent authority to stop operations that the RSO considers unsafe. The RSO must have adequate training to understand the hazards associated with radioactive material and be familiar with all applicable regulatory requirements. The RSO duties and responsibilities include ensuring radiological safety, security, and compliance with both the NRC and the U.S. Department of Transportation (DOT) regulations and the conditions of the license. Typically, these duties and responsibilities include the following:

    - Stop unsafe activities involving licensed material.
    - Ensure that radiation exposures are kept as low as is reasonably achievable (ALARA).
    - Oversee all activities involving radioactive material, including monitoring and surveying all areas in which radioactive material is used or stored.
    - Ensure that up-to-date operating, emergency, and security procedures are developed, implemented, maintained, and distributed, as appropriate.
    - Maintain an inventory of all radioactive material, as required. Ensure that possession, use, and storage of licensed material are consistent with the limitations in the license, the regulations, the Sealed Source and Device (SSD)

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registration certificate(s), and the manufacturer's recommendations and instructions.

- Oversee and coordinate the receipt, opening, and delivery of all packages of radioactive material arriving at the facility. This includes radiation surveys of all shipments arriving or leaving the facility, as well as packaging and labeling of radioactive material leaving the facility.
- Ensure individuals installing, relocating, maintaining, adjusting, or repairing devices containing sealed sources are trained and authorized by an NRC or Agreement State license.
- Ensure personnel training is conducted and is commensurate with the individual's duties regarding licensed material.
- Ensure documentation is maintained to demonstrate that individuals are not likely to receive, in one year, a radiation dose more than 10 percent of the allowable limits or that personnel monitoring devices are provided.
- Ensure personnel monitoring devices are used and exchanged at the proper intervals, and personnel radiation exposure and bioassay records are monitored, reviewed, and maintained, when necessary. Individuals are notified when radiation exposures are approaching established limits and appropriate corrective actions are taken.
- Properly secure radioactive material from unauthorized use or access.
- Support development and implementation of a security program for radioactive material in accordance with 10 CFR Part 37, "Physical Protection of Category 1 and Category 2 Quantities of Radioactive Material," if the licensee possesses an aggregated Category 1 or Category 2 quantity of radioactive material.
- Ensure documentation is maintained to demonstrate, by measurement or calculation, that the total effective dose equivalent to the individual member of the public likely to receive the highest dose from the licensed operation does not exceed the annual limit in 10 CFR 20.1301, "Dose limits for individual members of the public."
- Notify proper authorities of incidents, such as damage to or malfunction of sources/devices, excess breakthrough values for Mo-99/Tc-99m or Sr-82/Rb-82 generators, loss of licensed material, fire, theft.
- Serve as a point of contact for the NRC's and licensee's management during routine operations, emergencies, or incidents.
- Investigate and report to the NRC medical events and precursor events, identify cause(s) and appropriate corrective action(s), and ensure timely corrective action(s) are taken.
- Perform and document periodic audits, at least annually, of the radiation safety program to ensure that the licensee is complying with all applicable NRC regulations and the terms and conditions of the license.
- Ensure that the results of audits, identification of deficiencies, and recommendations for change are documented (and maintained for 3 years after the record is made) and provided to management for review; ensure that prompt action is taken to correct deficiencies.
- Ensure that the audit results and corrective actions are communicated to all personnel who use licensed material.
- Ensure corrective action(s) are developed, implemented, and documented when the licensee identifies violation(s) of regulations or license conditions or program weaknesses.
- Ensure that all incidents, accidents, and personnel exposure to radiation more than the 10 CFR Part 20 and 10 CFR Part 30 limits are investigated, their

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cause(s) are identified, appropriate corrective action(s) are implemented, and reports are submitted to NRC and other appropriate authorities, if required, within the required time limits.
    - Ensure that licensed material is transported, or offered for transport, in accordance with all applicable NRC and DOT requirements.
    - Ensure that radioactive waste is disposed of in accordance with NRC regulations and license conditions. Supervise and coordinate the radioactive waste disposal program, including effluent monitoring and recordkeeping on waste storage and disposal records. Oversee the storage of radioactive material not in current use, including waste.
    - Perform/oversee the inventory and leak testing on all sealed sources.
    - Oversee the calibration of radiation survey instruments.
    - Supervise decontamination operations.
    - Maintain up-to-date copies of NRC regulations, the license, revised licensee procedures, and ensure that the license is amended whenever there are changes in licensed activities, responsible individuals, or information or commitments provided to the NRC during the licensing process.
    - Submit amendment and renewal requests in a timely manner.
    - Assign tasks and duties to an ARSO, if applicable.

Associate Radiation Safety Officer (ARSO)

- A licensee may appoint one or more ARSOs to support the RSO. Effective January 19, 2019, and in accordance with the Final Rule "10 CFR Parts 30, 32 and 35 - Medical Use of Byproduct Material - Medical Event Definitions, Training and Experience, and Clarifying Amendments" (83 FR 33046), the regulations were amended to allow for ARSOs to be named on a medical license.

- An ARSO identified on a license or permit is responsible for the duties and tasks as assigned by the RSO, with written agreement from the licensee's management. Licensees with multiple program operating locations or multiple types of use can appoint a qualified ARSO at each location or for each type of byproduct material used. NRC requires that the ARSO be listed on the license to avoid confusion between individuals working in a radiation program and those that meet uniform T&E criteria and are formally delegated duties and task for oversight of parts of the radiation safety program. To be recognized as an ARSO by the NRC and Agreement States, the individual must meet clear and concise T&E requirements. As ARSOs have the same T&E requirements as an RSO, the ARSOs will qualify to be recognized by Agreement States and NRC to be named as RSOs or ARSOs on other licenses, for the same types of medical uses for which they are listed, without resubmitting those individuals' T&E documents.

- The ARSO cannot assume any RSO responsibilities unless the licensee designates, in writing, the ARSO as a temporary RSO.

- An ARSO may supervise and serve as a preceptor for an individual seeking to be named as the RSO or ARSO, but only for those medical uses for which the preceptor is authorized. For an individual to be named on a license as an ARSO, the individual must have experience in the radiation safety aspects of similar types of medical byproduct material use for which the applicant seeks the approval of the ARSO.

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- The term *Assistant* RSO is not recognized by the NRC under 10 CFR Part 35.

Authorized User (AU)

- An AU involved in medical use is responsible for radiation safety commensurate with use of byproduct material; administration of a radiation dose or dosage and how it is prescribed; direction of individuals under the AU's supervision in the preparation of byproduct material for medical use and in the medical use of byproduct material; and preparation of written directive (WD), if required.

- There is no NRC requirement that an AU must render an interpretation of a diagnostic image or results of a therapeutic procedure. The NRC recognizes that the AU may or may not be the physician who interprets such studies. Additionally, NRC regulations do not restrict who can read and interpret diagnostic scans or the results of therapeutic procedures involving the administration of byproduct material to individuals.

- Medical use as, defined under 10 CFR 35.2, is the intentional internal or external administration of byproduct material or radiation from byproduct material to patients or human research subjects under the supervision of an AU (see Section 4.2, "Supervision"). Individuals authorized for non-medical uses are sometimes called non-medical AUs. Non-medical uses are uses not intended for intentional exposure of humans (e.g., non-human – *in* vitro and animal research, certain types of calibration, and other types of uses under 10 CFR 35.65). A non-medical AU is not an AU as defined in 10 CFR 35.2, although an individual could serve as both a medical AU and a non-medical AU.

Authorized Medical Physicist (AMP)

- An AMP identified on a license or permit is responsible for calculations and other tasks associated with the administration of the radiation dose, including certain tasks associated with performing ophthalmic radiation therapy treatments as described in 10 CFR 35.433(b).

- An AMP is responsible for assisting the licensee in developing, implementing, and maintaining written procedures to provide high confidence that the administration is in accordance with the WD.

Ophthalmic Physicist (OP)

- An OP identified on a license or permit is responsible for calculating the activity of each Strontium-90 (Sr-90) source that is used to determine treatment times.

- An OP is responsible for assisting the licensee in developing, implementing, and maintaining written procedures to provide high confidence that the administration is in accordance with the WD.

- Although an OP performs the same tasks as described in 10 CFR 35.433(b) as does an AMP, the OP and AMP have different T&E requirements." (see Section 4.3, "Training").

