OFFICE OF NUCLEAR MATERIAL SAFETY AND SAFEGUARDS
INTERIM STAFF GUIDANCE
NMSS-ISG-03

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

Manuscript Completed: April 2025
Date Published: April 2025

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PAPERWORK REDUCTION ACT

This interim staff guidance contains voluntary guidance for implementing the mandatory information collections in 10 CFR Part 35 and NRC Form 313 that are subject to the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 et. seq.). These information collections were approved by the Office of Management and Budget (OMB), under control numbers 3150-0010 and 3150-0120 respectively. Send comments regarding these information collections to the FOIA, Library, and Information Collections Branch (T6-A10M), U.S. Nuclear Regulatory Commission, Washington, DC 205550001, or by e-mail to Infocollects.Resource@nrc.gov, and to the OMB reviewer at: OMB Office of Information and Regulatory Affairs (3150-0010 and 3150-0120), Attn: Desk Officer for the Nuclear Regulatory Commission, 725 17th Street, NW Washington, DC 20503.

PUBLIC PROTECTION NOTIFICATION

The U.S. Nuclear Regulatory Commission (NRC) may not conduct or sponsor, and a person is not required to respond to, a collection of information unless the document requesting or requiring the collection displays a currently valid OMB control number.

ABBREVIATIONS

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 for sealed source
AUT	authorized user therapy
CFR	*Code of Federal Regulations*
EMT	emerging medical technologies
FR	*Federal Register*
ISG	interim staff guidance
MML	master materials license
Mo-99	molybdenum-99
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
Tc-99m	technetium-99m
T&E	training and experience
WD	written directive

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 that 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), and ophthalmic physicists (OPs).

This ISG also provides criteria for the U.S. NRC staff and Agreement State regulators to evaluate such applications or license amendment requests. It clarifies 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 does the following:

- 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 to a medical-use license
- Details certain specialty board certifications recognized by the NRC
- Identifies the information and supporting documentation needed to complete the NRC Forms 313A series of forms
- Provides completed sample NRC Forms 313A and examples of supporting documents that licensees and applicants may refer to when developing their license requests
- Offers examples of recommended responses for various blocks on the NRC Forms 313A series of forms

As stated in the NRC's Medical Policy Statement, the agency regulates the use of radionuclides in medicine to ensure radiation safety of workers and the general public. The NRC minimizes intrusion into medical judgments, 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 ensure that the use of radionuclides is in accordance with the physician's directions. In developing specific regulatory approaches, the NRC considers industry and professional standards that define acceptable methods to achieve radiation safety.

2.0 APPLICABILITY AND USE

This ISG does not contain new expectations for implementing the T&E requirements. Rather, it consolidates the guidance previously contained in various referenced sources into a streamlined format to improve efficiency, clarity, and accessibility.

The NRC issues guidance to describe methods that the 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, licensees are free to demonstrate approaches and solutions that differ from those described in this guidance that 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 necessary determinations for approving individuals as AUs, RSOs, ARSOs, ANPs, AMPs, and OPs.

Applicants and staff should use this ISG in addition to the existing applicable guidance (e.g., NUREG-1556, "Consolidated Guidance About Materials Licenses," Volume 9, Revision 3, "Program-Specific Guidance About Medical Use Licenses," issued September 2019 (NRC, 2019)) until it is superseded by or incorporated in other guidance or rulemaking. Currently, the 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. The NRC staff intends to further review the guidance and make necessary revisions to enhance licensing efficiencies in the future. This will involve a thorough evaluation of comments received outside the scope of this ISG development, incorporating feedback and lessons learned, and further public engagement.

An individual who accesses an electronic version of this guidance document can navigate its contents 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 the reference material or relevant section 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 applicant or licensee, 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.

A licensee may seek NRC staff input for clarification on what is required under existing regulations and for the basis for the regulations. NRC staff will not draft or develop text for licensing requests or advise on decisions by the licensee related to license amendment or application submittals.

Sources of basic information about T&E for use by applicants and licensees for the medical use of byproduct material include the following:

- 10 CFR Part 35
- NUREG-1556, Volume 9, Revision 3 (NRC, 2019)
- NUREG-1516, "Management of Radioactive Material Safety Programs at Medical Facilities," issued May 1997 (NRC, 1997)
- Medical Uses Licensee Toolkit
- NRC Forms 313A series of forms
- Specialty Board Certifications Recognized by 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) (NRC, 2018b)

- Final Rule, “Medical Use of Byproduct Material,” published as a final rule on April 24, 2002 (67 FR 20250) (NRC, 2002)

- SECY-20-0005, “Rulemaking Plan for Training and Experience Requirements for Unsealed Byproduct Material (10 CFR Part 35),” dated January 13, 2020 (NRC, 2020)

- Staff Requirements Memorandum (SRM)-SECY-20-0005, dated January 27, 2022 (NRC, 2022)

3.0 BACKGROUND

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, or 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, the Commission directed the staff to develop implementation guidance to clarify expectations on how individuals fulfill T&E requirements and clarify the roles and responsibilities of persons subject to the T&E requirements. Guidance on medical T&E criteria found in NUREG-1556, Volume 9, Revision 3, is periodically updated concurrent with any regulatory changes. However, given the types of questions that the NRC and Agreement States routinely receive about T&E requirements, the NRC staff has determined that, until the next update to NUREG-1556, Volume 9, , supplemental guidance would benefit individuals applying for authorized individual status. The NRC staff determined that this ISG should address the following in response to the Commission’s direction:

- Expectations for individuals who 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)

- Completion of NRC Forms 313A series of forms and supporting documentation

4.0 GUIDELINES

To ensure high levels of radiation safety, medical use licensees are required to have highly qualified and experienced personnel who are knowledgeable about the technical and administrative radiation 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
- NUREG-1556, Volume 9, Revision 3, Section 8.7, "Item 7: Individual(s) Responsible for the Radiation Safety Program and Their Training and Experience"
- NUREG-1556, Volume 9, Revision 3, Section 8.7.1, "Radiation Safety Officer (RSO) and Associate Radiation Safety Officers (ARSOs)"
- NUREG-1556, Volume 9, Revision 3, Figure 8-2, "Licensing Examples of Potential Radiation Safety Officer (RSO) and Associate Radiation Safety Officer (ARSO) Arrangements"
- NUREG-1556, Volume 9, Revision 3, 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, "Definitions,") who meets either of the following criteria:

- Has 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
- Is identified as an authorized individual on an NRC or Agreement State radioactive materials medical use license, or permit issued by an NRC master materials license (MML) (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," they do define each specific type of authorized individual (AU, AMP, ANP, RSO, ARSO, and OP) who may be listed on a license or permit. The term "Authorized Individuals" generally refers 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 or 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.

4.1.2 Roles and Responsibilities

The regulations in 10 CFR 35.24, "Authority and responsibilities for the radiation protection program," 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 who 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).

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.

- Licensee management shall 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 who 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, and 35.26).

- Licensee management can delegate tasks or duties, but not the responsibility, to a management delegate. Appendix I to NUREG-1556, Volume 9, Revision 3, includes a sample delegation of authority.

- Licensee management must approve requests (in writing) for a license application, renewal, or amendment before submittal to the NRC of (1) any individual before allowing that individual to work as an RSO or ARSO, AU, ANP, AMP, or OP and (2) radiation protection program changes that do not require a license amendment and are permitted under 10 CFR 35.26, "Radiation protection program changes." The NRC requires that the information in the application be complete and accurate in all material aspects, in accordance with 10 CFR 30.9, "Completeness and Accuracy of Information." This includes preceptor attestations for authorized individuals.

- 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 (1) identifying radiation safety problems, (2) initiating, recommending, or providing corrective actions, (3) stopping

unsafe operations, and (4) 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, "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 mechanisms for oversight are adequate to determine that the radiation protection program, including the training of contractor staff, is effectively implemented by the appropriate individuals.

Radiation Safety Committee

- 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, Subpart E, "Unsealed Byproduct Material—Written Directive Required"; Subpart F, "Manual Brachytherapy"; and Subpart H, "Photon Emitting Remote Afterloader Units, Teletherapy Units, and Gamma Stereotactic Radiosurgery Units"; 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. EMT under 10 CFR Part 35, Subpart K, "Other Medical Uses of Byproduct Material or Radiation from Byproduct Material," are not considered in the requirement to establish an RSC, nor are AUs for EMT required to be part of the RSC unless specified as a license condition. Membership of the committee must include an AU for each type of use permitted by the license (except AUs for EMT unless specified as a license condition), 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 that the licensee considers appropriate such as an AU for an EMT.

- If 10 CFR 35.24(f) does not require the creation of an RSC, but the licensee still decides to establish this committee, then the RSC functions as management directs, and its duties are as assigned.

Radiation Safety Officer

- 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. Appendix I to NUREG-1556, Volume 9, Revision 3, includes a sample delegation of authority. 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 safely.

- 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 ensuring that radiation safety activities are being performed in accordance with licensee-approved procedures and regulatory requirements. The NRC requires the name of the current 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. As required by 10 CFR 35.14(b)(2) and 10 CFR 35.24, licensees must notify the NRC within 30 days of a temporary RSO performing the duties of an RSO.

- 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 an 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, but these duties and tasks are limited to the types of use for which the ARSO is listed on the license. The RSO shall not delegate the authority or responsibilities for implementing the radiation protection program (10 CFR 35.24(b)).

- 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.

- Nuclear medicine technologists can be an RSO if they have successfully completed all of the T&E requirements in 10 CFR 35.50, "Training for Radiation Safety Officer and Associate Radiation Safety Officer's," and agree 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 or contractors, to fill the role of RSO (if qualified in accordance with criteria in 10 CFR 35.50 or 10 CFR 35.57, "Training for experienced Radiation Safety Officer, teletherapy or medical physicist, authorized medical physicist, authorized user, nuclear pharmacist, and authorized nuclear pharmacist," and 10 CFR 35.59, "Recentness of training") or to provide support to the facility RSO. To fulfill the duties and responsibilities, the RSO should be on site 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. The licensee should, in its license amendment request or license application, identify other commitments of the consultant-RSO for other licensees, a description of how they will allocate time to permit the performance of RSO duties, the minimum amount of onsite time, and an in-house representative who will serve as the point of contact during the RSO's absence.

- A licensee must apply for and receive approval through a license amendment, before an individual can begin duties as a permanent RSO for an existing license in accordance with 10 CFR 35.13, "License amendments." 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(b)(2) and 10 CFR 35.24(c). 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 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, but are not limited to, the following:

  - Stop unsafe activities involving licensed material.

  - Ensure that radiation exposures are kept as low as is reasonably achievable.

  - 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 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 that individuals installing, relocating, maintaining, adjusting, or repairing devices containing sealed sources are trained and authorized by an NRC or Agreement State licensee.

  - Ensure that personnel training is conducted and is commensurate with the individual's duties regarding licensed material.

- Ensure that documentation is maintained to demonstrate that individuals are not likely to receive, in 1 year, a radiation dose more than 10 percent of the allowable limits or that personnel monitoring devices are provided.

- Ensure that 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 that 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 molybdenum (Mo)-99/technetium (Tc)-99m or strontium (Sr)-82/Rb-82 generators, loss of licensed material, fire, or 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 that 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 limits in 10 CFR Part 20, "Standards for Protection Against Radiation," and 10 CFR Part 30, Rules of General Applicability to Domestic Licensing of Byproduct Material," are investigated, their cause(s) are identified, appropriate corrective action(s) are taken, and reports are submitted to the NRC and other appropriate authorities, if required, within the stated 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, and 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

- A licensee may appoint one or more ARSOs to support the RSO. Consistent with 10 CFR 35.24(b), ARSOs can be named on a medical license.

- An ARSO identified on a license or permit is responsible for 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. ARSOs are named on medical-use licenses to avoid confusion between individuals named on a license as opposed to individuals working in a radiation program. This allows the individual to be recognized as an ARSO by the NRC and Agreement States as an RSO or ARSO for the same medical uses on another license without resubmitting T&E documentation.

- The ARSO cannot assume any RSO responsibilities unless the licensee designates, in writing, the ARSO as a temporary RSO. As required by 10 CFR 35.14(b)(2) and 10 CFR 35.24, licensees must notify the NRC within 30 days of a temporary RSO performing the duties of an 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.

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

Authorized User

- 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 directives (WDs), if required.

- There is no NRC requirement that an AU must interpret 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 nonmedical uses are sometimes called "nonmedical AUs." Nonmedical uses are those not intended for intentional exposure of humans (e.g., nonhuman uses such as in vitro and animal research, certain types of calibration, and other types of uses under 10 CFR 35.65, "Authorization for calibration, transmission, and reference sources"). A nonmedical AU is not an AU as defined in 10 CFR 35.2, although an individual could serve as both a medical AU and a nonmedical AU.

Authorized Medical Physicist

- An AMP identified on a license or permit is responsible for calculations and tasks associated with the administration of the radiation dose, including required tasks as described under 10 CFR Part 35, Subpart H, and required tasks associated with performing ophthalmic radiation therapy treatments as described in 10 CFR 35.433(b).

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

Ophthalmic Physicist

- An OP identified on a license or permit is responsible for calculating the activity of each Sr-90 source that is used to determine treatment times (10 CFR 35.433(b)(1)).

- 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 (10 CFR 35.433(b)(2)).

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

Authorized Nuclear Pharmacist

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

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, Section 8.8, "Training for Individuals Working in or Frequenting Restricted Areas"

- NUREG-1556, Volume 9, Revision 3, Appendix J, "Model Training Program"

- "Supplementary Information," Section III, "Summary of Public Comments and Responses to Comments," for 10 CFR 35.27, as published in the *Federal Register* on April 24, 2002 (67 FR 20250)

- Revised 10 CFR Part 35, 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:

Only AUs and ANPs identified on a medical use license under 10 CFR Part 35, or individuals working under the supervision of either an ANP or AU, are authorized to use or prepare byproduct material in the practice of medicine. Medical use, as defined in 10 CFR 35.2, 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.

The regulations in 10 CFR 35.11, "License required," permit licensees to allow individuals who are neither AUs nor ANPs to perform certain tasks under the supervision of an AU or an ANP who is named on the license or permit. The regulations in 10 CFR 35.27 provide training and oversight requirements for individuals working under the supervision of either an ANP or AU. The licensee is responsible for ensuring 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 authorized individual or that the authorized individual be physically present at all times during the use or preparation of such materials.

