

**From:** [Ayoade, Maryann](#)  
**To:** [Wu, Irene](#)  
**Subject:** FW: FW: REQUEST: Input on Questionnaire for NRC Training and Experience Evaluation  
**Date:** Tuesday, May 01, 2018 10:58:12 AM  
**Attachments:** [image001.png](#)

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**From:** Ribaldo, Cathy (NIH/OD/ORS) [E] [<mailto:ribaudoc@ors.od.nih.gov>]  
**Sent:** Monday, April 30, 2018 7:05 PM  
**To:** Ayoade, Maryann <[maryann.ayoade@nrc.gov](mailto:maryann.ayoade@nrc.gov)>  
**Subject:** [External\_Sender] FW: REQUEST: Input on Questionnaire for NRC Training and Experience Evaluation

Hi Ms. Ayoade,  
I wanted to forward you this additional response from an NIH clinical Authorized User in the hopes that it might not be too late for his input.  
Thank you!  
Cathy

Catherine Ribaldo  
Radiation Safety Officer  
Director, Division of Radiation Safety  
Office of Research Services, NIH  
Bldg 21 Rm 112  
Bethesda, MD 20892-6780  
301-594-1303 (direct)  
301-496-5774 (main)  
240-515-6798 (cell)  
[cribaldo@nih.gov](mailto:cribaldo@nih.gov)

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**From:** Fisher, Teresa (NIH/OD/ORS) [E]  
**Sent:** Monday, April 30, 2018 4:57 PM  
**To:** Ribaldo, Cathy (NIH/OD/ORS) [E] <[ribaudoc@ors.od.nih.gov](mailto:ribaudoc@ors.od.nih.gov)>  
**Subject:** FW: REQUEST: Input on Questionnaire for NRC Training and Experience Evaluation

It may be too late, but here is another response. This one from Frank.

Thank you,  
Teresa

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**From:** Lin, Frank (NIH/NCI) [E]  
**Sent:** Monday, April 30, 2018 4:52 PM  
**To:** Fisher, Teresa (NIH/OD/ORS) [E] <[teresa.fisher@nih.gov](mailto:teresa.fisher@nih.gov)>

**Subject:** RE: REQUEST: Input on Questionnaire for NRC Training and Experience Evaluation

Hi Teresa,

Sorry but I just saw this questionnaire today...

The list is already quite extensive and some of these questions are really hard to answer. However, generally speaking, I think to get the experience needed, a physician would need to undergo training similar to the type of training one gets in any medical subspecialty fellowship, which would need to include didactics to cover topics such as basic science (nuclear physics, radiochemistry, dosimetry, detectors, etc), US regulations (NRC + state regulations, protection, working with local Health Physics, etc), and of course the medical topics for each agent. In addition to didactics, I think there needs to be lots of hands-on experience. I think the current number of cases required for I131 for instance is 5, but that is probably too little. I would say 10 cases minimum. I think training for betas and alphas should be separate, as well as separate for oral vs IV/IP infusion of agents. There should also be some training in diagnostic agents such as gamma only agents, or combined beta/gamma agents. Testing can be done by exam + certification by authorized user.

One thing I would like to eventually see happen is to get the medical oncologists trained in using these agents. Something like a 1 year fellow for oncologists that would get them all the requirements mentioned here... and when they finish their training, will be able to administer radionuclide therapy.

Frank

Frank I. Lin, MD

Chief, Targeted Radionuclide Therapy Section  
Lasker Clinical Research Scholar  
Molecular Imaging Program/CCR/NCI/NIH  
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Bethesda, MD 20892-1088  
Ph (main): 301-496-7776  
Ph (direct): 240-760-6166 (new since 1/24/18)

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**From:** Fisher, Teresa (NIH/OD/ORS) [E]

**Sent:** Monday, April 23, 2018 5:27 PM

**To:** Chen, Clara (NIH/CC/NMD) [E] <[cchen1@cc.nih.gov](mailto:cchen1@cc.nih.gov)>; Ahlman, Mark (NIH/CC/LDRR) [F] <[mark.ahlman@nih.gov](mailto:mark.ahlman@nih.gov)>; Reynolds, James MD (NIH/CC/NMD) [V] <[jreynolds@cc.nih.gov](mailto:jreynolds@cc.nih.gov)>; Lin, Frank (NIH/NCI) [E] <[frank.lin2@nih.gov](mailto:frank.lin2@nih.gov)>; Carrasquillo, Jorge (NIH/NCI) [V] <[jorge.carrasquillo@nih.gov](mailto:jorge.carrasquillo@nih.gov)>

**Cc:** Ribaudoc, Cathy (NIH/OD/ORS) [E] <[ribaudoc@ors.od.nih.gov](mailto:ribaudoc@ors.od.nih.gov)>

**Subject:** FW: REQUEST: Input on Questionnaire for NRC Training and Experience Evaluation

**Importance:** High

Good afternoon,

The Radiation Safety Officer was sent a questionnaire from the NRC regarding current training and experience requirements for individuals administering radioactive materials that require a written directive. She intends to send a response but I believe you all are far more qualified to offer opinions on this subject since you have met these requirements and administer these radiopharmaceuticals. If you have feedback that you would like to make sure Cathy Ribaudo includes in her response to the NRC, please feel free to respond to this email. The deadline for a response is this Friday, the 27<sup>th</sup>. I apologize for the short notice. Any input you can provide would be greatly appreciated!

Thank you,  
Teresa

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**From:** Ayoade, Maryann <[maryann.ayoade@nrc.gov](mailto:maryann.ayoade@nrc.gov)>  
**Sent:** Tuesday, April 17, 2018 4:24 PM  
**To:** Ribaudo, Cathy (NIH/OD/ORS) [E] <[ribaudo@ors.od.nih.gov](mailto:ribaudo@ors.od.nih.gov)>  
**Cc:** Wu, Irene <[Irene.Wu@nrc.gov](mailto: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](mailto:maryann.ayoade@nrc.gov) and Irene Wu at [irene.wu@nrc.gov](mailto: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*  
Medical / Health Physicist  
Medical Radiation Safety Team  
Office of Nuclear Material Safety and Safeguards

U.S. Nuclear Regulatory Commission

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