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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-0209
Comment on FR Doc # 2019-10760

## Submitter Information

**Name:** Anonymous Anonymous
**Submitter's Representative:** Phil Goble
**Government Agency Type:** State
**Government Agency:** Utah Division of Waste Management and Radiation Control

## General Comment

See attached file(s)

## Attachments

State of Utah Comments - Docket ID NRC-2018-0230

State of Utah

GARY R. HERBERT
*Governor*

SPENCER J. COX
*Lieutenant Governor*

Department of
Environmental Quality

L. Scott Baird
*Interim Executive Director*

DIVISION OF WASTE MANAGEMENT
AND RADIATION CONTROL
Ty L. Howard
*Director*

July 3, 2019

Jennifer Borges
ATTN: Program Management, Announcements and Editing Staff
Mail Stop: TWFN-7-A60M
U.S. Nuclear Regulatory Commission
Washington, DC 20555-0001

RE: Docket ID NRC-2018-0230

Dear Ms. Borges,

This letter responds to the U.S. Nuclear Regulatory Commission's request regarding, *Draft Approaches for Addressing Training and Experience Requirements for Radiopharmaceuticals Requiring a Written Directive*, published in the Federal Register, Vol. 84, No. 85, Thursday May 2, 2019, in Notices pages 18874 through 18877. The State of Utah believes that more research needs to be conducted before rulemaking actions that may have severe unintended consequences precede.

Attached are the State of Utah's comments regarding the questions posed in the May 2, 2019, Federal Register for, *Draft Approaches for Addressing Training and Experience Requirements for Radiopharmaceuticals Requiring a Written Directive.*

If you have any questions, please call Gwyn Galloway at (801) 536-4258.

Sincerely,

Ty L. Howard, Director
Division of Waste Management and Radiation Control

TLH/GEG/kb

Enclosure: State of Utah comments regarding Docket ID NRC-2018-023 (DRC-2019-006272)



195 North 1950 West • Salt Lake City, UT
Mailing Address: P.O. Box 144880 • Salt Lake City, UT 84114-4880
Telephone (801) 536-0200 • Fax (801) 536-0222 • T.D.D. (801) 536-4284
*www.deq.utah.gov*

State of Utah Comments for Draft Approaches for Addressing Training and Experience Requirements for Radiopharmaceuticals Requiring a Written Directive

**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?***

Since each radiopharmaceutical may have a myriad of variables that could act differently chemically or biologically when administered to a patient, it is likely that each radiopharmaceutical will need to be evaluated on a case by case basis to determine if it is substantially different than those radiopharmaceuticals presently allowed by NRC requirements. Those radiopharmaceuticals that are determined to have a complexity that precludes it from being regulated under the provisions of 10 CFR 35.300 will have to be regulated under the provisions of 10 CFR 35.1000 unless the NRC modifies the radiopharmaceutical categories presently established. This is not a new approach to helping the NRC ready itself for the expected increase in number and complexity of future radiopharmaceuticals; however, the complexities of the radiopharmaceuticals will make it very difficult to create categories to address the variables and ranges of the variables that may be present in each of the radiopharmaceuticals.

The State is not familiar with the present process used by the NRC to review each radiopharmaceutical to determine whether regulation of the radiopharmaceutical should be under the provisions of §35.300 or §35.1000. However, if not currently involved as the radiopharmaceutical begins the US Food and Drug Administration process for approval of a new drug, if possible, the NRC could simultaneously review the potential hazards and concerns with the radiopharmaceutical. This would give the NRC the potential to have the radiopharmaceutical review and a determination made regarding its regulatory category prior to the release of the radiopharmaceutical's release for medical use.