AUs and ANPs should assign tasks they determine that supervised individuals can safely perform and provide the degree of supervision that each individual needs. It is frequently necessary for an AU or ANP to delegate specific tasks to others who are not authorized individuals for the use or preparation of byproduct material for medical use. Federal regulations do not require licensees to notify 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, 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, "Instruction to workers," the regulations in 10 CFR 35.27 require that supervised individuals be instructed 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 comply with the following:

- 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
- 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., an AU or ANP). The requirements also 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 (10 CFR 35.27). 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 supervised individuals is adequate for the duties performed by the individual.

Supervising AU or Supervising ANP

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

- A supervising individual who 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.

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. Byproduct material for medical use may also be prepared 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

- Medical Uses Licensee Toolkit

- Specialty Board Certifications Recognized by 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 (70 FR 16336)

- "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 satisfy the T&E requirements and be approved and listed as an authorized individual for uses identified on a medical use radioactive materials license:

- Board certification pathway
- Alternate T&E pathway (hereafter referred to as the "alternate pathway")
- Prior approval on an NRC or Agreement State license

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

4.3.1.1 Board Certification Pathway

The applicant or licensee may use a board certification pathway if the proposed new authorized individual is (1) certified by a board recognized by the NRC and listed on NRC's Specialty Board Certifications Recognized by the NRC Under 10 CFR Part 35 website as provided in 10 CFR 35.50(a), 35.51(a), 35.55(a), 35.190(a), 35.290(a), 35.390(a), 35.392(a), 35.394(a), 35.396(a), 35.490(a), 35.590(a), or 35.690(a), or (2) certified before October 24, 2005, by a board listed in 10 CFR 35.57.

The applicable regulatory requirements in 10 CFR Part 35 allow the NRC to recognize specialty board certifications. The certifying board is responsible for reviewing the board applicant's qualifications to determine whether the applicant has met the applicable requirements of 10 CFR Part 35. This pathway allows the applicant or licensee to submit a copy of the individual's board certificate rather than detailed information on each T&E element.

Note: An individual who is board eligible will not be considered for this pathway until the individual is board-certified. The NRC does not recognize examination status letters from specialty boards in lieu of an NRC-recognized specialty board certificate. If an individual has passed the examination of a board that is recognized by the NRC but has not yet received a certificate, the individual has the option of submitting the applicable required documentation of T&E using the alternate pathway.

Individuals seeking authorization through 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 Specialty Board Certifications Recognized by the NRC Under 10 CFR Part 35 website to verify consistency with the proposed individual's certificate. Board certificates should contain prescribed language and show issuance within specified dates as described on the website.

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 Forms 313A series of forms.

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

through 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 qualify only under the alternate pathway as the NRC does not have a regulation that recognizes OP boards.

The regulatory requirements refer to two main categories of training: (1) classroom and laboratory training and (2) supervised work experience. T&E also includes supervised clinical casework and device-specific training for some types of use. 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 (1) classroom and laboratory training or (2) supervised work experience. Note that a single hour of training may be counted only 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. Tables providing the minimum number of hours of T&E required for the alternate pathway for each of the authorized individuals can be found on the NRC's Medical Uses Licensee Toolkit website. On NRC Form 313A, the licensee/applicant should provide the number of clock hours spent on the topics listed in the regulatory requirements, ensuring to document hours in each of the topics listed in the regulations. If an individual seeks to credit more than 40 hours for a workweek, 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 NRC 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 requires only documentation (i.e., NRC license number or a copy of the Agreement State license) that the individual is listed on a medical use license issued by the NRC or Agreement State; permit issued by an NRC MML; permit issued by an NRC or Agreement State broad-scope licensee; or permit issued by an NRC MML broad-scope permittee. Adding an authorized individual is also contingent on having the same authorization for the same types of use(s) requested in the medical use license or application and the individual meeting 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, when 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)
- Coursework offered by an entity such as a licensee, hospital, or vendor
- Classroom learning activities such as lectures, seminars, or laboratory learning

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

For the regulatory body to determine whether the classroom and laboratory training requirements are met, the applicant should 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 who is currently authorized for the type of activities for which the individual is seeking authorization. Specifically, the supervising individual must meet specific requirements and have authorization for the same use or device categories that the proposed authorized individual is seeking. The supervising individual 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 supervising individual is authorized.

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 (e.g., 10 CFR 35.290(c)(1)(ii) and 10 CFR 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 the NRC does not specifically require these clinical activities, 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 applicable sections of 10 CFR Part 35 describe the specific elements required for each type of authorized individual supervised work experience may be remote (e.g., reviewing case histories or interpreting scans) or in person, depending on the clinical activity (e.g., hands-on medical use of the licensed material or delivery device). For supervised work experience, a standard workweek 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 workweek.

For RSOs, ARSOs, and ANPs, 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 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. In this case, a supervisor is an individual who provides frequent direction, instruction, and direct oversight of the supervised individuals as they complete the required work experience in the clinical use 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 should be completed in person. A physician who has experience with at least three cases in oral administration of greater than 33 millicuries (mCi) (1.22 gigabecquerels (GBq)) of sodium iodide I-131 also satisfies the requirement in oral administrations of less than or equal to 33 mCi (1.22 GBq) of sodium iodide I-131. 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 individuals have completed with the specific type of therapeutic medical unit for which they are seeking authorization. There is not a specified number of hours that must be completed. Device-specific training allows for the individual to receive training on the type of therapeutic medical unit and does not require that the training be specific to the model of the device. For example, individuals seeking authorization for a high-dose-rate remote afterloader need not have training on the specific model for which they are seeking authorization but simply training with a high-dose-rate remote afterloader to meet NRC T&E criteria. In some cases, 10 CFR 35.610(d) and/or 10 CFR 35.610(e) may require model-specific training.

The scope of the training may differ for each type of therapeutic medical unit. The training shall cover operating procedures, safety procedures, emergency procedures, operation of the device, safety of the device, and clinical use of the device. This element must be hands-on training with

the device for AMPs (10 CFR 35.51(c)) and for AUs of some of the EMT. The vendor of the device, an AU of the device, or an AMP of the device may provide this training. The regulatory body will likely verify authorizations for the supervising AU, 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, "Use of a sealed source in a remote afterloader unit, teletherapy unit, or gamma stereotactic radiosurgery unit," has been completed at the facility, the licensee can train its 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. In accordance with 10 CFR 35.610(d)(2), all individuals who operate the unit at the facility must receive operational and safety instruction, as appropriate to the individual's assigned duties, initially and at least annually. 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. License applications and amendment requests should contain information that would support a determination that the proposed authorized individual's continuing education demonstrates competency in the topics specified in the applicable regulations. The required number of hours 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 may include the following:

- Successful completion of classroom and laboratory review courses that include radiation safety practices related 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, comparable linear accelerator experience, or both, and completion of an in-service review of operating and emergency procedures relative to the therapy unit to be used by the applicant

Maintaining active certifications may not be sufficient documentation to demonstrate meeting the recentness of training requirements since the training must be relevant to the duties associated with the activities for which the individual is seeking authorization. Supplementary documentation is typically necessary for maintenance of certification to be used for this requirement.

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" section of the Medical Uses Licensee Toolkit
- NUREG-1556, Volume 9, Revision 3

EXPLANATION:

Regulations in 10 CFR 35.50 provide pathways by which authorized individuals may become an RSO or ARSO. A medical physicist who is certified by a specialty board recognized by the NRC under 10 CFR 35.51, "Training for an authorized medical physicist," may request authorization as the RSO or ARSO on a license or permit (10 CFR 35.50(c)(1)). Regulations found in 10 CFR 35.50(c)(2) allow 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.

An individual who has 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)).

All individuals seeking approval under 10 CFR 35.50(c) must have experience with the radiation safety aspects of all the types of use of byproduct material for which the individual will have RSO responsibilities or ARSO duties and tasks, and they must have training in radiation safety, regulatory issues, and emergency procedures for all the types of use for which a licensee seeks approval (10 CFR 35.50(d)). These individuals must also 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
- Medical Uses Licensee Toolkit
- NRC Forms 313A series of forms
- Emerging Medical Technologies website

EXPLANATION:

Multiple individuals 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 supervising individuals, as necessary. Some institutions may rely on the RSO, a physicist, or management to assist and guide the proposed authorized individual.

It is important for preceptors, residency coordinators, and supervising individuals to note that the NRC does not assess the medical competency of any authorized individual. The NRC only reviews T&E related to the radiation safety responsibilities of authorized individuals.

4.5.1 Adding New Authorized Individuals

Pursuant to 10 CFR 35.12, licensees are to use NRC Form 313, "Application for Materials License" for license applications, and may use NRC Form 313 or a letter containing all of the information required by NRC Form 313 for license 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 website or the NRC Forms website for the most current version of the forms and their associated instructions. Verify that the most current version of NRC Form 313A is being used by checking the "Expires" date in the top right-hand corner of the form. Additionally, the appendix to this ISG includes five different case scenarios along with completed sample NRC Forms 313A that shows the information and supplemental documentation that should be submitted by the applicant or licensee. The following are the six forms in the 313A series which a licensee can use to document T&E to request authorization for different roles:

- NRC Form 313A (RSO)—Radiation Safety Officer or Associate Radiation Safety Officer
- NRC Form 313A (AMP)—Authorized Medical Physicist and Ophthalmic Physicist
- NRC Form 313A (ANP)—Authorized Nuclear Pharmacist
- NRC Form 313A (AUD)—Authorized User requesting authorization for diagnostic uses defined under 10 CFR 35.100, "Use of unsealed byproduct material for uptake, dilution, and excretion studies for which a written directive is not required"; 10 CFR 35.200, "Use of unsealed byproduct material for imaging and localization studies for which a written directive is not required"; or 10 CFR 35.500, "Use of sealed sources and medical devices for diagnosis"
- NRC Form 313A (AUT)—Authorized User requesting authorization for use of unsealed radioactive material for therapy defined under 10 CFR 35.300, "Use of unsealed byproduct material for which a written directive is required"

- NRC Form 313A (AUS)—Authorized User requesting authorization for use of sealed sources defined under 10 CFR 35.400, "Use of sources for manual brachytherapy," or 10 CFR 35.600, "Use of a sealed source in a remote afterloader unit, teletherapy unit, or gamma stereotactic radiosurgery unit"

The forms are specific to medical use licensees.

At the time of this guidance, there is not a specific NRC Form 313A for an AU requesting authorization use for radioactive material defined under 10 CFR 35.1000, "Other medical uses of byproduct material or radiation from byproduct material." The T&E requirements for 10 CFR 35.1000 medical uses are determined on a case-by-case basis. The 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 accountable for authorized individuals working under its license. NUREG-1556, Volume 9, Revision 3, includes guidance on preparing amendment requests and notifications.

4.5.2 Adding Experienced Authorized Individuals

An applicant or licensee that is adding an experienced AU for medical uses, AMP, OP, ANP, RSO, or ARSO to its medical use application or license should provide a copy of the license or permit listing the applicant. This may be a medical use license issued by the NRC or an 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 in 10 CFR 35.59.

When adding an experienced ANP to the license, an applicant or licensee also may provide evidence that the individual is listed on an NRC or Agreement State commercial nuclear pharmacy license or is identified as an ANP by a commercial nuclear pharmacy authorized to identify ANPs. For individuals who have been previously authorized by, but are 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 require only 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 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 for the same types of use (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, "Specific Domestic Licenses of Broad-Scope for Byproduct Material"), 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 the license or permit, or the board certification. For approval of additional uses or devices, documentation verifying completion of additional training must also be provided under 10 CFR 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 Radium-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 who 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. The applicant or licensee should submit evidence of recentness of training in accordance with 10 CFR 35.59.

4.5.4 Recognition of Foreign-Trained Physicians and Physicists

For foreign-trained physicians, the following must be provided to the regulator as evidence of meeting the T&E requirements.

- Current license issued by 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
    - 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 United States, or a U.S. Territory, or Puerto Rico.

For foreign-trained physicists, the following must be provided to the regulator as evidence of meeting the T&E requirements:

- The master's and/or doctoral degrees from outside of the United States 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 or university was accredited at the time that the degree was granted. The licensee should also ensure that the graduate education program is accredited by referring to the website for the International Organization for Medical Physicists, which provides a global listing of graduate education programs in medical physics and the associated accreditation status.

- The applicant's transcript (or equivalent documentation), provided in English. 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 work experience 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 is documented.

- A written attestation, 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 is included.

4.6 General Instructions for Completing the NRC Form 313A Series of Forms

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 Forms 313A series of forms
- Specialty Board Certifications Recognized by the NRC Under 10 CFR Part 35

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 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:

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 of Forms:

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 Forms 313A series of forms or fill out some sections more than once. For example, an applicant requesting that a physician be authorized for 10 CFR 35.200 and 10 CFR 35.300 medical uses and as the RSO should complete three forms of the 313A series (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 or 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.

Provide a complete copy of the permit issued by the NRC MML, broad-scope licensee, or MML broad-scope permittee to identify an individual who is authorized under any of the following:

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

Personal information about employees or other individuals should not be submitted. Examples of private information are social security number, home address, home telephone number, date of birth, radiation dose information, patient records, clinical records or resident summaries.

4.6.1 NRC Form 313A (RSO) for Radiation Safety Officers and Associate Radiation Safety Officers

The T&E requirements for the RSO and ARSOs, as described in 10 CFR 35.50, 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 the three pathways. The appendix to this ISG includes two proposed RSO case scenarios along with completed sample NRC Form 313A (RSO) that shows the information and supplemental documentation that should be submitted by the applicant or licensee.

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 Approval on a License:

An applicant or licensee that is adding an experienced RSO/ARSO for medical uses to its license needs to provide only 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 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 the recentness of training requirements described in 10 CFR 35.59, if applicable.

All RSOs who 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 before 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 Board Certifications Recognized by the NRC Under 10 CFR Part 35 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 the NRC and is listed on NRC's Specialty Board Certifications Recognized by the NRC Under 10 CFR Part 35 website. The medical physicist should have 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 they 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 that the time period of use, the materials used, and the types of medical use meet the criteria in the regulation.

Supporting documentation for NRC Form 313A (RSO) would include a copy of a board certificate listed on the NRC's Specialty Board Certifications Recognized by the NRC Under 10 CFR Part 35 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 the 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). For example, for supervised work experience, a standard workweek of 40 hours per week for 52 weeks per year is considered full-time. If the proposed RSO is not obtaining supervised work experience on a full-time basis (i.e., 40 hours a week), the licensee should demonstrate that the equivalent of 1 year full-time is obtained (e.g., multiple entries of supervised work experience that add up to 1 year full-time).

