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Training and Experience Requirements for Different Categories of Radiopharmaceuticals

Comment On: NRC-2018-0230-0162

Draft Approaches for Addressing Training and Experience Requirements for Radiopharmaceuticals Requiring a Written Directive

Document: NRC-2018-0230-DRAFT-0199

Comment on FR Doc # 2019-10760

Submitter Information

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General Comment

Attached are comments from the American Society for Radiation Oncology (ASTRO) on the NRC's "Draft Approaches for Addressing Training and Experience Requirements for Radiopharmaceuticals Requiring a Written Directive".

Attachments

FINAL ASTRO TE Comments 5.2.19 FRN

July 2, 2019

Office of Administration
Attn: Program Management, Announcements and Editing Staff
Mail Stop: TWFN-7-A60M
US Nuclear Regulatory Commission
Washington, DC 20555-0001

Submitted via www.regulations.gov

Re: Draft Approaches for Addressing Training and Experience Requirements for Radiopharmaceuticals Requiring a Written Directive [NRC-2018-0230]

To whom it may concern:

The American Society for Radiation Oncology (ASTRO) appreciates the opportunity to provide comments on the *Draft Approaches for Addressing Training and Experience Requirements for Radiopharmaceuticals Requiring a Written Directive* published in the Federal Register on May 2, 2019.

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.

ASTRO appreciates the NRC granting a 30-day extension for comments. Given the seriousness of the draft approaches, and the potential long-term effects on the practice of medicine and the protection of public health and safety, we welcomed the additional time to fully think about and discuss the draft approaches.

ASTRO agrees with the Advisory Committee on the Medical Use of Isotopes (ACMUI), the Organization of Agreement States (OAS), and the Conference of Radiation Control Program Directors (CRCPD) – three organizations on which the NRC relies heavily for advice and insight on these types of issues – that support the current Training and Experience (T&E) requirements. In its report approved on February 26, 2019, the ACMUI stated that it “*strongly supports and reaffirms the Committee’s 2016 position on maintaining the current and existing AU [Authorized User] pathways (board certification and alternate pathway) as codified in the regulations, which are adequate for protecting public health and safety. Radionuclide therapy poses the highest risk and highest impact of all nuclear medicine procedures.*” In addition, the ACMUI “*does not recommend a limited-scope AU pathway for unsealed byproduct material for which a written directive is required.*” In its comment letter dated January 29, 2019, the OAS states “*the Board believes that from a regulator’s standpoint, tailored T&E requirements may need too many rule*

revisions as more and more radiopharmaceuticals are developed. Agreement state staff may be faced with making decisions based on insufficient information for new drugs and uses.” Finally, in its letter dated January 30, 2019, the CRCPD said *“the current requirements are reasonable and accessible, and they have provided decades of safe radiopharmaceutical therapy.”* While we understand there could be a commercial interest in relaxing the T&E requirements, physicians and the NRC, must put the interests, and safety, of their patients first.

In response to ASTRO member interest – nearly one-third of our members have expressed interest in learning more about radiopharmaceuticals – we are hosting a [radiopharmaceutical workshop](#) in conjunction with our 2019 annual meeting. This half day course is designed to teach clinical radiation oncologists everything they need to know to use radiopharmaceutical therapy safely and effectively for the benefit of their patients. It will provide a refresher on relevant physics, pharmacology, and radiobiology, as well as offer logistical and practical training in clinical use of radiopharmaceuticals. There will be specific breakout sessions on Ra-223, Lu-177 DOTATATE, Lu-177 PSMA agents, I-131 MIBG and Y-90 Microspheres. It will also cover important infrastructure, workflow and financial considerations. This special training course will enable radiation oncologists to provide the highest quality of patient-centered care in the use of radiopharmaceutical therapies. Three months before our annual meeting, we have 100 participants registered.

In addition, ASTRO and the Society for Nuclear Medicine and Molecular Imaging (SNMMI) are developing a consensus document to identify the steps in the process of care and the optimal workflows for radiopharmaceuticals. We will share the final document with the NRC when it is finalized, which we expect to be in mid-2020.

