1. Are the current pathways for obtaining AU status reasonable and accessible? Provide rationale for your answer.

The graduated approach to training and experience (T&E) established by the NRC appears reasonable and achievable (see §§35.190, 35.290, 35.390, 35.392, 35.394, and 35.396). The added levels of training and experience increase with the risk handling and administering of the radiopharmaceutical. The NRC recognizes the increased risk and stated in the Federal Register "§35.390 are handling material in quantities that can cause deterministic effects" (67 FR 20250 Apr 24, 2002).

2. Are the current pathways for obtaining AU status adequate for protecting public health and safety? Provide a rationale for your answer.

The current pathways required for obtaining AU status are only one component of protecting public health and safety. An AU does not constitute a single radiation protection program. An AU is either listed on a radioactive material license or approved under a specific license of broad scope. The radioactive material license application process provides the commitment to the regulatory for protecting the safety and health of the public by describing procedures, instrumentation, supervision, etc. The history of authorized user training and experience has evolved and at times stagnated from 1979.

For diagnostic studies (§§35.190, 35.290), the NRC recognizes the American Board of Radiology (ABR) certificate in Diagnostic Radiology with AU eligible status, as the ABR requires candidates to have 700 hours of experience to include 80 hours of didactic coursework. Prospective non-boarded AUs may document the 700 hours of experience to include 80 hours of didactic coursework and provide a preceptor attestation by a current AU.

Use of radiopharmaceuticals requiring a written directive requires another level of board certification and/or training and experience except for §§35.392 and 35.394, which is consistent with the classroom and laboratory training of §35.290 and work experience with 3 procedures MINUS the 700 hours of supervised clinical experience.

In 1978, the NRC published a notice of proposed rulemaking in the Federal Register (40 FR 11208, Mar 17, 1978). The NRC extensively describes their intent to continue evaluating physicians' training and experience and to offer alternative methods to determine if a physician is "competent to use byproduct material" while minimizing "its intrusion into medical judgements affecting the patient and into other areas traditionally considered to be a part of the practice of medicine."

US NRC Regulatory Guide 10.8 (January 1979) provided acceptable training and experience for authorized users as the NRC evaluated each physician's training and experience on a case-by-case basis. Several specific therapeutic procedures were listed under supervised clinical experience in unsealed therapeutic administration of radiopharmaceuticals. This guidance was later codified in 1986 (51 FR 36932, Oct 16, 1986). Note that the training and experience for therapeutic applications of unsealed radionuclides included 80 hours of classroom and supervised clinical experience in 10 cases of hyperthyroidism or cardiac dysfunction and 3 supervised cases for thyroid carcinoma. Understanding that nuclear medicine was a field still developing in the clinic, this was a very general amount of training (§35.930) and contained less training and experience as in §35.920; i.e., 200 hours of classroom and laboratory training and 500 hours of supervised work experience.

The 2002 revisions to 10 CFR 35 and the rational for the current training and experience of authorized uses was published in the Federal Register (67 FR 20250 Apr 24, 2002). Commenters felt that the proposed increase in the number of hours required for basic physics and safety in §35.390 would exclude endocrinologists from treating patients with hyperthyroidism and thyroid cancer. In response, the Commission and added §§35.392 and 35.394 maintaining the previously codified training and experience from 1986 in deference to a commenter wishing to see the training and experience at least equal to physicians seeking AU status under §35.290, while citing examples of bone marrow suppression after strontium administration and life threatening pulmonary edema after treatment of thyroid cancer with iodine-131 (67 FR 20250 Apr 24, 2002).

A review of reported medical events is suggested to determine if training and experience of authorized users is a causal factor in these events. One might look beyond to determine if the training and experience provided to a supervised individual was appropriate. §35.27 permits persons to prepare and administer radiopharmaceuticals under the supervision of an authorized user. The level supervision is defined by the licensee as per the Commission's Frequently asked questions about licensing medical use of byproduct material under revised 10 CFR Part 35 (https://www.nrc.gov/materials/miau/med-use-toolkit/faqs-part35.html).

3. Should the NRC develop a new tailored T&E pathway for these physicians? If so, what would be the appropriate way to categorize radiopharmaceuticals for tailored T&E requirements? If not, explain why the regulations should remain unchanged. [Some options to categorize radiopharmaceuticals include radiopharmaceuticals with similar delivery methods (oral, parenteral); same type of radiation characteristics or emission (alpha, beta, gamma, low energy photon); similar preparation method (patient-ready doses); or a combination thereof (e.g., radiopharmaceuticals containing alpha and beta-emitting radioisotopes that are administered intravenously and are prepared as patient-ready doses).]

I don't believe a new tailored T&E pathway is necessary. Pathways to individual radiopharmaceutical uses echoes to Reg Guide 10.8 circa 1979. The regulator would be back to reviewing AUs on a case-by-case basis.

It is conceivable that a clinic interested in administering radiopharmaceuticals develop procedures IAW §35.27, 'team-up' with an authorized user and file and application with their regulator. As mentioned previously, an entire radiation protection program is developed and submitted to the regulator to ensure the safe handling and administration of radiopharmaceuticals.