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

- National Registry of Radiation Protection Technicians 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 10 CFR 35.1000 uses), such as training records from the 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
  - DOT Course
  - HAZMAT Course
  - Radiation Instrumentation Course
  - Multi-Agency Radiation Survey and Site Investigation Manual
  - Medical Effects of Ionizing Radiation
  - Air Sampling for Radionuclides
- Other/additional documents provided (i.e., for 10 CFR 35.1000 uses)
  - 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 NRC Form 313A (RSO))

4.6.2 NRC Form 313A (AMP) for Authorized Medical Physicists and Ophthalmic Physicists

T&E requirements for AMPs described in 10 CFR 35.51 allow multiple pathways that 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. The appendix to this ISG includes a proposed AMP case scenario along with a completed sample NRC Form 313A (AMP) that shows the information and supplemental documentation that should be submitted by the applicant or licensee.

Prior Approval on a License:

An applicant or licensee that is adding an experienced AMP to its license needs to provide only 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 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 the recentness of training requirements in 10 CFR 35.59, if applicable.

All AMPs listed on a license after January 14, 2019, are required to meet the training requirements of 10 CFR 35.51(c) if they are seeking authorizations for new materials and medical uses for which they were not authorized before 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 Board Certifications Recognized by the NRC Under 10 CFR Part 35 website or included in 10 CFR 35.57(a)(3). The individual should have training in hands-on device operation, safety procedures, clinical use, and the operation of a treatment planning system.

Board-certified individuals who were not named as an AMP may be "grandfathered" for those materials and uses that they performed on or before October 24, 2005 if the individual was 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 that the time period of use, the materials used, and the types of medical use meet the criteria in the regulation.

Supporting documentation for NRC Form 313A (AMP) would include a copy of a board certificate recognized as listed on NRC's Specialty Board Certifications Recognized by the NRC Under 10 CFR Part 35 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). For example, for supervised work experience, a standard workweek of 40 hours per week for 52 weeks per year is considered full-time. If the proposed AMP is not obtaining training or supervised work experience on a full-time basis (i.e., 40 hours a week), the licensee should demonstrate that the equivalent of 1 year full-time is obtained (e.g., multiple entries of training or supervised work experience that add up to 1 year full-time).

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

Supporting documentation for NRC 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 10 CFR 35.1000 uses), such as training records from vendor
- Certificates or a syllabus from formal courses
- Other/additional documents provided (i.e., for 10 CFR 35.1000 uses)
  - 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 NRC Form 313A (AMP))

4.6.3 NRC Form 313A (ANP) for Authorized Nuclear Physicists

The T&E requirements for ANPs, as described in 10 CFR 35.55, "Training for an authorized nuclear pharmacist," allow multiple pathways for applicants to demonstrate that individuals are qualified as an ANP. Applicants should provide documentation that each individual is qualified under one of the three pathways. The appendix to this ISG includes a proposed ANP case scenario along with a completed sample NRC Form 313A (ANP) that shows the information and supplemental documentation that should be submitted by the applicant or licensee.

Prior Approval on a License:

An applicant or licensee that is adding an experienced ANP to its license needs to provide only an NRC or Agreement State license number or a copy of one of the following on which the individual is authorized for the same types of use(s) requested:

- Medical use license (if issued by an Agreement State)
- Commercial nuclear pharmacy license (if issued by an Agreement State)
- Permit issued by an NRC MML
- Permit issued by an NRC or Agreement State broad-scope licensee
- Permit issued by an NRC MML broad-scope permittee
- Authorization from a commercial nuclear pharmacy authorized to identify ANPs

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 the recentness of training requirements 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 Board Certifications Recognized by the NRC Under 10 CFR Part 35 website or included in 10 CFR 35.57(a)(2).

Supporting documentation for NRC Form 313A (ANP) would include a copy of a board certificate recognized as listed on NRC's Specialty Board Certifications Recognized by the NRC Under 10 CFR Part 35 website. The applicant or licensee would also need to provide evidence that the individual completed continuing education to meet the recentness of training requirements described in 10 CFR 35.59, if 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 for NRC Form 313A (ANP) includes the following:

- A copy of the State license to practice pharmacy (in accordance with 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 NRC Forms 313A (AUD), (AUT), (AUS) for Authorized Users

T&E requirements for AUs, 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, allow multiple pathways for applicants to 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, or the alternate pathway.

The NRC requires physicians, dentists, podiatrists, and pharmacists to be licensed by 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, 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).

The following NRC Forms 313A may be used to document T&E for proposed AUs:

- NRC Form 313A (AUD) for uses defined under 10 CFR 35.100, 35.200, and 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

The appendix to this ISG includes a proposed AU case scenario along with a completed sample NRC Form 313A (AUT) that shows the information and supplemental documentation that should be submitted by the applicant or licensee.

Prior Approval on a License:

An applicant or licensee that is adding an experienced AU to its license needs only to provide the 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 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 the recentness of training requirements in 10 CFR 35.59, if applicable.

Board Certification Pathway:

The board certification pathway, as provided in 10 CFR 35.190(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 Board Certifications Recognized by the NRC Under 10 CFR Part 35 website or included in 10 CFR 35.57(a)(3).

Board-certified individuals (i.e., physicians, dentists, or podiatrists) who were not named as an AU may be "grandfathered" for those materials and uses that they performed on or before October 24, 2005, if they 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 microcuries (µCi) (1.11 megabecquerels) (a quantity for which 10 CFR 35.40, "Written directives," requires a WD) would continue to be authorized for "imaging and localization involving greater than 30 µCi," even though after 2002 the physician was authorized under 10 CFR 35.300.

Supporting documentation for NRC Forms 313A (AUD), (AUT), (AUS) would include a copy of a board certificate recognized as listed on NRC's Specialty Board Certifications Recognized by the NRC Under 10 CFR Part 35 website. The applicant or licensee would also need to provide evidence that the individual completed continuing education to meet the 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 for Forms NRC Forms 313A (AUD), (AUT), (AUS), would include the following:

- State license
- License or permit listing preceptor as AU (except in cases where the residency program director serves as the preceptor)

- License or permit listing supervising 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
- Other/additional documents provided (i.e., for 10 CFR 35.1000 uses)
  - 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 Training and Experience Documentation for 10 CFR 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 that is not addressed in other parts of 10 CFR Part 35 (i.e., an EMT). 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.

Applicants and licensees are required to submit T&E information for individuals who are to serve as 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 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. The NRC will evaluate alternative T&E for 10 CFR 35.1000 uses other than those listed in guidance on a case-by-case basis to determine whether the T&E of the identified individuals is appropriate for the proposed use.

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, Appendix D, "Documentation of Training and Experience to Identify Individuals on a License," 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'" (NRC, 2018a)

- SECY-08-0179, "Recommendations on Amending Preceptor Attestation Requirements in 10 CFR Part 35, Medical Use of Byproduct Material," dated November 20, 2008 (NRC, 2008)

- Final Rule, "Medical Use of Byproduct Material—Recognition of Specialty Boards," dated March 30, 2005, 70 FR 16336 (NRC, 2005)

EXPLANATION:

A "preceptor attestation," also referred to as a "preceptor statement," is included in certain T&E requirements in 10 CFR Part 35. It is a signed statement provided by a preceptor that vouches for an individual's qualifications and completion of appropriate T&E and ability to function independently.

Some of the T&E requirements for authorized individuals in 10 CFR Part 35 require that an individual seeking authorization obtain a written attestation signed by a preceptor with that same authorization, stating 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 "Medical Use of Byproduct Material—Medical Event Definitions, Training and Experience, and Clarifying Amendments" (83 FR 33046) (NRC, 2018b), the regulations were amended to eliminate the requirement for preceptor attestations for almost all individuals certified by specialty boards recognized by the NRC or Agreement States on NRC's Specialty Board Certifications Recognized by the NRC Under 10 CFR Part 35 website 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, "Training for the parenteral administration of unsealed byproduct material requiring a written directive," will continue to need a preceptor attestation.

The regulations were also amended to incorporate the new language to clarify that the written attestation must verify that the individual is able to independently fulfill the radiation-safety-related duties, rather than state the individual has achieved a level of competency to function independently as an authorized individual. The purpose of the written attestations is to affirm the individual's ability to perform radiation-safety-related duties; they do not attest to the individual's clinical or medical competency. Medical competency is addressed by each state's medical board.

The following scenarios require a written and signed preceptor attestation:

- All individuals seeking authorization using 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, as applicable

- 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.)

Specialty boards are required to give an examination that assesses knowledge and competency in areas that include radiation safety to be recognized by the NRC. 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, as long as the provisions of 10 CFR 35.59 are met.

In the NRC Forms 313A series of forms, "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 ability to independently fulfill the duties of the position in areas that include radiation safety, as well as provide information concerning his or 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 Forms 313A series of forms.

The preceptor attestation page (Part II of the NRC Forms 313A series of forms) has different sections to be completed:

- Attestation to the proposed authorized individual's training
- Attestation for the device-specific training, as applicable
- Attestation for clinical casework, as applicable
- Attestation of the individual's ability to independently fulfill the radiation-safety-related duties as an authorized individual for the specific types of uses requested by the applicant
- 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.

Detailed information on documenting the required T&E and written preceptor attestation for the NRC Forms 313A series of forms can be found in NUREG-1556, Volume 9, Revision 3.

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

4.7.1 Preceptor

A preceptor is defined in 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 either of the following:

- An authorized individual who meets specific requirements and has authorization for the same use or device categories that the proposed authorized individual is seeking

- A residency program director who may provide attestation for physicians seeking to become AUs by affirming in writing that the attestation represents the consensus of the residency program faculty of which 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 T&E, 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), and 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 ANP on a license in accordance with 10 CFR 35.55(b)(2).

REFERENCES

U.S. Code of Federal Regulations, "Notices, Instructions and Reports to Workers: Inspection and Investigations," Part 19, Chapter I, Title 10, "Energy."

U.S. Code of Federal Regulations, "Standards for Protection Against Radiation," Part 20, Chapter I, Title 10, "Energy."

U.S. Code of Federal Regulations, "Rules of General Applicability to Domestic Licensing of Byproduct Material," Part 30, Chapter I, Title 10, "Energy."

U.S. Code of Federal Regulations, "Specific Domestic Licenses of Broad Scope for Byproduct Material," Part 33, Chapter I, Title 10, "Energy."

U.S. Code of Federal Regulations, "Medical Use of Byproduct Material," Part 35, Chapter I, Title 10, "Energy."

U.S. Code of Federal Regulations, "Physical Protection of Category 1 and Category 2 Quantities of Radioactive Material," Part 37, Chapter I, Title 10, "Energy."

U.S. Nuclear Regulatory Commission (NRC), 1997. NUREG-1516, "Management of Radioactive Material Safety Programs at Medical Facilities," May 1997, available at https://www.nrc.gov/reading-rm/doc-collections/nuregs/staff/sr1516/index.html.

NRC, 2002. "Medical Use of Byproduct Material," *Federal Register*, Vol. 67, p. 20250 (67 FR 20250), April 24, 2002, available at https://www.federalregister.gov/documents/2002/04/24/02-9663/medical-use-of-byproduct-material.

NRC, 2005. "Medical Use of Byproduct Material—Recognition of Specialty Boards," *Federal Register*, Vol. 70, p. 16336 (70 FR 16336), March 30, 2005, available at https://www.federalregister.gov/documents/2005/03/30/05-6103/medical-use-of-byproduct-material-recognition-of-specialty-boards.

NRC, 2008. SECY-08-0179, "Recommendations on Amending Preceptor Attestation Requirements in 10 CFR Part 35, Medical Use of Byproduct Material," November 20, 2008, ML083170176.

NRC, 2009. Staff Requirements Memorandum (SRM)-SECY-08-0179, "Staff Requirements—SECY-08-0179—Recommendations on Amending Preceptor Attestation Requirements in 10 CFR Part 35, Medical Use of Byproduct Material," January 16, 2009, ML090160275.

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APPENDIX

Guidance for Completing NRC Form 313A and Documentation of Training and Experience

An applicant or licensee may provide a copy of the board certificate and other documentation of training, experience, or clinical casework as indicated on the specific form of the NRC Forms 313A series for proposed authorized individuals to be listed on a medical use license. An Agreement State may require use of its own forms that are equivalent to the NRC Forms 313A. Applicants and licensees should contact the responsible officials in the Agreement State for guidance on the required form.

There are numerous pathways and unique scenarios to become an authorized individual; therefore, not all scenarios are presented in this guidance. However, the following case scenarios and associated NRC Forms 313A are provided to illustrate the necessary documentation needed to complete the forms, and the supporting documentation to be submitted by licensees (see NUREG-1556, "Consolidated Guidance About Materials Licenses," Volume 9, Revision 3, "Program-Specific Guidance About Medical Use Licenses," Appendix D, "Documentation of Training and Experience to Identify Individuals on a License," issued September 2019).

Case Scenario for Radiation Safety Officer – Board-Certified Medical Physicist Pathway

An NRC licensee is requesting that Niels Bohr, a medical physicist certified in July 2023 by the American Board of Medical Physics (ABMP), an NRC-recognized specialty board, to be added to its license as an RSO. Niels Bohr has never been listed on a radioactive materials license as an AMP or RSO. The licensee is authorized for medical uses under Title 10 of the *Code of Federal Regulations* (10 CFR) 35.100, 35.200, 35.300, 35.400, 35.600, and 35.1000 (SIR–Spheres use). Enrico Fermi was Niels Bohr's supervising individual providing the training in radiation safety, regulatory issues and emergency procedures for the types of medical uses on the license. Supporting documentation to be provided by the licensee includes the following:

- Copy of Niels Bohr's medical physics certification from ABMP
- Copies of the NRC or Agreement State licenses for the supervising individual providing the training in radiation safety, regulatory issues and emergency procedures (i.e., license number CA-123456 that lists Enrico Fermi as authorized for 10 CFR 35.100, 35.200, 35.300, 35.400, 35.600, and 35.1000 materials in this case scenario)

313A NRC Form 313A (RSO) HEADER:

- Insert the full name of the applicant and select the requested authorization (RSO or ARSO) and medical uses (e.g., 10 CFR 35.100, 35.200, 35.300, 35.400, 35.600, and 35.1000). Since many materials are EMT regulated under 10 CFR 35.1000, "Other medical uses of byproduct material or radiation from byproduct material" (e.g., Y-90 microspheres, gamma stereotactic radiosurgery), the licensee should annotate the type of use(s) requested in the license amendment request or application (e.g., SIR—Spheres).

313A NRC Form 313A (RSO) PART I—TRAINING AND EXPERIENCE

- Niels Bohr is certified by the ABMP (Block 1 selected).

313A (RSO) Part I, Section 5.a. Classroom and Laboratory Training

- Since Niels Bohr is a medical physicist certified by a specialty board that is recognized by the NRC, this section does not need to be completed.

313A (RSO) Part I, Section 5.b. Supervised Radiation Safety Experience

- Since Niels Bohr is a medical physicist certified by a specialty board that is recognized by the NRC, this section does not need to be completed.

