



UNITED STATES  
NUCLEAR REGULATORY COMMISSION  
WASHINGTON, D.C. 20555-0001

April 19, 2018

Cindy Tomlinson  
Senior Patient Safety and Regulatory  
Affairs Manager  
American Society for Radiation Oncology  
251 18<sup>th</sup> St. South, 8<sup>th</sup> Floor  
Arlington, VA 22202

SUBJECT: EVALUATION OF TAILORED TRAINING AND EXPERIENCE REQUIREMENTS  
FOR DIFFERENT CATEGORIES OF RADIOPHARMACEUTICALS

Dear Ms. Tomlinson:

The U.S. Nuclear Regulatory Commission (NRC) is currently evaluating the training and experience requirements for different categories of radiopharmaceuticals as directed by the Staff Requirements Memorandum for SECY-16-0080, "Final Rule: Medical Use of Byproduct Material – Medical Event Definitions, Training and Experience, and Clarifying Amendments (RIN 3150-AI63; NRC-2008-0175)" (Agencywide Documents Access and Management System Accession No. ML17229B284). Specifically, staff is looking at 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."

The NRC is asking for your assistance in completing the attached questionnaire, which you should have already received by e-mail. We are requesting 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]. Your voluntary response will help us in our evaluation.

In your response, make sure not to include any proprietary Information in accordance with 10 CFR 2.390, "Public inspections, exemptions, requests for withholding." For further information or for questions, please contact Maryann Ayoade at (301) 415-0862 or via e-mail at [Maryann.Ayoade@nrc.gov](mailto:Maryann.Ayoade@nrc.gov), or Irene Wu at (301) 415-1951 or via e-mail at [Irene.Wu@nrc.gov](mailto:Irene.Wu@nrc.gov).

Sincerely,

*/RA/*

Douglas R. Bollock, Chief  
Medical Safety and Events Assessment Branch  
Division of Materials Safety, Security, State,  
and Tribal Programs  
Office of Nuclear Material Safety  
and Safeguards

Enclosure:  
Questionnaire on the Evaluation of Tailored  
Training and Experience Requirements  
for Different Categories of Radiopharmaceuticals

SUBJECT: EVALUATION OF TAILORED TRAINING AND EXPERIENCE REQUIREMENTS  
FOR DIFFERENT CATEGORIES OF RADIOPHARMACEUTICALS.  
DATED: APRIL 19, 2018

IDENTICAL LETTERS SENT TO: See Attached

**ML18108A266(P)**

OFFICE	MSST/MSEB	MSST/MSEB	MSTR/MSEB
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DATE	4/19/18	4/19/18	4/19/18

**OFFICIAL RECORD COPY**

Identical Letters sent to:

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The American Board of  
Nuclear Medicine  
4555 Forest Park Blvd., Suite 119  
St. Louis, MO 63108-2173

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Council on Radionuclides  
and Radiopharmaceuticals, Inc.  
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Richmond, VA 23219

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Radiation Safety Officer  
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Radiological Physics – WWW 229  
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Radiation Safety Officer  
Department of the Army  
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Radiation Safety Officer  
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April 19, 2018

Daniel Pryma, MD  
Chair  
The American Board of  
Nuclear Medicine  
4555 Forest Park Blvd., Suite 119  
St. Louis, MO 63108-2173

SUBJECT: EVALUATION OF TAILORED TRAINING AND EXPERIENCE REQUIREMENTS  
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Division of Materials Safety, Security, State,  
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Enclosure:

Questionnaire on the Evaluation of Tailored  
Training and Experience Requirements  
for Different Categories of Radiopharmaceuticals



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April 19, 2018

Michael Guastella  
Director  
Council on Radionuclides  
and Radiopharmaceuticals, Inc.  
500 North Capitol Street, NW, Suite 210  
Washington, DC 20001-7407

SUBJECT: EVALUATION OF TAILORED TRAINING AND EXPERIENCE REQUIREMENTS  
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Dear Mr. Guastella:

