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January 29, 2019

May Ma
Office of Administration
Mail Stop: TWFN–7– A60M,
U.S. Nuclear Regulatory Commission,
Washington, DC 20555– 0001.

Submitted via www.regulations.gov

Re: Training and Experience Requirements for Different Categories of Radiopharmaceuticals [Docket ID NRC–2018–0230].

Dear Ms. Ma:

The American Society for Radiation Oncology (ASTRO) appreciates the opportunity to provide comments on *Training and Experience Requirements for Different Categories of Radiopharmaceuticals* published in the Federal Register on October 29, 2018.

ASTRO is the largest radiation oncology society in the world, with more than 10,000 members who specialize in treating patients with radiation therapies. As the leading organization in radiation oncology, biology and physics, the Society is dedicated to improving patient care through education, clinical practice, advancement of science and advocacy. ASTRO's highest priority has always been ensuring patients receive the safest, most effective treatments.

Please find our answers to the questions posed in the Federal Register Notice below.

A. Tailored Training & Experience Requirements

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

ASTRO believes that the current pathways for obtaining AU status under 10 CFR 35.390, 35.392, 35.394 and 35.396 are appropriate, protect the safety of patients, the public, and practitioners, and should not be changed. Radiopharmaceuticals are highly effective in treating cancer, with possible harmful effects to both the patient and the public if not used correctly and under the supervision of a highly trained physician.

The excellent safety record for radiopharmaceuticals can be attributed to the required training and experience for authorized users. Between 2014 and January 1, 2019, only 15 out of almost 8000 total events entered into RO-ILS: Radiation Oncology Incident Learning System®[1] are related to radiopharmaceuticals. As indicated in the self-reported data, none of these events were

[1] RO-ILS is the only medical specialty society-sponsored radiation oncology incident learning system. Sponsored by ASTRO and the American Association of Physicists in Medicine (AAPM), the mission of RO-ILS is to facilitate safer and higher quality care in radiation oncology by providing a mechanism for shared learning in a secure and non-punitive environment.

reported to either the NRC or an Agreement State. Additionally, in a presentation to the ACMUI on March 17, 2018, only 1 event using Ra-223 dichloride was reported during fiscal year 2017. This is a very small percentage of events when compared to Centers for Medicare and Medicaid Services (CMS) utilization data showing that there were approximately 3000 radiopharmaceutical infusions performed in 2017.

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

   ASTRO believes that the current, rigorous training and experience requirements contribute to the excellent safety record of radiopharmaceuticals. We believe that it is important that the person administering the radiopharmaceutical is appropriately trained in the safe handling, exposure risks, and the management of side effects of radiation.

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).]**

   ASTRO opposes tailoring training and experience based on categories of radiopharmaceuticals. We believe that tailoring the number of hours of training and experience required based on categories of radiopharmaceuticals will lead to confusion and complexity both for licensees, as well as for the NRC and Agreement States. Additionally, the training for radiopharmaceuticals should not change based on the type of radiopharmaceutical, therefore the minimum training would remain the same. We are also concerned that if new radiopharmaceuticals are approved for use that do not fit into one of the categories, then the NRC will have to promulgate additional regulations to include the new agents; a process that could take time to finalize, delaying patient access to potentially life-saving radiopharmaceuticals.

   The NRC's focus on patient safety and the safety of the general public as it develops training and experience requirements is appropriate. With this in mind, the NRC determined that the level of training required to administer these treatments must include either board certification or 700 hours of training and experience. The NRC intentionally designed these requirements to allow new agents to come to market, so the NRC does not have the burden of writing different regulations for every new drug that is developed. The rule was intended to classify agents by their similar properties and particular risk profiles. The classroom and clinical experiences encompassed by radiation oncology and nuclear medicine training programs provide appropriate levels of knowledge and skill for any current and future radioactive agents. ASTRO supports the NRC's intent to craft a generally applicable rule rather than one that necessitates a specific review of each new radionuclide that becomes commercially available.