313A (RSO) Part I, Section 5.c. Training in Radiation Safety, Regulatory Issues, and Emergency Procedures

- Document the name of the individual who provided training and the location and dates of the training. In this case, Niels Bohr did not receive any training for teletherapy uses

under 10 CFR 35.600, “Use of a sealed source in a remote afterloader unit, teletherapy unit, or gamma stereotactic radiosurgery unit,” and this section is left blank as she is not applying for this medical use.

  - Completion of section 5.c. of Form 313A (RSO) demonstrates that the requirements of 10 CFR 35.50(d) are met.

- Enter the name of the supervising individual providing the training; the license number on which the supervising individual is listed as an RSO, ARSO, AMP, ANP, or AU; and the medical uses for which the supervising individual is authorized.

  - *Note*: Enrico Fermi provided all the training in this case scenario. Training can be obtained from more than one authorized individual (RSO, ARSO, AMP, ANP, or AU), as appropriate, who is authorized for the type(s) of use for which the licensee is seeking approval, to supervise completion of the required training.

313A (RSO) Part II—PRECEPTOR ATTESTATION

- Since Niels Bohr is board-certified by a specialty board recognized by the NRC, the preceptor attestation section does not need to be completed.

NRC FORM 313A (RSO) (MM-DD-YYYY) U. S. NUCLEAR REGULATORY COMMISSION

APPROVED BY OMB: NO. 3150-0120 EXPIRES: (MM/DD/YYYY)

Estimated burden per response to comply with this mandatory collection request: 4.3 hours. Submittal of the application is necessary to determine that the applicant is qualified and that adequate procedures exist to protect the public health and safety. Send comments regarding burden estimate to the FOIA, Library, and Information Collections Branch (T-6 A10M), U.S. Nuclear Regulatory Commission, Washington, DC 20555-0001, or by email to Infocollects.Resource@nrc.gov, and the OMB Reviewer at: OMB Office of Information and Regulatory Affairs, (3150-0120), Attn: Desk Officer for the Nuclear Regulatory Commission, 725 17th Street NW, Washington, DC 20503. The NRC may not conduct or sponsor, and a person is not required to respond to, a collection of information unless the document requesting or requiring the collection displays a currently valid OMB control number.

RADIATION SAFETY OFFICER OR ASSOCIATE RADIATION SAFETY OFFICER TRAINING, EXPERIENCE AND PRECEPTOR ATTESTATION [10 CFR 35.57, 35.50]

Name of Individual ☑ RSO ☐ ARSO

Niels Bohr

Requested Authorization(s) *The license authorizes the following medical uses (check all that apply)*:

☑ 35.100 ☑ 35.200 ☑ 35.300 ☑ 35.400 ☐ 35.500 ☑ 35.600 (remote afterloader)

☐ 35.600 (teletherapy) ☐ 35.600 (gamma stereotactic radiosurgery) ☑ 35.1000 (SIR-Spheres)

PART I -- TRAINING AND EXPERIENCE

(Select one of the five methods below)

*Training and Experience, including board certification, must have been obtained within the 7 years preceding the date of application or the individual must have obtained related continuing education and experience since the required training and experience was completed. Provide dates, duration, and description of continuing education and experience related to the uses checked above.

☑ **1. Board Certification**

a. Provide a copy of the board certification.

b. If the board certification process has been recognized by the Commission or an Agreement State under 10 CFR 35.50;

(i) Go to the table in 5c and describe training provider and dates of training for each type of use for which authorization is sought.

(ii) Stop here

c. If the board certification was issued on or before October 24, 2005 and is listed in 10 CFR 35.57 (a)(2);

(i) Provide documentation demonstrating that the individual was using the requested materials and uses on or before October 24, 2005;

(ii) Stop here

OR

☐ **2. Current Radiation Safety Officer (RSO) or Associate Radiation Safety Officer (ARSO) Seeking Authorization to Be Recognized as a RSO or ARSO for the Additional Medical Uses Checked Above**

a. Use the table in section 5.c. to describe training in radiation safety, regulatory issues, and emergency procedures for the additional types of medical use for which recognition as RSO or ARSO is sought.

b. If board certified, provide a copy of the certificate and stop here.

c. If not board certified and not listed on a medical use license as an RSO before January 14, 2019, skip to and complete Part II Preceptor Attestation.

OR

☐ **3. Authorized User (AU), Authorized Medical Physicist (AMP), or Authorized Nuclear Pharmacist (ANP) identified on a license or permit in accordance with 10 CFR 35.50 (c)(2)**

a. Provide license number.

b. Use the table in section 5.c. to describe training in radiation safety, regulatory issues, and emergency procedures for all types of medical use on the license.

c. Stop here.

OR

RADIATION SAFETY OFFICER OR
ASSOCIATE RADIATION SAFETY OFFICER
TRAINING, EXPERIENCE AND PRECEPTOR ATTESTATION [10 CFR 35.57, 35.50] (continued)

☐ **4. Individuals applying simultaneously to be the RSO and AU on a new license**

☐ a. Documentation of training and experience to be a new AU is attached

☐ b. The new license application is attached.

c. Stop here.

OR

☐ **5. Structured Educational Program for Proposed RSO or ARSO**

a. Classroom and Laboratory Training

Description of Training	Location of Training	Clock Hours	Dates of Training*
Radiation physics and instrumentation			
Radiation protection			
Mathematics pertaining to the use and measurement of radioactivity			
Radiation biology			
Radiation dosimetry			
Total Hours of Training:			

**RADIATION SAFETY OFFICER OR
ASSOCIATE RADIATION SAFETY OFFICER
TRAINING, EXPERIENCE AND PRECEPTOR ATTESTATION [10 CFR 35.57, 35.50] (continued)**

5. **Structured Educational Program for Proposed RSO or ARSO (continued)**

b. Supervised Radiation Safety Experience

(If more than one supervising individual is necessary to document supervised work experience, provide multiple copies copies of this section.)

Description of Experience	Location of Training/ License or Permit Number of Facility	Dates of Training*
Shipping, receiving, and performing related radiation surveys		
Using and performing checks for proper operation of instruments used to determine the activity of dosages, survey meters, and instruments used to measure radionuclides		
Securing and controlling byproduct material		
Using administrative controls to avoid mistakes in administration of byproduct material		
Using procedures to prevent or minimize radioactive contamination and using proper decontamination procedures		
Using emergency procedures to control byproduct material		
Disposing of byproduct material		
Licensed Material Used (e.g., 35.100, 35.200, etc.)+		

\+ Choose all applicable sections of 10 CFR Part 35 to describe radioisotopes and quantities used: 35.100, 35.200, 35.300, 35.400, 35.500, 35.600 remote afterloader units, 35.600 teletherapy units, 35.600 gamma stereotactic radiosurgery units, emerging technologies (provide list of devices).

RADIATION SAFETY OFFICER OR ASSOCIATE RADIATION SAFETY OFFICER TRAINING, EXPERIENCE AND PRECEPTOR ATTESTATION [10 CFR 35.57, 35.50] (continued)

5. **Structured Educational Program for Proposed RSO or ARSO (continued)**

b. Supervised Radiation Safety Experience (continued)

(If more than one supervising individual is necessary to document supervised work experience, provide multiple copies of this section.)

Supervising Individual	License/Permit Number listing supervising individual as a Radiation Safety Officer or Associate Radiation Safety Officer

The supervising individual is authorized as the for the following medical uses:

☐ Radiation Safety Officer or the
☐ Associate Radiation Safety Officer

☐ 35.100 ☐ 35.200 ☐ 35.300 ☐ 35.400
☐ 35.500 ☐ 35.600 (remote afterloader) ☐ 35.600 (teletherapy)
☐ 35.600 (gamma stereotactic radiosurgery) ☐ 35.1000 ( )

c. Describe training in radiation safety, regulatory issues, and emergency procedures for all types of medical use on the license for the RSO or types of use for which the ARSO will be listed on the license.

Description of Training	Training Provided By	Dates of Training*
Radiation safety, regulatory issues, and emergency procedures for 35.100, 35.200, and 35.500 uses	Enrico Fermi, RSO	1 Dec 2020 - 15 Jan 2022
Radiation safety, regulatory issues, and emergency procedures for 35.300 uses	Enrico Fermi, RSO	1 Dec 2020 - 15 Jan 2022
Radiation safety, regulatory issues, and emergency procedures for 35.400 uses	Enrico Fermi, RSO	1 Dec 2020 - 15 Jan 2022
Radiation safety, regulatory issues, and emergency procedures for 35.600 - teletherapy uses		
Radiation safety, regulatory issues, and emergency procedures for 35.600 - remote afterloader uses	Enrico Fermi, RSO	1 Dec 2020 - 15 Jan 2022
Radiation safety, regulatory issues, and emergency procedures for 35.600 - gamma stereotactic radiosurgery uses		
Radiation safety, regulatory issues, and emergency procedures for 35.1000, specify use(s): SIR-Spheres, Theraspheres	Enrico Fermi, RSO	1 Dec 2020 - 15 Jan 2022

NRC FORM 313A (RSO)
(MM-DD-YYYY)

U. S. NUCLEAR REGULATORY COMMISSION

RADIATION SAFETY OFFICER OR
ASSOCIATE RADIATION SAFETY OFFICER
TRAINING, EXPERIENCE AND PRECEPTOR ATTESTATION [10 CFR 35.57, 35.50] (continued)

5. Structured Educational Program for Proposed RSO or ARSO (continued)

c. Training in radiation safety, regulatory issues, and emergency procedures for all types of medical use on the license (continued)

Supervising Individual *If training was provided by supervising RSO, ARSO, AU, AMP, or ANP. (If more than one supervising individual is necessary to document supervised training, provide multiple copies of this page.)*	License/Permit Number listing supervising individual
Enrico Fermi	CA-123456

License/Permit lists supervising individual as:

- [x] Radiation Safety Officer
- [ ] Associate Radiation Safety Officer
- [ ] Authorized User
- [ ] Authorized Nuclear Pharmacist
- [ ] Authorized Medical Physicist

Authorized as RSO, ARSO, AU, ANP, or AMP for the following medical uses:

- [x] 35.100
- [x] 35.200
- [x] 35.300
- [ ] 35.400
- [ ] 35.500
- [x] 35.600 (remote afterloader)
- [x] 35.600 (teletherapy)
- [ ] 35.600 (gamma stereotactic radiosurgery)
- [x] 35.1000 (SIR-Spheres)

d. Skip to and complete Part II Preceptor Attestation.

PART II – PRECEPTOR ATTESTATION

Note: This part must be completed by the individual's preceptor. The preceptor does not have to be the supervising individual as long as the preceptor provides, directs, or verifies training and experience required. If more than one preceptor is necessary to document experience, obtain a separate preceptor statement from each.

First Section

Structured Educational Program for Proposed RSO or ARSO

[ ] I attest that _____ has satisfactorily completed
Name of Proposed RSO/ARSO

a structural educational program consisting of both 200 hours of classroom and laboratory training and one year of full-time radiation safety experience as required by 10 CFR 35.50(b)(1).

AND

Second Section

[ ] I attest that _____ has training in
Name of Proposed RSO/ARSO

radiation safety, regulatory issues, and emergency procedures for the following types of use:

***Check all that apply*:**

- [ ] 35.100
- [ ] 35.200
- [ ] 35.300 oral administration of less than or equal to 33 millicuries of sodium iodide I-131, for which a written directive is required
- [ ] 35.300 oral administration of greater than 33 millicuries of sodium iodide I-131
- [ ] 35.300 Parenteral administration of any radioactive drug that contains a radionuclide that is primarily used for its electron emission, beta radiation characteristics, alpha radiation characteristics, or photon energy of less than 150 keV, for which a written directive is required

NRC FORM 313A (RSO)
(MM-DD-YYYY)

U. S. NUCLEAR REGULATORY COMMISSION

RADIATION SAFETY OFFICER OR
ASSOCIATE RADIATION SAFETY OFFICER
TRAINING, EXPERIENCE AND PRECEPTOR ATTESTATION [10 CFR 35.57, 35.50] (continued)

PART II – PRECEPTOR ATTESTATION (continued)

Check all *that apply:*

- ☐ 35.400
- ☐ 35.500
- ☐ 35.600 remote afterloader units
- ☐ 35.600 teletherapy units
- ☐ 35.600 gamma stereotactic radiosurgery units
- ☐ 35.1000 emerging technologies, including:

Third Section **AND**

☐ I attest that _____
Name of Proposed Radiation Safety Officer or Associate Radiation Safety Officer

is able to independently fulfill the radiation safety-related duties as:

☐ A Radiation Safety Officer for a medical use licensee.

OR

☐ An Associate Radiation Safety Officer for a medical use licensee.

Fourth Section
Complete the following for Preceptor Attestation and signature

☐ I am the Radiation Safety Officer for ☐ I am the Associate Radiation Safety Officer for

Name of Facility: _____

License/Permit Number: _____

Name of Preceptor (Typed or printed)	Telephone Number	Date

Signature

Case Scenario for Radiation Safety Officer—Alternate Pathway

An NRC licensee is asking that Isaac Newton be added to its license as an RSO. Isaac Newton is not board-certified and has never been listed on a radioactive materials license as an RSO. The licensee is authorized for medical uses under 10 CFR 35.100, 35.200, 35.300, 35.400, 35.600, and 35.1000 (SIR–Spheres use). Albert Einstein was Isaac Newton's supervising individual providing the training in radiation safety, regulatory issues and emergency procedures for the types of medical uses on the license. Albert Einstein also served as Isaac Newton's preceptor. Supporting documentation to be provided by the licensee for Isaac Newton includes the following:

- Course completion certificates for courses that apply toward the classroom and laboratory training requirements (e.g., the 40-hour medical RSO course (divided over four topics) and the DOT course in Isaac Newton's example)
- College transcripts showing completion of applicable college credits
  - Any personal information such as date of birth, student ID number, etc. should be redacted before submission to the NRC.
- Copies of the NRC or Agreement State licenses for the supervising individual and the preceptor (i.e., license number CA-123456 that lists Albert Einstein (who is serving as both the supervising individual and the preceptor) as authorized for 10 CFR 35.100, 35.200, 35.300, 35.400, 35.600, and 35.1000 materials in this case scenario)

313A (RSO) HEADER

- Insert the full name of the applicant and select the requested authorization (RSO or ARSO) and medical uses (e.g., 10 CFR 35.100, 35.200, 35.300, 35.400, 35.600, and 35.1000). Since many materials are EMT regulated under 10 CFR 35.1000 (e.g., Y-90 microspheres, gamma stereotactic radiosurgery), the licensee should annotate the type of use(s) requested in the license amendment request or application (e.g., SIR–Spheres).

