

05/04/2018

Douglas R. Bollock, Chief
Medical Safety and Events Assessment Branch
Division of Materials Safety, Security, State and Tribal Programs
Office of Nuclear Material Safety and Safeguards

RE: Questionnaire on the Evaluation of Tailored Training and Experience Requirements for Different Categories of Radiopharmaceuticals

Dear Mr. Bollock,

Please allow me to thank you for the opportunity to provide feedback to your questionnaire and for seeking feedback from the radiation community regarding training & experience of Authorized Users (AU) using radiopharmaceuticals. I requested that two of our higher ranking physicians also provide feedback to your questionnaire as I highly value their expertise in these matters, regardless of whether we agree or disagree. I believe they have earned the respect of the radiation community and the opportunity to provide this feedback. They may or may not have already provided this to your office.

Below are my comments categorized by the questionnaire's format & numbering system:

1. a. v. In units of radiation and radioactivity, physicians should also be familiar with radiation dose (effective vs. absorbed, etc.). In my experience, it has been proven difficult for an American Board of Radiology certified physician who is 'AU Eligible' to distinguish between Air Kerma, Skin Dose, and Effective Dose (CEDE).

1. e. Physicians should also be familiar with documenting justification for release of patients without instructions under general patient release determination. In smaller medical institutions, the AU physician may be tasked with serving as the Radiation Safety Officer of the licensed facility. Not all AU's are particularly keen on remembering the record-keeping regulations in 10 CFR 35 and we've witnessed that documentation for justification for release is not readily available (even if they are just referencing a Regulatory Guidance document).

1. g. Under the Radiation Biology section, physicians should be able to delineate between physical half-life, biological half-life, and effective half-life.

1. g. vii. Pharmacological effects of specific drugs and resulting radiation doses, route of administration and route of elimination should also include physician's understanding of methods to affect the rate of elimination.

1. i. When it mentions anything regarding NRC requirements, it should simply reference that there are Agreement States and that AUs should be also familiar with State regulatory requirements depending on where they are practicing.

1. i. Regarding license amendments under item vii, there should also be a section before this that discusses the different types of licenses available so that physicians are aware of the different types of licensing actions that they might be tasked with doing and what type of approval it requires.

1. i. xii. In the section for transportation requirements, there should also be a section covering the DOT exemption for physicians travelling with radiopharmaceuticals for medical use.

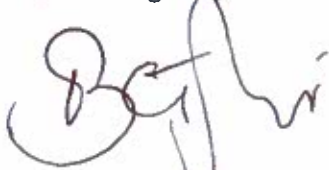
2. j. iv. Building from section 1.e., the documented justification should specify whether the release is justified via calculation or by measurement and should be documented as such.

Outside the scope of the questionnaire is the overarching concern that the other two physicians I've discussed this with and I have is the enforcement of the training and experience requirements from the NRC with regard to radiopharmaceutical therapies. UCLA is very unique in the sense that our Nuclear Medicine Department is separate from our Radiology Department. When the practice of nuclear medicine therapy becomes a cost-saving measure that is more and more recently categorized as a specialty under general radiology, it poses a disservice and potentially dangerous situation for patients undergoing radiopharmaceutical therapies.

I would recommend to the NRC to query the Radiology residency programs throughout the United States and ask the program directors to assess whether or not the 700 hours (200 lecture hours and 500 hours of experience) are being met. I would also recommend that a competency examination be implemented either by the NRC or an American Board that specifically qualifies Nuclear Medicine physicians in radiopharmaceutical therapies. Please keep in mind, this excludes diagnostic imaging modalities.

Again, thank you very much for this opportunity to comment on the questionnaire. If you have any other requests for feedback, please do not hesitate to reach out to me in the future.

Kindest regards,



Bryan Ruiz, CHP
Radiation Safety Officer
UCLA Environment, Health & Safety
Radiation Safety Division