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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-0077
Comment on FR Doc # 2018-23521

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General Comment

See attached file(s)

Attachments

NRC T and E comments Cardinal Health

January 25, 2019

May Ma
Office of Administration
Mail Stop TWFN–7– A60M
U.S. Nuclear Regulatory Commission
Washington, DC 20555-0001

RE: DOCKET ID NRC–2018–0230, TRAINING AND EXPERIENCE REQUIREMENTS FOR DIFFERENT CATEGORIES OF RADIOPHARMACEUTICALS; FEDERAL REGISTER VOL. 83, NO. 209; OCTOBER 29, 2018

Dear Ms. Ma:

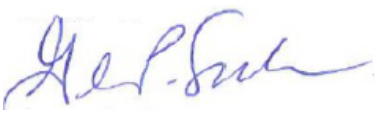
Cardinal Health Nuclear & Precision Health Solutions (Cardinal Health) appreciates the opportunity to comment on the U.S. Nuclear Regulatory Commission (NRC) request for comment on Training and Experience Requirements for Different Categories of Radiopharmaceuticals; Federal Register Vol. 83, No. 209; October 29, 2018. Cardinal Health operates nuclear pharmacies and PET drug manufacturing sites that prepare and dispense radiopharmaceuticals in patient-ready doses for administration to patients in health care facilities throughout the United States.

On October 29, 2018, the U.S. Nuclear Regulatory Commission (NRC) requested comments on its training and experience (T&E) requirements. This letter is in response to NRC's request for input on whether tailored T&E requirements for different categories of radiopharmaceuticals for which a written directive is required should be established. This input will be used to determine whether significant regulatory changes to the NRC's T&E requirements for authorized users (AUs) are necessary.

Cardinal Health believes that the current regulatory requirement of 700-hours of training and experience to become a licensed AU to administer alpha-, beta-, or beta-gamma- emitting radiotherapies (patient ready, non-imaging radiotherapies) is excessive if these radiopharmaceuticals are provided by a licensed nuclear pharmacy as patient-ready doses and require no manipulation by the end user. As you are aware many novel therapies are being researched at this moment and if steps are not taken the modify the training requirements with this rulemaking, we believe that patient access to important radiopharmaceutical drugs will remain restricted to patients living within a suitable proximity of a large medical institution or suitable specialized physicians. Cardinal Health is in support of modifying the AU T&E requirements to allow for increased patient access to these essential radiopharmaceuticals.

Please do not hesitate to contact me at (614)757-9586 if you have questions.

Sincerely,



Glenn P. Sullivan
Director, Health Physics
Corporate Radiation Safety Officer
Cardinal Health Nuclear Pharmacy Services