313A (RSO) PART I—TRAINING AND EXPERIENCE

- Isaac Newton is seeking authorization using the alternate pathway (Block 5 selected).

313A (RSO) Part I, Section 5.a. Classroom and Laboratory Training

- Demonstrate completion of at least 200 hours of classroom and laboratory training in five key radiation protection areas (radiation physics and instrumentation, radiation protection, mathematics pertaining to the use and measurement of radioactivity, radiation biology, and radiation dosimetry).
- Include the location of training, number of hours per topic, and dates of training.
  - It is acceptable to list a course over several topics. However, hours may be counted in only one category.

313A (RSO) Part I, Section 5.b. Supervised Radiation Safety Experience

- Demonstrate completion of at least 1 year of full-time radiation safety experience under the supervision of an individual identified as an RSO/ARSO on an NRC or an Agreement State license or permit issued by an NRC MML that authorizes similar type(s) of use(s) of byproduct material.
  - The supervised work experience must cover all seven of the listed categories.
  - Supervised work experience can be obtained at more than site and by more than one individual. In this case, multiple copies of this section of Form 313A(RSO) can be provided.
- Include the location of experience, license/permit number of the facility, and dates of experience.
- Provide the name of the supervising individual, the license number on which the supervising individual is listed as an RSO (or ARSO), and the medical uses for which the supervising individual is authorized.

313A (RSO) Part I, Section 5.c. Training in Radiation Safety, Regulatory Issues, and Emergency Procedures

- Document the name of the individual who provided training and the location and dates of the training.
  - Completion of section 5.c. of Form 313A (RSO) demonstrates that the requirements of 10 CFR 35.50(d) are met.
- Provide the name of the supervising individual providing the training; the license or permit number on which the supervising individual is listed as an RSO, ARSO, AMP, ANP, or AU; and the medical uses for which the supervising individual is authorized.
  - *Note*: Albert Einstein provided all the training in this case scenario. Training can be obtained by more than one authorized individual (RSO, ARSO, AMP, ANP, or AU), as appropriate, who is authorized for the type(s) of use for which the licensee is seeking approval, to supervise the required training.

313A (RSO) Part II – PRECEPTOR ATTESTATION

- The preceptor should attest to the following:
  - The applicant has completed the 200 hours of classroom and laboratory training.
  - The applicant has completed training in radiation safety, regulatory issues, and emergency procedures for the requested medical applications. This section must match the “header section” on page 1.
  - The applicant is able to independently fulfill the radiation-safety-related duties as an RSO.

- Select the preceptor's authorization (RSO or ARSO), and provide the name of the preceptor's facility, the license/permit number on which the preceptor is listed as an RSO (or ARSO), the name of the preceptor, and telephone number.

- Have the preceptor sign and date the preceptor section.

NRC FORM 313A (RSO) (MM-DD-YYYY) U. S. NUCLEAR REGULATORY COMMISSION

APPROVED BY OMB: NO. 3150-0120 EXPIRES: (MM/DD/YYYY)

Estimated burden per response to comply with this mandatory collection request: 4.3 hours. Submittal of the application is necessary to determine that the applicant is qualified and that adequate procedures exist to protect the public health and safety. Send comments regarding burden estimate to the FOIA, Library, and Information Collections Branch (T-6 A10M), U.S. Nuclear Regulatory Commission, Washington, DC 20555-0001, or by email to Infocollects.Resource@nrc.gov, and the OMB Reviewer at: OMB Office of Information and Regulatory Affairs, (3150-0120), Attn: Desk Officer for the Nuclear Regulatory Commission, 725 17th Street NW, Washington, DC 20503. The NRC may not conduct or sponsor, and a person is not required to respond to, a collection of information unless the document requesting or requiring the collection displays a currently valid OMB control number.

RADIATION SAFETY OFFICER OR ASSOCIATE RADIATION SAFETY OFFICER TRAINING, EXPERIENCE AND PRECEPTOR ATTESTATION [10 CFR 35.57, 35.50]

Name of Individual ☑ RSO ☐ ARSO

Isaac Newton

Requested Authorization(s) *The license authorizes the following medical uses (check all that apply)*:

☑ 35.100 ☑ 35.200 ☑ 35.300 ☑ 35.400 ☐ 35.500 ☑ 35.600 (remote afterloader)

☐ 35.600 (teletherapy) ☐ 35.600 (gamma stereotactic radiosurgery) ☑ 35.1000 (SIR-Spheres)

PART I -- TRAINING AND EXPERIENCE
(Select one of the five methods below)

*Training and Experience, including board certification, must have been obtained within the 7 years preceding the date of application or the individual must have obtained related continuing education and experience since the required training and experience was completed. Provide dates, duration, and description of continuing education and experience related to the uses checked above.

☐ **1. Board Certification**

a. Provide a copy of the board certification.

b. If the board certification process has been recognized by the Commission or an Agreement State under 10 CFR 35.50;

(i) Go to the table in 5c and describe training provider and dates of training for each type of use for which authorization is sought.

(ii) Stop here

c. If the board certification was issued on or before October 24, 2005 and is listed in 10 CFR 35.57 (a)(2);

(i) Provide documentation demonstrating that the individual was using the requested materials and uses on or before October 24, 2005;

(ii) Stop here

OR

☐ **2. Current Radiation Safety Officer (RSO) or Associate Radiation Safety Officer (ARSO) Seeking Authorization to Be Recognized as a RSO or ARSO for the Additional Medical Uses Checked Above**

a. Use the table in section 5.c. to describe training in radiation safety, regulatory issues, and emergency procedures for the additional types of medical use for which recognition as RSO or ARSO is sought.

b. If board certified, provide a copy of the certificate and stop here.

c. If not board certified and not listed on a medical use license as an RSO before January 14, 2019, skip to and complete Part II Preceptor Attestation.

OR

☐ **3. Authorized User (AU), Authorized Medical Physicist (AMP), or Authorized Nuclear Pharmacist (ANP) identified on a license or permit in accordance with 10 CFR 35.50 (c)(2)**

a. Provide license number.

b. Use the table in section 5.c. to describe training in radiation safety, regulatory issues, and emergency procedures for all types of medical use on the license.

c. Stop here.

OR

RADIATION SAFETY OFFICER OR ASSOCIATE RADIATION SAFETY OFFICER TRAINING, EXPERIENCE AND PRECEPTOR ATTESTATION [10 CFR 35.57, 35.50] (continued)

☐ **4. Individuals applying simultaneously to be the RSO and AU on a new license**

☐ a. Documentation of training and experience to be a new AU is attached

☐ b. The new license application is attached.

c. Stop here.

OR

☑ **5. Structured Educational Program for Proposed RSO or ARSO**

a. Classroom and Laboratory Training

Description of Training	Location of Training	Clock Hours	Dates of Training*
Radiation physics and instrumentation	Medical RSO Course America University - 3 credit hr course	10 37.5	1-5 Jun 2020 Jan-May 2021
Radiation protection	Medical RSO Course Medical Effects of Ionizing Radiation Nuclear Medicine AU Course	10 32 40	1-5 Jun 2020 6-8 Jul 2020 1-5 Sep 2021
Mathematics pertaining to the use and measurement of radioactivity	Department of Transportation: RAM Shipment Course Medical RSO Course	32 10	1-4 Mar 2020 1-5 Jun 2020
Radiation biology	America University - 3 credit hr course	37.5	Sep-Dec 2020
Radiation dosimetry	Medical RSO Course America University - 3 credit hr course	10 37.5	1-5 Jun 2020 Sep-Dec 2021
Total Hours of Training:	256.5		

**RADIATION SAFETY OFFICER OR
ASSOCIATE RADIATION SAFETY OFFICER
TRAINING, EXPERIENCE AND PRECEPTOR ATTESTATION [10 CFR 35.57, 35.50] (continued)**

5. Structured Educational Program for Proposed RSO or ARSO (continued)

b. Supervised Radiation Safety Experience

(If more than one supervising individual is necessary to document supervised work experience, provide multiple copies copies of this section.)

Description of Experience	Location of Training/ License or Permit Number of Facility	Dates of Training*
Shipping, receiving, and performing related radiation surveys	University Hospital Trenton, CA CA-123456	1 Dec 2020 - 15 Jan 2022
Using and performing checks for proper operation of instruments used to determine the activity of dosages, survey meters, and instruments used to measure radionuclides	University Hospital Trenton, CA CA-123456	1 Dec 2020 - 15 Jan 2022
Securing and controlling byproduct material	University Hospital Trenton, CA CA-123456	1 Dec 2020 - 15 Jan 2022
Using administrative controls to avoid mistakes in administration of byproduct material	University Hospital Trenton, CA CA-123456	1 Dec 2020 - 15 Jan 2022
Using procedures to prevent or minimize radioactive contamination and using proper decontamination procedures	University Hospital Trenton, CA CA-123456	1 Dec 2020 - 15 Jan 2022
Using emergency procedures to control byproduct material	University Hospital Trenton, CA CA-123456	1 Dec 2020 - 15 Jan 2022
Disposing of byproduct material	University Hospital Trenton, CA CA-123456	1 Dec 2020 - 15 Jan 2022
Licensed Material Used (e.g., 35.100, 35.200, etc.)+ 35.100, 200, 300, 400, 600 - remote afterloader, and 35.1000 SIR Spheres	University Hospital Trenton, CA CA-123456	1 Dec 2020 - 15 Jan 2022

\+ Choose all applicable sections of 10 CFR Part 35 to describe radioisotopes and quantities used: 35.100, 35.200, 35.300, 35.400, 35.500, 35.600 remote afterloader units, 35.600 teletherapy units, 35.600 gamma stereotactic radiosurgery units, emerging technologies (provide list of devices).

NRC FORM 313A (RSO)
(MM-DD-YYYY)

U. S. NUCLEAR REGULATORY COMMISSION

RADIATION SAFETY OFFICER OR
ASSOCIATE RADIATION SAFETY OFFICER
TRAINING, EXPERIENCE AND PRECEPTOR ATTESTATION [10 CFR 35.57, 35.50] (continued)

5. Structured Educational Program for Proposed RSO or ARSO (continued)

b. Supervised Radiation Safety Experience (continued)

(If more than one supervising individual is necessary to document supervised work experience, provide multiple copies of this section.)

Supervising Individual	License/Permit Number listing supervising individual as a Radiation Safety Officer or Associate Radiation Safety Officer
Albert Einstein	CA-123456

The supervising individual is authorized as the for the following medical uses:

- ☑ Radiation Safety Officer or the
- ☐ Associate Radiation Safety Officer

- ☑ 35.100
- ☑ 35.200
- ☑ 35.300
- ☑ 35.400
- ☐ 35.500
- ☑ 35.600 (remote afterloader)
- ☑ 35.600 (teletherapy)
- ☐ 35.600 (gamma stereotactic radiosurgery)
- ☑ 35.1000 (SIR-Spheres, Theraspheres)

c. Describe training in radiation safety, regulatory issues, and emergency procedures for all types of medical use on the license for the RSO or types of use for which the ARSO will be listed on the license.

Description of Training	Training Provided By	Dates of Training*
Radiation safety, regulatory issues, and emergency procedures for 35.100, 35.200, and 35.500 uses	Albert Einstein, RSO	1 Dec 2020 - 15 Jan 2022
Radiation safety, regulatory issues, and emergency procedures for 35.300 uses	Albert Einstein, RSO	1 Dec 2020 - 15 Jan 2022
Radiation safety, regulatory issues, and emergency procedures for 35.400 uses	Albert Einstein, RSO	1 Dec 2020 - 15 Jan 2022
Radiation safety, regulatory issues, and emergency procedures for 35.600 - teletherapy uses		
Radiation safety, regulatory issues, and emergency procedures for 35.600 - remote afterloader uses	Albert Einstein, RSO	1 Dec 2020 - 15 Jan 2022
Radiation safety, regulatory issues, and emergency procedures for 35.600 - gamma stereotactic radiosurgery uses		
Radiation safety, regulatory issues, and emergency procedures for 35.1000, specify use(s): SIR-Spheres, Theraspheres	Albert Einstein, RSO	1 Dec 2020 - 15 Jan 2022

NRC FORM 313A (RSO)
(MM-DD-YYYY)

U. S. NUCLEAR REGULATORY COMMISSION

RADIATION SAFETY OFFICER OR ASSOCIATE RADIATION SAFETY OFFICER TRAINING, EXPERIENCE AND PRECEPTOR ATTESTATION [10 CFR 35.57, 35.50] (continued)

5. Structured Educational Program for Proposed RSO or ARSO (continued)

c. Training in radiation safety, regulatory issues, and emergency procedures for all types of medical use on the license (continued)

Supervising Individual *If training was provided by supervising RSO, ARSO, AU, AMP, or ANP. (If more than one supervising individual is necessary to document supervised training, provide multiple copies of this page.)*	License/Permit Number listing supervising individual
Albert Einstein	CA-123456

License/Permit lists supervising individual as:

☑ Radiation Safety Officer ☐ Associate Radiation Safety Officer
☐ Authorized User ☐ Authorized Nuclear Pharmacist ☐ Authorized Medical Physicist

Authorized as RSO, ARSO, AU, ANP, or AMP for the following medical uses:

☑ 35.100 ☑ 35.200 ☑ 35.300 ☑ 35.400
☐ 35.500 ☑ 35.600 (remote afterloader) ☑ 35.600 (teletherapy)
☐ 35.600 (gamma stereotactic radiosurgery) ☑ 35.1000 (SIR-Spheres, Theraspheres)

d. Skip to and complete Part II Preceptor Attestation.

PART II – PRECEPTOR ATTESTATION

Note: This part must be completed by the individual's preceptor. The preceptor does not have to be the supervising individual as long as the preceptor provides, directs, or verifies training and experience required. If more than one preceptor is necessary to document experience, obtain a separate preceptor statement from each.

First Section

Structured Educational Program for Proposed RSO or ARSO

☑ I attest that Isaac Newton (Name of Proposed RSO/ARSO) has satisfactorily completed a structural educational program consisting of both 200 hours of classroom and laboratory training and one year of full-time radiation safety experience as required by 10 CFR 35.50(b)(1).

