

From: Ribaldo, Cathy (NIH/OD/ORS) [E]
To: [Ayoade, Maryann](#)
Cc: [Wu, Irene](#)
Subject: [External_Sender] RE: REQUEST: Input on Questionnaire for NRC Training and Experience Evaluation
Date: Saturday, April 28, 2018 10:00:21 AM
Attachments: [image001.png](#)

Hi Ms. Ayoade,

Apologies for the late response – I had hoped to canvass the Clinical Authorized Users at my hospital for their input. In the end I only got this one useful response, as everyone else just said the document was already sufficiently comprehensive and thorough. I'm including the detailed response below in quotes:

“One area of knowledge relates to gamma camera instrumentation and possibly PET camera instrumentation. Some of the dosimetric approaches such as bexxar (no longer available) and Y-90 microembolization require use of a gamma camera in one case to determine half life, or in the case of Iodine to determine uptake, and in the case of microsphere to determine fraction in lung

One route of education that I think is effective - certainly for a newer modality - has been for the manufacturer to provide an in-service. Also provide under supervision. I think for some material it becomes somewhat redundant and if you know how to perform one therapy, the others follow. Training in one technique will often allow you to do therapy in another similar technique (ie requires similar skills). Board certification should be sufficient for certain written directive procedures.

An exam and/or attestation from an authorized user could act as a means to test competency, as could a certification of having successfully completed training.”

I hope this is useful in your efforts to collect information. I will forward you any additional responses I may receive from our users, even if past the deadline, because it still may be useful feedback for your group.

Thank you,
Cathy

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From: Ayoade, Maryann <maryann.ayoade@nrc.gov>
Sent: Tuesday, April 17, 2018 4:24 PM
To: Ribaudo, Cathy (NIH/OD/ORS) [E] <ribaudoc@ors.od.nih.gov>
Cc: Wu, Irene <Irene.Wu@nrc.gov>
Subject: REQUEST: Input on Questionnaire for NRC Training and Experience Evaluation

Dear Ms. Ribaudo,

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,

Maryann O. N. Ayoade
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