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Docket: NRC-2018-0230
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-0166
Comment on FR Doc # 2019-10760

Submitter Information

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General Comment

Dear NRC,

Please find the attached comments in response to NRC-2018-0230. Thank you for the opportunity to provide input regarding this very important issue.

With Best Regards,

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Attachments

NRC-2018-0230.Comments.CHIN

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?

The NRC should develop guidelines with the consultation of specialties trained in the use of radiation for medical purposes – the American Board of Radiology and the American Board of Nuclear Medicine. Specialists with the expertise would be the most appropriate consultants to develop safety policies and practices. These organizations have developed the appropriate use guidelines, and would be most appropriate to implement the practice.

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?

No. As with many complex medical procedures and therapies, patients in rural areas are often accustomed to travel to more urban areas or medical centers to receive specialized treatments. Allowing low volume, high complexity medical procedures in rural areas by less than fully trained medical providers does not provide the best care or safety for patients.

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?

B.1 For a limited AU for Alpha and Beta emitters – The training should be comprehensive to include radiation for medical purposes beyond simply "beta emitters" and "alpha emitters". For example, "beta" and "alpha" emitters commonly have secondary gamma emissions (e.g. 177Lu, and 223Ra, respectively), and precautions would be different based on emissions. Incomplete knowledge provided from incompletely trained providers can erode patients' confidence in the medical profession, or result in radiation safety issues such as unintended contaminations. Unlike non-radioactive drugs, the potential effect of improper use or storage can be widespread if not properly controlled. For example, a lost or stolen dose of 200mCi of 177Lu DOTATATE due to improper security could result in contamination of a large area and many individuals very quickly, with long lasting contamination due to the long half-lives of many therapeutic radionuclides (e.g. 6.7 days for 177Lu). For fully trained AU professionals whose medical practice relies on maintenance of Authorized User status, the accountability for compliance with regulations is also much higher.

B.2 For a limited AU for patient ready unit doses – training should be comprehensive based on the same rationale as above.

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

Radiopharmaceutical classification should be prioritized based on the primary emission defined as the highest percentage of their decay. T&E should, however, encompass all emissions because secondary emissions are quite common.

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

Dose administration would need to be foolproof, which unfortunately, is extremely difficult to achieve. All potential variations and clinical scenarios would need to be accounted for. The judgement of a fully trained authorized user is needed for these potentially high risk procedures.

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

It would require a formal curriculum, performance evaluations, demonstrations of proficiency, achieving competency milestones, and successfully passing a test. These requirements are essentially the same as a formal board certified training program.

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)?

The definition of small practice probably excludes them from being credentialed without association with a larger institution. Large institutions have the infrastructure and personnel to appropriately train AU's, monitor and document on a routine basis, and ensure compliance.

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

1. Radiopharmaceutical Team - Ultimately, the responsibility to meet the requirements would rely on the authorized user, regardless of whoever is on the team. The first impression of this division of labor and responsibility sounds appealing. Implementing this would be impractical or nearly impossible. Accountability for each individual's responsibilities is difficult with individuals typically reporting to different supervisors. The main problem is that smaller hospitals typically have limited resources and personnel to fill these roles. Also, licensees developing their own policies does not really make sense because they lack the input of a fully trained AU.
2. **Team AUs with Authorized Administrators** – This is the most practical solution to a potential limited number of AUs. A fully trained AU would define the procedures and protocols based on the specific therapy. The Authorized Administrator would be trained by the AU, but ultimately the AU would bear the responsibility of safety, appropriate use and compliance. The full training and judgement of the AU will be present, accountability will be maintained, and access to therapies would improve because of this time savings. With this time saved by the AA performing less complex therapies, the AU can devote more time to complex clinical scenarios, providing better care. This team will be able to treat more patients by improving overall operational efficiency.
3. Partner limited-Trained AT with Authorized Nuclear Pharmacist – This, unfortunately, still lacks the expertise of a fully trained AU.

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

Team AUs with Authorized Administrators is the proposal that best fulfills the needs of the patient, and provides improved access to radiopharmaceutical therapies. It fulfills the need for high level expertise and judgement provided by highly trained AUs, saves time and improves access, maintains AU accountability, and is feasible to implement. It is can also reduce overall cost by improving efficiency.

This would be easy to implement from the regulatory perspective. This proposal 1) would not compromise training and education, 2) eliminates the need for additional assessments of limited training, 3) has no impact on the medical organizations currently providing full training, 4) eliminates or markedly reduce concerns about implementation, 5) has minimal unintended consequences as this maintains the current high level training, and 6) maintains NRC regulatory oversight and regulation of radiopharmaceuticals.

QUESTIONS 14-19: please see above