Authorized Nuclear Pharmacist (ANP)

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- An ANP identified on a license or permit is responsible for the preparation of radiopharmaceuticals under the provisions of 10 CFR 35.100(b), 35.200(b), 35.300(b) or 35.1000 licensing guidance found at NRC's Medical Uses Licensee Toolkit web page.

4.2 Supervision

REGULATORY REQUIREMENTS:

10 CFR 19.12, 10 CFR 35.2, 35.11, 35.27

OTHER REFERENCES:

- NUREG-1556, Volume 9, Revision 3 "Consolidated Guidance About Materials Licenses: Program-Specific Guidance About Medical Use Licenses," Section 8.8, "Training for Individuals Working in or Frequenting Restricted Areas"
- NUREG-1556, Volume 9, Revision 3 "Consolidated Guidance About Materials Licenses: Program-Specific Guidance About Medical Use Licenses," Appendix J, "Model Training Program"
- "Supplementary Information," Section III, "Summary of Public Comments and Responses to Comments" for §35.27, as published in the Federal Register on April 24, 2002 (67 FR 20250)
- Revised 10 CFR Part 35, "Medical Use of Byproduct Material," published as a proposed rule on August 13, 1998 (63 FR 43516) and as a final rule on April 24, 2002 (67 FR 20250)

EXPLANATION:

The regulations in 10 CFR 35.11, "License Required," permits licensees to allow individuals who are neither AUs nor ANPs to performed certain tasks under the Supervision of an AU or an ANP that is named on an NRC or Agreement State license, or permit. The regulations in 10 CFR 35.27, "Supervision," provide training and oversight requirements for individuals working under the supervision of either an ANP or AU. The licensee is responsible for assuring that all supervised individuals have been properly trained and instructed in accordance with direction, instruction, and oversight provided by the AU or ANP. The requirements for supervision do not require the physical presence of the authorized individual or that the authorized individual be physically present at all times during the use or preparation of such materials.

Only AUs and ANPs identified on a medical use license under 10 CFR Part 35, are authorized to use or prepare byproduct material in the practice of medicine. Medical use—as defined in 10 CFR 35.2 as including the receipt, possession, or transfer, of byproduct material—must be under the supervision of an AU in accordance with 10 CFR 35.27. All medical preparation of byproduct material for medical use must be under the supervision of an ANP or an AU.

AUs and ANPs are best suited for determining tasks that supervised individuals can perform and the degree of supervision that each individual needs. It is frequently necessary for an AU or ANP to delegate specific to others who are not authorized individuals for the use or preparation of byproduct material for medical use. These provisions do not require notification of the NRC that an AU has delegated tasks associated with the medical use of byproduct material to another individual under the AU's supervision, e.g., tasks such as package receipt;

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radiopharmaceutical preparation and administration; and disposal of the radioactive waste. The supervisor or supervising individual is referred to as the “supervising AU” or “supervising ANP”, and the individual being supervised is referred to as the “supervised individual” or “individual under the supervision of an AU or ANP.”

In addition to the requirements in 10 CFR 19.12, the regulations in 10 CFR 35.27 require that instructions be given to supervised individuals in written radiation protection procedures, WD procedures, regulations, and license conditions with respect to the use of byproduct material. The instructions may be provided in various ways, including in person training, online training, online protocol review, and other informal training. Additionally, 10 CFR 35.27 requires the supervised individual to follow the:

- instructions of the supervising AU for medical uses of byproduct material,
- instructions of the supervising ANP or supervising AU for preparation of byproduct material for medical uses, and
- written radiation protection procedures and WD procedures established by the licensee.

4.2.1 Purpose of Supervision

The requirements for supervision allow supervised individuals to receive, possess, prepare, use, and transfer byproduct material under the supervision of an authorized individual (i.e., AU or ANP). The requirements are also in place to ensure that individuals working under the supervision of an AU or ANP receive adequate training.

4.2.2 Roles and Responsibilities

Licensee

- The licensee must instruct supervised individuals in, and require supervised individuals to follow, the licensee’s written radiation protection procedures, WD procedures, applicable medical regulations, license conditions, and procedures for preparing byproduct material for medical use. The supervising authorized individual is also expected to have been instructed in these same procedures, regulations, and license conditions.
- The licensee is responsible for ensuring that both supervised and supervising individuals receive adequate and applicable training.
- The licensee is not only responsible for the acts and omissions of the supervised individual, but also for the acts and omissions of the supervising individual.
- The licensee is responsible for ensuring that the T&E of individuals working under the supervision of an AU or ANP is adequate.

Supervising AU or Supervising ANP

- An AU or ANP may delegate specific to others who are not authorized individuals for the use or preparation of byproduct material for medical use.

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- A supervising individual that provides supervised work experience for a potential authorized individual may also serve as the preceptor. The preceptor does not have to be the supervising individual, as long as the preceptor directs or verifies that the required T&E was completed. See Section 4.8, “Preceptors.”

Supervised Individual or Individual under the supervision of the AU or ANP

- Nuclear Medicine Technologists, radiation therapists, or other personnel may use byproduct material for medical use under an AU’s supervision, in accordance with 10 CFR 35.27.

- Technologists, or other personnel, may prepare byproduct material for medical use under an ANP’s supervision, in accordance with 10 CFR 35.27. Preparation of byproduct material for medical use may also be performed under the supervision of a physician who is an AU.

4.3 Training

REGULATORY REQUIREMENTS:

10 CFR 30.33(a)(3), 35.50, 35.51, 35.55, 35.57, 35.59, 35.190, 35.290, 35.390, 35.392, 35.394, 35.396, 35.490, 35.590, 35.690

OTHER REFERENCES:

- NUREG-1556, Volume 9, Revision 3 "Consolidated Guidance About Materials Licenses: Program-Specific Guidance About Medical Use Licenses”
- Medical Uses Licensee Toolkit
- Specialty Board Certification Recognized by the NRC Under 10 CFR Part 35
- “Supplementary Information,” Section IV, 'Summary of Public Comments and Responses to Comments,’ Part II, 'General Issues,’ Issue 7, 'Should the term "laboratory training' be defined?" as published in the Federal Register on March 30, 2005, and Supplementary Information, Section III, "Summary of Public Comments and Responses to Comments," Part II, "General Issues," Item E, "Training and Experience," Issue 6, "How Long Should the Training Programs Be for Individuals Who Would Like To Become AUs Under "§35.190, 35.290, and 35.390?," as published in the Federal Register on April 24, 2002 (67 FR 20250)

EXPLANATION:

4.3.1 Pathways for Authorized Individual Approval

The regulations in 10 CFR Part 35 provide three primary pathways for individuals seeking to become authorized and listed on a medical use radioactive materials license to satisfy the T&E requirements and be approved and listed as an authorized individual for uses identified on a license:

- Board certification pathway

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- Alternate training and experience pathway (hereinafter referred to as the "alternate pathway")
- Prior approval on a license

Licensees or applicants should provide documentation that each individual under one pathway.

4.3.1.1 Board Certification Pathway

The applicant or licensee may use board certification pathway if the proposed new authorized individual is: a) certified by a board recognized by the NRC and listed on NRC's website for specialty board certifications as provided in 10 CFR 35.50(a), 10 CFR 35.51(a), 10 CFR 35.55(a), 10 CFR 35.190(a), 10 CFR 35.290(a), 10 CFR 35.390(a), 10 CFR 35.392(a), 10 CFR 35.394(a), 10 CFR 35.396(a), 10 CFR 35.490(a), 10 CFR 35.590(a), or 10 CFR 35.690(a), or b) certified prior to October 24, 2005, by a board listed in 10 CFR 35.57.

The applicable regulatory requirements in 10 CFR Part 35 allow for the NRC to recognize specialty boards certifications that have demonstrated meeting the requirements. The certifying board is responsible for reviewing the board applicant's qualifications to determine whether the applicant has met the requirements in the applicable requirements in 10 CFR Part 35. This pathway allows the proposed individual and licensee to submit a copy of board certificate rather than detailed information on each T&E element. *Note:* An individual that is board-eligible will not be considered for this pathway until the individual is board certified.

Individuals seeking authorization via the board certification must have a certificate from a specialty board that is recognized by the NRC. To ensure that the board certification is current, the applicant or licensee should review the sample certificate for a recognized specialty board on NRC's Medical Uses Licensee Toolkit to verify consistency with the proposed individual's certificate.

