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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

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General Comment

See attached file(s)

Attachments

Re-NRC-2018-0230-NC-Comments

NC DEPARTMENT OF
HEALTH AND HUMAN SERVICES
Division of Health Service Regulation

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TO: Sarah Lopas, Office of Nuclear Material Safety and Safeguards, U.S. Nuclear Regulatory Commission
FROM: David Crowley, Radioactive Materials Branch, North Carolina Radiation Protection Section
DATE: June 14, 2019
SUBJ: Comments for Docket ID NRC-2018-0230, Approaches for Addressing Training and Experience (T&E) Requirements for Radiopharmaceuticals Requiring a Written Directive

Thank you for the opportunity to comment and provide feedback based upon the experiences and opinions held within North Carolina's Agreement State Program (NC); it is vital to the success of the National Materials Program (NMP) to have contributions and buy in from all of its partners and stakeholders. The NMP should keep the following thoughts in mind while selecting a path forward: the basis for our current requirements, scope of authority to pass these requirements, and the value added or removed from impacted stakeholders.

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?

NC believes there is sufficient and robust enough regulatory framework to support all future radiopharmaceuticals; it is proven through current practices of evaluating new emerging medical technologies in 10 CFR Part 35.1000. That said, the NMP will need to stand ready to review new drugs, treatment methods, specialized handling criteria, and other safety concerns so that additional guidance may be generated if merited. Additionally, the NMP needs to develop more effective procedures for moving technologies out of 35.1000, whether with rulemaking efforts, periodic re-evaluations, or providing guidance documents showing how those materials may be licensed within existing rules.

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?

NC is unaware of any specific issues where the current T&E requirements are limiting patient access to nuclear medicine therapies. Patient access to medical treatments should not be a driving factor for the NMP to promulgate new rules (this issue would be addressed by state, regional or local healthcare networks); however, new rules must not impede a citizen's ability to receive medical care.

The challenges with current T&E requirements stem from the fact that there is a large focus on competency to deliver nuclear medicine therapies accurately and safely. NC believes that the medical competency and accuracy of these procedures is outside the bounds of the NMP's jurisdiction, and that the regulating agencies do not maintain trained medical staff capable of determining whether an authorized user (AU) is truly competent to administer radiopharmaceuticals for use in humans. Instead, agencies rely on preceptor attestations to verify that competency. This system is flawed and in ways that potentially affect training of new AUs. One such flaw is that a healthcare organization may not

support bringing in out of network staff to avoid competitors gaining the experience and hours needed to reach competency. Two, some physicians have said that they feel liable for the work of those they sign attestations for and are unwilling to accept that burden. Three, hospital business pressures may require signing for new staff by more senior staff, even if they have not truly become competent. With this system, NMP staff must accept the word of another individual to gain confidence in the proficiency of yet another person; the staff really are not able to question this without themselves being a similarly trained and competent AU.

There are already a number of pathways within the status quo for individuals to become AUs. It is manageable, but can still be a complex question that facilities and NMP staff must answer. For instance, which boards are or are not approved, does it have the right year or markings on the certificates, were case histories properly documented, how about the hours logged, did they do actual cases or manufacturer guided test cases, was the training recent enough, etc.? NC recommends that the NMP seek a more objective method to confirm competency in safe use of materials, and that method similarly apply to regular reassessments for an AUs competency. The NMP should de-emphasize competency in medical care and leave that to professional organizations to; it does not belong in our regulations or oversight activities.

One major flaw is the idea of AU supervision and what activities they may or may not assign to other personnel. Currently, there is a focus on the AU T&E; however, NMP rules give very little attention to the folks actually handling or administering the radiopharmaceuticals. If the major concern is the safety of radioactive material users, patients, and members of the public, then it seems more focus should be paid to those actually handling materials on a day to day basis and not only concern with T&E of those writing the written directives.

Lastly, as a colleague put so eloquently on a recent government-to-government call discussing this topic, "who does the NMP protect with these regulations and from what hazards?" If the intention is to protect a patient from a doctor who may make medical errors then this surely crosses over into the region of quality of care and practice of medicine. Instead, the focus of NMP regulations should be on established health physics practices, ensuring that users keep doses and risks of contaminations to an absolute minimum.

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?

NC does not support limited T&E requirements at this time. It will further complicate matters for facilities but also NMP staff; this may lead to a susceptibility for errors or inadvertent abuse of the T&E pathways while approving individuals as competent radiopharmaceutical users.

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

The NRC should not categorize training based on emission types; while different, it is not that much different. T&E needs to remain comprehensive enough that an AU for unsealed materials understands all types of emissions, handling and safety precautions, hazards associated with each and then the vulnerable anatomical areas pertaining to those uses.

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

NC does not support an expedited T&E pathway to determine who can only use unit-doses. Many things can still go wrong with unit doses, including that the pharmacy incorrectly draws them at the start. A sufficient amount of training still needs to cover the administration, planning treatment doses, operating and emergency procedures, risks to patients and hospital staff, contamination control, medical events, etc. In addition, as in the response to #3 above, limited T&E pathways and approvals will further complicate matters for who can or cannot perform procedures.

