



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 18th St. South, 8th 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, or Irene Wu at (301) 415-1951 or via e-mail at 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

C. Tomlinson

- 3 -

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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St. Louis, MO 63108-2173

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

Mike Fuller
Radioactive Material Program Supervisor
Virginia Department of Health
Office of Radiological Health
109 Governor Street, 7th Floor
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Radiation Safety Officer
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Radiological Physics – WWW 229
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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
FOR DIFFERENT CATEGORIES OF RADIOPHARMACEUTICALS

Dear Dr. Pryma:

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

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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
FOR DIFFERENT CATEGORIES OF RADIOPHARMACEUTICALS

Dear Mr. Guastella:

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

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

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
FOR DIFFERENT CATEGORIES OF RADIOPHARMACEUTICALS

Dear Mr. Nath:

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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
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Dear Dr. Spaerstein:

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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
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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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Dear Mr. Ruiz:

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April 19, 2018

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
FOR DIFFERENT CATEGORIES OF RADIOPHARMACEUTICALS

Dear Dr. Dam:

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

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

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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
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Dear MAJ. Alston:

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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, or Irene Wu at (301) 415-1951 or via e-mail at 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

Catherine Ribaud
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. Ribaud:

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

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

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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