The applicant or licensee will need to provide a copy of the board certification along with other necessary documentation of T&E (e.g., clinical casework, device-specific training), as indicated on the specific form of the NRC Form 313A series.

4.3.1.2 Alternate Pathway

The required T&E under the alternate pathway is essentially equivalent to the board certification pathway for the same type of licensed use, with the exception that T&E must be acquired via a residency training program under the board certification pathway for certain types of uses. Also, the alternate pathway requires a written attestation except for individuals qualifying as AUs for sealed source for diagnosis. OPs can only qualify under the alternate pathway as the NRC does not have a regulation under which it recognizes OP boards.

The regulatory requirements refer to two main categories of training: (i) classroom and laboratory training, and (ii) supervised work experience. T&E also includes supervised clinical casework (if applicable) and device-specific training (if applicable). The applicable regulatory requirements in 10 CFR Part 35 define the required hours or number of cases for each element. All hours credited to classroom and laboratory training must relate directly to radiation safety and safe handling of byproduct material and be allocated to one of the topics in the regulations. Each hour of training involving performance of radiation safety tasks or hands-on use of byproduct material may be credited to either (i) classroom and laboratory training, or (ii)

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supervised work experience. Note that a single hour of training may only be counted once and may not be credited to both categories.

The specific number of hours needed for each T&E element will depend on the type of approval sought. On the Form 313A, the licensee/applicant should provide the number of clock hours spent on the topics listed in the regulatory requirements and ensure to document hours for each topic. If an individual seeks to credit more than 40-hours for a work week, then supplemental information should be provided to illustrate the total number of hours spent on the T&E element.

The proposed authorized individual may receive the required classroom and laboratory training, supervised work experience, and clinical casework at a single training facility or at multiple training facilities; therefore, space is provided to identify each location and date of training or experience on the Form 313A. The date should be provided in the month/day/year (mm/dd/yyyy) format.

4.3.1.3 Prior Approval on a License

Adding an authorized individual to a medical-use license or application only requires documentation (i.e. NRC license number or a copy of the license) that the individual is listed on a medical-use license issued by the NRC or Agreement State, a permit issued by an NRC MML, a permit issued by an NRC or Agreement State broad scope licensee, or a permit issued by an NRC master material broad scope permittee, provided that the individual is authorized for the same types of use(s) requested in the application under review, and the individual meets the recentness of training criteria described in 10 CFR 35.59.

4.3.2 Types of Training

There are four elements of T&E for a proposed authorized individual:

- Classroom and laboratory training
- Supervised work experience
- Supervised clinical casework
- Device-specific training

4.3.2.1 Classroom and Laboratory Training

The proposed authorized individual may obtain the required classroom and laboratory training in any number of settings, locations, and educational situations. For example, at some medical teaching/university institutions, a course may be provided for that specific need and taught in consecutive days. In other training programs, the period may be a semester or quarter as part of the formal curriculum.

Also, the classroom and laboratory training may be obtained using a variety of other instructional methods. Therefore, the NRC will broadly interpret “classroom and laboratory training” to include various types of instruction, including online training, as long as it meets the specific clock hour requirements, and the subject matter relates to radiation safety and safe handling of byproduct material for the uses requested:

- formal education (e.g., undergraduate coursework, graduate coursework, medical school coursework);

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- coursework offered by an entity such as a licensee, hospital, or vendor; or
- classroom learning activities such as lectures or laboratory learning.

For online or other training programs unfamiliar to the NRC, the training entity may be contacted by the NRC to discuss the training program components (course outline, test, mechanism to ensure proposed individual completed the training and test) and to ensure that the program satisfies the required elements.

In order for the regulatory body to determine whether the classroom and laboratory training requirements are met, the applicant may need to provide information such as a transcript, completion certificate, course description, syllabus, outline, or learning objectives. The number of hours is based on time engaged in the learning activity. For a typical collegiate course, the total number of hours of class time may be counted rather than the credit hours received for the course.

4.3.2.2 Supervised Work Experience

Supervised work experience must be performed under the supervision of an individual that is currently authorized for the type of activities for which the individual is seeking authorization. The supervised work experience for proposed physician AUs must include, but is not limited to, the subject areas listed in the applicable T&E requirements. The NRC recognizes that physicians in training may not dedicate all of their supervised work experience time specifically to the subject areas listed in the regulatory requirements (i.e., §35.290(c)(1)(ii) and §35.390(b)(1)(ii)) and will be attending to other clinical matters involving the medical use of the material (e.g., reviewing case histories or interpreting scans). Even though these clinical activities are not specifically required by the NRC, this type of supervised clinical experience may be credited toward the 'supervised work experience' category to obtain the required total of 700 hours of T&E, but not to the classroom and laboratory training category. The specific elements required for each type of authorized individual are described in the applicable sections of 10 CFR Part 35. Supervised work experience may be remote or in-person depending on the activity. For supervised work experience, a standard work week of 40 hours per week for 52 weeks per year is used to demonstrate the number of work experience hours that have been completed by an individual. Clear justification and support for claiming more than 40 hours per week should be provided to support a deviation from a standard work week.

For authorized individuals other than an AU (i.e. RSO, ARSO, ANP, AMP, OP), all the hours of applicable supervised experience should be allocated to the topics specified in the regulations. If the individual has other duties during this time period, those hours should be omitted from the summation of the work experience hours.

Note: If the proposed new authorized individual had more than one supervisor, the requested information must be provided for each supervising individual.

4.3.2.3 Supervised Clinical Casework

Individuals seeking certain authorization may be required to complete supervised clinical casework. This is considered a sub-element of the supervised work experience. For RSOs, ARSOs, ANPs, and AU's, the NRC requires that supervised clinical casework be conducted under the supervision of an authorized individual in a licensed material use program. In this case, a supervisor is an individual who provides frequent direction, instruction, and direct oversight of the student as the student completes the required work experience in the clinical use

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of byproduct material. Supervision may occur at various licensed facilities, from a large teaching university hospital to a small private practice.

The individual seeking authorization may submit a list of dates and procedure types performed under the supervision of an AU. Casework should be presented for each type of use for which the individual is seeking authorization. Casework must be completed in person. The authorizations for the supervising AU will likely be verified by the regulatory body so the applicant or licensee should submit a copy of the license for which the supervising AU is listed.

4.3.2.4 Device-Specific Training

Individuals seeking certain authorizations may need to complete device-specific training. This element refers to training that the individual has completed with the specific type of device for which they are seeking authorization. There are not a specified number of hours that must be completed. Device-specific training allows for the individual to receive training on the type of device and does not require that the training be specific to the model of the device. For example, an individual seeking authorization for HDR need not have training on the specific model for which they are seeking authorization but simply training with an HDR. It should be noted that model specific training may be required in some cases under 10 CFR 35.610(d) and or 10 CFR 35.610(e). The scope of the training may differ for each type of device. In general, the operating procedures, safety procedures, emergency procedures, operation of the device, safety of the device, and clinical use of the device shall be covered in the training. This element must be completed in-person with the device. This element may be satisfied through training provided by the vendor of the device, an AU of the device, or an AMP of the device. The authorizations for the supervising AU will likely be verified by the regulatory body so the applicant or licensee should submit a copy of the license for which the supervising AU or AMP is listed.

When device manufacturer training for units under 10 CFR 35.600 has been completed at the facility, the licensee can provide training to their own staff under the provisions of 10 CFR 35.610(d)(2) if there are no additional manufacturer upgrades that affect the operation and safety of the unit. If there are additional manufacturer upgrades that affect the operation and safety of the unit, the provisions of 10 CFR 35.610(d)(1) apply and only the device manufacturer or an individual certified by the device manufacturer to provide the training can train the licensee's staff. If the device manufacturer certifies someone on the licensee's staff to provide the training, that individual can provide the training to other licensee staff members.