**Question 2:** **Is there a challenge with the current training and experience requirements— such as concerns regarding patient access to radiopharmaceuticals—that should be addressed through a rulemaking?**

There is no reliable data to demonstrate that there is a patient access concern and that access to radiopharmaceutical treatments are limited due to a shortage of AUs. There are numerous reasons that may limit access to radiopharmaceutical treatments that do not involve the availability of AUs. In the past few years, many medical facilities have closed due to financial strains and there is concern that the closures in rural areas are increasing at an accelerated rate. The availability of AUs authorized to provide radiopharmaceutical treatments in areas with closed medical facilities would obviously exist; however, the root cause in these instances is not the training and experience requirements for AUs. There are many potential reasons for limited access to various medical treatments including radiopharmaceutical treatments; however, no data has been collected and evaluated to determine if there is limited access. Since there are many reasons that may limit patient accessibility, the State recommends that the NRC collect and evaluate data regarding the availability of radiopharmaceutical treatments to verify that there is limited access and if so, the root cause for the limited access. Until data is collected and evaluated, the NRC should not enter into rulemaking to decrease the training and

experience for AUs since this could lead to issues involving patient safety, effectiveness of the treatments and many unintended consequences.

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

Safe and effective use of the radiopharmaceuticals requires more than just walking through a few cases (NRC usually requires three cases). It requires performing enough cases under the supervision of an experienced AU so that each step in the process becomes routine and familiar, and that situations outside of the routine have been encountered and managed successfully. The development of such expertise requires hands-on experience in many clinical cases under a variety of situations. Therefore, radiopharmaceutical treatments that involve complex administration protocols may not be appropriate to approve for AUs with limited training and experience since they do not have the experience and knowledge to recognize that an administration protocol was not properly followed or to address the potential issues that may arise from the resulting improperly administered dose. As examples:

- Will the AU with limited approvals be able to estimate the dose the patient received if the issue involved the delivery of the radiopharmaceutical?
- Would the AU be able to estimate the dose and patient risks associated with a delivery of the radiopharmaceutical to the wrong treatment area?
- Would the AU be able to determine the effectiveness of a treatment if the patient was underdosed or to determine how to correct the underdosage?

If the NRC approves AUs with limited training and experience to use radiopharmaceuticals with administrative protocols that are more complex, the administrative protocol should be evaluated to determine if the administrative protocol is straight forwarded or the administration protocol adds to the potential for a medical event if not correctly followed. If an improperly followed protocol can increase the potential for a medical event, the training and experience must include the potential errors that may occur in following the protocol and how to recognize that an error has occurred. Additionally, the training and experience must include the risks, hazards and appropriate responses to potential situations that may arise from improperly following the protocol.

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

Categorization of radiopharmaceuticals with mixed emissions could be very complex and would most likely need to be evaluated on a case by case basis due to the myriad of variables that could be involved.

***Question 5: Under what conditions should a radiopharmaceutical be considered ‘‘patient ready’’ such that the training and experience requirements could be tailored?***

The Board of Pharmacy has requirements for labeling patient doses. Doses delivered to facilities for the use of a specific patient are required to have the patient's name, the date and time of calibration, and other specified information. A dose that is labeled for a specific patient could therefore be defined

as a unit dose or a patient specific dose provided the licensee makes no adjustment to the dose prior to the administration.

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

Unless a standardized examination can be developed by the relevant radiological professional organizations, a competency-based evaluation would not necessarily ensure that an AU had the appropriate training and experience for administering radiopharmaceuticals. A true competency-based approval would not include a minimum amount of training or experience necessary to administer the radiopharmaceutical. Therefore, an AU could conceivably be approved to administer the radiopharmaceuticals without having addressed any complications or issues with an administration of a radiopharmaceutical because none occurred during the few cases they conducted to show their competency.

***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)?***

There should be no limited AU status based on abridged training and experience because it could lead to hazardous situations and compromise patient care. However, if the NRC approves a limited AU approach, a standard curriculum for limited AUs should be developed by the relevant radiological professional organizations. A written preceptor statement should be required to document successful completion of the training and experience.

If the licensee is to develop their own training program, the requirements would need to be written in a more prescriptive manner and state the topics that must be covered within the training program. The licensee must submit their training program with the license application to ensure these topics and clinical experience that are covered in the training program. Additionally, the licensee must be required to maintain documentation regarding the training and experience. Preceptor statements certifying the successful completion of the training and experience criteria must be required. The final approval of the AU would need to be made by the Radiation Safety Officer and the Medical Director of the facility. This approach will add complexity and time involved in reviewing the training and experience of AUs during inspections.