Please find our answers to the questions posed in the Federal Register Notice below. We also urge the NRC to review our previous comments and statements on this very important topic.

A. Status Quo

Question 1: If the “Status Quo” is maintained, how should the NRC ready itself for the expected increase in number and complexity of future radiopharmaceuticals?

As we have stated in previous comment letters, ASTRO believes that maintaining the status quo is appropriate, protects the safety of patients, the public, and practitioners, and should not be changed. 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 radiopharmaceutical that is developed. 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.

Question 2: Is there a challenge with the current T&E requirements—such as concerns regarding patient access to radiopharmaceuticals—that should be addressed through a rulemaking?

ASTRO believes that the current NRC regulations ensure that patients have access to safe and effective treatments. We do not believe that rulemaking is warranted.

As we have mentioned in previous comment letters, 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 2018, approximately 1,779 radiation oncologists were certified with an Authorized User Eligibility designation. In addition, we estimate that there are approximately 2,200 radiation oncology facilities in the United States. Together with current radiation oncology AUs, the 783 radiation oncology residents currently in residency programs, and nuclear medicine-trained AUs nationwide, there are enough AUs to administer radiopharmaceuticals even with new radionuclides becoming available.

When compared to the over one million patients treated with radiation oncology treatments each year, 3,000 radiopharmaceutical infusions (based on 2017 Centers for Medicare and Medicaid Services (CMS) utilization data, which is the most recent data available) is a very small number. We believe that the focus on the number of AUs is misguided.

We look forward to seeing the NRC staff analysis of licensee data, both from NRC regulated states, and Agreement States, as we continue to believe that 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. We continue to 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.

B. Tailored Training and Experience Requirements

Question 3: How should the complexity of the radiopharmaceutical administration protocol be considered in establishing the T&E requirements for the limited approaches described in Sections B.1 and B.2 below?

ASTRO reiterates our opposition to tailored T&E requirements 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. 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 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

These study guides are periodically updated to reflect changes in use and type of radiopharmaceuticals.

1. Limited AU for Alpha- or Beta-Emitting Radiopharmaceuticals

Question 4: How should the NRC categorize radiopharmaceuticals with mixed emissions?

ASTRO again reiterates our opposition to tailored T&E requirements based on categories of radiopharmaceuticals. Although the penetration of alpha and beta particles is less than gamma rays, such a characteristic is minor and has no real impact on the overall expertise needed by an authorized user to provide safe radiopharmaceutical therapy. Thorough knowledge of radiobiology, radiation physiology, radiochemistry, dosimetry (when available), ability to perform radiation activity assays, and appropriate handling of spills and intravenous infiltration, to mention a few, are no different for alpha and beta emitters. We believe that the current requirement for those seeking AU status outside of the board certification pathway is the minimum needed to be properly trained and should not be reduced or changed. Preceptor attestation should be consistent with the current Part 35 requirements as finalized in the July 16, 2018 Final Rule.

ASTRO believes that this, and the other draft approaches, would not provide the proper level of expertise to safely perform these procedures.

2. Limited AU for Unit-Dose, Patient-Ready Radiopharmaceuticals

Question 5: Under what conditions should a radiopharmaceutical be considered “patient ready” such that the T&E requirements could be tailored?

ASTRO again reiterates our opposition to tailored T&E requirements based on categories of radiopharmaceuticals. As we mentioned in our response to Question 4 above, although the penetration of alpha and beta particles is less than gamma rays, such a characteristic is minor and has no real impact on the overall expertise needed by an authorized user to provide safe radiopharmaceutical therapy. Thorough knowledge of radiobiology, radiation physiology, radiochemistry, dosimetry (when available), ability to perform radiation activity assays, and appropriate handling of spills and intravenous infiltration, to mention a few, are no different for alpha and beta emitters. We believe that the current requirement for those seeking AU status outside of the board certification pathway is the minimum needed to be properly trained and should not be reduced or changed. Preceptor attestation should be consistent with the current Part 35 requirements as finalized in the July 16, 2018 Final Rule.