4.3.3 Recentness of Training

The required T&E, including the board certification pathway, alternate pathway, and prior approval on a license, must be obtained within the 7 years preceding the date of the application, or the individual must document having completed related continuing education, and experience since obtaining the required T&E as described in 10 CFR 35.59. The NRC does not specify a certain number of hours or elements that must be included in the continuing education and experience. However, the continuing education and experience must be relevant to the duties associated with the activities for which the individual is seeking authorization. The number of hours required of continuing education and clinical experience depends on the period of time the individual has not been involved in licensed activities and how closely the individual's recent educational and work experience are related to the proposed area of medical use and is reviewed on a case-by-case basis. Acceptable continuing education and experience includes the following:

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- successful completion of classroom and laboratory review courses that include radiation safety practices relative to the proposed type of authorized medical use (this review may include various instruction, including online training, as long as the subject matter relates to radiation safety and safe handling of byproduct material for the uses requested).

- practical and laboratory experience with patient procedures using radioactive material for the same use(s) for which the applicant is requesting authorization.

- practical and laboratory experience under the supervision of an AU at the same or another licensed facility that is authorized for the same use(s) for which the applicant is requesting authorization.

- for therapy devices, experience with the therapy unit and/or comparable linear accelerator experience and completion of an in-service review of operating and emergency procedures relative to the therapy unit to be used by the applicant.

4.4 Authorized individuals Seeking to Become an RSO/ARSO

REGULATORY REQUIREMENTS:

10 CFR 35.13, 35.24, 35.50, 35.51, 35.55, 35.57, 35.59, 35.190, 35.290, 35.390, 35.392, 35.394, 35.433, 35.490, 35.590, 35.690

OTHER REFERENCES:

- "Authorized Individuals" of the Medical Uses Licensee Toolkit
- NUREG-1556, Volume 9, Revision 3 "Consolidated Guidance About Materials Licenses: Program-Specific Guidance About Medical Use Licenses"

EXPLANATION:

Regulations, under 10 CFR 35.50(c)(2), allows an individual who is an AU, AMP, or ANP identified on a medical license or permit to request authorization as the RSO or ARSO on a license or permit when the individual has experience with the radiation safety aspects of similar types of byproduct material for which the individual will have RSO responsibilities or ARSO duties and tasks. This individual has training in the radiation safety, regulatory issues, and emergency procedures for the types of use for which a licensee seeks approval. The proposed AU, AMP, or ANP must also meet the recentness of training criteria described in 10 CFR 35.59.

An individual who is not yet been named as an AU on a medical license or permit, but is qualified to be an AU, may apply for and be authorized simultaneously as the RSO and the AU on the same new medical use license (10 CFR 35.50(c)(3)). The individual must have experience with radiation safety aspects of the types of use of byproduct material for which the individual is seeking simultaneous authorization, and training in the radiation safety, regulatory issues, and emergency procedures for the types of use for which a licensee seeks approval (10 CFR 35.50(d)). A proposed AU seeking authorization under the alternate pathway must also obtain a written attestation signed by a preceptor RSO, that the individual:

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has satisfactorily completed the required T&E and has achieved a level of radiation safety knowledge sufficient to function independently as an RSO for a medical use licensee. The proposed AU must meet the recentness of training criteria described in 10 CFR 35.59.

4.5 Documentation of T&E to Identify Proposed Authorized Individuals on a License

REGULATORY REQUIREMENTS:

10 CFR 35.2, 35.13, 35.50, 35.51, 35.55, 35.57, 35.59, 35.190, 35.290, 35.390, 35.392, 35.394, 35.396, 35.490, 35.491, 35.590, 35.690

OTHER REFERENCES:

- NUREG-1556, Volume 9, Revision 3 "Consolidated Guidance About Materials Licenses: Program-Specific Guidance About Medical Use Licenses"
- Medical Uses Licensee Toolkit
- NRC Form 313A series
- Emerging Medical Technologies website

EXPLANATION:

There are multiple individuals that may be involved in the process of demonstrating T&E for an individual seeking authorization. The proposed authorized individual should be responsible for gathering relevant documentation that demonstrates fulfillment of the requirements, preparing the necessary paperwork, and working with other individuals such as preceptors, residency coordinators, and/or supervising individuals as necessary. Some institutions may rely on the RSO, a physicist, or management to provide assistance and guidance to the proposed authorized individual.

It is important for preceptors, residency coordinators, and supervising individuals to note that the NRC does not assess medical competency of any authorized individual. The NRC solely reviews T&E related to the radiation safety responsibilities of authorized individuals. Additional discussion on this topic can be found in Section 4.8.1 of this ISG.

4.5.1 Adding New Authorized Individuals

Per 10 CFR 35.12, licensees are to use NRC Form 313, "Application for Materials License" for license applications, amendments or renewals, or a letter containing information required by NRC Form 313 for amendments or renewals. Licensees should use the most current version of the applicable NRC Form 313A to document T&E for adding an authorized individual to its license. Refer to the NRC Medical Uses Licensee Toolkit web page or the NRC Forms web page for the most current version of the forms and their associated instructions. Verify that the most current version of the NRC Forms 313A is being used by checking the "Expires" date in the right, top-hand corner of the form. Additionally, Appendix A of this ISG provides the necessary documentation that should be submitted with each the various NRC Forms 313A for different scenarios. The following are the six current NRC Form 313As which can be used by a licensee to document T&E to request authorization for different individuals:

- NRC Form 313A (RSO) - Radiation Safety Officer & Associate Radiation Safety Officer
- NRC Form 313A (AMP) - Authorized Medical Physicist and Ophthalmic Physicist

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- NRC Form 313A (ANP) - Authorized Nuclear Pharmacist
- NRC Form 313A (AUD) - Authorized User requesting authorization for diagnostic uses defined under 10 CFR 35.100, 10 CFR 35.200, or 10 CFR 35.500.
- NRC Form 313A (AUT) - Authorized User requesting authorization for use of unsealed radioactive material for therapy defined under 10 CFR 35.300
- NRC Form 313A (AUS) - Authorized User requesting authorization for use of sealed sources defined under 10 CFR 35.400 or 10 CFR 35.600

The forms are specific to medical-use licensees. Non-medical licensees must provide similar information although there is not a specific form for these licensees.

At the time of this guidance, there is not a specific 313A form for an AU requesting authorization use for radioactive material defined under 10 CFR 35.1000. The T&E requirements for 10 CFR 35.1000 medical uses are determined on a case-by-case basis. NRC has developed licensing guidance, including T&E guidance, for certain 10 CFR 35.1000 medical uses, which is available on the NRC's "Emerging Medical Technologies" website.

It is important to note that the communication to the regulatory authority must come from the license holder (or licensee), not the individual seeking approval as an authorized individual. The licensee is the responsible entity and is responsible for authorized individuals working under its license. Guidance on preparing amendment requests and notifications can be found the NUREG-1556 Volume 9, Revision 3.

4.5.2 Adding Experienced Authorized Individuals

An applicant or licensee who is adding an experienced AU for medical uses, AMP, OP, ANP, RSO or ARSO to its medical use license or application should provide a copy of the license or permit listing the applicant. This may be a medical-use license issued by the NRC or Agreement State, a permit issued by an NRC MML, a permit issued by an NRC or Agreement State broad scope licensee, or a permit issued by an NRC master material broad scope permittee, provided that the individual is authorized for the same types of use(s) requested in the application under review, and that the individual meets the recentness of training criteria described in 10 CFR 35.59.

When adding an experienced ANP to the license, the applicant also may provide evidence by supplying a license or permit that the individual is listed on an NRC or Agreement State commercial nuclear pharmacy license or identified as an ANP by a commercial nuclear pharmacy authorized to identify ANPs. For individuals who have been previously authorized by, but not currently listed on, the commercial nuclear pharmacy license, medical broad scope license, or MML medical broad scope permit, the applicant should submit either verification of previous authorizations granted or evidence of acceptable T&E.

Some situations may only require a notification by the licensee to the regulatory authority. For example, if a proposed authorized individual is identified as an AMP, OP, ANP, or AU for a medical use on an Agreement State license, a license amendment is not needed to permit the individual to begin work as an authorized individual under the NRC license (See 10 CFR 35.13(b) and 10 CFR 35.57). For licensees other than those possessing a Type A specific license of broad scope for medical use (issued under 10 CFR Part 33), the licensee is required by 10 CFR 35.14(a) to notify and provide to the NRC within 30 days of the individual beginning work for the licensee as an AMP, OP, ANP, or AU a copy of: 1) the license; or 2) the

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permit; or 3) the board certification and along with documentation verifying completion of additional training under 10CFR 35.51(c) for an AMP; additional case experience required in 10 CFR 35.390(b)(1)(ii)(G) for an AU under 10 CFR 35.300; or device-specific training in 10 CFR 35.690(c) for an AU under 10 CFR 35.600.