There are multiple aspects in the practice of medicine that determine the appropriate course of diagnosis and treatment of patients to include the use of radiopharmaceuticals. Such aspects the NRC recognizes as outside their scope of authority. It would seem a disservice to patients to minimize the required T&E of the responsible AU and potentially dilute the area of expertise.

4. Should the fundamental T&E required of physicians seeking limited AU status need to have the same fundamental T&E required of physicians seeking full AU status for all oral and parenteral administrations under 10 CFR 35.300?

If the T&E seeking limited AU status is changed to that of the current §§35.392 and 35.394, the Commission should look at the T&E codified in 1986 and the reasons for increasing the T&E, particularly for §35.390 and comments received in 2002. Was access to treatments with iodine-131 a rational for leaving the T&E requirements for the oral administration of iodine-131 to those from 1986? If so, one might consider the recent exhibits presented to the ACMUI as substantive (see Meeting of the Advisory Committee on the Medical Use of Isotopes, Thursday, March 10 2016, available at https://www.nrc.gov/docs/ML1610/ML16109A042.pdf).

5. How should the requirements for this fundamental T&E be structured for a specific category of radiopharmaceuticals?
    a. Describe what the requirements should include:
        i. Classroom and laboratory training— What topics need to be covered in this training requirement? How many hours of classroom and laboratory training should be required? Provide the basis for the number of hours. If not hours, explain how this training should be quantified. [Note: The topics currently required in the regulations to be included in the classroom and laboratory training and work experience are listed in 10 CFR 35.390, 35.392, 35.394, and 35.396.]
        ii. Work experience—What should the work experience requirement involve? How many hours of work experience should be required and what is the minimum number of patient or human research subject administrations that an individual must perform? Provide the basis for the number of hours and administrations. What should be the qualifications of the supervising individual?
        iii. Competency—How should competency be evaluated? Should a written and/or practical examination by an independent examining committee be administered? Provide a rationale for your answer.
    b. Should a preceptor attestation be required for the fundamental T&E? Provide a rationale for your answer.
    c. Should the radiopharmaceutical manufacturer be able to provide the preceptor attestation? Provide a rational for your answer.
    d. Who should establish and administer the curriculum and examination? Provide specific group(s). [Some options are: NRC, medical specialty boards, medical professional societies, educational professional groups, and NRC in collaboration with any or more of the aforementioned groups.]
    e. Should AU competency be periodically assessed? If so, how should it be assessed, how often, and by whom?

A preceptor attestation should accompany all alternate pathways toward achieving authorized user status.

A radiopharmaceutical manufacturer should only have the ability to precept an AU is when the signing individual is a current AU listed on a license for that modality.

Competency in medical practice should be left to the medical facility (not the licensee). If there are concerns with a physician's practice and they are an AU, it is up to the medical facility to review and handle accordingly. If the concerns involve the safe handling and administration of radiopharmaceuticals, the effectiveness of the management triangle concept (see NUREG-1516) is tested; RSO, executive management and the radiation safety committee, where appropriate.

A. NRC's Recognition of Medical Specialty Boards

1. What boards other than those already recognized by the NRC (American Board of Nuclear Medicine [ABNM], American Board of Radiology [ABR], American Osteopathic Board of Radiology [AOBR], Certification Board of Nuclear Endocrinology [CBNE]) could be considered for recognition for medical uses under 10 CFR 35.300?
2. Are the current NRC medical specialty board recognition criteria sufficient? If not, what additional criteria should the NRC use?

I am not aware if the ABR subspecialty in nuclear radiology results in AU eligible on the board. The requirement for that subspecialty is 1 year in a nuclear radiology fellowship or one year in a nuclear medicine residency program accredited by the ACGME or the RCPSC (see https://www.theabr.org/diagnostic-radiology/subspecialties/nuclear-radiology/requirements-registration). If that subspecialty does not result in AU eligible, the subspecialty should be recognized.

In addition, candidates that successfully completed the ABR exam are provided a letter of completion with a statement of AU eligibility and an ABR identification number. The Commission should consider accepting this letter acknowledging completion of the recognized board in that there is an additional period (several months) before the certificates are mailed to the candidate.

B. Patient Access

1. Is there a shortage in the number of AUs for medical uses under 10 CFR 35.300? If so, is the shortage associated with the use of a specific radiopharmaceutical? Explain how.
2. Are there certain geographic areas with an inadequate number of AUs? Identify these areas.
3. Do current NRC regulations on AU T&E requirements unnecessarily limit patient access to procedures involving radiopharmaceuticals? Explain how.
4. Do current NRC regulations on AU T&E requirements unnecessarily limit research and development in nuclear medicine? Explain how.

These exhibits were offered in the comments to the revisions to 10 CFR 35 (67 FR 20250 Apr 24, 2002). A review of that process and the results thereof should be revisited.

C. Other Suggested Changes to the T&E Regulations

1. Should the NRC regulate the T&E of physicians for medical uses?
2. Are there requirements in the NRC's T&E regulatory framework for physicians that are non-safety related?
3. How can the NRC transform its regulatory approach for T&E while still ensuring that adequate protection is maintained for workers, the general public, patients, and human research subjects?

No comment.