AND

Second Section

☑ I attest that Isaac Newton (Name of Proposed RSO/ARSO) has training in radiation safety, regulatory issues, and emergency procedures for the following types of use:

***Check all that apply*:**

☑ 35.100 ☑ 35.200
☑ 35.300 oral administration of less than or equal to 33 millicuries of sodium iodide I-131, for which a written directive is required
☑ 35.300 oral administration of greater than 33 millicuries of sodium iodide I-131
☑ 35.300 Parenteral administration of any radioactive drug that contains a radionuclide that is primarily used for its electron emission, beta radiation characteristics, alpha radiation characteristics, or photon energy of less than 150 keV, for which a written directive is required

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(MM-DD-YYYY)

U. S. NUCLEAR REGULATORY COMMISSION

RADIATION SAFETY OFFICER OR
ASSOCIATE RADIATION SAFETY OFFICER
TRAINING, EXPERIENCE AND PRECEPTOR ATTESTATION [10 CFR 35.57, 35.50] (continued)

PART II – PRECEPTOR ATTESTATION (continued)

Check all *that apply:*

- [x] 35.400
- [ ] 35.500
- [x] 35.600 remote afterloader units
- [ ] 35.600 teletherapy units
- [ ] 35.600 gamma stereotactic radiosurgery units
- [x] 35.1000 emerging technologies, including:

Y-90 SIR-Spheres

Third Section

AND

- [x] I attest that Isaac Newton

Name of Proposed Radiation Safety Officer or Associate Radiation Safety Officer

is able to independently fulfill the radiation safety-related duties as:

- [x] A Radiation Safety Officer for a medical use licensee.

OR

- [ ] An Associate Radiation Safety Officer for a medical use licensee.

Fourth Section
Complete the following for Preceptor Attestation and signature

- [x] I am the Radiation Safety Officer for
- [ ] I am the Associate Radiation Safety Officer for

Name of Facility: University Hosptial

License/Permit Number: CA-123456

Name of Preceptor (Typed or printed)	Telephone Number	Date
Albert Einstein	(123) 456-7890	4/1/2023

Signature

NRC FORM 313A (RSO) (MM-DD-YYYY) PAGE 6

Case Scenario for Authorized Medical Physicist—Alternate Pathway

An NRC licensee is asking that Nikola Tesla, a medical physicist, be added to its license as an AMP. Nikola Tesla is not board-certified and has never been listed on a radioactive materials license as an AMP. Nikola Tesla is seeking authorization for remote afterloaders under 10 CFR 35.600, "Use of a sealed source in a remote afterloader unit, teletherapy unit, or gamma stereotactic radiosurgery unit." Marie Curie was Nikola Tesla's supervising individual for the medical physics training and work experience. Marie Curie also served as Nikola Tesla's preceptor. Supporting documentation to be provided by the licensee includes the following:

- College diploma or transcripts demonstrating completion of relevant degree (physics, medical physics, other physical science, engineering, or applied mathematics)
  - Any personal information such as date of birth, student ID number, etc. should be redacted before submission to the NRC.
- Copies of the NRC or Agreement State licenses for the supervising individual and the preceptor (i.e., license number NC-001001 that lists Marie Curie as authorized for remote afterloaders under 35.600 in this case scenario)

313A (AMP) HEADER

- Insert the full name of the proposed AMP (or OP), select the requested authorization (AMP or OP) and the medical use(s) (e.g., 35.600 remote afterloader unit(s)).
  - In this example, Nikola Tesla is requesting authorization for the use of remote afterloader units.

313A (AMP) PART I—TRAINING AND EXPERIENCE

- Nikola Tesla is seeking authorization using the alternate pathway (Block 3 selected).

313A (AMP) Part I, Section 3.a. Education

- List the degree, major, and college or university at which the degree was obtained.

313A (AMP) Part I, Section 3.b. Supervised Full-Time Medical Physics Training and Work Experience

- Verify 1 year of full-time training in medical physics and 1 year of full-time work experience in medical physics.
  - The training and work experience must have been acquired in clinical radiation facilities that provide high-energy external beam therapy (photons and electrons with energies greater than or equal to 1 million electron volts) and brachytherapy services.
- Name the individual(s) who provided the training in medical physics and who supervised the work experience.

- Document the location of the training facility, NRC or Agreement State license number or permit number, medical devices used, and dates of the training and work experience.
  - The supervised work experience must cover all applicable listed categories.
  - The 1 year of full-time medical physics training and 1 year of full-time work experience cannot be concurrent.
  - Supervised work experience can be obtained at more than one site and from more than one individual. In this case, multiple copies of this section of Form 313A(AMP) can be provided.
- Name the supervising individual, the license or permit number on which the supervising individual is listed as an AMP, and the medical uses for which the supervising individual is authorized.
  - If the individual supervising the applicant is not identified as an AMP on an NRC or an Agreement State license or permit issued by an NRC MML, evidence that the supervising medical physicist meets the T&E requirements for the types of use for which the applicant is seeking authorization must be submitted.

313A (AMP) Part I, Section 3.c. Training in Radiation Safety, Regulatory Issues, and Emergency Procedures

- Document the name of the individual or vendor who provided training and the location and dates of the training.
  - Completion of section 3.c. of Form 313A (RSO) demonstrates that the requirements of 10 CFR 35.51(c) are met.
- Provide the name of the supervising individual providing the training; the license or permit number on which the supervising individual is listed as an AMP; and the medical uses for which the supervising individual is authorized.
  - *Note*: Marie Curie provided all the training in this case scenario. Training can be obtained from more than one AMP who is authorized for the type(s) of use for which the licensee is seeking approval.

313A (AMP) Part I, Section 4. Education, Training, and Experience for Proposed Ophthalmic Physicist

Since Nikola Tesla is not seeking authorization as an OP, this section does not need to be completed.

313A (AMP) PART II—PRECEPTOR ATTESTATION

- Have the preceptor attest to the following:
  - Completion of 1 year of full-time training in medical physics and an additional year of full-time work experience

- Completion of training for the uses for which authorization is sought
- Ability to independently fulfill the radiation-safety-related duties as an AMP in the uses for which authorization is sought

- Select the preceptor's authorization and provide the name of the preceptor's facility, the license/permit number on which the preceptor is listed as an AMP, the name of the preceptor, and the telephone number.
- Have the preceptor sign and date the preceptor section.

NRC FORM 313A (AMP) (MM-DD-YYYY) U. S. NUCLEAR REGULATORY COMMISSION

APPROVED BY OMB: NO. 3150-0120 EXPIRES: (MM/DD/YYYY)

Estimated burden per response to comply with this mandatory collection request: 4.3 hours. Submittal of the application is necessary to determine that the applicant is qualified and that adequate procedures exist to protect the public health and safety. Send comments regarding burden estimate to the FOIA, Library, and Information Collections Branch (T-6 A10M), U.S. Nuclear Regulatory Commission, Washington, DC 20555-0001, or by email to Infocollects.Resource@nrc.gov, and the OMB Reviewer at: OMB Office of Information and Regulatory Affairs, (3150-0120), Attn: Desk Officer for the Nuclear Regulatory Commission, 725 17th Street NW, Washington, DC 20503. The NRC may not conduct or sponsor, and a person is not required to respond to, a collection of information unless the document requesting or requiring the collection displays a currently valid OMB control number.

AUTHORIZED MEDICAL PHYSICIST OR OPHTHALMIC PHYSICIST, TRAINING, EXPERIENCE AND PRECEPTOR ATTESTATION

[10 CFR 35.51, 35.57(a)(3), and 35.433]

Name of Individual: Nikola Tesla

☑ Authorized Medical Physicist

☐ Ophthalmic Physicist (go to Page 4)

Requested Authorization(s) (check all that apply)

☐ 35.400 Ophthalmic use of strontium-90

☑ 35.600 Remote afterloader unit(s)

☐ 35.600 Teletherapy unit(s)

☐ 35.600 Gamma stereotactic radiosurgery unit(s)

PART I -- TRAINING AND EXPERIENCE *(Select one of the three methods below)*

*Training and Experience, including Board Certification, must have been obtained within the 7 years preceding the date of application or the individual must have obtained related continuing education and experience since the required training and experience was completed. Provide dates, duration, and description of continuing education and experience related to the uses checked above.

☑ ***AUTHORIZED MEDICAL PHYSICIST***

☐ **1. Board Certification**

a. Provide a copy of the board certification.

b. If the board certification process has been recognized by the Commission or an Agreement State under 10 CFR 35.51:

(i) Go to the table in 3.c. and describe training provider and dates of training for each type of use for which authorization is sought.

(ii) Stop here.

c. If the board certification was issued on or before October 24, 2005 and is listed in 10 CFR 35.57(a)(3), attach:

(i) Documentation that the individual performed each use checked above on or before October 24, 2005.

(ii) Dates, duration, and description of continuing education and experience within the past seven years for each use checked above.

(iii) Stop here.

☐ **2. Current Authorized Medical Physicist Seeking Additional Authorization for use(s) checked above**

a. Go to the table in section 3.c. to document training for new device.

b. If board certified, provide a copy of the certificate and stop here.

c. If listed on a license or a permit before January 14, 2019 as an authorized medical physicist, stop here.

d. If not board certified skip to and complete Part II Preceptor Attestation.

☑ **3. Education, Training, and Experience for Proposed Authorized Medical Physicist**

a. Education: Document master's or doctor's degree in physics, medical physics, other physical science, engineering, or applied mathematics from an accredited college or university.

Degree	Major Field
Master's Degree	Medical Physics

College or University
Northeast Carolina State University

b. Supervised Full-Time Medical Physics Training and Work Experience in clinical radiation facilities that provide high-energy external beam therapy (photons and electrons with energies greater than or equal to 1 million electron volts) and brachytherapy services.

☑ Yes. Completed 1 year of full-time training in medical physics (for areas identified below) under the supervision of Marie Curie who meets the requirements for an Authorized Medical Physicist.

AND

☑ Yes. Completed 1 year of full-time work experience in medical physics (for areas identified below) under the supervision of Marie Curie who meets the requirements for an Authorized Medical Physicist.

NRC FORM 313A (AMP)
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AUTHORIZED MEDICAL PHYSICIST OR OPHTHALMIC PHYSICIST, TRAINING, EXPERIENCE AND PRECEPTOR ATTESTATION [10 CFR 35.51, 35.57(a)(3), and 35.433] (continued)

3. **Education, Training, and Experience for Proposed Authorized Medical Physicist (continued)**

b. Supervised Full-Time Medical Physics Training and Work Experience (continued)
If more than one supervising individual is necessary to document supervised training, provide multiple copies of this page.

Description of Training/ Experience	Location of Training/License or Permit Number of Training Facility/Medical Devices Used+	Dates of Training*	Dates of Work Experience*
Medical Physics	Greensboro County Hospital Greensboro, NC License # NC-001001 Varian Bravos	Oct 2020 - Oct 2021	Nov 2021 - Nov 2022
Performing sealed source leak tests and inventories	Greensboro County Hospital Greensboro, NC License # NC-001001 Varian Bravos	Oct 2020 - Oct 2021	Nov 2021 - Nov 2022
Performing decay corrections	Greensboro County Hospital Greensboro, NC License # NC-001001 Varian Bravos	Oct 2020 - Oct 2021	Nov 2021 - Nov 2022
Performing full calibration and periodic spot checks of external beam treatment unit(s)	N/A		
Performing full calibration and periodic spot checks of stereotactic radiosurgery unit(s)	N/A		
Performing full calibration and periodic spot checks of remote afterloading unit(s)	Greensboro County Hospital Greensboro, NC License # NC-001001 Varian Bravos	Oct 2020 - Oct 2021	Nov 2021 - Nov 2022
Conducting radiation surveys around external beam treatment unit(s), stereotactic radiosurgery unit(s), remote after loading unit(s)	Greensboro County Hospital Greensboro, NC License # NC-001001 Varian Bravos	Oct 2020 - Oct 2021	Nov 2021 - Nov 2022

Supervising Individual**	License/Permit Number listing supervising individual as an authorized Medical Physicist
Marie Curie	NC-001001

for the following types of use:

☑ Remote afterloader unit(s) ☐ Teletherapy unit(s) ☐ Gamma stereotactic radiosurgery unit(s)

\+ Training and work experience must be conducted in clinical radiation facilities that provide high-energy external beam therapy (photons and electrons with energies greater than or equal to 1 million electron volts) and brachytherapy services.

* 1 year of Full-time medical physics training and 1 year of full time work experience cannot be concurrent.

** If the supervising medical physicist is not an authorized medical physicist, the licensee must submit evidence that the supervising medical physicist meets the training and experience requirements in 10 CFR 35.51 and 35.59 for the types of use for which the individual is seeking authorization.

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(MM-DD-YYYY)

U. S. NUCLEAR REGULATORY COMMISSION

AUTHORIZED MEDICAL PHYSICIST OR OPHTHALMIC PHYSICIST, TRAINING, EXPERIENCE AND PRECEPTOR ATTESTATION [10 CFR 35.51, 35.57(a)(3), and 35.433] (continued)

3. Education, Training, and Experience for Proposed Authorized Medical Physicist (continued)

c. Describe training provider and dates of training for each type of use for which authorization is sought.

Description of Training	Training Provider and Dates		
	Remote Afterloader	Teletherapy	Gamma Stereotactic Radiosurgery
Hands-on device operation	Varian Bravos, provided by Varian and Marie Curie, AMP Greensboro County Hospital December 6-8, 2021	N/A	N/A
Safety procedures for the device use	Varian Bravos, provided by Varian and Marie Curie, AMP Greensboro County Hospital December 6-8, 2021	N/A	N/A
Clinical use of the device	Varian Bravos, provided by Marie Curie, AMP Greensboro County Hospital December 6-8, 2021	N/A	N/A
Treatment planning system operation	Varian Bravos, provided by Marie Curie, AMP Greensboro County Hospital December 6-8, 2021	N/A	N/A

Supervising Individual *If training is provided by Supervising Medical Physicist, (If more than one supervising individual is necessary to document supervised training, provide multiple copies of this page.)*	License/Permit Number listing supervising individual as an authorized Medical Physicist
Marie Curie	NC-001001

for the following types of use:

☑ Remote afterloader unit(s) ☐ Teletherapy unit(s) ☐ Gamma stereotactic radiosurgery unit(s)

Authorization Sought	Device	Training Provided By	Dates of Training
35.400 Ophthalmic Use of strontium-90	N/A		

d. Skip to and complete Part II Preceptor Attestation.

AUTHORIZED MEDICAL PHYSICIST OR OPHTHALMIC PHYSICIST, TRAINING, EXPERIENCE AND PRECEPTOR ATTESTATION [10 CFR 35.51, 35.57(a)(3), and 35.433] (continued)

4. Education, Training, and Experience for Proposed Ophthalmic Physicist

a. Complete the table below to document education;

Degree	Major Field
College or University	

b. Supervised Full-Time practical training and experience in medical physics

☐ Yes. Completed 1 year of full-time training in medical physics under the supervision of _____ medical physicist at _____

AND

☐ Yes. Completed 1 additional year of full-time work experience in medical physics at _____ under the supervision of _____ medical physicist.