Administering radiopharmaceuticals is not as simple as ordering it from a radiopharmacy and injecting it into a patient. Only with a high level of knowledge could an AU:

1. Develop the general policies, the standard operating procedures, and the quality assurance checks for their radiopharmaceutical program.
2. Ensure that safe radiation protection procedures are followed throughout the procedure.
3. Determine whether it is appropriate for the patient to receive the radiopharmaceutical, including having the knowledge of whether the radiopharmaceutical can be given to special patient populations like pregnant or lactating women, or patients of childbearing age.
4. Ensure the patient receives any required pre-treatment laboratory and/or imaging studies.
5. Determine the required dose and enter the dose into the written directive.
6. Order any additional medications and or drugs prior to delivery of the radiopharmaceutical.
7. Ensure that the radiopharmaceutical is received from the radiopharmacy in either the nuclear medicine, radiology, or radiation oncology department. (This is determined by the facility and varies from site to site.)
8. Ensure that the receiving department checks that the dose from the radiopharmacy is correct and accurate.
9. Confirm that the dose is correct and accurate. If there is an error to the dose, the AU is responsible for making a decision on if/how to proceed.
10. Administer the radiopharmaceutical or supervise the administration by appropriately trained personnel.
11. Monitor and treat any adverse reactions in the patient.
12. Handle 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.

3. Limited AU for Any One Parenteral Radiopharmaceutical

ASTRO again reiterates our opposition to tailored T&E requirements based on categories of radiopharmaceuticals. We believe that the current requirement for those seeking AU status outside of the board certification pathway is sufficient and should not be reduced or changed.

Preceptor attestation should be consistent with the current Part 35 requirements as finalized in the July 16, 2018 Final Rule.

4. Emerging Radiopharmaceuticals

ASTRO again reiterates our opposition to tailored T&E requirements based on categories of radiopharmaceuticals. We believe that the current requirement for those seeking AU status outside of the board certification pathway is sufficient and should not be reduced or changed.

As mentioned earlier in this comment letter, we believe that tailoring the number of hours of training and experience required based on categories of radiopharmaceuticals, or on potential users of the radiopharmaceuticals, will lead to confusion and complexity both for licensees, as well as for the NRC and Agreement States. We are also concerned about the time needed for the NRC to conduct individual reviews of each emerging radiopharmaceutical and produce guidance under 10 CFR 35.1000, *Other Medical Uses of Byproduct Material or Radiation from Byproduct Material*, for each one. This review, and subsequent guidance document production will take time, delaying patient access to potentially life-saving radiopharmaceuticals.

C. Performance-Based

1. Competency-Based Evaluation

Question 6: How could a competency-based evaluation ensure appropriate training and experience for AUs administering radiopharmaceuticals?

ASTRO does not believe an exam or other competency-based approaches can assure the appropriate depth of knowledge and expertise that come with the didactic and hands-on experience of the current T&E requirements. ASTRO opposes any changes to the current T&E requirements. We believe the current requirements for those seeking AU status outside of the board certification pathway is sufficient and should not be changed.

2. Credentialing of Authorized Users

Question 7: How could physicians in small practices be credentialed (e.g., physicians not associated with hospitals or other large institutions and their credentialing boards)?

ASTRO believes that allowing licensees to develop and use their own policies and procedures to make self-determinations of whether their credentialed physicians have the appropriate T&E to be an AU for one or more radiopharmaceuticals is potentially dangerous. This could cause confusion and result in inconsistent requirements among licensees, which could easily lead to poor patient care and disparate patient outcomes

D. Team-Based

Question 8: How should the AU's radiation safety responsibilities be clearly distinguished from other members of the team?

ASTRO believes that partnering an AU with either an Authorized Administrator (AA) or an Authorized Nuclear Pharmacist (ANP) would not provide the knowledge and experience needed to provide safe and effective radiopharmaceutical therapy. These adjunctive staff do not have the breadth or depth of knowledge to relieve the AU of his/her responsibilities. The AU is responsible for the radiation safety of the radiopharmaceutical, as well as for the administration of the radiopharmaceutical. ASTRO is concerned that this recommendation would allow an AU to not be present for the administration of the radiopharmaceutical, which would put patients and personnel at risk.