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April 19, 2018

Mike Fuller  
Radioactive Material Program Supervisor  
Virginia Department of Health  
Office of Radiological Health  
109 Governor Street, 7<sup>th</sup> Floor  
Richmond, VA 23219

SUBJECT: EVALUATION OF TAILORED TRAINING AND EXPERIENCE REQUIREMENTS  
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Dear Mr. Fuller:

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Michael Bohan  
Radiation Safety Officer  
Yale – New Haven Hospital  
Radiological Physics – WWW 229  
20 York Street  
New Haven, CT 06510

SUBJECT: EVALUATION OF TAILORED TRAINING AND EXPERIENCE REQUIREMENTS  
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Dear Mr. Bohan:

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April 19, 2018

Ravinder Nath, PhD  
Director of Radiation Physics  
Yale – New Haven Hospital  
Radiation Oncology  
20 York Street – CB 3  
New Haven, CT 06510

SUBJECT: EVALUATION OF TAILORED TRAINING AND EXPERIENCE REQUIREMENTS  
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Dear Mr. Nath:

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April 19, 2018

Lawrence Spaerstein, MD  
Director of Nuclear Medicine  
Yale – New Haven Hospital  
Nuclear Medicine  
20 York Street Smilow 2  
New Haven, CT 06510

SUBJECT: EVALUATION OF TAILORED TRAINING AND EXPERIENCE REQUIREMENTS  
FOR DIFFERENT CATEGORIES OF RADIOPHARMACEUTICALS

Dear Dr. Spaerstein:

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April 19, 2018

Mary Beth Taormina  
Radiation Safety Officer  
Virginia Commonwealth University  
Office of Environmental Health & Safety  
P.O. Box 980112  
Richmond, VA 23298-0112

SUBJECT: EVALUATION OF TAILORED TRAINING AND EXPERIENCE REQUIREMENTS  
FOR DIFFERENT CATEGORIES OF RADIOPHARMACEUTICALS

Dear Ms. Taromina:

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April 19, 2018

Bryan Ruiz  
Radiation Safety Officer  
The Regents of the University  
of California, Los Angeles  
UCLA Radiation Safety Division  
501 Westwood Plaza, Fourth Floor  
Los Angeles, CA 90095-1605

SUBJECT: EVALUATION OF TAILORED TRAINING AND EXPERIENCE REQUIREMENTS  
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Hung Dam, MD  
Radiation Safety Committee Chair  
Christiana Care Health Services, Inc.  
Management Suite – Room 1270  
4755 Olgetown-Stanton Road  
Newark, DE 19718

SUBJECT: EVALUATION OF TAILORED TRAINING AND EXPERIENCE REQUIREMENTS  
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Dear Dr. Dam:

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Thomas Moenster  
Radiation Safety Officer  
Missouri Baptist Medical Center  
3015 N. Ballas Road  
St. Louis, MO 63131

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In your response, make sure not to include any proprietary Information in accordance with 10 CFR 2.390, "Public inspections, exemptions, requests for withholding." For further information or for questions, please contact Maryann Ayoade at (301) 415-0862 or via e-mail at [Maryann.Ayoade@nrc.gov](mailto:Maryann.Ayoade@nrc.gov), or Irene Wu at (301) 415-1951 or via e-mail at [Irene.Wu@nrc.gov](mailto:Irene.Wu@nrc.gov).

Sincerely,

*/RA/*

Douglas R. Bollock, Chief  
Medical Safety and Events Assessment Branch  
Division of Materials Safety, Security, State,  
and Tribal Programs  
Office of Nuclear Material Safety  
and Safeguards

Enclosure:  
Questionnaire on the Evaluation of Tailored  
Training and Experience Requirements  
for Different Categories of Radiopharmaceuticals



UNITED STATES  
NUCLEAR REGULATORY COMMISSION  
WASHINGTON, D.C. 20555-0001

April 19, 2018

Kimberly Alston, MAJ  
Radiation Safety Officer  
Uniformed Services University  
of the Health Sciences  
4301 Jones Bridge Road  
Bethesda, MD 20814