4.5.3 Adding Experienced Authorized Individuals Who Only Used Accelerator-Produced Nuclear Materials, or Discrete Sources of Ra-226, or Both, for Medical or Nuclear Pharmacy Uses

Regulations in 10 CFR 35.57(a)(4) and 10 CFR 35.57(b)(3) allow "grandfathering" of RSOs, physicians, podiatrists, dentists, medical physicists, and nuclear pharmacists that used only accelerator-produced radioactive materials, discrete sources of radium (Ra)-226, or both for medical or nuclear pharmacy uses at a Government agency or federally recognized Indian Tribe before November 30, 2007, or at all other locations of use before August 8, 2009, or an earlier date as noticed by the NRC, when using these materials for the same uses. The applicant or licensee that is adding one of these experienced individuals to its medical-use license should document that the individual used only accelerator-produced radionuclides, or discrete sources of Ra-226, or both, for medical or nuclear pharmacy uses before or during the dates specified and that the materials were used for the same uses requested. This documentation may be, but is not restricted to, evidence that the individual was listed on an Agreement State or NRC license or permit authorizing these materials for the requested uses.

4.5.4 Recognition of Foreign Trained Physicians and Physicists

For foreign trained physicians who received their training outside of the United States, the following must be provided to the regulator as evidence of meeting the T&E requirements.

- License from a State or Territory of the United States, the District of Columbia, or the Commonwealth of Puerto Rico to prescribe drugs in the practice of medicine

- Documentation of the work experience that was completed under the supervision of an AU who meets the applicable T&E requirements in 10 CFR Part 35, and
    - A copy of the license or permit that lists the supervisor as an AU for the uses requested.

- A written attestation signed by a preceptor AU who meets the applicable T&E requirements in 10 CFR Part 35.
    - A copy of the license or permit that lists the preceptor as an AU for the uses requested.

The supervising AU and the preceptor AU must be a physician licensed to practice medicine in the U.S., or a Territory of the U.S., or Puerto Rico.

For foreign trained physicists who received their training outside of the United States, the following must be provided to the regulator as evidence of meeting the T&E requirements:

- The masters and/or doctoral degrees from outside of the US are from an accredited college or university. This should include submission of the diploma and transcript demonstrating that the degree was issued. The licensee should verify that the college/university is accredited. The licensee should also refer to the web site for the

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International Organization for Medical Physicists which provides a global listing of graduate education programs in medical physics and the associated accreditation status.

- The licensee should ensure that foreign degrees other than physics, medical physics, other physical science, engineering and applied mathematics are equivalent to one of these listed degrees. The licensee should provide a transcript (or equivalent documentation) from the applicant and ensure that this documentation be provided in English.

- Documentation of the work experience that was completed under the supervision of an individual who meets the requirements for an AMP in 10 CFR 35.51 for the type(s) of use for which the individual is seeking authorization.

- A written attestation is signed by a preceptor AMP who meets the applicable T&E requirements in 10 CFR 35.51 for each type of therapeutic medical unit for which the individual is requesting to become an AMP.

- A copy of the license or permit that lists the supervising individual and preceptor.

4.6 General Instructions for Completing the NRC Form 313A Series.

REGULATORY REQUIREMENTS:

10 CFR 35.50, 35.51, 35.55, 35.57, 35.59, 35.190, 35.290, 35.390, 35.392, 35.394, 35.396, 35.490, 35.590, 35.433, 35.491, 35.690

OTHER REFERENCES:

- NRC Form 313A series
- Specialty Boards Certifications Recognized by the NRC

EXPLANATION:

Name of proposed authorized individual:

Provide the individual's complete legal name so that the NRC can distinguish the individual from others with a similar name. Include terminal degree designation(s) and documentation as applicable to the review of the proposed authorized individual. *Note:* Do not include personal or private information (e.g., date of birth, social security number, home address, personal telephone number) as part of the qualification documentation. As a reminder, licensees have no more than 30 days to inform the NRC of an authorized individual's name change per 10 CFR 35.14(b)(1).

Requested Authorization(s):

Indicate authorizations requested and fill in the blanks as provided.

T&E Documentation:

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Indicate the applicable T&E pathway (i.e., board certification pathway, alternate pathway, or authorization on another license), as documented on the form.

Additional Considerations for Completing the NRC Form 313A Series:

If the applicant or licensee is proposing an individual for more than one type of authorization, the applicant may need to either submit multiple forms in the NRC Form 313A series or fill out some sections more than once. For example, an applicant that requests a physician be authorized for 10 CFR 35.200 and 10 CFR 35.300 medical uses and as the RSO, should provide three completed NRC Form 313A series forms (i.e., NRC Form 313A (RSO), NRC Form 313A (AUD) and NRC Form 313A (AUT)). If the applicant or licensee has multiple supervising individuals, more than one form/page may be used to document supervised work experience.

To identify any individual (i.e., proposed individual or supervising individual or preceptor) currently or previously listed on a license, provide the license on which the individual was identified.

To identify an individual who is authorized under a:

- medical use permit issued by an NRC MML;
- permit issued by an NRC or Agreement State broad scope medical-use licensee; or
- permit issued by an NRC MML broad scope medical-use permittee

provide a complete copy of the permit issued by the NRC MML, broad scope licensee, or MML broad scope permittee.

4.6.1 Form 313A (RSO) for RSOs and ARSOs

The T&E requirements for the RSO and ARSOs, as described in 10 CFR 35.50 and provide multiple pathways that applicants or licensees can use to demonstrate that individuals are qualified as an RSO or ARSO. Applicants should provide documentation that each individual is qualified under one of three pathways.

When an applicant wants to identify one or more ARSOs, the applicant must identify the types of use (e.g., 10 CFR 35.200, 10 CFR 35.300) of byproduct material for which the proposed authorized individual may be assigned duties and tasks under the licensee's program in the oversight of the radiation safety program.

Prior authorization on a license:

An applicant or licensee who is adding an experienced RSO/ARSO for medical uses to its license only needs to provide an NRC license number or a copy of the license (if issued by an Agreement State), a copy of a permit issued by an NRC MML, a permit issued by an NRC or Agreement State broad-scope licensee, or a permit issued by an NRC MML broad-scope permittee on which the individual is authorized for the same with types of use(s) requested.

Alternatively, the applicant or licensee may provide a statement signed by the RSO or chairperson of the RSC similar to the following:

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"__(name of authorized individual)___ was authorized under __(name of license/permit)__broad scope license number__(license number)__ to use (materials authorized to use)___ during ___(time frame)__."

The applicant or licensee would also need to provide evidence that the individual completed continuing education to meet recentness of training requirements described in 10 CFR 35.59, if applicable.

All RSOs that are listed on a license after January 14, 2019, are required to meet the training requirements of 10 CFR 35.50(d) if they are seeking authorizations for new materials and medical uses for which they were not authorized prior to this date.

Board Certification Pathway:

The board certification pathway, as provided in 10 CFR 35.50(a), requires certification by a specialty board whose certification process has been recognized and is listed on NRC's Specialty Boards Certifications Recognized by the NRC website or included in 10 CFR 35.57(a)(2), and has training in radiation safety, regulatory issues, and emergency procedures for the types of use for which a licensee seeks approval.

Qualification may also be demonstrated by a medical physicist who has been certified by a specialty board whose certification process has been recognized for AMPs by NRC that is listed on the Specialty Boards Certifications Recognized by the NRC website, and has experience with the radiation safety aspects of similar types of byproduct material and training in radiation safety, regulatory issues, and emergency procedures for the types of use for which a licensee seeks approval (10 CFR 35.50(d)).

Board-certified individuals that were not named as an RSO may be "grandfathered" for those materials and uses that these individuals performed on or before October 24, 2005, if the individual was board-certified by any of the boards listed in 10 CFR 35.57(a)(2) on or before October 24, 2005. The applicant must provide documentation that the individual used the materials and performed the medical uses before October 24, 2005, to meet the requirements to be an RSO or ARSO for those materials and uses. This documentation will be reviewed on a case-by-case basis to verify the time period of use, the materials used, and the types of medical use meet the criteria in the regulation.