1. Radiopharmaceutical Team

This approach would include additional team members who generally do not administer radiopharmaceuticals. It is unclear why additional team members would be necessary to administer radiopharmaceuticals, especially since the AU must be present as they are ultimately responsible for the administration of the radiopharmaceutical as well as the supervision of all aspects of patient care.

2. Team AUs with Authorized Administrators

While ASTRO believes that advanced practice providers (such as nurse practitioners, physicians assistants, nuclear medicine technologist, or nuclear medicine advanced associate) 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 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.

3. Partner Limited-Trained AUs with Authorized Nuclear Pharmacists

Question 9: How should the radiation safety responsibilities be divided between the AU and ANP?

AUs are responsible for not only the administration of a radiopharmaceutical, but also for supervising all aspects of patient care, including radiation safety. Much like our comments above regarding authorized administrators, ASTRO does not see the value in adding an ANP to the process and opposes this suggestion.

IV. Additional Questions for Consideration

Question 10: What are the advantages and disadvantages of the draft approaches?

As we have outlined above, ASTRO believes that making any changes to the current regulations would put patients and the public, at risk.

Question 11: Are there significant costs or benefits associated with any of the approaches?

Even with the extended comment period, given the complexity of these proposals, ASTRO has not had time to fully analyze the financial costs or benefits to any of these approaches beyond what is already included in this comment letter.

Question 12: Would any of the draft approaches impact patient access to radiopharmaceuticals or address stakeholder concerns of overly burdensome (regulatory) requirements?

ASTRO believes that the current regulatory requirements are not burdensome and should not be changed. Please see our response to Question 2 above for our response regarding patient access.

Question 13: For the draft approaches that consider tailored hours of T&E, what are the appropriate numbers of hours and what radiation safety topics should comprise the limited T&E?

ASTRO again reiterates our opposition to tailored T&E requirements based on categories of radiopharmaceuticals. We believe that the current requirement for those seeking AU status outside of the board certification pathway is sufficient and should not be reduced or changed.

Question 14: Should the NRC consider inclusion of a formal radiation safety competency assessment and periodic reassessments for any of the draft approaches above? If so, who should establish and administer these assessments?

AUs who are board certified through the NRC-recognized boards receive ongoing training that includes radiation safety.

Question 15: How would the draft approaches impact the medical organizations that use the NRC's T&E requirements as a basis for establishing their training programs?

With the exception of maintaining the status quo, the draft approaches would lead to significant confusion and variable training quality, as programs would suddenly be left to figure it out on their own.

Question 16: Are there concerns regarding implementation and/or viability for any of the approaches discussed above?

As we have already mentioned elsewhere in this comment letter, with the exception of maintaining the status quo, we believe that the other approaches will cause variability in implementation, putting patients at risk.

Question 17: Are there any unintended consequences of the draft approaches?

ASTRO believes that by reducing the T&E requirements, or changing them in any way, could put patients at risk. The excellent safety record for radiopharmaceuticals can be attributed to the required training and experience for AUs. Between January 2014 and May 2019, only 16 out of 9,848 total events entered into RO-ILS: Radiation Oncology Incident Learning System®¹ were related to radiopharmaceuticals. As indicated in the self-reported data, none of these events have been reported to either the NRC or an Agreement State. Additionally, as noted in a presentation to the ACMUI on April 3, 2019, only 1 event using Ra-223 dichloride was reported during 2018, the same number as in 2017. This is a very small percentage of events when compared to CMS utilization data showing that there were approximately 3,000 radiopharmaceutical infusions performed in 2017.

Question 18: Which of the draft approaches best positions the NRC to effectively regulate future radiopharmaceuticals?

ASTRO believes that maintaining the status quo best positions the NRC to effectively regulate future radiopharmaceuticals.

Question 19: Should the NRC continue to play a role in the review and approval of AUs?

Yes. The NRC is the appropriate agency to regulate the T&E of physicians for medical uses.

We appreciate the opportunity to provide comments on this important matter regarding patient safety 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

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.