SUBJECT: EVALUATION OF TAILORED TRAINING AND EXPERIENCE REQUIREMENTS  
FOR DIFFERENT CATEGORIES OF RADIOPHARMACEUTICALS

Dear MAJ. Alston:

The U.S. Nuclear Regulatory Commission (NRC) is currently evaluating the training and experience requirements for different categories of radiopharmaceuticals as directed by the Staff Requirements Memorandum for SECY-16-0080, "Final Rule: Medical Use of Byproduct Material – Medical Event Definitions, Training and Experience, and Clarifying Amendments (RIN 3150-AI63; NRC-2008-0175)" (Agencywide Documents Access and Management System Accession No. ML17229B284). Specifically, staff is looking at 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."

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UNITED STATES  
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WASHINGTON, D.C. 20555-0001

April 19, 2018

Catherine Ribaldo  
Radiation Safety Officer  
Department of Health &  
Human Services  
National Institutes of Health  
21 Wilson Drive, MSC 6780  
Bethesda, MD 20892-6780

SUBJECT: EVALUATION OF TAILORED TRAINING AND EXPERIENCE REQUIREMENTS  
FOR DIFFERENT CATEGORIES OF RADIOPHARMACEUTICALS

Dear Ms. Ribaldo:

The U.S. Nuclear Regulatory Commission (NRC) is currently evaluating the training and experience requirements for different categories of radiopharmaceuticals as directed by the Staff Requirements Memorandum for SECY-16-0080, "Final Rule: Medical Use of Byproduct Material – Medical Event Definitions, Training and Experience, and Clarifying Amendments (RIN 3150-AI63; NRC-2008-0175)" (Agencywide Documents Access and Management System Accession No. ML17229B284). Specifically, staff is looking at 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."

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April 19, 2018

Kevin Martilla  
Radiation Safety Officer  
Department of the Army  
Brooke Army Medical Center  
Attn: MCHE-ZHP-H  
(Health Physics Service)  
3551 Roger Brooke Drive,  
Building 3600  
Fort Sam Houston, JBSA, TX 78234-6200

SUBJECT: EVALUATION OF TAILORED TRAINING AND EXPERIENCE REQUIREMENTS  
FOR DIFFERENT CATEGORIES OF RADIOPHARMACEUTICALS

Dear Mr. Martilla:

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UNITED STATES  
NUCLEAR REGULATORY COMMISSION  
WASHINGTON, D.C. 20555-0001

April 19, 2018

Kaisha Nesmith, CPT  
Radiation Safety Officer  
Department of the Army  
Womack Army Medical Center  
2817 Reilly Road  
Attn: MCXC-DPM-RP Office  
Fort Bragg, NC 28310

SUBJECT: EVALUATION OF TAILORED TRAINING AND EXPERIENCE REQUIREMENTS  
FOR DIFFERENT CATEGORIES OF RADIOPHARMACEUTICALS

Dear CPT. Nesmith:

The U.S. Nuclear Regulatory Commission (NRC) is currently evaluating the training and experience requirements for different categories of radiopharmaceuticals as directed by the Staff Requirements Memorandum for SECY-16-0080, "Final Rule: Medical Use of Byproduct Material – Medical Event Definitions, Training and Experience, and Clarifying Amendments (RIN 3150-AI63; NRC-2008-0175)" (Agencywide Documents Access and Management System Accession No. ML17229B284). Specifically, staff is looking at 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."

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April 19, 2018

Suyog Chhetri, CPT  
Radiation Safety Officer  
Department of the Army  
Carl R. Darnall Army Medical Center  
36065 Santa Fe Avenue  
Fort Hood, TX 76544-4752

SUBJECT: EVALUATION OF TAILORED TRAINING AND EXPERIENCE REQUIREMENTS  
FOR DIFFERENT CATEGORIES OF RADIOPHARMACEUTICALS

Dear CPT. Chhetri:

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