Supporting documentation to the Form 313A (RSO) would include a copy of board certificate recognized as listed on NRC's Specialty Boards Certifications Recognized by the NRC website. Additional training may also need to be documented under 10 CFR 35.50(d). The applicant or licensee would also need to provide evidence that the individual completed continuing education to meet recentness of training requirements described in 10 CFR 35.59, if applicable. Proposed RSOs who are board certified do not need to provide a preceptor attestation.

Alternate Pathway:

The alternate pathway requires the proposed RSO to meet a structured educational program of 200 hours of classroom and laboratory training (10 CFR 35.50(b)(1)(i)), 1 year of full-time supervised radiation safety work experience (10 CFR 35.50(b)(1)(ii)), a preceptor attestation (10 CFR 35.50(b)(2)), and completion of training as specified in 10 CFR 35.50(d).

Supporting documentation to the Form 313A (RSO) may include some of the following:

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- NRRPT Certificate
- Diploma or transcripts
- Continuing education and experience records
- Documentation of specific radiation safety training for each use on the license
- Documentation of device-specific training (10 CFR 35.600 and possibly 35.1000 uses)
    - Training records from vendor
- A list of prior Health Physics/RSO occupational positions and duty descriptions
- Certificates or a syllabus from formal courses (examples)
    - Health Physics Course
    - Radiation Safety Officer Course
    - Medical RSO Course
    - Department of Transportation (DOT) Course
    - HAZMAT Course
    - Radiation Instrumentation Course
    - MARSSIM
    - Medical Effects of Ionizing Radiation
    - Air Sampling for Radionuclides
- Other/Additional Documents Provided i.e., for 35.1000
    - Memorandum from a vendor listing radiation safety training course completion
        - List of patient case involvement
- A copy of the license or permit from Preceptor Attestation (supporting documentation for Part II, "Fourth Section" of Form 313A (RSO))

4.6.2 Form 313A (AMP) for AMPs and OPs

T&E requirements for AMPs are described in 10 CFR 35.51 and allow multiple pathways which applicants can use to demonstrate that individuals are qualified as an AMP. Applicants should provide documentation that each individual is qualified under one of the three pathways.

Prior approval on a license:

An applicant or licensee who is adding an experienced AMP to its license only needs to provide an NRC license number or a copy of the license (if issued by an Agreement State), a copy of a permit issued by an NRC MML, a permit issued by an NRC or Agreement State broad-scope licensee, or a permit issued by an NRC MML broad-scope permittee on which the individual is authorized for the same with types of use(s) requested.

Alternatively, the applicant or licensee may provide a statement signed by the RSO or chairperson of the RSC similar to the following:

> "(name of authorized individual) was authorized under (name of license/permit) broad scope license number (license number) to use (materials authorized to use) during (time frame)."

The applicant or licensee would also need to provide evidence that the individual completed continuing education to meet recentness of training requirements described in 10 CFR 35.59, if applicable.

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All AMPs that are listed on a license after January 14, 2019, are required to meet the training requirements of or 10 CFR 35.51(c) if they are seeking authorizations for new materials and medical uses for which they were not authorized prior to this date.

Board Certification Pathway:

The board certification pathway, as provided in 10 CFR 35.51(a), requires certification by a specialty board whose certification process has been recognized and is listed on NRC's Specialty Boards Certifications Recognized by the NRC website or included in 10 CFR 35.57(a)(3), and has training in hands-on device operation, safety procedures, clinical use, and the operation of a treatment planning system.

Board-certified individuals that were not named as an AMP may be "grandfathered" for those materials and uses that these individuals performed on or before October 24, 2005 if the individual was board-certified by any of the boards listed in 10 CFR 35.57(a)(3) on or before October 24, 2005. The applicant must provide documentation that the individual used the materials and performed the medical uses before October 24, 2005, to meet the requirements to be an AMP for those materials and uses. This documentation will be reviewed on a case-by-case basis to verify the time period of use, the materials used, and the types of medical use meet the criteria in the regulation.

Supporting documentation to the Form 313A (AMP) would include a copy of board certificate recognized as listed on NRC's Specialty Boards Certifications Recognized by the NRC website. Additional training may also need to be documented under 10 CFR 35.51(c). The applicant or licensee would also need to provide evidence that the individual completed continuing education to meet recentness of training requirements described in 10 CFR 35.59, if applicable. Proposed AMPs who are board certified do not need to provide a preceptor attestation.

Alternate Pathway:

The alternate pathway requires the proposed AMP to meet a structured educational program of a master's or doctor's degree in physics, medical physics, other physical science, engineering or applied mathematics from an accredited college or university as required in 10 CFR 35.51(b)(1)); 1 year of full-time training in medical physics and an additional year of full-time supervised work experience (10 CFR 35.51(b)(1)); a preceptor attestation (10 CFR 35.51(b)(2)); and completion of training as specified in 10 CFR 35.51(c).

OPs can only qualify under this pathway as the NRC does not have a regulation under which it recognizes ophthalmic physicist boards. The T&E requirements for ophthalmic physicists are described in 10 CFR 35.433(a)(2). The NRC Form 313A (AMP) may be used to document T&E for individuals seeking authorization for Sr-90 for ophthalmic treatments.

Supporting documentation to the Form 313A (AMP) would include the following:

- Diploma or transcripts
- Continuing education and experience records
- Documentation of specific radiation safety training for each use on the license
- Documentation of device-specific training (10 CFR 35.600 and possibly 35.1000 uses)
    - Training records from vendor
- Certificates or a syllabus from formal courses

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- Other/Additional Documents Provided i.e., for 10 CFR 35.1000
    - Memorandum from a vendor listing radiation safety training course completion
        - List of patient case involvement
- A copy of the license or permit from Preceptor Attestation (supporting documentation for Part II, "Fourth Section" of Form 313A (AMP))

4.6.3 Form 313A (ANP) for ANPs

The T&E requirements for ANPs, as described in 10 CFR 35.55 and allow multiple pathways which applicants can use to demonstrate that individuals are qualified as an ANP. Applicants should provide documentation that each individual is qualified under one of the three pathways.

Prior approval on a license:

An applicant or licensee who is adding an experienced ANP to its license only needs to provide an NRC or Agreement State license number or a copy of the:

- medical-use license (if issued by an Agreement State), or
- commercial nuclear pharmacy license (if issued by an Agreement State), or
- permit issued by an NRC MML, or
- permit issued by an NRC or Agreement State broad-scope licensee, or
- permit issued by an NRC MML broad-scope permittee, or
- authorization from a commercial nuclear pharmacy authorized to identify ANPs

on which the individual is authorized for the same types of use(s) requested.

Alternatively, the applicant or licensee may provide a statement signed by the RSO or chairperson of the RSC similar to the following:

> "_(name of authorized individual)_ was authorized under _(name of license/permit)_ broad scope license number _(license number)_ to use (materials authorized to use)___ during ___(time frame)_."

The applicant or licensee would also need to provide evidence that the individual completed continuing education to meet recentness of training requirements described in 10 CFR 35.59, if applicable.

Board Certification Pathway:

The board certification pathway, as provided in 10 CFR 35.55(a), requires certification by a specialty board whose certification process has been recognized and is listed on NRC's Specialty Boards Certifications Recognized by the NRC website or included in 10CFR 35.57(a)(2).

Supporting documentation to the Form 313A (ANP) would include a copy of board certificate recognized as listed on NRC's Specialty Boards Certifications Recognized by the NRC website. The applicant or licensee would also need to provide evidence that the individual completed continuing education to meet recentness of training requirements described in 10 CFR 35.59, if

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applicable. Proposed ANPs who are board certified do not need to provide a preceptor attestation.

Alternate Pathway:

The alternate pathway requires the proposed ANP to meet a structured educational program of 200 hours of classroom and laboratory training (10 CFR 35.55(b)(1)(i)) supervised practical experience in nuclear pharmacy (10 CFR 35.55(b)(1)(ii)), and a preceptor attestation (10 CFR 35.55(b)(2)).

