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Docket: NRC-2018-0230
Training and Experience Requirements for Different Categories of Radiopharmaceuticals

Comment On: NRC-2018-0230-0001
Training and Experience Requirements for Different Categories of Radiopharmaceuticals

Document: NRC-2018-0230-DRAFT-0050
Comment on FR Doc # 2018-23521

Submitter Information

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Submitter's Representative: Matt Dennis
Organization: CRD Associates

General Comment

Thank you for the opportunity to provide public comment on Training and Experience Requirements for Different Categories of Radiopharmaceuticals (NRC-2018-0230).

Finding the right balance between patient access to alpha and beta therapeutic radiopharmaceuticals and the appropriate levels of training and experience needed for the administration of these radionuclide therapies is an important issue. In a recent editorial in the Journal of Nuclear Medicine, Razmaria, Calais, and Czernin describe why extensive training and education is required to administer radionuclide therapies. In the context of describing the myriad of topics that must be mastered for proper radionuclide administration, they mention that radiation protection, largely a nonissue when it comes to diagnostic applications, is clearly a patient, personnel, and public safety issue in the context of radiotherapeutics. They end the editorial by suggesting that relaxing current training and experience requirements will put patients and the public at risk.

As the CEO of Lucerno Dynamics, an innovative medical device company, I believe I can provide additional insight regarding patient safety for your consideration. For several years Lucerno has been focused on the misadministration of radiopharmaceuticals during the injection into patients. While the injection process is only one aspect of the overall administration of radiopharmaceuticals, it is an important one. It is also an aspect that has not been studied commensurate with other injection processes outside of nuclear medicine.

Lucernos technology can not only help clinicians identify the misadministration of radiopharmaceuticals but can also help them reduce their occurrence. Our technology has been used to monitor over 14,000 radiopharmaceutical injections by nearly 100 technologists or nuclear medicine physicians in 15 centers in the US, Japan and Singapore. Our findings demonstrate that misadministrations vary by center and by technologists within a center. Our findings also demonstrate that even highly trained, experienced, and credentialed clinicians can misadminister radiopharmaceuticals. This may occur as a result of the patients anatomy, technique inappropriate to the specific patient, or other factors.

We agree with Razmaria et al. that the misadministration of diagnostic radiopharmaceutical is largely a radiation protection nonissue. However, since routine monitoring of the injection quality is currently not present in nuclear medicine, diagnostic radiopharmaceutical misadministration can go unnoticed by patients and clinicians. As a result, a misadministration can negatively affect the sensitivity and quantification of the nuclear medicine study and in some cases patient management. A misadministration of radionuclide therapy, on the other hand, will be an immediate and serious patient issue. We believe that it is essential to monitor and report on the quality of radiopharmaceutical injections. Today, there is technology that is safe, fast, inexpensive, and patient-friendly, that can in real time provide quality control for every patient by dynamically capturing the quality of radiopharmaceutical injections. This same technology can also identify factors associated with misadministrations. When centers use this quality assurance information to improve their injection processes and reduce their infiltration rates, they are increasing their competency.

In our judgment, questions 5(a)iii and 5(e) from this public comment request regarding mechanisms for evaluating competency and periodic assessment of competency are critical. Routine use of existing technology, which provides both real-time quality control information to AU and the clinical team responsible for the patient, as well as quality assurance information, can protect patients, help the health care delivery system improve, and demonstrate competence.
As the NRC continues evaluating these issues, we would be happy to discuss these comments, answer any questions you may have, or provide additional information with respect to this issue.

Sincerely,

Ron Lattanze
Chief Executive Officer

Attachments

LD public comment on NRC regulation

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January 21, 2019

Kristine L. Svnicki, Chair
U.S. Nuclear Regulatory Commission
Washington, DC 20555-0001

Daniel S. Collins
Director, Division of Materials Safety, Security, State and Tribal Programs
Office of Nuclear Material Safety and Safeguards

Re: Training and Experience Requirements for Different Categories of Radiopharmaceuticals (NRC-2018-0230)

SUBMITTED ELECTRONICALLY VIA www.regulations.gov

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