If more than one supervising individual is necessary to document supervised training, provide multiple copies of this page.

c. Complete the table below to document training and supervised work experience.

Description of Training	Location of Training/License or Permit Number of Training Facility	Dates of Training*
The creating, modifying, and completing written directives.		
Procedures for administrations requiring a written directive		
Performing the calibration measurements of brachytherapy sources as detailed in 10 CFR 35.432		
Supervising Individual	License/Permit Number	

d. Stop here

NRC FORM 313A (AMP)
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U. S. NUCLEAR REGULATORY COMMISSION

AUTHORIZED MEDICAL PHYSICIST OR OPHTHALMIC, TRAINING, EXPERIENCE AND PRECEPTOR ATTESTATION [10 CFR 35.51, 35.57(a)(3), and 35.433] (continued)

PART II – PRECEPTOR ATTESTATION

Note: This part must be completed by the individual's preceptor. The preceptor does not have to be the supervising individual as long as the preceptor provides, directs, or verifies training and experience required. If more than one preceptor is necessary to document experience, obtain a separate preceptor statement from each.

First Section
Complete the following:

☑ I attest that **Nikola Tesla** (Name of Proposed Authorized Medical Physicist) has satisfactorily completed the 1-year of full-time training in medical physics and an additional year of full-time work experience as required by 10 CFR 35.51(b)(1).

AND

Second Section
Complete the following:

☑ I attest that **Nikola Tesla** (Name of Proposed Authorized Medical Physicist) has training for the types of use for which authorization is sought that include hands-on device operation, safety procedures, clinical use, and the operation of a treatment planning system.

AND

Third Section
Complete the following:

☑ I attest that **Nikola Tesla** (Name of Proposed Authorized Medical Physicist) is able to independently fulfill the radiation safety-related duties as an Authorized Medical Physicist for the following:

- ☐ 35.400 Ophthalmic use of strontium-90
- ☐ 35.600 Teletherapy unit(s)
- ☑ 35.600 Remote afterloader unit(s)
- ☐ 35.600 Gamma stereotactic radiosurgery unit(s)

AND

Fourth Section
Complete the following for preceptor attestation and signature:

☑ I meet the requirements in 10 CFR 35.51, 35.57, or equivalent Agreement State requirements for Authorized medical physicist for the following:

- ☐ 35.400 Ophthalmic use of strontium-90
- ☐ 35.600 Teletherapy unit(s)
- ☑ 35.600 Remote afterloader unit(s)
- ☐ 35.600 Gamma stereotactic radiosurgery unit(s)

Name of Facility:	License/Permit Number:
Greensboro County Hospital	NC-001001

Name of Preceptor (Typed or Printed)	Telephone Number	Date
Marie Curie	(123) 456-7889	1 Apr 23

Signature

Case Scenario for Authorized Nuclear Pharmacist—Alternate Pathway

An NRC licensee is requesting that Lise Meitner, a nuclear pharmacist, be added to its license as an ANP. Lise Meitner is not board-certified and has never been listed on a radioactive materials license as an ANP. Rolf Sievert was Lise Meitner's supervising individual for the nuclear pharmacy work experience. Robert Oppenheimer was Lise Meitner's preceptor. Supporting documentation to be provided by the licensee includes the following:

- A copy of the State/territory license to practice pharmacy
- Copies of the NRC or Agreement State licenses for the supervising individual and the preceptor (i.e., license number CO-ABC123 that authorizes Rolf Sievert and Robert Oppenheimer as ANPs in this case scenario)

313A (ANP) HEADER

- Insert the full name of the proposed ANP and the State or territory where licensed.
  - A copy of the state/territory license to practice pharmacy should be provided with the application.

313A (ANP) PART I—TRAINING AND EXPERIENCE

- Lise Meitner is seeking authorization using the alternate pathway (Block 2 selected).

313A (ANP) Part I, Section 2.a. Classroom and Laboratory Training

- Demonstrate completion of at least 200 hours of classroom and laboratory training in five key radiation protection areas (radiation physics and instrumentation, radiation protection, mathematics pertaining to the use and measurement of radioactivity, chemistry of byproduct material for medical use, and radiation biology).
- Include the location of training, number of hours per topic, and dates of training.
  - It is acceptable to list a course over several topics. Hours may be counted only in one category.

313A (ANP) Part 1, Section 2.b. Supervised Practical Experience in a Nuclear Pharmacy

- Demonstrate completion of at least 700 hours in a structured educational program, which includes a minimum of 200 hours of classroom and laboratory training (section 2.a. of Form 313A (ANP)).
- Include the location of experience, license/permit number of the facility, number of hours per topic, and dates of experience.
  - The supervised work experience must cover all five of the listed categories.

- Supervised work experience can be obtained at more than site and from more than one individual. In this case, multiple copies of this section of Form 313A(RSO) can be provided.

- Provide the name of the supervising individual and the license number on which the supervising individual is listed.

313A (ANP) PART II—PRECEPTOR ATTESTATION

- Have the preceptor attest that the proposed ANP has completed the 700-hour structured educational program, consisting of both practical experience in nuclear pharmacy and 200 hours of classroom and laboratory training, and is able to independently fulfill the radiation safety duties as an ANP.

- Provide the name of the preceptor, the name of the facility, and the license/permit number on which the preceptor is listed, and the telephone number.

- Have the preceptor sign and date the preceptor section.

NRC FORM 313A (ANP) (MM-DD-YYYY) U. S. NUCLEAR REGULATORY COMMISSION	APPROVED BY OMB: NO. 3150-0120 EXPIRES: (MM/DD/YYYY)
AUTHORIZED NUCLEAR PHARMACIST TRAINING, EXPERIENCE, AND PRECEPTOR ATTESTATION [10 CFR 35.55]	Estimated burden per response to comply with this mandatory collection request: 4.3 hours. Submittal of the application is necessary to determine that the applicant is qualified and that adequate procedures exist to protect the public health and safety. Send comments regarding burden estimate to the FOIA, Library, and Information Collections Branch (T-6 A10M), U.S. Nuclear Regulatory Commission, Washington, DC 20555-0001, or by email to Infocollects.Resource@nrc.gov, and the OMB Reviewer at: OMB Office of Information and Regulatory Affairs, (3150-0120), Attn: Desk Officer for the Nuclear Regulatory Commission, 725 17th Street NW, Washington, DC 20503. The NRC may not conduct or sponsor, and a person is not required to respond to, a collection of information unless the document requesting or requiring the collection displays a currently valid OMB control number.

Name of Proposed Authorized Nuclear Pharmacist	State or Territory Where Licensed
Lise Meitner	Colorado

PART I -- TRAINING AND EXPERIENCE

(Select one of the two methods below)

* Training and Experience, including board certification, must have been obtained within the 7 years preceding the date of application or the individual must have obtained related continuing education and experience since the required training and experience was completed. Provide dates, duration, and description of continuing education and experience related to the nuclear pharmacy uses.

☐ **1. Board Certification**

a. Provide a copy of the board certification and stop here.

☑ **2. Structured Educational Program for Proposed Authorized Nuclear Pharmacist**

a. Classroom and Laboratory Training.

Description of Training	Location of Training	Clock Hours	Dates of Training*
Radiation physics and instrumentation	Mercy Hospital, Cortez, CO	40	Nov 2021 - Nov 2022
Radiation protection	Mercy Hospital, Cortez, CO	40	Nov 2021 - Nov 2022
Mathematics pertaining to the use and measurement of radioactivity	Mercy Hospital, Cortez, CO	65	Nov 2021 - Nov 2022
Chemistry of byproduct material for medical use	Mercy Hospital, Cortez, CO	60	Nov 2021 - Nov 2022
Radiation biology	Mercy Hospital, Cortez, CO	10	Nov 2021 - Nov 2022
Total Hours of Training:		215	

NRC FORM 313A (ANP)
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AUTHORIZED NUCLEAR PHARMACIST TRAINING, EXPERIENCE, AND PRECEPTOR ATTESTATION [10 CFR 35.55] (continued)

2. Structured Educational Program for Proposed Authorized Nuclear Pharmacist (continued)

b. Supervised Practical Experience in a Nuclear Pharmacy.

Description of Experience	Location of Experience/License or Permit Number of Facility	Clock Hours	Dates of Experience*
Shipping, receiving, and performing related radiation surveys	Mercy Hospital, Cortez, CO CO-ABC123	100	Nov 2021 - Nov 2022
Using and performing checks for proper operation of instruments used to determine the activity of dosages, survey meters, and, if appropriate, instruments used to measure alpha- or beta-emitting radionuclides	Mercy Hospital, Cortez, CO CO-ABC123	100	Nov 2021 - Nov 2022
Calculating, assaying, and safely preparing dosages for patients or human research subjects	Mercy Hospital, Cortez, CO CO-ABC123	100	Nov 2021 - Nov 2022
Using administrative controls to avoid medical events in administration of byproduct material	Mercy Hospital, Cortez, CO CO-ABC123	110	Nov 2021 - Nov 2022
Using procedures to prevent or minimize radioactive contamination and using proper decontamination procedures	Mercy Hospital, Cortez, CO CO-ABC123	90	Nov 2021 - Nov 2022
	Total Hours of Experience:	500	
Supervising Individual			
Rolf Sievert			

c. Go to and complete Part II Preceptor Attestation.

NRC FORM 313A (ANP)
(MM-DD-YYYY)

U. S. NUCLEAR REGULATORY COMMISSION

AUTHORIZED NUCLEAR PHARMACIST TRAINING, EXPERIENCE, AND PRECEPTOR ATTESTATION [10 CFR 35.55] (continued)

PART II – PRECEPTOR ATTESTATION

Note: This part must be completed by the individual's preceptor. The preceptor does not have to be the supervising individual as long as the preceptor provides, directs, or verifies training and experience required. If more than one preceptor is necessary to document experience, obtain a separate preceptor statement from each.

First Section
Complete the following:

Structured Educational Program

☑ I attest that Lise Meitner has satisfactorily completed a 700-hour structured
Name of Proposed Authorized Nuclear Pharmacist

educational program consisting of both practical experience in nuclear pharmacy and 200 hours of classroom and laboratory training, as required by 10 CFR 35.55(b)(1) and is able to independently fulfill the radiation safety-related duties as an authorized nuclear pharmacist.

Second Section
Complete the following for preceptor attestation and signature:

I am an Authorized Nuclear Pharmacist for Mercy Hospital Cortez, CO,
Nuclear Pharmacy or Medical Facility

CO-ABC123.
License/Permit Number

Name of Preceptor	Signature	Telephone Number	Date
Robert Oppenheimer		(123) 456-7890	04/01/2024

Case Scenario for Authorized User—Alternate Pathway

An NRC licensee is requesting that Henri Becquerel, a physician, be added to its license as an AU. Henri Becquerel is not board-certified and has never been listed on a radioactive materials license as an AU. Henri Becquerel is seeking authorization for medical uses under 10 CFR 35.300, "Use of unsealed byproduct material for which a written directive is required." Wilhelm Roentgen was Henri Becquerel's supervising individual for the supervised work experience and clinical case experience. Wilhelm Roentgen also served as Henri Becquerel's preceptor. Supporting documentation to be provided by the licensee includes the following:

- A copy of the State/territory license to practice
- Copies of the NRC or Agreement State licenses for the supervising individual and the preceptor (i.e., license number AL-123456 that lists Wilhelm Roentgen (who is serving as both the supervising individual and the preceptor) as authorized for 10 CFR 35.390 materials in this case scenario)
- Casework

313A (AUT) HEADER

- Insert the full name of the proposed AU, the State or territory where licensed, and requested authorizations (e.g., 10 CFR 35.300).
  - Under "Requested Authorization(s)," a licensee/applicant has several options:
    - Authorization for sodium iodide I-131 requiring a written directive in quantities less than or equal to 1.22 gigabecquerels (GBq) (33 millicuries (mCi))
    - Authorization for both sodium iodide I-131 requiring a written directive in quantities less than or equal to 1.22 GBq (33 mCi) AND quantities greater than or equal to 1.22 GBq (33 mCi)
    - Authorization for parenteral administrations (e.g., Xofigo®, Lutathera®, Pluvicto™)
  - In this example, Henri Becquerel would select "35.300 Use of unsealed byproduct material for which a written directive is required" as Henri Becquerel is seeking approval for all medical uses that fall under 10 CFR 35.300.

313A (AUT) PART I—TRAINING AND EXPERIENCE

- Henri Becquerel is seeking authorization using the alternate pathway (Block 3 selected).

313A (AUT) Part I, Section 3.a. Classroom and Laboratory Training

- Select the requested authorizations (e.g., 10 CFR 35.590, “Training for use of sealed sources and medical devices for diagnosis”).
- Demonstrate completion of at least 700 hours of T&E, including a minimum of 200 hours of classroom and laboratory training in five key radiation protection areas (radiation physics and instrumentation, radiation protection, mathematics pertaining to the use and measurement of radioactivity, chemistry of byproduct material, and radiation biology).
- Include the location of training, number of hours per topic, and dates of training.
  - Hours may be counted only in one category.

313A (AUT) Part I, Section 3.b. Supervised Work Experience

- Select the requested authorizations (e.g., 10 CFR 35.390).
- Document the location of the training facility, NRC or Agreement State license number or permit number, confirmation, and dates of the work experience.
  - The supervised work experience e must cover all five of the listed categories.
  - Supervised work experience can be obtained at more than site. In this case, multiple copies of this section of Form 313A(AUT) can be provided.
- Provide the name of the supervising individual, the license or permit number on which the supervising individual is listed as an AU, and the medical uses for which the supervising individual is authorized.
  - The supervising AU must have experience in administering dosages in the same dosage category or categories as the individual requesting AU status.

313A (AUT) Part I, Section 3.c. Supervised Clinical Case Experience

- Document the number of supervised clinical cases in each category, location of the training facility, NRC or Agreement State license number or permit number, and dates of the experience.
  - The clinical case work experience must cover all three of the listed categories.
  - Supervised work experience can be obtained at more than one site. In this case, multiple copies of this section of Form 313A(AUT) can be provided.
- Provide the name of the supervising individual, the license or permit number on which the supervising individual is listed as an AU, and the medical uses for which the supervising individual is authorized.
  - The supervising AU must have experience in administering dosages in the same dosage category or categories as the individual requesting AU status.