Supporting documentation to the Form 313A (ANP) would include:

- a copy of the state license to practice pharmacy (per 10 CFR 35.55(a)(2)).
- diploma or transcripts
- continuing education and experience records
- certificates or a syllabus from formal courses by their employer or an educational institution
- vendor specific training certificates for radioactive drug preparation

4.6.4 Forms 313A (AUD), (AUT), (AUS) for AUs

T&E requirements for AUs are described in 10 CFR 35.57, 35.190, 35.290, 35.390, 35.392, 35.394, 35.396, 35.490, 35.491, 35.590, and 35.690 and allow multiple pathways which applicants can use to demonstrate that individuals are qualified as an AU. Applicants should provide documentation that each individual is qualified under one of the three pathways: prior approval on a license, board certification pathway, and alternate pathway.

The NRC requires physicians, dentists, podiatrists, and pharmacists to be licensed by a State or territory of the U.S., the District of Columbia, or the Commonwealth of Puerto Rico to prescribe drugs in the practice of medicine, as well as licensed in the practice of dentistry, podiatry, or pharmacy, respectively (see definitions of “physician,” “dentist,” “podiatrist,” and “pharmacist” in 10 CFR 35.2, “Definitions”).

The following 313A series of forms may be used to document T&E for proposed AUs:

- NRC Form 313A (AUD) for uses defined under 10 CFR 35.100, 10 CFR 35.200, and 10 CFR 35.500
- NRC Form 313A (AUT) for uses defined under 10 CFR 35.300
- NRC Form 313A (AUS) for uses defined under 10 CFR 35.400 and 10 CFR 35.600

Prior approval on a license:

An applicant or licensee who is adding an experienced AU to its license only needs to provide NRC license number or a copy of the license (if issued by an Agreement State), a copy of a permit issued by an NRC MML, a permit issued by an NRC or Agreement State broad-scope licensee, or a permit issued by an NRC MML broad-scope permittee on which the individual is authorized for the same with types of use(s) requested.

Alternatively, the applicant or licensee may provide a statement signed by the RSO or chairperson of the RSC similar to the following:

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"__(name of authorized individual)___ was authorized under __(name of license/permit)__broad scope license number__(license number)__ to use (materials authorized to use)___ during ___(time frame)__."

The applicant or licensee would also need to provide evidence that the individual completed continuing education to meet recentness of training requirements described in 10 CFR 35.59, if applicable.

Board Certification Pathway:

The board certification pathway, as provided in 10 CFR 35.190(a), (a), 35.290(a), 35.390(a), 35.392(a), 35.394(a), 35.490(a), 35.590(a), and 35.690(a), requires certification by a specialty board whose certification process has been recognized and is listed on NRC's Specialty Boards Certifications Recognized by the NRC website or included in 10 CFR 35.57(a)(3).

Board-certified individuals (i.e., physicians, dentists, or podiatrists) that were not named as an AU may be "grandfathered" for those materials and uses that these individuals performed on or before October 24, 2005 if the individual were board-certified by any of the boards listed in 10 CFR 35.57(b)(2) on or before October 24, 2005. The applicant must provide documentation that the individual used the materials and performed the medical uses before October 24, 2005, to meet the requirements to be an AU for those materials and uses. This documentation will be reviewed on a case-by-case basis to verify that the time period of use, the materials used, and the types of medical use, meet the criteria in the regulation. For example, a physician who was authorized to use sodium iodide (I-131) for imaging and localization, involving greater than 30 µCi [1.11 MBq] (a quantity for which a WD is required under 10 CFR 35.40), would continue to be authorized for "imaging and localization involving greater than 30 µCi" even though after 2002 it was authorized under 10 CFR 35.300.

Supporting documentation to the Forms 313A (AUD), (AUT), (AUS) would include a copy of board certificate recognized as listed on NRC's Specialty Boards Certifications Recognized by the NRC website. The applicant or licensee would also need to provide evidence that the individual completed continuing education to meet recentness of training requirements described in 10 CFR 35.59, if applicable. Proposed AUs who are board certified do not need to provide a preceptor attestation.

Alternate Pathway:

The alternate pathway requires the proposed AU physician to have completed a specified number of hours of classroom and laboratory training, supervised work experience, case experience, and a preceptor attestation (10 CFR 35.190(b), 35.290(b), 35.390(b), 35.392(b), 35.394(b), 35.490(b), 35.590(b), and 35.690(b)).

Supporting documentation to the Forms 313A (AUD), (AUT), (AUS), would include the following:

- State license
- License or permit listing individual as AU
- Continuing education and experience records
- Documentation of specific radiation safety training for each use on the license
- Certificates or a syllabus from formal courses

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- Other/Additional Documents Provided i.e., for 10 CFR 35.1000
    - Memorandum from a vendor listing radiation safety training course completion
    - List of patient case involvement
- Vendor specific training certificates for device-specific training

4.6.5 T&E Documentation for 35.1000

The regulations in 10 CFR 35.1000 describe the process to obtain a license, or an amendment to a license, for a new medical use of byproduct material or radiation from byproduct material, which is not addressed in other parts of 10 CFR Part 35 (i.e., an emerging medical technology). It does not include specific T&E requirements for AUs of emerging technologies because the training requirements necessary for the safe use of byproduct material in new technologies are not known in advance. The NRC has developed licensing guidance, including T&E guidance, for certain 10 CFR 35.1000 medical uses. This information is available on the NRC public website Emerging Medical Technologies.

Applicants and licensees are required to submit T&E information for individuals who are to serve authorized individuals (RSOs, ARSOs, AUs, AMPs, OPs, and ANPs) in accordance with 10 CFR 35.12(b)(1), for the purpose(s) for which licensed material will be used. The NRC will evaluate this information on a case-by-case basis to determine whether the T&E of the identified individuals is appropriate for the proposed use.

A preceptor statement may need to be submitted as instructed in the licensing guidance. In this case, the preceptor could be an AU for the same 10 CFR 35.1000 use. For individuals seeking AU recognition for new (i.e., not previously licensed) medical uses under 10 CFR 35.1000, the written attestation may be from a person (or persons) knowledgeable about the radiation safety aspects of the new medical use and the associated equipment (e.g., vendor or manufacturer), rather than from an AU.

4.7 Preceptor Attestation

REGULATORY REQUIREMENTS:

10 CFR 35.2, 35.50, 35.51, 35.55, 35.57, 35.59, 35.190, 35.290, 35.390, 35.392, 35.394, 35.396, 35.490, 35.491, 35.690

OTHER REFERENCES:

- NUREG-1556, Volume 9, Revision 3 "Consolidated Guidance About Materials Licenses: Program-Specific Guidance About Medical Use Licenses," Appendix D, Pages D-5 and D-6
- Guidance for the Final Rule, "Medical Use of Byproduct Material—Medical Event Definitions, Training and Experience, and Clarifying Amendments" Effective January 2019 and Comment Resolution for Proposed Guidance on the Proposed Rule "Medical Use of Byproduct Material—Medical Event Definitions, Training and Experience, and Clarifying Amendments"
- SECY-08-0179, Policy Issue (Notation Vote), "Recommendations on Amending Preceptor Attestation Requirements in 10 CFR Part 35, Medical Use of Byproduct Material," November 20, 2008

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- SECY-08-0179 - Recommendations on Amending Preceptor Attestation Requirements in 10 CFR PART 35, Medical Use of Byproduct Material (ML083170176)
- Final Rule, Medical Use or Byproduct Material – Recognition of Specialty Boards, 70 FR 16336

EXPLANATION:

A "Preceptor Attestation," also referred to as a "Preceptor Statement" is a part of certain required T&E in 10 CFR Part 35 and is a necessary component for evaluating an individual's qualification. It is a signed statement provided by a preceptor individual that vouches for an individual's completion of appropriate T&E and ability to function independently.

Some of the T&E requirements for authorized individuals in 10 CFR Part 35 generally require that an individual seeking authorization obtain a written attestation signed by a preceptor with that same authorization being sought, that the individual has satisfactorily completed the necessary T&E requirements and is able to independently fulfill the radiation safety-related duties of the position for which authorization is sought.

