From: Bohan, Michael
To: Wu, Irene
Cc: Ayoade, Maryann; Nath, Ravinder; Saperstein, Lawrence
Subject: [External_Sender] RE: REQUEST: Input on Questionnaire for NRC Training and Experience Evaluation
Date: Thursday, April 26, 2018 3:22:19 PM
Attachments: image001.png

Hi Irene & Maryann,

Here are YNHH's comments on the questionnaire you sent on April 13th.

1. The training syllabus looks appropriate.

2. The additional topics also look appropriate.

3. We believe that a physician enrolled in a Nuclear Medicine residency program, approved by an appropriate residency accreditation committee, would achieve the necessary training and experience for full authorized user status for the use of all types of radiopharmaceuticals. However, the NRC should maintain an abbreviated pathway to allow diagnostic radiology, interventional radiology and radiation oncology residents to achieve limited authorized user status for specific radiopharmaceutical use, such as I-131 NaI for hyperthyroidism & thyroid cancer, Y-90 microspheres for selective internal radiation therapy (SIRT) and Ra-223 Xofigo for the treatment of prostate & breast cancer metastases, respectively. If these pathways are not maintained, then these services may not be available at many community level medical institutions.

4. We believe that a physician's knowledge in the use of radiopharmaceuticals and ability to function independently can be assessed by examination by an appropriate medical specialty board and/or by an attestation by a qualified authorized user. For career pathway reasons, the ability to qualify by preceptor statements should be maintained because the board certification process usually takes at least a year after graduation from a residency program. This could prevent new graduates from fully practicing medicine in their specialty upon graduation, until the board certification process is complete.

5. With regard to the syllabus and additional topics listed in questions 1 & 2, this should be provided by reference in guidance documents and should not be directly incorporated into the regulations.

Regards,

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YaleNewHavenHealth

From: Wu, Irene [mailto:Irene.Wu@nrc.gov]
Sent: Friday, April 13, 2018 4:00 PM
To: Bohan, Michael
Cc: Ayoade, Maryann; Nath, Ravinder; Saperstein, Lawrence
Subject: REQUEST: Input on Questionnaire for NRC Training and Experience Evaluation

Dear Mr. Bohan,

The NRC is seeking input on its evaluation of the training and experience requirements for radiopharmaceuticals under Title 10 of the *Code of Federal Regulations* (10 CFR) 35.390, "Training for use of unsealed byproduct material for which a written directive is required." We would like to request your voluntary feedback on four areas: (1) the fundamental knowledge necessary for administering any radiopharmaceutical under 10 CFR 35.390; (2) the additional knowledge necessary for administering specific types of radiopharmaceuticals under 10 CFR 35.390; (3) how to best acquire this knowledge; and (4) how this knowledge and ability to function independently should best be evaluated [i.e., competency].

Attached is a questionnaire for your completion. In your response, make sure not to include any proprietary Information in accordance with 10 CFR 2.390, "Public inspections, exemptions, requests for withholding." Your voluntary response will help our evaluation. Please return your completed questionnaire to Maryann Ayoade at maryann.ayoade@nrc.gov and Irene Wu at irene.wu@nrc.gov by **Friday, April 27, 2018**. If you have any questions about this questionnaire, please email or call Maryann Ayoade (301-415-0862) or Irene Wu (301-415-1951). You will also be receiving a formal letter regarding this request for your voluntary response.

Thank you,

Irene Wu, P.E.
Project Manager
Office of Nuclear Material Safety and Safeguards
Division of Materials Safety, Security, State, and Tribal Programs
U.S. Nuclear Regulatory Commission

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