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

As with the delegation of duties for the Associate Radiation Safety Officer, the AU's radiation safety responsibilities must be delineated in writing and acknowledged by the AU's signature. The same approach must be used for each team member responsible for radiation safety duties. The Medical Director and the Radiation Safety Officer would need to work together to develop the duties and responsibilities for each team member. When completed, the listed duties and responsibilities for each team member would need to be approved by the RSO, the Medical Director, and the Radiation Safety Committee, if an RSC is required. The duties and responsibilities of each team member should be included in the licensee's radioactive materials license and changes to the listed duties should require a license amendment.

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

Unless the medical profession substantially changes, the potential for an AU and an ANP to be working together is improbable. Very few, if any, medical facilities employ ANPs. Data regarding the number of ANPs employed at medical facilities who would be available to provide radiation safety-related support is needed.

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

- For many of the draft approaches, substantial training will be necessary for NRC, Agreement State and Licensee personnel.
- It appears that many of the draft approaches would add to the workload of NRC and Agreement State staff due to either more licensing review or adding time and complexity to inspections.
- The draft approaches could introduce inconsistency for AU training and experience criteria at different facilities, or in different States.
- Without standardized training and experience, personnel changes (Medical Director, RSO) at medical facilities could result in changes to training and experience requirements, or duties and responsibilities. This could cause inconsistency with the training and experience criteria within facilities and potential confusion for medical and radiation safety personnel.

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

- Training costs and increases to personnel workloads could significantly increase personnel costs for the NRC, the Agreement States, and licensees.
- Many of the draft approaches will cause an increase in recordkeeping, and the development, maintenance, and implementation of additional procedures for licensees.
- AUs and licensees may incur additional costs for obtaining documentation to demonstrate the AU meets different training and experience criteria at different facilities.
- Since it is unknown if access to the radiopharmaceutical treatments is limited or if limited, if the limiting factor is a shortage of AUs, there may be significant costs to implement a program that does not alleviate or address the root cause of the issue. Therefore, it cannot be stated that there is a benefit for associated with increasing the number of AUs.

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

Since there is no data indicating that there is an issue with patient access to radiopharmaceutical treatments, it is unknown if implementing any of the draft approaches will increase patient access to the treatments. The NRC is encouraged to gather data to research the issue more thoroughly before asserting that patient access is limited due to the number of available AUs. If it is determined that there is an issue with patient access, the NRC is encouraged to determine the root cause for the limited access.

Any of the limited approaches that allow a facility to name their own AUs for radiopharmaceutical treatments would address any licensee's concerns regarding regulatory requirements for approval of AUs; however, these concerns may be replaced by concerns for increased staff workloads for in house AU approvals and necessary recordkeeping.

***Question 13 For the draft approaches that consider tailored hours of training and experience, what are the appropriate numbers of hours and what radiation safety topics should comprise the limited training and experience?***

The appropriate numbers of hours and radiation safety topics for AUs approved to administer radiopharmaceutical treatments using limited training and experience are best determined by the relevant radiological professional organizations. Each organization will have the background to determine the amount of knowledge and experience necessary to administer each of the radiopharmaceutical treatments and to understand the associated risks and hazards.

***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?***

Yes. NRC should require a formal radiation safety competency assessment and periodic reassessment for AUs receiving limited training and experience. The assessments should be administered by approved representatives of the relevant radiological professional organizations.

***Question 15 How would the draft approaches impact the medical organizations that use the NRC's training and experience requirements as a basis for establishing their training programs?***

The current training and experience regulations are an integral part of current American Board of Radiology (ABR), American Board of Nuclear Medicine (ABNM) and American Osteopathic Board of Radiology (AOBR) certification requirements for Authorized User (AU)-eligibility, are essential for patient, personnel and care-giver safety, and are not burdensome for training programs, the Nuclear Regulatory Commission (NRC), or Agreement States. Therefore, implementing the draft approaches could substantially impact these organizations depending on the approach that is implemented.