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

NC supports a competency based T&E evaluation both initially and at regular intervals. This needs to cover the areas that the NMP holds jurisdiction over and not extend into the practice of medicine. Thus a competency exam may cover topics such as general radiation safety topics, regulatory compliance concepts, security of materials, labeling and posting requirements, reporting events, written directives, obligations to patients, and medical event identification. The Advisory Committee on the Medical Uses of Isotopes (ACMUI) made this recommendation as a requirement for any limited scope pathways, but the NMP should go further and instead substitute it universally for T&E preceptor attestations.

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)?

Physicians in practices large or small need to pass the same competency based examinations; the rest can be decided from within the medical industry.

Additionally, during the public meetings held these past months, there was an outcry supporting the volume of hours AUs dedicate to honing their craft. The NMP would not publish a statement telling residency or fellowship programs to reduce the number of hours taken to attain certifications, but simply would stop inquiring after those items. It would be up to healthcare providers, professional societies and certification programs to maintain that excellence in medical care.

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

Teamwork is almost always a benefit; however, in this circumstance it poses to add complexity and potential gaps for assigned responsibilities. At a minimum, the AU in the team needs to demonstrate the same base competency required to practice independently. Certain duties or responsibilities could then be delegated, if contained in a written procedure at the facility, and then supervised by the AU.

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

NC recommends this determination be made by the facility, but only if the AU and ANP are both capable of practicing individually. The AU holds an overall responsibility to the patient and healthcare team, a pharmacist could be there to ensure safe handling of materials before administration and that an accurate dosage is prepared for the AU in accordance with the written directive.

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

The greatest advantage would be making a shift away from weighing a single individual's assessment of another's competency (current system of using preceptor attestations), and going to a system that there is an initial and reoccurring objective assessment to determine if someone is competent in the use, handling and administration of radioactive materials. These treatments have the capacity to deliver life changing radiopharmaceuticals; changes should improve that individual's quality of life but if administered in error they could also be a detriment.

Disadvantages for any of the limited approaches would include further splitting of T&E pathways. This will add more confusion to the already complicated pathways.

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

Costs may be associated with time and effort of eventual rulemaking, but also in contracting or establishing competency based examinations for AUs. If the NMP is spending less time reviewing T&E due to a simplification of current status quo and a possible implementation of competency based exams, then it would free up staff hours that can be assigned to higher significance issues. Note that a large portion of amendment actions are reviewing AU additions or deletions.

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

The idea of applying a more performance based approach along with competency examinations would make the requirements less arbitrary, more in line with NMP regulatory authority, and give more objective and thorough analysis of an individual's competency to administer radiopharmaceuticals. This less burdensome approach should increase patient access to radiopharmaceuticals as the requirements would be less prescriptive and complex, thus becoming less burdensome.

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?

Any number of hours, including the currently implemented sets of hours seem arbitrary until the NMP is able to justify or provide sound evidence to the contrary. NC asks that if the status quo is maintained, or if any other tailored T&E hour requirements are generated then that there is a rigorous study conducted to determine the acceptable number of hours.

Additionally, not everyone learns concepts and then uses them competently within the same period of time. Strongly urge NMP to establish the number of hours not based on the time that a midpoint or peak distribution of AUs become competent, but rather that a certain number of hours such that 95% or more of AUs would achieve competency.

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 absolutely and for all of the approaches including the status quo. The NMP could implement a standard or method for establishing certifying entities and independent certifying organizations similar to that of Appendix A in 10 CFR Part 34 for Radiographer Certification. It could be that certain professional organizations or medical boards would want to apply and become one such organization; they would need to administer examinations with certain content and adhering to set protocols. As it

stands, some board certifications tailor their requirements to meet the status quo option of T&E, it would not be that much of a leap for them to have break out sections on their board examinations to meet requirements of these competency exams.

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?

Those organizations would have more flexibility if transitioned to more performance based approaches, they would certainly adapt. Residency and fellowship programs can only get but so short, there will be a great deal of time for new AUs to develop their medical practice within those areas. Medical competency should not be a subject topic for the NMP, but rather safe handling and regulatory compliance matters.

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

None at present, but NC is confident that the NMP will sufficiently address any concern in time.

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

None come to mind at this time. Unintended consequences are unknown most of the time; otherwise, they would simply be intended consequences. With any rulemaking there is a risk for unintended consequence. The NMP should base their decisions on the information they have and not on fear of what may or may not happen. The good thing about rulemaking is if there is a bad rule passed then it can be revised, repealed, or additional supporting regulations may be passed.

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

A performance based approach with competency examinations would offer more flexibility moving forward over any prescriptive requirements or further fracturing of the status quo training pathways.

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

Much of what is reviewed currently appears to fall under competency in practicing medicine and less to do with health, safety, and security of materials. Therefore, it does not fit entirely within the NMP's authorities and should not be a continued role in the extent it is today.