   Administering radiopharmaceuticals is not as simple as ordering a patient-ready dose from a radiopharmacy and injecting it into a patient. In general, clinics administering radiopharmaceuticals follow these steps:

1. The AU develops the general policies, the standard operating procedures, and the quality assurance checks for their radiopharmaceutical program.
2. The AU ensures that safe radiation protection procedures are followed throughout the procedure.
3. The AU determines whether or not it is appropriate for the patient to receive the radiopharmaceutical.
4. The patient receives any required pre-treatment laboratory and/or imaging studies.
5. The AU must determine the required dose and will enter the dose into the written directive.
6. The AU orders any additional medications and or drugs prior to delivery of the radiopharmaceutical.
7. The radiopharmaceutical is received from the radiopharmacy in either the nuclear medicine, radiology, or radiation oncology department. (This is determined by the facility varies from site to site.)
8. The receiving department checks that the dose from the radiopharmacy is correct and accurate.
9. The AU confirms that the dose is correct and accurate. If there is an error to the dose, the AU makes a decision on if/how to proceed.
10. The AU administers the radiopharmaceutical or will supervise the administration by appropriately trained personnel.
11. The AU monitors adverse reactions of the patient and handles any radioactive spills that may have occurred.

The above description assumes that the ordering, receiving, administration, and clean up goes as planned. However, without proper and extensive training, how would the AU know how to clean spills? How would the AU understand limits of dose variation? Would the AU know how to use a dose calibrator to assess the dose, and change it if necessary? Would the AU know how to dispose of tubing and syringes? What about flushing the IV? Would the AU know how to use a Geiger counter to detect a spill? Would the AU know how to handle a person who is accidentally contaminated? Would the AU be able to appropriately and competently supervise ancillary staff? Would an AU know how to handle the accidental delivery into the interstitial tissues of the body (i.e., “IV infiltration”) or into an artery? Would the AU be able to make appropriate decisions based on radiobiology and the effects of multiple prior therapies on the patient (i.e., external beam therapy)? Ultimately, it is the AU who is responsible for the safety of the patient, the providers, and the public. It would be irresponsible to leave this to someone with inadequate training and experience.

The appropriate training and experience to qualify for the practice of radiopharmaceutical therapy is addressed in the study guides of the specialty certification boards:

- https://www.theabr.org/radiation-oncology/initial-certification/the-qualifying-exam/studying-for-the-exam/medical-physics-radiation-oncology
- https://www.theabr.org/radiation-oncology/initial-certification/the-qualifying-exam/studying-for-the-exam/radiation-cancer-biology
- https://abnm_wordpress_uploads.s3.amazonaws.com/wordpress/wp-content/uploads/Content_Manual.pdf

During the January 10 and January 22, 2019 public workshops, several commenters suggested that the NRC allow advanced practice providers to receive limited AU status, allowing them to administer, and even prescribe, radiopharmaceuticals. While ASTRO believes that advanced practice providers (such as nurse practitioners and physicians assistants) and other non-physician members of the radiation oncology treatment team can play an important role in the ongoing management of patients receiving radiation therapy, we strongly oppose this suggestion. Not only would it undermine the intent of having a physician involved, it could upend NRC's current regulatory framework. AUs are responsible for not only the administration of a radiopharmaceutical, but also for supervising all aspects of patient care. We believe that a board-certified/board-eligible radiation oncologist (or other similarly credentialed provider) is the clinically appropriate physician to supervise and administer radiation treatments.

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?**

   ASTRO opposes granting limited AU status. We believe that consistency in requirements alleviates confusion for licensees, the NRC and the Agreement States and protects the health and safety of patients.

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.**

      ASTRO opposes the development of T&E for specific categories of radiopharmaceuticals.

   b. **Should a preceptor attestation be required for the fundamental T&E? Provide a rationale for your answer.**

      It is unclear whether this question refers to fundamental T&E for specific categories of radiopharmaceuticals, or fundamental T&E for all radiopharmaceuticals. ASTRO opposes the development of T&E requirements for specific categories of radiopharmaceuticals. Preceptor attestation should be consistent with the current Part 35 requirements as finalized in the July 16, 2018 Final Rule.

   c. **Should the radiopharmaceutical manufacturer be able to provide the preceptor attestation? Provide a rational for your answer.**

      No. Only an AU should be allowed to provide the preceptor attestation. Manufacturers can be useful in familiarizing practitioners with the performance of new therapy options but are not a replacement for an AU.

   d. **Who should establish and administer the curriculum and examination? Provide specific group(s).**

      It is unclear whether this question refers to curriculum and examination for specific categories of radiopharmaceuticals, or for all radiopharmaceuticals. ASTRO opposes the development of T&E for specific categories of radiopharmaceuticals and believes that the

exam for all radiopharmaceuticals should be administered by a medical specialty certification board recognized by the NRC.

e. Should AU competency be periodically assessed? If so, how should it be assessed, how often, and by whom?