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

The implied use of this limited AU is in a smaller facility where the person would, more likely than at an academic medical center, be the perceived "expert." There may be no other AU available at the facility; however, the AU with limited training and experience would not have the experience or breadth of knowledge to handle unusual occurrences and may compromise patient safety. The limited AU may not be able to recognize or evaluate and address incorrect administrations that result in medical events. Evaluation of doses to the patient would be beyond the experience and knowledge of a limited AU if the dosage is delivered to the wrong treatment site. Additionally, the limited AU may not have the necessary knowledge to address other questions and concerns that may arise regarding the use of radiopharmaceuticals. Safe and effective use of radiopharmaceuticals requires a thorough knowledge and understanding of the modality and experience with the myriad of potential risks and hazards to

patients, staff and the public. Like any specialization in medicine, gaining the necessary training and experience takes time. Shortening the training and experience requirements could lead to unsafe practices where unrecognized or unfamiliar situations arise. The comprehensive training requirement provides a wider knowledge.

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

- Since the NRC will have no longer specify training and experience requirements in the regulations, there will be no compatibility category associated with training and experience requirements for these materials. NRC has long maintained that compatibility with training and experience requirements is very important, has direct transboundary implications and the requirements must essentially be identical to the NRC's requirements. With no specific NRC requirements in place, each State (Agreement and Non-Agreement) could adopt regulations each State determines is necessary to ensure the health and safety of individuals in the State. This will create inconsistent training and experience criteria across the nation as is found with the regulation of the use of x-ray devices. Because of this, regulations for the use of x-ray devices range from no specific requirements to very specific requirements for training and experience and/or certifications. This may cause various concerns and issues for facilities and States.

- States across the nation have varying degrees of regulatory authority over training and experience, certifications, or licensing for individuals using radiation. Some States will have no authority within the Radiation Control Agency to oversee compliance with training and experience that is not specified in NRC regulations and required for the compatibility of the program.

- If AUs are still to be identified on radioactive materials licenses, then an individual approved as an AU in a State with no specific requirements will qualify to be named as an AU in a State that has stringent requirements.

- To add to potential inconsistencies with training and experience criteria, medical facilities run by national corporations may need to have separate criteria for each State in which they operate. It is also possible that medical facilities operated by corporations may standardize their procedures and individuals who might have qualified as an AU at another medical facility in a State with less stringent standards might not meet the training and experience criteria set by the corporate facility in the same State.

- Implementing the draft approaches could increase the workload for NRC and Agreement State personnel through more license processing, increased inspection complexity or volume of inspections, or both.

- For draft approaches that no longer list AUs on radioactive materials licenses, the pathway for accepting an AU because they have previously been named on a license will no longer be an option and may actually delay an AU's ability to practice if they move to a new facility. It is unlikely that a medical facility will automatically approve aphysician to use radiopharmaceuticals until the facility has verified that the physician meets the facility's

training and experience criteria. This is especially true for those facilities holding accreditations or certifications from organizations like The Joint Commission.

- With any option using a competency-based evaluation as a basis for an AUs approval, there is a concern regarding having a sufficient number of physicians willing to sign a preceptor statement that another physician is "competent." Prior to 2002, there was an issue with preceptor physicians signing a document that stated another physician was "competent" to use specific radioactive materials. Many physicians would not sign the statements because they did not want to be responsible or liable for stating that another physician was competent. If the NRC proposes reinstating competency-based preceptor statements, the approach could be counterproductive and decrease the number of AUs available due to the unavailability of preceptors willing to sign the statements.

- If the NRC and Agreement States no longer approved AUs and previous approval on a license is no longer an option, small established medical facilities and new medical facilities may have difficulties being established due to the availability of preceptors willing to provide attestation statements for physicians at the medical facility.

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

Radiopharmaceutical therapy has been a safe treatment modality for decades. Very few medical events have been reported for these therapies. Lessening the training and experience requirements could jeopardize the safety and effectiveness for these treatments the status quo is working and there is nothing to indicate that the position must be changed.

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

Yes. There has been no data or information collected to demonstrate that the status quo is an ineffectual or overly burdensome way to handle approval of AUs. In order to maintain consistency of AU training and experience across the nation, it is necessary for NRC to continue to play a role in the review and approval of AUs.