313A (AUT) PART II—PRECEPTOR ATTESTATION

- For the first, second, and third sections, have the preceptor attest to the following:
  - The applicant has completed 700 hours of T&E, including 200 hours of classroom and laboratory training for 10 CFR 35.390 authorization.
  - The applicant has acquired clinical case experience in the categories for which the individual is requesting AU status.
  - The applicant can independently fulfill the radiation-safety-related duties as an AU in the uses for which authorization is sought.
- For the fourth section, since Henri Becquerel is not seeking authorization for use of 10 CFR 35.396, “Training for the parenteral administration of unsealed byproduct material requiring a written directive,” byproduct material, this section does not need to be completed.
- For the fifth section, select the preceptor’s authorization, and provide the name of the preceptor’s facility, the license/permit number on which the preceptor is listed as an AU, the name of the preceptor, and telephone number.
- Have the preceptor sign and date the preceptor section.

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APPROVED BY OMB: NO. 3150-0120 EXPIRES: (MM/DD/YYYY)

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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]

Name of Proposed Authorized User	State or Territory Where Licensed
Henri Becquerel	Alabama

Requested Authorization(s) *(check all that apply)*:

☑ 35.300 Use of unsealed byproduct material for which a written directive is required

OR

☐ 35.300 Oral administration of sodium iodide I-131 requiring a written directive in quantities less than or equal to 1.22 gigabecquerels (33 millicuries)

☐ 35.300 Oral administration of sodium iodide I-131 requiring a written directive in quantities greater than 1.22 gigabecquerels (33 millicuries)

☐ 35.300 Parenteral administration of any radioactive drug that contains a radionuclide that is primarily used for its electron emission, beta radiation characteristics, alpha radiation characteristics, or photon energy of less than 150 keV, for which a written directive is required.

PART I -- TRAINING AND EXPERIENCE
(Select one of the three methods below)

* Training and Experience, including board certification, must have been obtained within the 7 years preceding the date of application or the individual must have related continuing education and experience since the required training and experience was completed. Provide dates, duration, and description of continuing education and experience related to the uses checked above.

☐ **1. Board Certification**

a. Provide a copy of the board certification.

b. For 35.**390**, provide documentation on supervised case experience. The table in section 3.c. may be used to document this experience.

c. For 35.**396**, provide documentation on classroom and laboratory training, supervised work experience, and supervised clinical case experience. The tables in sections 3.a., 3.b., and 3.c. may be used to document this experience. Skip to and complete Part II Preceptor Attestation.

d. For a board certification issued on or before October 24, 2005 that is listed in 10 CFR 35.57(b)(2)(ii), provide the following:

(i) Documentation that the individual performed each use checked above on or before October 24, 2005.

(ii) Dates, duration, and description of continuing education and experience within the past seven years for each use checked above.

e. Stop here.

☐ **2. Current 35.300, 35.400, or 35.600 Authorized User Seeking Additional Authorization**

a. Authorized User on Materials License _____ under the requirements below or equivalent Agreement State requirements *(check all that apply)*:

☐ 35.390 ☐ 35.392 ☐ 35.394 ☐ 35.490 ☐ 35.690

b. If currently authorized for a subset of clinical uses under 35.300, provide documentation on additional required supervised case experience. The table in section 3.c. may be used to document this experience. If board certified, provide a copy of the certificate and stop here. If not board certified then provide completed Part II Preceptor Attestation.

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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] (continued)

c. If currently authorized under 35.490 or 35.690 and requesting authorization for 35.396, provide documentation on classroom and laboratory training, supervised work experience, and supervised clinical case experience. The tables in sections 3.a., 3.b., and 3.c. may be used to document this experience. Also provide completed Part II Preceptor Attestation.

☑ **3. Training and Experience for Proposed Authorized User**

a. Classroom and Laboratory Training ☑ 35.390 ☐ 35.392 ☐ 35.394 ☐ 35.396

Description of Training	Location of Training	Clock Hours	Dates of Training*
Radiation physics and instrumentation	University Hospital Huntsville, AL	50	2 Jan - 30 Dec 2020
Radiation protection	University Hospital Huntsville, AL	40	2 Jan - 30 Dec 2020
Mathematics pertaining to the use and measurement of radioactivity	University Hospital Huntsville, AL	40	2 Jan - 30 Dec 2020
Chemistry of byproduct material for medical use	University Hospital Huntsville, AL	40	2 Jan - 30 Dec 2020
Radiation biology	University Hospital Huntsville, AL	50	2 Jan - 30 Dec 2020
	Total Hours of Training: 220		

b. Supervised Work Experience ☑ 35.390 ☐ 35.392 ☐ 35.394 ☐ 35.396

(If more than one supervising individual is necessary to document supervised training, provide multiple copies of this page.)

Supervised Work Experience	**Total Hours of Experience:** 510		
Description of Experience Must Include:	Location of Experience/License or Permit Number of Facility	Confirm	Dates of Experience*
Ordering, receiving, and unpacking radioactive materials safely and performing the related radiation surveys	University Hospital 678 Hope Drive, Huntsville, AL AL-123456	☑ Yes ☐ No	2 Jan - 30 Dec 2020
Performing quality control procedures on instruments used to determine the activity of dosages and performing checks for proper operation of survey meters	University Hospital 678 Hope Drive, Huntsville, AL AL-123456	☑ Yes ☐ No	2 Jan - 30 Dec 2020
Calculating, measuring, and safely preparing patient or human research subject dosages	University Hospital 678 Hope Drive, Huntsville, AL AL-123456	☑ Yes ☐ No	2 Jan - 30 Dec 2020
Using administrative controls to prevent a medical event involving the use of unsealed byproduct material	University Hospital 678 Hope Drive, Huntsville, AL AL-123456	☑ Yes ☐ No	2 Jan - 30 Dec 2020
Using procedures to contain spilled byproduct material safely and using proper decontamination procedures	University Hospital 678 Hope Drive, Huntsville, AL AL-123456	☑ Yes ☐ No	2 Jan - 30 Dec 2020

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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] (continued)

3. Training and Experience for Proposed Authorized User (continued)

b. Supervised Work Experience (continued)

Supervising Individual	License/Permit Number listing supervising individual as an authorized user
Wilhelm Roentgen	AL-123456

Supervising individual meets the requirements below, or equivalent Agreement State requirements *(check all that apply)***:*

- ☑ 35.390
- ☐ 35.392
- ☐ 35.394
- ☐ 35.396
- ☐ 35.57

With experience administering dosages of:

- ☑ Oral NaI-131 requiring a written directive in quantities less than or equal to 1.22 gigabecquerels (33 millicuries)
- ☑ Oral NaI-131 in quantities greater than 1.22 gigabecquerels (33 millicuries)
- ☑ Parenteral administration of any radioactive drug that contains a radionuclide that is primarily used for its electron emission, beta radiation characteristics, alpha radiation characteristics, or photon energy of less than 150 keV, for which a written directive is required.

** Supervising Authorized User must have experience in administering dosages in the same dosage category or categories as the individual requesting authorized user status.

c. Supervised Clinical Case Experience

If more than one supervising individual is necessary to document supervised work experience, provide multiple copies of this page.

Description of Experience	Number of Cases Involving Personal Participation	Location of Experience/License or Permit Number of Facility	Dates of Experience*
Oral administration of sodium iodide I-131 requiring a written directive in quantities less than or equal to 1.22 gigabecquerels (33 millicuries)	N/A [Since three cases were completed with I-131 greater than 33 mCi, then these cases are not required (as per the endnote on 35.390(b)(G)(2)]	N/A	N/A
Oral administration of sodium iodide I-131 requiring a written directive in quantities greater than 1.22 gigabecquerels (33 millicuries)	three cases: 126 mci 160 mCi 220 mCi [Information may also be provided on a seperate sheet]	University Hospital Huntsville, AL AL-123456	January 16, 2020 January 20, 2020 January 20, 2021
Parenteral administration of any radioactive drug that contains a radionuclide that is primarily used for its electron emission, beta radiation characteristics, alpha radiation characteristics, or photon energy of less than 150 keV, for which a written directive is required.	Three cases: Xofigo 0.89 mCi Lutathera 204 mCi Pluvicto 200 mCi [On an attached sheet provide dates and supervising AU]	University Hospital Huntsville, AL AL-123456	February 4, 2020 February 11, 2020 March 4, 2020

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(for uses defined under 35.300) [10 CFR 35.57, 35.390, 35.392, 35.394, and 35.396] (continued)

3. Training and Experience for Proposed Authorized User (continued)

c. Supervised Clinical Case Experience (continued)

Supervising Individual	License/Permit Number listing supervising individual as an authorized user
Wilhelm Roentgen	AL-123456

Supervising individual meets the requirements below, or equivalent Agreement State requirements *(check all that apply)***:*

☑ 35.390	With experience administering dosages of:
☐ 35.392	☑ Oral NaI-131 requiring a written directive in quantities less than or equal to 1.22 gigabecquerels (33 millicuries)
☐ 35.394	☑ Oral NaI-131 in quantities greater than 1.22 gigabecquerels (33 millicuries)
☐ 35.396	☑ Parenteral administration of any radioactive drug that contains a radionuclide that is primarily used for its electron emission, beta radiation characteristics, alpha radiation characteristics, or photon energy of less than 150 keV, for which a written directive is required.
☐ 35.57	

** Supervising Authorized User must have experience in administering dosages in the same dosage category or categories as the individual requesting authorized user status.

d. Provide completed Part II Preceptor Attestation.

PART II – PRECEPTOR ATTESTATION

Note: This part must be completed by the individual's preceptor. The preceptor does not have to be the supervising individual as long as the preceptor provides, directs, or verifies training and experience required. If more than one preceptor is necessary to document experience, obtain a separate preceptor statement from each.

By checking the boxes below, the preceptor is not attesting to the individual's "general clinical competency."

First Section
Check one of the following for the requested authorization:

For 35.390:

☑ I attest that Henri Becquerel (Name of Proposed Authorized User) has satisfactorily completed the 700 hours of training and experience, including a minimum of 200 hours of classroom and laboratory training, as required by 10 CFR 35.390 (b)(1).

For 35.392:

☐ I attest that _____ (Name of Proposed Authorized User) has satisfactorily completed the 80 hours of classroom and laboratory training, as required by 10 CFR 35.392(c)(1), and the supervised work and clinical case experience required in 35.392(c)(2).

For 35.394:

☐ I attest that _____ (Name of Proposed Authorized User) has satisfactorily completed the 80 hours of classroom and laboratory training, as required by 10 CFR 35.394 (c)(1), and the supervised work and clinical case experience required in 35.394(c)(2).

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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] (continued)

Second Section

☑ I attest that Henri Becquerel has satisfactorily completed the required clinical case
Name of Proposed Authorized User

experience required in 35.390(b)(1)(ii)G listed below:

☑ Oral NaI-131 requiring a written directive in quantities less than or equal to 1.22 gigabecquerels (33 millicuries)

☑ Oral NaI-131 in quantities greater than 1.22 gigabecquerels (33 millicuries)

☑ Parenteral administration of any radioactive drug that contains a radionuclide that is primarily used for its electron emission, beta radiation characteristics, alpha radiation characteristics, or photon energy of less than 150 keV, for which a written directive is required.

Third Section

☑ I attest that Henri Becquerel is able to independently fulfill the radiation safety-related
Name of Proposed Authorized User

duties as an authorized user for the medical uses authorized under 10 CFR 35.300 for:

☑ Oral NaI-131 requiring a written directive in quantities less than or equal to 1.22 gigabecquerels (33 millicuries)

☑ Oral NaI-131 in quantities greater than 1.22 gigabecquerels (33 millicuries)

☑ Parenteral administration of any radioactive drug that contains a radionuclide that is primarily used for its electron emission, beta radiation characteristics, alpha radiation characteristics, or photon energy of less than 150 keV, for which a written directive is required.

Fourth Section

For 35.396:

Current 35.490 or 35.690 authorized user:

☐ I attest that _____ is an authorized user under 10 CFR 35.490 or 35.690
Name of Proposed Authorized User

or equivalent Agreement State requirements, has satisfactorily completed the 80 hours of classroom and laboratory training, as required by 10 CFR 35.396 (b)(1), and the supervised work and clinical case experience required by 35.396(b)(2), and is able to independently fulfill the radiation safety-related duties as an authorized user under 10 CFR 35.300 for:

☐ Parenteral administration of any radioactive drug that contains a radionuclide that is primarily used for its electron emission, beta radiation characteristics, alpha radiation characteristics, or photon energy of less than 150 keV, for which a written directive is required.

OR

Board Certification:

☐ I attest that _____ has satisfactorily completed the board certification
Name of Proposed Authorized User

requirements of 35.396(a)(3), has satisfactorily completed the 80 hours of classroom and laboratory training required by 10 CFR 35.396 (b)(1) and the supervised work and clinical case experience required by 35.396(b)(2), and is able to independently fulfill the radiation safety-related duties as an authorized user under 10 CFR 35.300 for:

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(for uses defined under 35.300) [10 CFR 35.57, 35.390, 35.392, 35.394, and 35.396] (continued)

Fifth Section

Complete one of the following for the attestation and signature:

☑ **Authorized User**

☑ I meet the requirements below, or equivalent Agreement State requirements, as an authorized user for:

☑ 35.390 ☐ 35.392 ☐ 35.394 ☐ 35.396 ☐ 35.57 for 35.300 uses

☑ I have experience administering dosages in the following categories for which the proposed Authorized User is requesting authorization:

- ☑ Oral NaI-131 requiring a written directive in quantities less than or equal to 1.22 gigabecquerels (33 millicuries)
- ☑ Oral NaI-131 in quantities greater than 1.22 gigabecquerels (33 millicuries)
- ☑ Parenteral administration of any radioactive drug that contains a radionuclide that is primarily used for its electron emission, beta radiation characteristics, alpha radiation characteristics, or photon energy of less than 150 keV, for which a written directive is required.

OR

☐ **Residency Program Director:**

☐ I affirm that the attestation represents the consensus of the residency program faculty where at least one faculty member is an authorized user who meets the requirements below or equivalent Agreement State requirements:

☐ 35.390 ☐ 35.392 ☐ 35.394 ☐ 35.396 ☐ 35.57 for 35.300 uses

☐ I affirm that this facility member has experience in administering dosages in the same dosage category or categories for which the individual is requesting authorized user status and concurs with the attestation I am providing as program director.

☐ I affirm that the residency training program is approved by the:

- ☐ Residency Review Committee of the Accreditation Council for Graduate Medical Education
- ☐ Royal College of Physicians and Surgeons of Canada
- ☐ Council on Post-Graduate Training of the American Osteopathic Association

☐ I affirm that the residency training program includes training and experience specified in:

☐ 35.390 ☐ 35.392 ☐ 35.394 ☐ 35.396

Name of Facility:	License/Permit Number:	
University Hospital	AL-123456	
Name of Preceptor or Residency Program Director (Typed or Printed)	**Telephone Number**	**Date**
Henri Becquerel	(123) 456-7890	08/03/2024
Signature		

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