It is unclear whether this question refers to curriculum and examination for specific categories of radiopharmaceuticals, or for all radiopharmaceuticals. ASTRO opposes the development of T&E for specific categories of radiopharmaceuticals and believes that the current regulatory framework, in accordance with Part 35 as finalized in the July 16, 2018 Final Rule, be maintained.

B. 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?

The ABNM, ABR, AOBR, CBNE are the appropriate medical specialty boards.

2. Are the current NRC medical specialty board recognition criteria sufficient? If not, what additional criteria should the NRC use?

We believe that the current NRC medical specialty board recognition criteria are sufficient.

C. 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.

ASTRO does not believe that there is a shortage of radiation oncology AUs for medical uses under 10 CFR 35.300. The American Board of Radiology (ABR) estimates that between 2007 and 2017, approximately 1,650 radiation oncologists were certified by the ABR with an Authorized User Eligibility designation and may become AUs. In addition, we estimate that there are approximately 2,200 radiation oncology facilities in the United States. Together with current radiation oncology AUs, the 773 radiation oncology residents currently in residency programs, and nuclear medicine-trained AUs nationwide, there are likely enough AUs to administer radiopharmaceuticals.

When compared to the over one million patients treated with radiation oncology treatments each year, 3000 radiopharmaceutical infusions is a very small number. We believe that the focus on the number of AUs – regardless of specialty – using radiopharmaceuticals without consideration of the frequency of use is misguided.

At both the December 11, 2018 and January 10, 2019 public meetings, NRC staff discussed their work analyzing licensee data for the 13 states that the NRC regulates and will ask the Agreement States for their licensee data. We understand that the partial shutdown of the Federal Government delayed the formal request to the Agreement States. We also understand that this request for data will be voluntary, and it is possible that not all of the Agreement States will submit data. Complete and accurate data on the number of AUs that can administer

radiopharmaceuticals is needed and necessary for the NRC to make an informed decision. The NRC should not base their decision solely on the data from 13 states, nor should they rely on anecdotal data. We urge the NRC not to make any recommendations until as much data as possible is gathered and analyzed, even if the final report is delayed.

2. **Are there certain geographic areas with an inadequate number of AUs? Identify these areas.**

   We do not believe there are certain geographic areas with an inadequate number of AUs. There are likely geographic areas where a patient may have to travel to an AU for treatment, but such travel likely would also be required to see another medical specialist. Access to care issues should not be addressed by lowering the training and experience required to provide specialized procedures. Finally, we urge the NRC not to base decisions regarding changes in regulations solely on anecdotal and incomplete data.

3. **Do current NRC regulations on AU T&E requirements unnecessarily limit patient access to procedures involving radiopharmaceuticals? Explain how.**

   ASTRO believes that the current NRC regulations ensure that patients have access to safe and effective treatments.

4. **Do current NRC regulations on AU T&E requirements unnecessarily limit research and development in nuclear medicine? Explain how.**

   ASTRO is not aware of any limitations on research and development in therapeutic uses of radiopharmaceuticals.

D. Other Suggested Changes to the T&E Regulations

1. **Should the NRC regulate the T&E of physicians for medical uses?**

   Yes. The NRC is the appropriate agency to 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?**

   No.

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?**

   ASTRO supports periodic review of the requirements and supports the work being done by the NRC's Advisory Committee on the Medical Use of Isotopes (ACMUI), as well as by the NRC staff to thoroughly review the data and engage stakeholders in this process. We continue to believe that the excellent safety record for radiopharmaceuticals can be attributed to the required training and experience for authorized users, and therefore should not be changed.

We appreciate the opportunity to provide comments on this important matter and look forward to continuing to work with the NRC. Should you have any questions, please contact Cindy Tomlinson, Senior Patient Safety and Regulatory Affairs Manager at cindy.tomlinson@astro.org or 703.839.7366.

Sincerely,

Laura I. Thevenot
Chief Executive Officer