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Training and Experience Requirements for Different Categories of Radiopharmaceuticals

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Training and Experience Requirements for Different Categories of Radiopharmaceuticals

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Name: Michael Baxter
Submitter's Representative: Michael T. Baxter
Organization: American Pharmacists Association

General Comment

On behalf of the American Pharmacists Association-Academy of Pharmacy Practice and Management (APhA-APPM) Nuclear Pharmacy Practice Special Interest Group (SIG), consisting of over 2,200 members. please consider the following comments to the specific questions contained in the NRCs request for comments on the training and experience (T&E) requirements for authorized users (AUs). (See, attached .PDF for full comments).

If you have any questions or require additional information, please contact Michael Baxter, Director of Regulatory Affairs, at mbaxter@aphanet.org or by phone at (202) 429-7538.

Attachments

APhA Comments on AU NRC v Jan 29 19 v4

[Comments submitted electronically to: www.regulations.gov]

January 29, 2019

Attention: May Ma, Office of Administration
Mail Stop: TWFN-7-A60M
U.S. Nuclear Regulatory Commission (NRC)
Washington, DC 20555-0001

RE: Training and Experience Requirements for Different Categories of Radiopharmaceuticals [Docket ID NRC-2018-0230]

Dear Ms. Ma:

On behalf of the American Pharmacists Association-Academy of Pharmacy Practice and Management (APhA-APPM) Nuclear Pharmacy Practice Special Interest Group (SIG), consisting of over 2,200 members. please consider the following comments to the specific questions contained in the NRC's request for comments on the training and experience (T&E) requirements for authorized users (AUs).

III. Specific Requests for Comments

A. Tailored Training & Experience Requirements

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).]

The NRC already has tailored T&E requirements. 10 CFR 35.390(b)(1)(i)(G) delineates training specific to: the type of delivery method (oral or parenteral), the activity (less than or greater than 33 mCi for sodium iodide I-131), and the type of radiation emission (beta, or photon energy of less than 150 keV, and all others).[1]

5. How should the requirements for this fundamental T&E be structured for a specific category of radiopharmaceuticals?

[1] See, NRC. §35. 10 CFR35.390(b)(1)(i)(C) Available at: https://www.nrc.gov/reading-rm/doc-collections/cfr/part035/part035-0390.html

a. Describe what the requirements should include:

i. **Classroom and laboratory training—What topics need to be covered in this training requirement? How many hours of classroom and laboratory training should be required? Provide the basis for the number of hours. If not hours, explain how this training should be quantified. [Note: The topics currently required in the regulations to be included in the classroom and laboratory training and work experience are listed in 10 CFR 35.390, 35.392, 35.394, and 35.396.]**

ii. **Work experience—What should the work experience requirement involve? How many hours of work experience should be required and what is the minimum number of patient or human research subject administrations that an individual must perform? Provide the basis for the number of hours and administrations. What should be the qualifications of the supervising individual?**

If a ready-to-administer radiopharmaceutical is available in its final form and no further manipulation occurs, the current training requirement in 10 CFR 35.390(b)(1)(ii)(C) "…and safely preparing patient or human research subject dosages"[2] would not be applicable for these products. The provision would have to be changed to accommodate ready-to-administer radiopharmaceuticals.

D. Other Suggested Changes to the T&E Regulations

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?

The APhA-APPM Nuclear Pharmacy Practice SIG recommends AU T&E requirements should recognize the various health care team members involved in handling and administering radiopharmaceuticals safely and effectively, including nuclear pharmacists, physicians, medical technologists, and health physicists. As you may know, 90% of radiopharmaceuticals are dispensed by an Authorized Nuclear Pharmacist (ANP). Given the varying roles and expertise, the 700-hours requirement may need to be decreased. However, it is difficult to quantify a level of training or expertise by set number of hours versus competency-based training. The current safety record for therapeutic and diagnostic radiopharmaceuticals are the result of the individuals of this team who must be recognized in any restructuring of AU T&E requirements. Additionally, while alpha and beta emitting radiopharmaceuticals are dispensed and delivered to health care facilities as ready-to-administer doses, new alpha and beta emitters have added the important task of specialized calibration of the dose calibrator to ensure the correct amount of radioactivity is dispensed.

In conclusion, APhA-APPM's Nuclear Pharmacy Practice SIG and our over 2,200 members believes it is critical to recognize the important role of ANPs and their medication expertise in the health care team.

[2] Ibid.

Thank you again for the opportunity to provide information on this important issue. We look forward to working with the NRC on this important topic. If you have any questions or require additional information, please contact Michael Baxter, Director of Regulatory Affairs, at mbaxter@aphanet.org or by phone at (202) 429-7538.

Sincerely,

APhA-APPM Nuclear Pharmacy Practice SIG Members

cc: Stacie S. Maass, RPh, JD, Senior Vice President, Pharmacy Practice and Government Affairs
Kristine L. Svinicki, NRC Chairman
Jeff Baran, NRC Commissioner
Stephen G. Burns, NRC Commissioner
Annie Caputo, NRC Commissioner
David A. Wright, NRC Commissioner
Annette L. Vietti-Cook, Secretary of the NRC