Effective January 19, 2019, and in accordance with the Final Rule "10 CFR Parts 30, 32 and 35 - Medical Use of Byproduct Material - Medical Event Definitions, Training and Experience, and Clarifying Amendments" (83 FR 33046), the regulations were amended to eliminate the requirement for preceptor attestations for almost all individuals certified by specialty boards recognized by NRC or Agreement States on NRC's website for specialty board certifications or listed in 10 CFR 35.57. The NRC determined that preceptor attestations are unnecessary for individuals certified by the currently recognized boards or for "grandfathered" boards listed in 10 CFR 35.57, provided that the provisions of 10 CFR 35.59 are met. Individuals applying under the alternate pathway and all physicians applying to be AUs under the provisions of 10 CFR 35.396 will continue to need a preceptor attestation. The regulations were also amended to incorporate the new language that the written attestation must verify that the individual is able to independently fulfill the radiation safety-related duties, rather than has achieved a level of competency to function independently as an authorized individual. The NRC had intended "level of competency" in current attestations to refer to radiation safety competency. However, the medical community expressed concern that this could be interpreted to be as an attestation of medical competency. Therefore, the NRC revised the attestation statements to no longer include the word "competency." Additionally, it should be noted that the attestation is specific to the individual's ability to perform radiation safety-related duties and is not an attestation to the individual's clinical or medical competency. Medical competency is addressed by each State's medical board.

A written and signed preceptor attestation is required in the following scenarios:

- all individuals seeking authorization via the alternate pathway, except for individuals qualifying as AUs for sealed source for diagnosis

- board certified individuals seeking AU authorization under the provisions of 10 CFR 35.396

- medical uses that are or have been licensed under 10 CFR 35.1000

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- AUs, RSOs, and AMPs who have received additional training for new medical uses and who initially qualified under the alternate pathway seeking authorization for a new medical use. An attestation statement is not needed if these authorized individuals initially qualified under the board certification pathway.

In order for the boards to be recognized, they are required to give an examination that assesses knowledge and competency in areas that include radiation safety. Therefore, the NRC finds that preceptor attestations are unnecessary for individuals certified by the currently recognized boards or for "grandfathered" boards listed in 10 CFR 35.57, provided that the provisions of 10 CFR 35.59 are met.

The NRC Form 313A series, "Part II – Preceptor Attestation," may be used to document what the preceptor is attesting to and the preceptor qualifications. The preceptor must complete an attestation of the proposed user's training, experience, and competency to independently fulfill the duties of the position in areas that include radiation safety, as well as provide information concerning his/her own qualifications and sign the attestation. Because there are a number of different pathways to obtain the required T&E for different authorized individuals, specific instructions are provided for each form in the NRC Form 313A series.

The Preceptor Attestation page (Part II of the NRC Form 313A series) has different sections to be completed:

1. The attestation to the proposed authorized individual's training
2. the attestation for the device-specific training
3. the attestation of the individual's competency to function independently as an authorized individual for the specific devices requested by the applicant
4. specific information about the preceptor's authorizations to use licensed material, in addition to the preceptor's signature

The preceptor for a proposed new authorized individual must fill out all applicable sections of this page. The preceptor for an authorized individual seeking additional authorizations must complete the applicable preceptor information sections.

NOTE: NUREG-1556, Volume 9, Revision 3, provides detailed information on the NRC Form 313A series that the allow for documentation of the required T&E and signatory for the written preceptor attestation.

Part 3, "Medical Use Questions and Answers Effective January 2019," of the Guidance for the Final Rule "Medical Use of Byproduct Material – Medical Event Definitions, Training and Experience, and Clarifying Amendments" (83 FR 33046), includes a description of the specific changes to the requirements for written attestations, as well as related questions and answers.

4.7.1 Preceptor

A preceptor is defined under 10 CFR 35.2 as an individual who provides, directs, or verifies the T&E required for an individual to become an AU, AMP, ANP, RSO, or ARSO. A preceptor may be:

1. an authorized individual that meets specific requirements and has authorization for the same use or device categories that the proposed authorized individual is seeking; or

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2. a residency program director that may provide attestation for physicians seeking to become AUs by affirming in writing that the attestation represents the consensus of the residency program faculty where at least one faculty member is an AU for the uses requested and concurs with the attestation provided by the residency program director.

The preceptor must attest in writing that the proposed authorized individual has satisfactorily completed the appropriate T&E requirements and is able to independently fulfill the radiation safety-related duties of an authorized individual. The preceptor must meet specific requirements and have authorization for the same use or device categories that the proposed authorized individual is seeking. The preceptor may be employed at a different facility than the proposed authorized individual (e.g., previous place of work or someone from the proposed individual's educational program. Applicants should include a copy of the license to demonstrate the materials and uses for which the preceptor is authorized.

A preceptor authorized individual that meets the applicable requirements may serve as a supervising individual (see Section 4.2, "Supervision"). The preceptor does not have to be the supervising individual as long as the preceptor provides, directs, or verifies the required T&E. If more than one preceptor is necessary to document the training and experience, the licensee must provide a separate written attestation from each preceptor.

In accordance with the preceptor attestation requirements in 10 CFR Part 35, Subparts B, D, E, F, G, and H:

- RSOs and ARSOs may serve as preceptors for an individual seeking to be named as the RSO or ARSO on a license if they have experience with the radiation safety aspects of similar types of use of byproduct material for which the RSO/ARSO is providing the attestation. (See 10 CFR 35.50(b)(2)).

- AUs may serve as preceptors for an individual seeking to be named as an AU on a license in accordance with 10 CFR 35.190(c)(2), 35.290(c)(2), 35.390(b)(2), 35.392(c)(3), 35.394(c)(3), 35.396(b)(3), 35.490(b)(3), 35.690(b)(3).

- AMPs may serve as preceptors for an individual seeking to be named as an AMP on a license in accordance with 10 CFR 35.51(b)(2).

- ANPs may serve as preceptors for an individual seeking to be named as an AU on a license in accordance with 10 CFR 35.55(b)(2).

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REFERENCES

[References List will be updated prior to issuance of the ISG]

(1) Title 10 of the *Code of Federal Regulations* Part 35, “Medical Use of Byproduct Material”
(2) NUREG-1556, Volume 9, Revision 3 "Consolidated Guidance About Materials Licenses: Program-Specific Guidance About Medical Use Licenses”
(3) NUREG-1516, “Management of Radioactive Material Safety Programs at Medical Facilities”
(4) Medical Use of Byproduct Material: Policy Statement (65 FR 47654; August 3, 2000)
(5) Authorized Individuals | NRC.gov
(6) Medical Uses Licensee Toolkit
(7) NRC: Package ML19217A318 -SECY-20-0005: Rulemaking Plan for Training and Experience Requirements for Unsealed Byproduct Material (10 CFR Part 35)
(8) SECY-21-0013: Rulemaking Plan to Establish Requirements for Rubidium-82 Generators and Emerging Medical Technologies (nrc.gov)
(9) SRM-SECY-20-0005, “Rulemaking Plan for Training and Experience Requirements for Unsealed Byproduct Material (10 CFR Part 35)”
(10) Final Rule “10 CFR Parts 30, 32 and 35 - Medical Use of Byproduct Material - Medical Event Definitions, Training and Experience, and Clarifying Amendments” (83 FR 33046)
(11) NRC Forms 313A series:
   i. NRC Form 313A (AMP), Authorized Medical Physicist or Ophthalmic Physicist, Training, Experience and Preceptor Attestation [10 CFR 35.51, 35.57(a)(3), and 35.433]. (01-2020)
   ii. NRC Form 313A (ANP), Authorized Nuclear Pharmacist Training, Experience, and Preceptor Attestation [10 CFR 35.55]. (01-2020)
   iii. NRC Form 313A (AUD), Authorized User Training, Experience, and Preceptor Attestation (for uses defined under 35.100, 35.200, and 35.500) [10 CFR 35.57, 35.190, 35.290, and 35.590]. (01-2020)
   iv. NRC Form 313A (AUS), Authorized User Training, Experience, and Preceptor Attestation (for uses defined under 35.400 and 35.600) [10 CFR 35.57, 35.490, 35.491, and 35.690]. (01-2020)
   v. NRC Form 313A (AUT), Authorized User Training, Experience, and Preceptor Attestation (for uses defined under 35.300) [10 CFR 35.57, 35.390, 35.392, 35.394, and 35.396]. (01-2020)
   vi. NRC Form 313A (RSO), Radiation Safety Officer or Associate Radiation Safety Officer Training, Experience, and Preceptor Attestation [10 CFR 35.57, 35.50]. (01-2020)

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